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TITLE: Continuous Pre-hospital Data as a Predictor of Outcome Following Major Trauma: A Study Using Improved and Expanded Data

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14. ABSTRACT This study is designed to acquire near continuous physiologic measurements, beginning at the earliest practical time after injury, on large numbers of injured patients with severe trauma. The study will utilize commercially available FDA-certified monitoring equipment, operating in a fleet of front-line ground EMS ambulances currently serving a large metropolitan area with multiple trauma centers, and operating within an existing mobile wireless network. First Responders represent the earliest opportunity to acquire meaningful medical data in injury cases. This data will be correlated with significant clinical outcomes within the first 24 hours of admission and entered into a research database. Analysis of this database may allow development of models that predict outcome and the need for life-saving procedures. During the reporting period, a proof-of-concept process for manually collecting, processing, and reporting pre-hospital physiological data was defined. Research protocols were developed and IRB approvals obtained. Fielding of physical and electronic data collection facilities for this project, and to pave the way for future sustained data collection, was accomplished. Pre-hospital patient data was acquired and processed. Analysis supports the proposed hypothesis that ground EMS systems can provide earlier inception of data recording than helicopter services.						
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Introduction

The objective of this project was to develop, implement, and test a capability to collect relevant physiological and treatment data for seriously injured trauma patients in support of the U.S. Army's "Advanced Capabilities for Combat Medics" program. The information that was sought included pre-hospital physiological data for qualifying patients as well as post-arrival and outcome data. This project represents one of the first attempts to accomplish these tasks in support of the Advanced Capabilities for Combat Medics program within a system of ground ambulances responding to incidents and caring for and transporting patients to Level 1 Trauma Centers. Ground Emergency Medical Services (EMS) represent the earliest practical opportunity, for most civilian traumatic injury cases, to begin to acquire needed patient data. This project builds upon the existing LifeLink mobile telemedicine network in San Antonio to accomplish these goals. The scope of the subject project was to establish preliminary data collection capabilities in five EMS ambulances operating within the LifeLink network and one receiving hospital, to establish required research protocols and approvals to facilitate the data collection and research operations, to operate the data collection system for one month, and to examine the resulting data and draw preliminary conclusions about the capabilities of initiating pre-hospital data collection relatively early in qualifying trauma injury cases.

The work planned during this project included development of the capability to extract and process data from the physiological monitor that was used by the EMS system to acquire and monitor patient vital signs during patient treatment and transport. This was accomplished for the monitor that was in use within the participating ground EMS units. After the planned patient data collection interval was completed, however, a new and more capable physiological monitor was adopted by the participating ground EMS system. Based on this development, an additional task (Task 4 of the Statement of Work [SOW] for the subject project) was proposed and approved to facilitate work to develop a data extraction and process capability for the new monitor.

Body

This section of the report presents discussion and significant accomplishments/problems encountered in the conduct of the subject project. The section is organized to present this information as associated with relevant tasks and subtasks of the approved SOW including the modification to include the additional Task 4.

TASK 1 To implement the EMS ambulance fleet for data collection and obtain Institutional Review Board (IRB) approvals for data collection protocols.

Subtask 1.a Investigate monitor configuration and data collection process.

The target population for data collection in this project was adult trauma patients being transported Code 3 to Brooke Army Medical Center (BAMC) by the San Antonio Fire Department, Emergency Medical Services (SAFD EMS) division, in ambulances equipped with suitable monitors and operating within the LifeLink project. In order to acquire and use the

electronic physiological data collected on these patients, it was necessary to understand the monitor configuration (setup) that would be used by paramedics in routine patient care practice in the field subject to approved patient care protocols used by the service. It was also necessary to understand and define monitor configuration parameters and process issues to assure that the desired data could be captured, stored, and communicated/retrieved for use in the project.

The SAFD EMS system provides pre-hospital patient care under the medical license of the SAFD EMS Medical Director, who is also Medical Director and faculty member at the Department of Emergency Health Services at the The University of Texas Health Science Center at San Antonio (UTHSCSA).

Southwest Research Institute (SwRI[®]) negotiated and concluded agreements with Medtronic Emergency Response Systems, Inc. (Medtronic) who is the manufacturer of the LifePak 12 physiological monitor used by SAFD EMS during patient care and data collection operations for the subject project. Additional agreements with the Medical Director for SAFD EMS, through UTHSCSA, and the U.S. Army Institute of Surgical Research (USAISR), which manages the Advanced Capabilities for Combat Medics research task area under the U.S. Army's Combat Casualty Care program, were negotiated and concluded for the subject project. Part of the USAISR program is commonly called the "Trauma Vitals" project, which requires patient data such as that provided by the subject SwRI project.

Pre-hospital physiological data collection for this project was to be based on existing protocols for patient care and monitoring during the pre-hospital interval of patient care as prescribed by the Medical Director. SwRI investigated and documented the established protocols for EMS monitoring for the population for this study. Three reference patient data files were acquired for engineering purposes using volunteer paramedics as subjects. The three reference files were used in developing and testing the pre-hospital data acquisition and upload process.

The monitor configuration used by SAFD EMS for the target population for this study included parameters such as Electrocardiogram (EKG), Heart Rate (HR), Non-Invasive Blood Pressure (NIBP), Oxygen Saturation (SPO₂), and other data. The monitor was capable of acquiring and storing a single (waveform) channel of EKG data continuously and acquiring/storing all active EKG (waveform) channels for short periods after being triggered by a defined event or a manual command. Additional discrete numerical physiological data such as NIBP and event data as detected by the monitor were also acquired and stored within the monitor for eventual retrieval.

The pre-hospital data collection process for this project was required to be transparent to the patient care and transport mission of EMS as specified by the approved research protocol. This requirement guided the development of the process planned for the subject study, and SwRI worked closely with staff at SAFD EMS and the SAFD EMS Medical Director to accomplish this. The data collection process to be used during the subject study was viewed as a proof-of-concept (POC) process that was expected to yield usable data. The initial POC data collection operations included many manual operations to identify and collect the needed data for qualified cases. The POC data acquisition process development included development and use of technical processes and building blocks that would be extendable to more automatic and efficient data acquisition methodologies in the future.

During a typical EMS run for adult cases, the physiological monitor was applied to the patient, and an EKG strip and discrete numerical parameter values were acquired and manually entered in an EMS run sheet. If the patient vital signs were unstable or worrisome to the paramedic, the patient would be monitored for a longer period during the transport, and additional EKG strips and data would be acquired and included in the run sheet. For potentially qualifying patients for the subject study, paramedics attempted to acquire monitor data during the entire pre-hospital care interval by leaving the monitor attached and running until the unit reached a receiving hospital. The LifePak 12 monitors used in this project were configured such that when the monitor was turned off after a monitoring session, waveforms and data acquired during the monitoring session were automatically stored in a patient data archive file within the monitor. The archived data files stored in the monitor were encrypted in a proprietary data format, and further work was required in order to access the raw data.

Medtronic produces and sells software that is designed to retrieve and process patient data for post-run reporting and review; however, this software is proprietary and changes the data file at each stage of processing, including retrieval from the monitor. For this reason, SwRI researched and tested independent computer communications processes that could be used for retrieval of desired archived data from the LifePak 12 monitor without changing or corrupting the file or included data. SwRI implemented communications software that was script-driven and could be loaded and executed from other software applications for retrieving stored files from the LifePak 12. This provided the opportunity for future refinement and automation in the data acquisition process, including the potential for wireless data file transfers using the LifeLink network.

Using the independent data communications technique, SwRI was able to recover archived patient data from the monitor used in a qualifying EMS run and store the un-corrupted, but proprietary, data files on a laptop computer. As a quality control measure, SwRI also developed and tested the capability to import copies of recovered data files into Medtronic commercial case reporting software for review of the file and data records before leaving the EMS ambulance. This enabled SwRI to be sure that files of interest were successfully recovered. Only test copies of recovered archived files were reviewed using the commercially available product as the process altered the files. At that point in the process, patient data files were only identifiable by the individual monitor serial number (co-relatable with the individual EMS unit) and the date and time of the event as contained in the file data.

SwRI and Medtronic collaborated to develop a special data extractor utility that allowed SwRI to process retrieved proprietary patient data files to produce data that was usable by the Trauma Vitals database. Patient data collected and provided by SwRI to the Trauma Vitals program was processed using the special data extractor utility.

The output of the data extractor utility was in the form of multiple eXtensible Markup Language (XML) data files. The content and structure of the XML data files conform to data format specifications as developed by USAISR to facilitate data transmission and exchange between physiologic monitor data files and the Trauma Vitals database.

Subtask 1.b Implement data collection configuration in five ambulances.

The original SAFD EMS LifeLink ambulance fleet was being retired and replaced with new vehicles due to age and wear. SwRI accomplished the task of coordinating access to the relevant vehicles with SAFD EMS in order to remove the LifeLink equipment. The equipment recovery task was accomplished by SwRI and the Texas Department of Transportation (TxDOT) at a SAFD facility. Five removed LifeLink equipment sets were refurbished, tested, and prepared for installation in replacement ambulances by SwRI.

Gaining access to an active ambulance for upgrade required that the subject ambulance be removed from active service and replaced with a backup vehicle including movement of active operational and patient care equipment to the backup ambulance. Installation of LifeLink equipment involved significant disassembly and technical preparation of each ambulance, including routing of cabling and installing antennas. This work was followed by re-assembly of the ambulance and test of the installed system. Once the upgrade was completed, the ambulance could be returned to SAFD EMS for re-configuration and acceptance for return-to-service. Snapshots of the project ambulances during typical LifeLink equipment installations are presented in Figures 1 through 4 for reference.



Figure 1. Ambulance in LifeLink Lab at SwRI during Upgrade

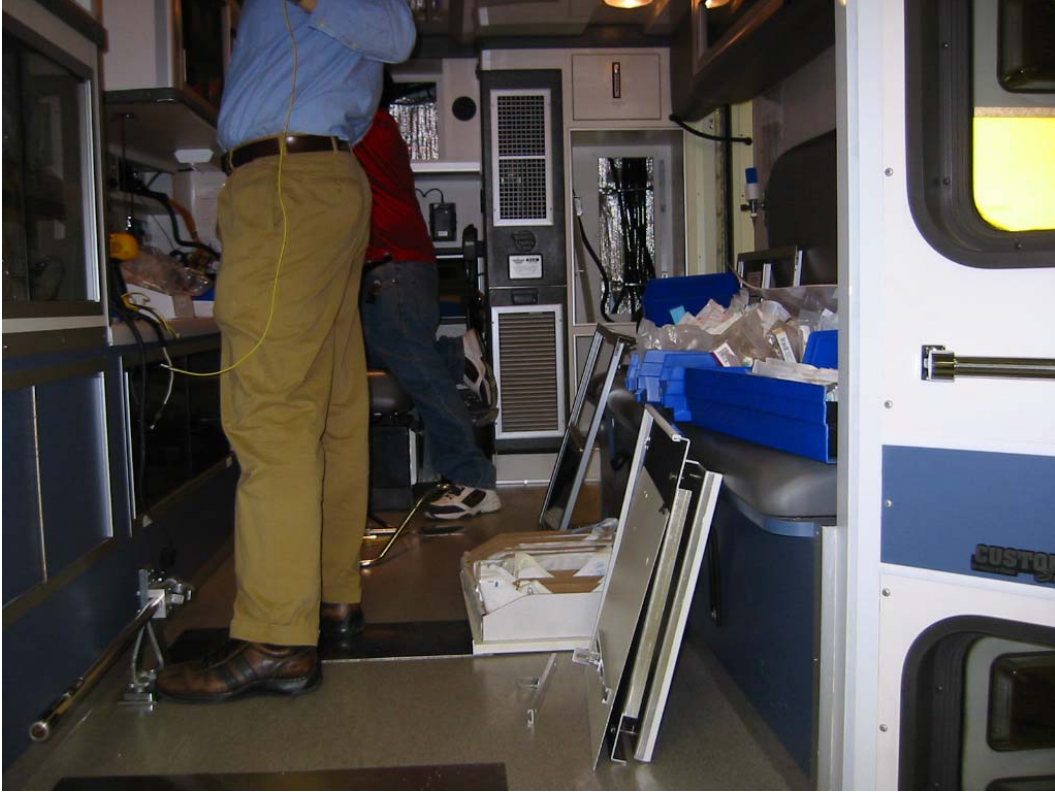


Figure 2. Work Inside Patient Cabin during Upgrade



Figure 3. In-Process LifeLink Equipment Install-Forward Bulkhead



Figure 4. In-Process LifeLink Equipment Install-Headseat Area

SwRI and SAFD coordinated access to the five project ambulances, and installation, test of LifeLink equipment, and return-to-service for the five ambulances was accomplished in the March through May 2006 timeframe. The unique SAFD EMS identification numbers for the five project ambulances and the dates of return-to-service are presented in Table 1.

Table 1. SAFD EMS Ambulance and Date of Return-to-Service After LifeLink Upgrade

SAFD EMS Vehicle Number	Date of Return-to-Service
#8481	4/6/2006
#8487	4/13/2006
#8480	4/28/2006
#8490	5/5/2006
#8479	5/12/06

New SAFD EMS ambulances were specified to contain special wiring and other accommodations built into the ambulances to accommodate installation and operation of LifeLink equipment. During the installation of refurbished LifeLink equipment, however, it was discovered that some of the pre-arranged wiring and accommodations were omitted or incorrectly installed at the factory. SwRI developed a work-around for these problems for currently available newer SAFD EMS ambulances and coordinated correction of the problems with SAFD EMS and the ambulance manufacturer for future vehicles.

Access by SwRI to SAFD EMS ambulances for upgrade and test was limited during the subject project due to a number of issues and surprises. There was, however, steady communication and

paced progress, and permission to access the needed equipment was achieved late in January 2006. Some of the delaying factors are listed below for completeness:

1. There was a delay in negotiating and concluding appropriate agreements between SwRI and SAFD EMS. The delays were primarily in processing the agreement through the city's legal department, which represents SAFD in such matters. The delays were not due to lack of support for the subject project within SAFD; however, SAFD management was grappling with acute general budget and organized labor issues in an environment of strained municipal government operations during recent times.

SwRI ultimately formed a working agreement with SAFD EMS that was similar to other types of public/private cooperative programs within municipal departments. SwRI formed consulting agreements with relevant SAFD EMS staff with approval of SAFD and other city administration. This was similar to arrangements that were made to hire off-duty police officers to provide traffic control or security at special events, etc. The consulting agreements provided a mechanism to compensate SAFD EMS staff for project activities that were accomplished during off-duty periods and that were in addition to their SAFD EMS duties. Such project activities included coordinating and providing access to ambulances for upgrade work by SwRI. SAFD EMS consultant staff also provided services to identify potential qualifying cases and to identify and gain access to operating ambulances and monitors as needed to recover pre-hospital physiological data for qualifying cases. Additionally, EMS case files, run-sheets, and case forms for qualifying cases and with personal identification information deleted were provided to SwRI by SAFD EMS consultant staff. Routine operations by the EMS crews accomplished acquisition of the raw pre-hospital physiological data and case file information during patient care, so these activities did not need to be included in the defined scope of project-related activities for SwRI consultants.

The SAFD EMS staff consulting rates were based on usual pay rates for the affected SAFD staff and not overtime or other accelerated pay rates. The consulting rates and estimated hours were consistent with budget estimates that were defined during project planning, and therefore, reflected planned costs to the project. With these arrangements in place, SwRI had mechanisms and approvals in place to proceed with work on ambulances and pre-hospital data collection that required support by SAFD EMS staff.

2. There is a desire to install the LifeLink equipment in new or nearly new ambulances in order to achieve the longest "life" of the operational vehicles in the fleet. This involved considerable coordination between SwRI and SAFD EMS staff to select vehicles and wait for their availability or delivery.

3. Recent regional emergency events also were problematic for this work. Major hurricanes Katrina and Rita were both located in the Gulf of Mexico during the time that SwRI was attempting to initiate access to ambulances for equipment installation and test. South Texas coastal regions were within landfall forecasts for both of these storms. Planning and coordination for emergency management, mutual aid, search/rescue, and evacuation operations before and after these storms made landfall were a priority at SAFD during this time. The National Disaster Medical System (NDMS) was implemented for the first time as thousands of victims with

medical problems were evacuated to San Antonio, committing many SAFD ambulances and staff to “double duty.” These issues limited SwRI’s ability to focus attention on plans and arrangements for access to the needed ambulances.

4. SAFD EMS had been upgrading the physiological monitors used in its field ambulances to the LifePak 12 monitor manufactured by Medtronic Emergency Response Systems in recent years. Not all of the SAFD ambulances were upgraded to include the LifePak 12 monitors due to municipal budget issues. SAFD ambulances that were not upgraded to the LifePak 12 monitor used the earlier LifePak 10 monitor. Unlike the LifePak 12, the LifePak 10 did not have the capability to store acquired physiological data or to communicate such data to other devices. Both of these functions were needed in order to collect electronic data for this project. There were enough LifePak 12 monitors available in the service to populate the ambulances planned for participation in this project.

The LifePak 12 monitor required special configuration to enable communication of archived files, etc., to other devices. SwRI coordinated with SAFD EMS and Medtronic to facilitate this configuration for all of the SAFD EMS LifePak 12 monitors that were in service. This task was accomplished by SwRI and staff from Medtronic at a SAFD EMS facility in San Antonio.

Subtask 1.c Specify adaptations required for database.

USAISR worked with SwRI to develop and implement a set of data file specifications for physiologic monitor data files that were to be uploaded into the Trauma Vitals Database. The development of the LifePak 12 data extractor utility by SwRI and Medtronic was performed subject to the development of XML data file specifications for the Trauma Vitals program. Output files produced by the special SwRI project LifePak 12 data extractor utilities were specifically formatted to meet the data file specifications.

There were three basic types of electronic data files described for use in the Trauma Vitals program for each qualifying case.

1. Parameter files were structured XML electronic documents that contained identifying information (monitor serial number and time/date, etc.), and information about discrete parametric measurements recorded by the monitor. This information included the type of measurement (such as Heart Rate), the units of the measurement, the time of the measurement, the range of values encountered, and the value measured for the parameter. Separate files were developed for each parameter that was included in the monitor data for each qualifying case.
2. Numeric files were also structured XML electronic documents that contained identifying information (monitor serial number and time/date, etc) and information reflecting sequential numerical sample values for waveforms that were captured during use of the monitor. The information included the type of parameter waveform acquired (such as Electrocardiogram Lead II), the sample rate used in the measurement, the units of the measurement, the time of the measurement, the range of values encountered, and a stream of values reflecting the discrete sample values measured at sample intervals for the parameter waveform. Separate

files were developed for each waveform parameter that was included in the monitor data for each qualifying case.

3. The third type of file was the Event file. Event files were also structured XML electronic documents that contained identifying information (monitor serial number and time/date, etc.) and information about discrete events and parametric measurements recorded by the monitor in response to events. Events could result from manual operations on the monitor such as an operator initiating a “print” command, or could be triggered by internal monitor events such as periodic timed measurements of patient blood pressure, etc. The information in the event file included the type of event (such as “print”) or resulting measurement (such as Heart Rate), the time of the event or measurement, the units of the measurement, and the values measured for parameters included in the measurement. A summary event file that included multiple events and measurements and corresponding information that provided a “history” of the monitor case files was developed.

Subtask 1.d Develop and submit protocols for three IRB approvals (local, one hospital, and the Human Subjects Research Review Board [HSRRB]).

SwRI and USAISR collaborated on development and approval of the protocols for research and data collection involving human subjects for the subject project. The protocols were developed by amending the existing protocol originally approved by the BAMC IRB for pre-hospital data collection at USAISR (actually, a number of incremental amendments). The amended protocol was first submitted and approved by the IRB at BAMC and then at the Multi-Assurance IRB at UTHSCSA. The UTHSCSA IRB was the IRB charged with oversight for SwRI, University Hospital, and others in the San Antonio area. Finally, the subject protocols were submitted and approved by the Human Subjects Research Review Board (HSRRB) at Ft. Detrick.

The title of the protocol was “Capture and Analysis of Prehospital Trauma Vital Signs for Enhanced Remote Triage and Prediction of Life Saving Interventions.” The approved protocol was identified with HSRRB Log No. A-12859b, and notice of the approval of continuing review and amendment of the protocol by HSRRB was received in February 2005.

The research protocol amendments essentially added additional study sites (including SwRI, SAFD EMS, and BAMC) and additional Associate Investigators and other criteria required to enable the data collection and data handling/processing planned for the subject project. Portions of the protocol dealing with operations and data relative to the SAFD EMS system were developed with aid and approval by the Medical Director for SAFD EMS. Subsequent approved amendments have added additional co-investigators and study sites.

Subtask 1.e Semi-Annual Report.

Quarterly reports (or substituted participation in Programmatic Line Reviews) were submitted for the subject project. A semi-annual report was planned in the proposed SOW, but would have been redundant and was not included in the reporting requirements for the subject project.

TASK 2 To implement adaptations for the existing Trauma Vitals Database for San Antonio data and set up the data collection organization.

Subtask 2.a Implement data collection facilities at one hospital.

In preparation for the subject project pre-hospital and post-arrival data collection operations, SwRI met with staff from USAISR and BAMC to discuss and coordinate the work. SwRI and USAISR collaborated to implement a modification to the existing CRDA between the two institutions to accommodate delivery by SwRI of planned financial support to USAISR for related Research Nurse data collection activities, and SwRI subsequently processed the planned Inter-Agency Transfer of these funds to USAISR.

Subtask 2.b Implement database adaptations.

The Trauma Vitals database was modified to process physiological data uploads using specified XML data files for the LifePak 12 monitors used by SAFD EMS for pre-hospital physiological data collection. The database system was modified to provide data import and exchange between multiple data collection centers. These modifications allowed data collected through the SwRI project to be imported and shared on the system using the same formats currently supported by other data collection sites.

Work was accomplished to provide a native interface for the XML numeric and waveform data formats identified for the project. This part of the system was implemented as part of a new server-side architecture developed by USAISR to replace the initial Java-based system. The new Hypertext Preprocessor (PHP)-based system was designed to allow for better data management and processing as new data collection sites were added to the Trauma Vitals project. Moving data processing and database access functionality to the server provided increased performance for data sites that had limited data connection capabilities.

Subtask 2.c Implement the data collection system and familiarize EMS and hospital personnel with project procedures.

SwRI coordinated pre-hospital data collection activities with SAFD EMS during the month of February 2006. SwRI configured two laptop computers to accomplish raw archived data file retrieval from the LifePak 12 monitors using the data communication algorithm developed by SwRI. One of the laptops was provided to SAFD EMS staff associated with the subject project, and one was maintained by relevant SwRI staff. Each of the laptop computers was also configured to process LifePak 12 archived data using the commercially available data management software provided by Medtronic Emergency Response Systems. Relevant SAFD EMS staff were trained on procedures for acquiring archived patient data from the LifePak 12 monitor using the specially configured laptop computers used for this purpose.

SAFD EMS crews associated with participating ground ambulance operations (24 hours/day and 7 days/week) were briefed on the data collection project and asked to maximize the “monitor time” for all Code 3 trauma patients that were cared for during the data collection period, and to

alert the SAFD EMS Shift Commander's office after a qualifying transport. The SAFD EMS Medical Director provided medical oversight and collaborative support during operations for this process.

SwRI coordinated with the SAFD EMS Shift Commander's office to provide routine evaluation and identification of qualifying cases handled by the organization as reported by ambulance crews. Qualifying cases were also independently identified by routine review of new cases entered into the SAFD EMS records system, at intervals of one to two days of operations, during the data collection period. Once qualifying cases were identified, SAFD and/or SwRI staff coordinated to access the particular ambulance involved in each qualifying case and retrieve the case-related pre-hospital physiological data from the onboard LifePak 12 monitor.

Additionally, SwRI coordinated with research staff at USAISR to prepare for post-arrival data collection for the subject ground EMS qualifying cases and to arrive at a mutual understanding of information content and procedures.

SwRI also worked to acquire and extract case timing information from runsheets and case files as well as from collected monitor data to support the investigation of elapsed time intervals between estimated times of injury and the beginning of data collection for qualifying cases. USAISR was also able to access equivalent information for helicopter services operating within the San Antonio area. With this information, USAISR was able to conduct a statistical analysis of the elapsed times between injury and the start of data collection for the two types of services.

Subtask 2.d Annual Report.

An annual report for the subject program was delivered on June, 20, 2005 as planned.

TASK 3 To conduct operations to collect data.

Subtask 3.a Collect hospital and pre-hospital data derived from existing practices for Code 3 trauma patients transported to one hospital by SAFD LifeLink ambulances for one month.

The subject project plan and SOW included work to collect target data for qualifying patients transported by the five project ambulances to one hospital. During project discussions and preparations, however, it became apparent that relevant USAISR staff was positioned to collect patient data for qualifying helicopter cases at University Hospital as well as BAMC, and this presented the opportunity to include data collection for patients transported by the ground EMS system to University Hospital in addition to BAMC within the current scope of operations. A decision was later reached between SwRI and USAISR to also include data collection for SAFD EMS qualifying cases transported by ground ambulances to Willford Hall Medical Center (WHMC). All three of these hospitals were Level 1 Trauma Centers accepting patients from the surrounding municipal area. Also, since the initial manual data collection operations was not designed to make use of the LifeLink equipment in the project ambulances, SwRI was able to expand the ground EMS data collection work beyond the five LifeLink-equipped ambulances and to include each of the ten SAFD EMS units equipped with the data-capable LifePak 12

monitor. These steps were taken in order to increase the number of qualifying cases for which data could be collected for the subject research purposes.

SwRI and SAFD EMS worked together to identify and collect pre-hospital data for twenty-eight qualifying patients during the POC data collection period. SAFD EMS run-sheets and case forms for each of the identified cases were also collected, with personal identifying data deleted. These forms provided case-specific information such as case times and a short abstract of the case and paramedic observations, as well as noted parameter values and treatments administered in the field, etc.

Two of the identified cases were excluded due to not meeting the requirements set forth in the approved research protocol (underage), and the pre-hospital data for one case was un-readable. Twenty-five qualified cases and related pre-hospital data were therefore identified for further processing.

Subtask 3.b React to problems in facilities and organizations.

SAFD EMS uses 3-digit ambulance identity numbers to dispatch and track individual operating ambulances and crews during fleet operations. These are commonly called “unit numbers”. When vehicles are taken out of service for maintenance, etc. and replaced with “backup” vehicles, the unit number stays with the crew and backup vehicle.

During initial data collection operations, SwRI encountered errors in identifying and associating pre-hospital data collected for qualifying cases with SAFD EMS records. SAFD EMS 3-digit unit numbers had originally been programmed into the LifePak 12 monitors as they had been assigned to the operating units. During the course of operations over time, however, vehicles and monitors had been substituted or otherwise moved among the SAFD EMS unit assignments. Therefore, there was often confusion because collected electronic patient data files for identified cases were reporting different unit numbers than actual unit numbers after the data was processed and readable. This caused difficulty and uncertainty in the required association of electronic pre-hospital data files with identified cases. Through a process of analysis and elimination, however, the scope of this problem became understood, and corrective actions were identified. The unique serial numbers for the LifePak 12 monitors were included in the electronic data files, and these serial numbers were correlated with the actual SAFD EMS unit numbers involved in respective qualifying cases. A “translation table” was set up to facilitate correct identification of electronic pre-hospital data files with SAFD EMS records centered on the 3-digit unit numbers.

Subtask 3.c Review and analyze data and refine procedures.

Qualifying code 3 trauma cases that were cared for during the pre-hospital interval by SAFD EMS during the data collection period were identified. Electronic files of pre-hospital physiological data for qualifying cases were recovered from the monitors in use during the case retrospectively. EMS run-sheets and case-file forms without personal identifying information but containing relevant case time and other diagnosis, care, and treatment data needed for the subject research and analysis program were also collected for qualifying cases.

The encrypted electronic pre-hospital data files were processed to yield data files that were readable and usable in the Trauma Vitals program. SAFD EMS unit identification and time information within the processed files facilitated association between the electronic files and the run-sheets for the qualifying cases. Identified cases that did not meet the requirements of the approved protocol (underage, etc.) or for which electronic data files were corrupted or suspect were excluded from the study.

Elapsed times between estimated times-of-injury and the onset of post-injury pre-hospital data collection were derived from data within the SAFD EMS records and the electronic data files.

The identified qualifying cases and associated data files and case time data were reviewed for accuracy by SwRI and SAFD EMS consultant staff. The qualifying case data was then reviewed by the Medical Director for SAFD EMS, who is also a Co-Principal Investigator for the subject project and therefore familiar with the operations and goals of the program.

SwRI provided the resulting processed electronic pre-hospital data files for qualifying cases to USAISR, along with associated SAFD EMS run-sheets and case-file forms with personal identifying information deleted, for use in the Advanced Capabilities for Combat Medics research program. SwRI also provided a summary of relevant case times to USAISR as derived from the subject data.

A primary area of investigation relative to the hypothesis proposed for the subject research included evaluation of the potential that collection of target pre-hospital patient data can begin earlier in qualifying trauma cases within a ground EMS first responder service than for helicopter ambulance services. Often, helicopter services are launched after first responders are on a scene to assess the need for air transport. Ground EMS services often treat, stabilize, and package patients for air transport while helicopters are enroute to a scene. Helicopter services also typically operate over much larger geographical areas than ground EMS systems.

Using data for qualifying ground EMS cases provided by SwRI, USAISR conducted an analysis of the time intervals between estimated time-of-injury and the onset of acquisition of patient physiological data (Initial Data Delay - IDD) for the 25 ground EMS cases versus a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 Trauma Centers by air services. Comparative analysis of the two data sets by SwRI and USAISR demonstrated that, for these samples, the helicopter service experienced an almost 15 minutes longer Mean Initial Data Delay (MIDD) than the MIDD experienced by the ground EMS first responder system. Analysis of the variances between the two data sets showed a significant difference between the two groups ($p < 0.05$). A summary of statistical values derived from analysis of the two data populations is presented in Table 2.

Table 2. Statistical Summary of Initial Data Delay Times for Air and Ground Services

	Ground EMS Service (n=25);(hr:min:sec)	Helicopter Service (n=57);(hr:min:sec)	Δ =Gnd-Air (hr:min:sec)
Mean Initial Data Delay (MIDD)	00:23:15	00:37:59	00:14:44
Standard Deviation	00:07:25.6	00:19:34.8	00:12:09.2
Range	00:32:26	01:28:41	00:56:15
95% Confidence Interval Upper bound	00:26:19	00:43:11	00:16:52
95% Confidence Interval Lower Bound	00:20:12	00:32:48	00:12:36

The operational significance of the shorter IDD experienced in the ground EMS system is that physiological data reflecting parametric measurements and trends for severely injured patients begins sooner after an injury. For these samples, the helicopter data began 63.4% (MIDD) later than the ground EMS system after the estimated time-of-injury. This data supports the hypothesis proposed for this research. The clinical significance of earlier post-injury onset of data capture for code 3 trauma patients within the Advanced Capabilities for the Combat Medic program will continue to be investigated by USAISR and SwRI.

Subtask 3.d Final Report.

This report is the Final Report.

TASK 4 To investigate and begin implementation of new SAFD EMS physiological monitor pre-hospital data collection interfaces and operations:

SAFD EMS had been using a mix of physiological monitors in its operating fleet due to budget constraints, with about one-third of the fleet using the data-capable LifePak 12 monitor. SAFD EMS recently adopted a system-wide conversion to a new physiological monitor, and the conversion to the new monitor occurred after SwRI and SAFD EMS completed the planned pre-hospital electronic data collection operations for this project. The new monitor was a Philips HeartStart MRx, which appeared to be capable of storing and delivering patient data acquired during emergency response operations. While this change would require adjustments in order to continue Trauma Vitals data collection and research operations and improvements, the long-term benefits would include many expanded opportunities for Trauma Vitals data collection and research. SwRI requested and received approval for a six-month no-cost time extension for the subject project in order to react to the equipment change in project ambulances. The planned added work was reflected in an additional task (TASK 4) added to the approved SOW.

Subtask 4.a Investigate new SAFD EMS monitor configuration and data extraction/processing tools.

SwRI met with SAFD EMS staff and the SAFD EMS Medical Director on numerous occasions to understand the protocols and standard operations that define the configuration and use of the

new monitor for qualifying cases for this project. For routine code 3 adult trauma cases, the monitor is applied to the patient early in the response and typically after the patient is in the ambulance. Electrocardiograph (ECG) and End Tidal Carbon Dioxide (ETCO₂) parameters are acquired and are available on the screen of the monitor as scrolling waveforms, and this data is also captured in the monitor memory. Additionally, discrete values for Non-Invasive Blood Pressure (NIBP), Oxygen Saturation (SPO₂), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Heart Rate (HR), Pulse Rate (PR), Respiration Rate (RR), and Blood Pressure Pulse Rate (BPPR) are measured or derived by the instrument and made available to the operator and captured in the device memory. Events relative to a patient monitoring session, either prompted by operator commands or by monitoring alarm conditions, etc. are also captured in the device memory.

Commercially available software tools compatible with the MRx that have been identified by SwRI are designed to meet operational needs of EMS systems and provide case reporting capabilities, to include viewing of waveforms and noted measurements and events on a computer screen. The tools are also capable of providing electronic case summary reports to be included in medical charts and for quality control and other medical records purposes. The case summary reporting is designed to comply with National EMS Information System (NEMSIS) standard reporting formats, as sponsored and adopted by the Centers for Disease Control (CDC), the National Highway Traffic and Safety Administration (NHTSA), and others.

The use of such products does not produce or preserve data content for this project. Much of the detail information, including digital sampled values of acquired waveforms, is discarded, changed, or otherwise corrupted in the processing that occurs once raw data from the monitor memory is imported and processed to produce viewable or storable report products for the targeted EMS and medical records purposes. Consultation with Philips Medical Systems engineering staff by SwRI reinforced that much needed information for this project acquired and stored within the monitor is discarded or changed during processing by the case review program products to produce the NEMSIS-compliant reports and summaries.

Subtask 4.b Investigate new SAFD EMS monitor data collection interfaces and process compatible with ground EMS operations.

SwRI met with representatives from Philips Medical Systems and obtained user documentation for the Philips HeartStart MRx monitor. SwRI also accessed working models of the monitor at SAFD EMS to test and evaluate the monitor's data management capabilities and interfaces. SwRI participated in numerous meetings and discussions with engineering and development staff at Philips Medical Systems, supplier of the MRx, to better understand the data management capabilities provided by the monitor and plans for improvement.

Currently, to acquire data stored in the monitor, an operator must engage the controls and display of the monitor in a sequence of interactive operations to identify, select, and transfer data from the monitor memory to a small memory card. The operator must have prior knowledge of information about the case of interest, including which monitor was used and the date and time (as recorded by the clock within the monitor) of the incident. The operator must enter a data management mode on the monitor and navigate through several screens to select the appropriate

case file. Once the file of interest is selected, the operator can cause the file to be transferred to a Compact Flash (CF) memory card that is plugged into a port provided on the monitor. The CF card can then be removed and the file can be moved to another computer using the CF card. The data in each case file at this point consists of a series of XML and binary files containing coordinated but distributed information about measurements and events recorded during use. The structure and format variables reflected in the raw data files is proprietary. The raw data files extracted from the monitor memory require significant interpretation and processing to arrive at the data content and format needed for the Trauma Vitals program.

The memory available in the monitor is finite. The system can store approximately fifty typical case files as generated in use by SAFD EMS. Fewer files will be stored if the files become large due to extended operations or using data-intensive modes of operation. While qualifying cases for this project use relatively simple monitor processing configurations, the monitor also provides 12-lead ECG and defibrillator functions for cardiac cases. Some operational modes used by SAFD EMS can generate very large stored data files. As for the LifePak 12 monitor, if data for a case of interest is not recovered soon after a qualifying case is active, the data stored in the monitor may be lost. Continued use of the monitor by SAFD EMS results in additional cases stored in the monitor memory, and the “oldest” case files in the monitor memory are deleted as needed to accommodate new case file data.

Subtask 4.c Develop and test proof-of-concept pre-hospital data collection and process capability based on new physiological monitor and Data Integration Software Development Kit tools.

SwRI worked with SAFD EMS to acquire reference case file data provided by the MRx monitor configured as used for qualifying cases for this project. Healthy volunteers (SAFD EMS paramedics) conducting monitor training sessions on each other produced the reference files, and SwRI accessed the monitor after the event to extract the reference data files.

With support from Philips Medical Systems engineering and research staff, SwRI researched and developed a capability to interpret and process the reference raw data files derived from the monitor memory to produce the data content and format needed for the Trauma Vitals program. The procedures developed by SwRI to process the raw monitor data is a proof-of-concept approach. Research and use of the procedures by SwRI indicated that data content needed for the Trauma Vitals program is available in the raw data files produced by the MRx monitor. The research and procedures also demonstrated that SwRI understands the basic structure and content of the monitor files sufficiently to interpret the data and produce the XML data files needed for import of case data into the Trauma Vitals project database. Future work is needed to improve, enhance, and further validate the SwRI-developed proof-of-concept data processing capabilities.

Key Research Accomplishments

- Pre-hospital physiological data and corresponding EMS run-sheets and case forms were collected, processed, and delivered to USAISR for use in the Trauma Vitals project.

- Comparative statistical analyses of data sets relevant to the aims of the subject project and resulting from ground and air data collection operations were conducted and the results reported. Results of the analysis support the hypothesis proposed in this research program (see Reportable Outcomes below).
- The planned renewal of five LifeLink project ambulances was completed and the vehicles were returned to service.
- Agreements for the subject project are in place between SwRI and USAISR, UTHSCSA, SAFD, and Medtronic.
- A proof-of-concept ground EMS pre-hospital data collection process was defined and is the basis of the work for the project.
- The research protocol for project data collection and research was developed and submitted. Local IRB and HSRRB approvals were obtained.
- LifePak 12 monitors in the LifeLink EMS fleet were configured to accommodate data storage and extraction.
- An independent raw-data recovery process and tool for the LifePak 12 physiological monitor were developed and tested.
- A special physiological data-extraction utility to process LifePak 12 monitor data into reports consistent with the content and format needs for the Trauma Vitals Database program was developed and tested.
- A new monitor (Philips MRx Heartstart) was adopted by SAFD EMS to replace the mix of LifePak monitors in the system, and MRx monitors were deployed throughout the entire fleet. The capabilities and configuration of the MRx monitor and commercially available data processing products relative to this project were researched and evaluated.
- MRx data collection interfaces and operational processes that may be consistent with routine ground EMS operations were explored, and opportunities and problems were defined.
- The content and structure of data files produced by the MRx monitor during patient care were researched and a proof-of-concept capability to extract and process this data for use in the Trauma Vitals program was developed.

Reportable Outcomes

- Pre-hospital physiological data and EMS run-sheets and case forms for 25 qualifying adult code 3 trauma cases cared for by the crews of a fleet of ten SAFD EMS ground ambulances and transported to three Level 1 Trauma Centers have been acquired. The data has been processed to conform to the needs of the Trauma Vitals database program and delivered to USAISR to facilitate related research activities. The number of qualifying cases for which data was collected exceeded expectations significantly because the project team was able to involve twice the number of participating ambulances and additional participating hospitals in the data collection process than planned.
- USAISR conducted an analysis of the time intervals between estimated time-of-injury and the onset of acquisition of patient physiological data (Initial Data Delay - IDD) for the 25 qualifying ground EMS cases for which data was collected versus a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 Trauma Centers

by air services. Comparative analysis of the two data sets by SwRI and USAISR demonstrated that the helicopter service experienced an almost 15 minutes longer Mean Initial Data Delay (MIDD) than the MIDD experienced by the ground EMS first responder system. The operational significance of the shorter IDD experienced in the ground EMS system is that physiological data reflecting parametric measurements and trends for severely injured patients begins sooner after an injury in the ground system. For these samples, the helicopter data collection began 63.4% (MIDD) later post-injury than in the ground EMS system. These results are interpreted to substantiate the hypothesis proposed for the subject project.

- SwRI has developed a new initiative to support and expand the data collection and research operations that are part of the Trauma Vitals program. The Parameter-based Remote Objective Pre-Hospital Emergency Triage (PROPHET) program has achieved first-year funding support, and future support is anticipated.
- Five operational ambulances have been equipped and tested to operate within the LifeLink network and have been returned to service within the SAFD EMS system.
- The subject project, the Trauma Vitals project, and the PROPHET initiative were displayed and showcased during the 2004 Annual Meeting and Convention of the Intelligent Transportation Society of America (ITSA). During this major convention in San Antonio, a live emergency management exercise was conducted by municipal public safety agencies. The drill exercise was a simulated “suicide bomber” attack inside a convention hall with multiple casualties. A LifeLink-equipped ambulance along with remote diagnostic ultrasound (linked to Brooke Army Medical Center) and Trauma Vitals demonstrations and displays were integral parts of the exercise. The exercise was a well-advertised and well-attended feature of the ITSA convention. Approximately 30 volunteer victims with moulage were assessed and evacuated during the exercise. The ITSA organization maintains a major emphasis on the interaction of transportation systems and emergency response issues, and future potential collaborations are currently being explored.

- Required list of persons receiving pay from this project:
 - Aguilar, John
 - Bielke, Peggy
 - Boehme, Kiel
 - Dore, Monica
 - Fritz, Justin
 - Gordon, Donald
 - Gutierrez, Michael
 - Kinkler Jr., Ernest, S
 - Lents, Danny
 - Martinez, Elia
 - Moczygemba, Mark
 - Montes, John
 - Rudewick, Todd
 - Rusk, Sherry
 - Williams, Kari

Conclusions

Significant amounts of high quality, but difficult to acquire, data are needed for the Trauma Vitals project. The nature of the research program suggests that obtaining data for trauma patients during the prehospital phase is advantageous to development of future triage, treatment, and decision support systems. Collection of data and trending parameters beginning soon after an injury occurs may yield particularly relevant and usable information.

The development of a system to collect data using a fleet of ground EMS ambulances operating in a large municipality that routinely transport trauma patients to both military and civilian trauma centers was the focus of this project. Further, the existence of a widely distributed mobile broadband digital communications link between ambulances in the field and the trauma centers (the LifeLink project) can facilitate more transparent and easily managed data collection in the emergency patient pre-hospital care environment.

During the subject project, the foundation has been laid to implement the data collection operations as described above. A proof-of-concept process for manually collecting, processing, and providing pre-hospital physiological data for qualifying trauma patients has been defined and implemented. Research protocols involving human subjects for this project have been developed, and required IRB and HSRRB approvals have been obtained. The implementation of physical and electronic accommodations to facilitate proof-of-concept data collection within a ground EMS system and pave the way for future practical expansion and automation of the data collection and upload process has been accomplished.

A larger volume of the target data was collected than planned during the time available for these operations. This was due to recognition of un-planned opportunities for the project partners to make adjustments during the data collection period to increase the number of participating ground ambulances and hospitals to add to the number of qualifying cases encountered. Analysis

of the project data and comparison of the analysis results to a similar data sample collected within operations of a helicopter EMS service shows that data collection activities within primary patient care protocols began significantly earlier in the injury events within the ground-based system.

Subsequent to the completion of the planned data collection operations, SAFD EMS embarked on a system-wide change to a new, more capable monitor to be used in patient care. This change resulted in more than three times as many operating ambulances that could support data collection available to the project. The change also required the project team to learn about the capabilities and functions of the new monitor and to adapt to the different data characteristics and formats produced by it in order to prepare for continued data collection operations. SwRI worked with SAFD EMS and the manufacturer of the new monitor to understand the current and planned data management capabilities of the new device. SwRI acquired relevant reference volunteer-patient data from the new monitor and developed, with the support of the manufacturer, a proof-of-concept capability to extract and process the raw monitor data to meet the needs of the Trauma Vitals project.

Finally, SwRI has developed an initiative based on the subject initial project to include future automation, expansion, and extension of the data collection and Trauma Vitals research. The PROPHET initiative has achieved initial funding support, and it is anticipated that this support will be continued and expanded in the future. The PROPHET program and its relationship to emergency patient care was showcased during a live emergency drill within a major convention during the reporting period. Future plans for the PROPHET program include refinement, automation, extension, and expansion of the data collection efforts. Additional research components will be added to further analyze collected data to help identify meaningful predictive trends and algorithms and to expand data gathering and research work to include additional potential field triage advances. It is anticipated that this work will ultimately lead to deployable prototype equipment, field and clinical trials, and development/distribution of the technologies to military as well as civilian casualty care organizations.