Award Number:
DAMD17-03-2-0061

TITLE:
Demonstrating Innovative Solutions to Care for Others Via Electronic Real-time Information and Emergency Services (DISCOVERIES).

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REPORT DATE:
October 2009

TYPE OF REPORT:
Final

PREPARED FOR:
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE	Form Approved OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-Oct-2009	Final	1 SEP 2003 - 30 SEP 2009

4. TITLE AND SUBTITLE
Demonstrating Innovative Solutions to Care for Others Via Electronic Real-time Information and Emergency Services (DISCOVERIES).

5a. CONTRACT NUMBER
DAMD17-03-2-0061

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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Ft. Detrick, MD 21702

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Unlimited

13. SUPPLEMENTARY NOTES
N/A

14. ABSTRACT DISCOVERIES' primary purpose has been to establish an integrated prehospital and hospital telemedicine test bed at Loma Linda University Medical Center. This test bed will facilitate research into prehospital care, which is critical to providing timely, evidence-based medical care to the wounded soldier on the battlefield. Significant accomplishments include: the establishment of a Center for Prehospital Care, Education, and Research; development of an Emergency Medical Services Fellowship; and implementation of an automated prehospital data collection system. Additionally, the project has produced two technologies that will enhance the emergency response in critical incidents—(1) an off-road capable Mobile Telemedicine Vehicle (MTV), and (2) the Advanced Emergency Geographic Information System (AEGIS). Both of these technologies allow real-time information to be available to incident managers and responders to improve consequence management.

15. SUBJECT TERMS
None provided.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
U	U	U	UU	60	909-558-7611

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Introduction

DISCOVERIES' primary purpose has been to establish an integrated prehospital and hospital telemedicine test bed at Loma Linda University Medical Center. This test bed facilitates research into prehospital care, which is critical to providing timely, evidence-based medical care to the wounded soldier on the battlefield. During the past 30 years, prehospital care has experienced explosive development and growth. Despite this considerable growth, there continues to be a lack of adequate evidence on how emergency medical services (EMS) systems influence patient outcomes for most medical conditions, and how they affect the overall health of the communities they serve. Establishment of a prehospital test bed will provide an opportunity for military and civilian organizations to determine the medical and economic value of new technologies in an urban, rural, and wilderness prehospital setting. Significant accomplishments include: the establishment of a Center for Prehospital Care, Education, and Research; development of an Emergency Medical Services Fellowship; and implementation of an automated prehospital data collection system. Additionally, the project has produced two technologies that will enhance the emergency response in critical incidents:(1) an off-road capable Mobile Telemedicine Vehicle (MTV), and (2) the Advanced Emergency Geographic Information System (AEGIS). Both of these technologies allow real- time information to be available to incident managers and responders to improve consequence management. The project also included three research protocols examining the efficiency and satisfaction of use of the electronic medical record, and the use of telemedicine in a nursing home population.

Body

Scientific Progress in Terms of the Tasks or Objectives Listed in the Statement of Work for this Contract

Task 1: Create The Center for Pre-hospital Care, Education, and Research (CPCER)

Milestones 1: Hire Personnel

Milestone 2: Obtain/Occupy Space

Milestone 3: Grand Opening of Center with Website

Milestone 4: Begin EMS Fellowship Program

Optimal patient care prior to arrival at the hospital does not exist in a vacuum. Ideal prehospital care is inextricably linked to education of prehospital care providers and outcomes-based research. This is reflected in the document, the *EMS Agenda for the Future.* This document united the many professional groups participating in EMS with the common goal of improving system performance. The National Highway Traffic Safety Administration (NHTSA), which has been responsible for creating national standards for EMS education, operations and system development since the 1970s, supported the creation of this consensus-based national EMS strategic plan. It was clear to these experts that EMS treatments must be based on evidence if we are to improve patient outcomes and overall community health. [1]

Critical to the education of prehospital providers is the need to include "knowledge translation" into their practice. Most EMS professionals, however, are not trained to critically evaluate whether evidence supports the use of new treatments. The Center for Prehospital Care, Education, and Research (CPCER) promotes the concept that EMS physicians should provide prehospital personnel with the tools to link clinical research to clinical care. This will lead to a

culture within EMS of promoting research and demanding evidence before implementing new system modifications, medications, or other therapies. As EMS care continues to evolve and become more sophisticated, the need for high quality education for EMS personnel is essential.

Task 1 of DISCOVERIES, to establish the Center for Prehospital Care, Education, and Research, has worked to accomplish this goal. The established Center offers a coordinated approach to prehospital care, education, and research from the schools of nursing, medicine, allied health, and the academic healthcare center, which currently offer services to prehospital personnel. An office where prehospital personnel can register for classes, have questions answered, or get updated about upcoming events was established.

Or, "one stop shopping" via our website, www.lluems.com, gives 24 hour access. The Center provides a centralized resource that can assist prehospital care providers and others with continuing education, patient care issues, and research related to the prehospital environment.

An additio nal outco me of this task was the establishment of an Emergency Medical Services Fellowship. Offered to emergency medicine physicians who are interested in increasing t heir knowledge of prehospital systems by additional training, we have had three fello ws successfully complete their t raining. These fello ws work closely with EMS personnel to provide medical direction and research opportunities. Projects developed by the fellows, in conjunction with the achievemen ts of DISCOVERIES, include quality assu rance activities as well as e valuation of new and e xisting policies, procedures, technologies, and equipment.

Fellows have man y opportunities to be involved in EMS activities, including Air Rescue, Event Med icine (in cluding major concerts, motocross and NASCAR races, an d the Baja 1000) at many of the local venues as well a s internation ally, and disaster drills and regional exercises.

Task 2: Develop and Implement an Integrated Hospital and Prehospital Data Collection System for a Telemedicine Test Bed

Milestones 5: Begin Prehospital Automated Data Collection

Milestone 6: Go Live with Wireless Emergency Department Documentation

Milestone 7: Go Live with Integrated Hospital and Pre-hospital Data Collection

Millions of dollars are being spent in EMS for care that isn't evidence based. W hat we once thought made sense doesn't once it is rig orously studied. However, many barriers to obtain ing the evidence exist--diverse EM S systems with different medical pro tocols nationwide, no standardized EMS data set, most EMS data collection is via a paper r eport, and d ata from the numerous care providers is not linked. For several years the National Highwa y a nd Traffic

Safety Agency (NHTSA) has called for outcomes-based research in EMS with clearly defined and proven methodologies.[2] In response, the Emergency Medical Services Outcomes Project (EMSOP) has focused its efforts on recommending methodology and outcomes that could be used to assess effectiveness of EMS care.[3] They have recommended six general outcomes categories for use as benchmarks in EMS research and include improving survival, limiting disability, alleviating discomfort, increasing satisfaction, and cost-effectiveness. EMSOP also developed a set of emergency medical conditions that they felt should take precedence in outcomes research. The outcome measure judged to be most important for many conditions was not survival, but relief of discomfort. Unfortunately, most research in EMS does not use this methodology. A review of the EMS literature found that retrospective and case series predominated. Very rarely were meaningful outcomes reported.[4]

EMSOP also indicated that outcome measures are a function of both the treatment characteristics and the risk adjustment variables[5,6]. The authors note, for example, that to determine if prehospital CPR affects survival, one must know specifics about the treatment, such as who was performing CPR and what technique they were using. One would also need to know about risk adjustment variables to put the outcome in context, such as whether or not this was a witnessed arrest, the age of the patient, and/or the presence of other medical conditions. The effect of the treatment intervention on the outcome measure can only be interpreted in the context of these risk adjustment variables. Without meticulous data collection this cannot be accomplished. The EMSOP authors note that without such risk adjustment measures "the information available from current out-of-hospital databases will be insufficient to answer outcomes questions." Obtaining risk adjustment measures will require "linkage of data from emergency department, inpatient, outpatient, and in some cases, autopsy records…" Findings from the nations EMS Research Agenda echo these sentiments.[7] There is a call for integrated information systems, increased research funding, and better consent mechanisms for research participation. Establishment of an integrated system that links the prehospital record with the emergency department and hospital records is necessary to perform research into this vital area. The DISCOVERIES Project, through Task 2, allowed for collection and analysis of risk adjustment and outcomes variables in a variety of patients and settings.

General consensus from the regional EMS agencies was to purchase hardware and software from HealthWare Solutions for the electronic prehospital data collection tool. The participating agencies were selected for their diverse geographic locations and have collectively created a

test bed representative of urban, rural, and wilderness environments. The agencies have received and implemented the electronic system into their prehospital patient care. Additionally, Inland Counties Emergency Medical Agency (ICEMA), the governing body of EMS in San Bernardino County, CA sought and received approval for a Department of Homeland Security (DHS) grant to complete the HealthWare Solutions integration after DISCOVERIES started the pilot program, thus expanding the current system to all the local agencies. Currently, the local paramedic educational centers include training in the data collection system so that all graduating paramedics will be able to utilize the system. This expansion of the program was a direct result of the initial efforts by the DISCOVERIES Project.

The Emergency Department electronic real-time physician documentation system is now well-established. This system allows the emergency physician to do electronic bedside order entry, histories, and physical documentation. While historically this has been done on paper or dictated, electronic capture of this data will allow a completely searchable integrated prehospital and hospital database to be utilized for outcomes-based research projects.

The integrated prehospital and hospital data collection system also included the development and implementation of an interface between the prehospital data collection devices and the hospital medical record. This interface allows all patient information to reside in one database, facilitating retrieval for research. This system has been completed and tested. In the future, when all county agencies are equipped with electronic record capability through the DHS grant, data collection on a county-wide basis can be initiated. This will result in an incredible database for outcomes research.

Task 3: Create a Regional Emergency Telemedicine Command Center and Network

Milestone 8: Start Using Integrated Pre-hospital Geographic Information System

Milestone 9: Successful Telemedicine Consult with Prehospital Site

Milestone 10: Trial Mobile Emergency Telemedicine Equipped Response Vehicle

Access to timely and appropriate medical care is currently limited for large segments of the population. Several factors have contributed to this problem, including closure of many emergency departments and acute care hospitals, an expanding population, increasing numbers of uninsured patients, skyrocketing physician liability rates, and shortage of nursing

staff. Additionally, medical expertise tends to be centralized in large urban centers, leaving many smaller and rural areas underserved.

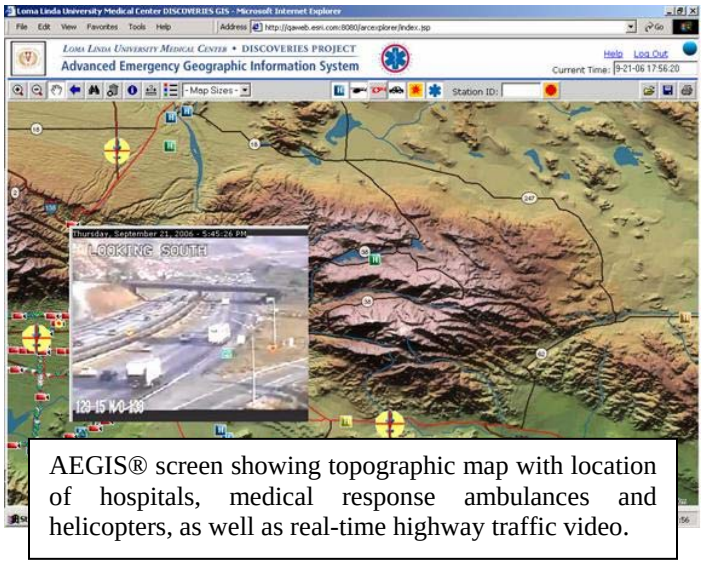
Loma Linda University Medical Center (LLUMC) is in an ideal position to address this problem via the use of telemedicine. Currently the Emergency Department provides medical direction for over 2,000 advanced life support (ALS) scene calls per month as a paramedic base station. All contacts are originated by paramedics and communications is via an 800 MHz trunked radio system or cellular phone. In addition, LLUMC receives approximatly 300 patients each month that are transferred for higher level of care from outlying emergency departments, nursing homes, military bases, jails, and other facilities. One aim of the project was to demonstrate the capability of a telemedicine connection to prehospital and transferring facilities. This would permit earlier specialist evaluation of patients, improving patient care, avoiding unnecessary transfers, and resulting in better resource utilization.

With this is mind, the DISCOVERIES project created a regional Emergency Telemedicine Command Center (ETCC) and network. The ETCC established a telemedicine 'hub and spoke' system to maximize and leverage all the health care resources available at Loma Linda University Medical Center and provide real-time telemedicine consultation service to nursing homes, mass gatherings, disaster scenes, and underserved areas. This capability has been successfully demonstrated in multiple settings, including a local nursing home and urgent care clinic. DISCOVERIES has also worked with other University and Medical Center groups to establish a telemedicine connection to multiple clinics and emergency departments throughout Southern California.

The Emergency Telemedicine Command Center at Loma Linda University Medical Center

As one 'spoke' of this network, DISCOVERIES developed a Mobile Telemedicine Vehicle (MTV) prototype for emergency and disaster response. This vehicle, off-road capable and outfitted with state-of-the-art satellite communications and telemedicine connectivity, can connect the ETCC with field resources at disaster incidents. Additionally, the MTV has all the state-of-the-art technology of the ETCC, allowing it to function as a mobile command center in the event the emergency department or hospital is involved in a disaster. Specialized communications enhancements within the MTV provide a "bridge" between various communications equipment (800 MHz radios, cellular, HAM, etc.) that results in interoperability among various agencies and communications hardware involved in incident response. Additional medical equipment, including teleradiology, provides the ability to assess and treat patients and support triage activities, both *in situ* and via telemedicine to the LLUMC emergency department. Disasters that result in multiple casualties, interruptions in transportation networks, communication infrastructure failures, and issues of contamination may create an environment where it is not possible to bring patients to the emergency department. Several authors [8-13] have recommended using telemedicine to assist with triage and provide care or consultation during such disasters. The MTV can help with all of these functions, as well as provide an adjunct to, or even replacement of, an area's communication system. The MTV has been tested at multiple venues, including NASCAR events and the American Motocross Association races. The MTV had its first actual deployment to the Esperanza Fire, where patients were seen, treated, and discharged at the site, eliminating unnecessary transports to local emergency departments and allowing responders to return to the field. More information about the MTV can be accessed at http://video.google.com/videoplay?docid=8335735774831241047.

Integral to responding to emergency situations is the ability to provide useful, up-to-date information about the incident. DISCOVERIES has developed an emergency medical services (EMS) tool using geographic information systems (GIS) that integrates both static and dynamic data into a "smart map." This Advanced Emergency Geographic Information System (AEGIS) allows the user to view information such as topographic maps, jurisdictional boundaries, location of resources



AEGIS® screen showing topographic map with location of hospitals, medical response ambulances and helicopters, as well as real-time highway traffic video.

(e.g. hospitals, fire stations, police departments,) and major venues in an integrated graphic. Dynamic layers, including real-time helicopter, ambulance, and fire apparatus locations, highway traffic flow, weather conditions, and hospital diversion status, coupled with the static layers, give the EMS administrator a greatly increased situational awareness and the ability to utilize their resources much more effectively. The AEGIS is used on a daily basis in the emergency department by Mobile Intensive Care Nurses (MICNs) to make informed resource and destination decisions from the ETCC. The system can be used in the field by Incident Commanders and responders for improved situational awareness and improved emergency management as well. The AEGIS was demonstrated during the Esperanza Fires and was well-received by attending agencies. AEGIS has completed its testing phase and marketing opportunities are being explored.

Task 4: Study the Medical and Economic Value of a Regional Telemedicine Network in an Urban, Rural, and Wilderness Environment.

Milestones 11: Local IRB Approval

Milestone 12: Military IRB Approval

Milestone 13: Collect Data

Milestone 14: Submit Research Article

Three proposed studies were approved by Loma Linda University's Institutional Review Board and subsequently approved by an HSRRB review. *See attached protocols (Appendix A)*

- **The Effect of an Electronic Medical Record Data Collection System on EMS Provider Efficiency (EMSE)**

This study was to evaluate if the introduction of an electronic medical record system would facilitate Emergency Medicine Service (EMS) activities by reducing time spent on paperwork. The pre-implementation data collection for EMSE was initially collected, but due to improper collection technique, the data was discarded. This delay made the project unable to be completed as the agencies being tested had already implemented the electronic medical record system, thus no pre-implementation data was available. The study was discontinued.

- **The Effect of Electronic Medical Record Data Collection System on EMS Provider Satisfaction (EMSS)**

This study proposed that EMS providers would prefer an electronic medical record to a paper record. Thirty-five paramedics were initially enrolled in the study and completed the pre-implementation survey. The follow-up survey was administered three months after the implementation of the electronic medical record. Out of the initial 35 paramedics surveyed, 24 were available for completion of the follow-up survey. The other 11 were not available as they were no longer employed with the ambulance company. An additional group of paramedics that were to be tested could not participate because their agency made a decision to not implement the electronic medical record within the study period. The results of the study were thus limited due to the small numbers completing the study. General consensus among those studied felt that the electronic medical record was more difficult to use than the paper form, made it more difficult to care for the patient and transfer care, and overall were less satisfied than using the paper form. *(See Appenidx B).* It should be noted that the number of subjects was limited, that the paper form has been in use for years, whereas the electronic form was only in use for three months at the time of the survey, and that there are always barriers to utilizing new technology.

- **The Effect of Telemedicine on Prehospital Care of Nursing Home Patients.**

This study proposed to evaluate the use of telemedicine in a select population of nursing home patients. Both the feasibility of telemedicine technology as well as practical effects on transfer decisions were to be examined. Training in the use of the telemedicine equipment, both for the physicians in the ED and for the nursing staff at the nursing home were completed. Consent of potential patients at the skilled nursing facility was completed and updated on a weekly basis. Additionally, research personnel were present during peak hours of the day to help facilitate the telemedicine component at the site. Despite these interventions, no patients were enrolled in the study. A full report of the study and barriers encountered is attached *(See Appendix C).*

An additional project addressing telemedicine application in management and treatment of trauma patient was proposed but unable to receive HRPO approval due to complications with the ability to provide adequate informed consent.

Key Research Accomplishments

- Created and opened the Center for Prehospital Care, Education, and Research
- Established an Emergency Medical Services Fellowship
- Developed and implemented an integrated prehospital and hospital documentation and data collection system
- Created a regional Emergency Telemedicine Command Center
- Developed and demonstrated real-time telemedicine consultation capability to a local clinic and nursing home
- Designed and deployed an off-road capable mobile emergency telemedicine equipped response vehicle (MTV) (Patent Application Number: PCT/US2007/077931 http://www.wipo.int/pctdb/en/wo.jsp?WO=2008022051)
- Developed a geographic information system for improved resource utilization of local emergency medical services and for use during mass casualty incidents (AEGIS)
- Initiated three research protocols examining the electronic medical record user's satisfaction and efficiency, and telemedicine connection to a nursing home

Reportable Outcomes

DISCOVERIES has completed all the proposed tasks involving the development and implementation of an integrated prehospital and hospital telemedicine test bed. Technologies utilized include an electronic medical record, a regional telemedicine command center, mobile telemedicine vehicle with advanced communications capability, and a geographic information system for emergency services. These technologies have been tested at various venues and continue to be evaluated and updated. The establishment of a telemedicine connection between the LLUMC emergency department and a local nursing home was completed and physicians in the emergency department trained in the use of the equipment.

Conclusion

DISCOVERIES has successfully established a telemedicine test bed that allows research, evaluation, and validation of new technologies, treatments and protocols within urban, rural, and wilderness environments. These environments can replicate conditions faced in any location, including the battlefield. An integrated data collection system, along with easy access to numerous educational activities from the Center for Prehospital Care, Education, and Research, will facilitate investigations into prehospital care and outcomes-based research. The development of the telemedicine network and emergency medical geographic information system enhances field responses during daily emergencies and large-scale critical events. Telemedicine technologies have the potential of leveraging the expertise of a tertiary care medical center to any location in the world, expediting and improving the emergency response and medical care in real time. The MTV can bring that expertise to many underserved communities and to disaster sites. The Advanced Emergency Geographic Information System (AEGIS) allows real-time information to be available to incident managers and responders at command centers and in the field, enhancing situational awareness and decision-making. These accomplishments contribute to the field of emergency medicine by offering for the first time reliable evidence on which to base patient care.

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Appendices

Appendix A: Research Protocols

Appendix B: Electronic Medical Record Satisfaction Survey and Results

Appendix C: Prehospital Emergency Telemedicine: Challenges to Implementation in a Prospective Research Study

Appendix A

DISCOVERIES Project
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DISCOVERIES Project – Experimental Protocol

Title: The effect of an electronic medical record data collection system on EMS provider efficiency.

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The effect of an electronic medical record data collection system on EMS provider efficiency

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(See attached letter)

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San Bernardino, CA 92410
Contact: Henry Vasquez, EMS Coordinator
(See attached letter)

Time Required to Complete: 3/22/2007 to 3/21/2008

Hypothesis: Introduction of an electronic medical record system will facilitate EMS (Emergency Medical Services) activities by reducing time spent on paperwork.

Purpose: The purpose is to determine if introduction of an electronic data collection system will facilitate EMS activities by reducing time spent on paperwork.

Materials: An electronic (Panasonic Toughbook Tablet PC) data collection system (HealthWare Solutions, Eureka, CA) will replace a standard paper system for EMS providers in the San Bernardino area (AMR- American Medical Response and San Bernardino City Fire Department) (see attached for hardware and software specs). The electronic data collection will include not only all data collected via the paper form, but all NEMSIS minimum data elements (www.nemsis.org). First responders and transporting medics will be issues a tablet pc for use in documentation of patient assessment and treatment. This will replace an existing paper data collection system.

Study Population: The target population is the community of EMS providers in southern California. The sample population will include EMS providers with the San Bernardino City Fire Department (SBCFD) and the AMR-San Bernardino unit. These two agencies include over 100 providers with a wide range of experience and backgrounds. The two agencies are representative of typical EMS systems in southern California. Together they represent municipal agencies, commercial transport systems, and first responders.

A convenience sample will be used such that whenever the researcher is available for data collection, the EMS providers will be eligible for participation. Potential subject candidates will be those on duty when the researcher is available. Inclusion criteria will be consenting EMS providers able to read and comprehend English during periods when the researcher is available. Only licensed EMS providers from SBCFD and AMR will be eligible. Exclusion criteria for subjects will be when the EMS provider does not with to participate. Subject recruitment will occur through contact with the above-mentioned agencies.

Since there are no previous studies looking at the effects of electronic data collection on Prehospital provider efficiency it is not possible to make an accurate sample size calculation for this study. However, based on previous studies looking at response intervals approximately 100 observations seems reasonable (Meislin – 1999).

Procedure/Protocol Design: A researcher serving as an observer will travel with EMS providers and not the amount of time spent on various activities. Medic activities will arbitrarily be divided into patient care tasks, documentation tasks, and other activities. The time spent on each of these tasks will be monitored in the Out-of-service EMS time interval (Meislin et al, 1999). Times will start upon dispatch to a call and finish once all patient care and documentation is completed and the ambulance is back in service for another call.

The observer will use a dual electronic timepiece to facilitate documentation of task times. Both documentation and patient care tasks will be measured directly (see attached data collection form). Inter-rater reliability scores will be calculated for both the task time collection and the EMS interval records. In these cases data from two observers recording the same medic will be compared. For this purpose, ten consecutive cases will be compared both before and after implementation of the electronic data collection system. A kappa (k) statistics will be calculated.

Measures will be made for a two-month period prior to initiation of the electronic record system. A subsequent two-month measurement period will follow tow months after installation of the electronic system in order to assure that the components are working correctly prior to data collection. Availability of study personnel will permit entry of approximately 100 EMS calls before and 100 EMS calls after implementation of the electronic data collection system. An attempt will be made to evenly distribute the calls between the two agencies. All subjects will be observed both before and after implementation of the electronic data collection system. Some subjects may be observed more them once during both of these intervals. Subjects will be tracked for subsequent observations by identifying information on the data form. All Prehospital care personnel unitizing the electron data collection system will receive standard orientation and training by the vendor (Healthware Solutions, Eureka, CA) and their EMS agency. The two month installation and training period will serve as a sufficient wash out interval to mitigate against changes in proficiency with time.

Research Interventions that the Subject will Experience:

1. On duty EMS providers will be consented by the researcher/observer prior to any data collection. There are no clinical assessments or evaluations made prior to entry in the study.
2. The researcher/observer will accompany the EMS provider on ambulance calls. During that time the researcher/observer will record the time spent by the EMS provider on various tasks as described in the protocol. No data collection will be made during other times (before and after ambulance calls).
3. The researcher/observer will not be involved in patient care in any way. The researcher/observer will make their recordings from a discrete distance so as not to interfere with the EMS provider's activities. At the request of the EMS provider may be participating in the experiment on several occasions over the course of 5 months.
4. The researcher/observer will make recordings only during the out-of-service interval.
5. Participation will include recordings made prior to and after implementation of an electronic medical record data collection system. For this reason, the EMS provider may be participating in the experiment on several occasions over the course of 5 months.

Primary Outcomes: Differences in the amount of time spent on documentation tasks by EMS providers will be compared before and after implementation of the electronic medical record using a paired t-test.

Secondary outcomes: The amount of times spent on patient care, documentation, and other tasks before and after the electronic record will be compared using ANOVA. In particular, Changes in the Out-of-service Interval and changes in times spent on patient care related tasks after the intervention will be looked at. Additional information regarding response interval metrics and definitions may be found in Meislin et al bibliography.

Description of the Informed Consent Process: Written informed consent will be obtained one time on an individual basis from the EMS providers involved in the project prior to participation in the study. The consent process will take place at the EMS agency and will be

administered by the qualified researcher/observer. An independent third party will be present. This third party will be another EMS provider, not participating in the study, and they will also serve to witness the event. Adequate time will be provided for the consent process including time for decision-making and questions. Informed consent will be obtained at a time convenient to the EMS providers such as during their shift change. One copy of the Informed Consent Document (ICD) will be given to the subject. The researcher will keep a second copy.

California Experimental Subject's Bill of Rights: The study does not involve an experimental clinical procedure and the California Experimental Subject's Bill of Rights does not therefore apply.

HIPAA considerations: The data being collected are not part of the subject's Protected Health Information (PHI) and therefore the provisions of the Health Insurance Portability and Accountability Act (HIPAA) do not apply.

Risks/Benefits:

There is no benefit for the subject to participate in this study.

Risks are related to the inconvenience of having an observer accompany the EMS provider on service calls. There will be some loss of privacy in the workplace. The observer is also potentially obtrusive to the normal work flow of these care givers. To minimize these risks, the researcher/observer will maintain a discrete distance from the worker and will exit the scene on request.

Risks are also related to the confidentiality of the data. The data will not be shared with anyone and will be kept in a locked and secure location. Specifically, the EMS agencies (AMR and SBCFD) will not have access to the data. They will only see the published results in aggregate without individual or agency identifiers. After data collection is complete, the data base will be purged of individual identifiers (name, run number, date, etc.).

This observational study will expose these subjects to minimal risk.

Adverse Events:

There are no foreseeable adverse events associated with participation in this study. Nevertheless any serious or unexpected adverse events will be immediately reported to the Principal Investigator, Lea Lynch, MD by calling 909-558-4000 and asking the hospital operator to page Dr. Lynch at 4505. They will also be reported to the local IRB (IRB administrator, Office of Sponsored Research, 11188 Anderson Street, Loma Linda, CA 92350).

Unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study and all subject deaths will be promptly reported by phone (301-619-2165), by e-mail (hsrrb@det.amedd.army.mil), or by fax (301-619-7803) to the Army

Surgeon General's Human Subjects Research Review Board. A complete written report will follow the initial notification. In addition to the methods above, the complete report will be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZB-QH, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

Disposition of Data: A complete data set will be kept for a period of one year or until the data collection is complete. A de-identified set of data and consent forms will be kept for an additional period of two years. The DISCOVERIES project authorized personnel (Lea Lynch, Stephen Corbett, Brett McPherson, Hal Marlow) will maintain the data. The raw data, consent forms, and electronic storage media will be kept in a locked file cabinet in suite 220 (primary investigator's office) of the Loma Linda University Medical Center, 11155 Mt. View Avenue, Loma Linda, CA 92354. Any incomplete data sets will be destroyed. There will be no consequences for subjects that decide to withdraw from study.

As a part of the U.S. Army Medical Research and Materiel Command's (USAMRMC) responsibility to protect human subject in research, representatives of the USAMRMC may review research records.

Protocol Modifications: Any protocol modifications will be simultaneously submitted to both the local IRB (Loma Linda University Medical Center) and the HSRRB for review prior to implementation. In addition to notifying the local IRB, the Human Subject Research Review Board (HSRRB) will be notified of any protocol deviations.

Protocol Deviations: Protocol deviations will be immediately reported to the Principal Investigator by calling 909-558-4000 and asking the hospital operator to page Dr. Lynch at 4505. They will also reported to the local IRB (IRB administrator, Office of Sponsored Research, 11188 Anderson Street, Loma Linda, CA).

Roles and Responsibilities of the Study Personnel:

Elizabeth Lea Lynch, MD: Principal Investigator, Project Oversight

Stephen W. Corbett, MD, PhD: Research Coordinator, experimental design, data analysis, manuscript preparation.

Brett McPherson, RN: Project Manager, consent and recruitment of subjects, data collections, data entry, records maintenance.

Harold J. Marlow, PhD: Research Manager, consent and recruitment of subjects, data collection, entry, and analysis, manuscript preparation, records maintenance.

Gwyneth Zimmerman, PhD: Statistical Support and consultant, experimental design.

Bibliography:

Meislin HW, Conn JB, Conroy C, Tibbitts, M; Emergency medical services agency definitions of response intervals. *Ann Emerg Med* 1999; 34: 453-458.

Appendix A

DISCOVERIES Project
Center for Prehospital Care, Education, and Research
Loma Linda University Medical Center

11155 Mt View Ave Suite 220
Loma Linda, CA 92354
(909) 558-7611

DISCOVERIES Project – Experimental Protocol

Title: The effect of an electronic medical record data collection system on EMS provider satisfaction.

Principal Investigator:

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Research Coordinator:

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The effect of an electronic medical record data collection system of EMS provider satisfaction.

Project Manager:

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Locations of Study:

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Department of Emergency Medicine
Loma Linda University Medical Center
11234 Anderson St.
Loma Linda, CA 92354

American Medical Response
7925 Center Avenue
Rancho Cucamonga, CA 91730
Contact: Edward Van Horne, Director of Operations
(See attached letter)

San Bernardino City Fire Department
200 East Third Street
San Bernardino, CA 92410
Contact: Henry Vasquez, EMS Coordinator
(See attached letter)

Time Required to Complete: 4/27/2007 to 4/26/2008

Hypothesis: Emergency Medical Services (EMS) providers will prefer an electronic medical record.

Purpose: The purpose is to determine whether EMS providers will prefer an electronic medical record to a conventional paper medical record.

Materials: An electronic data collection system (HealthWare Solutions, Eureka, CA) will replace a standard paper system from EMS providers in the San Bernardino area (AMR-American Medical Response and San Bernardino City Fire Department). First responders and transporting medics will be issues a PDA/tablet for use in documentation of patient assessment and treatment. This will replace an existing paper data collection system.

Study Population: The target population is the community of EMS providers in southern California. The sample population will include EMS providers with the San Bernardino City Fire Department (SBCFD) and the AMR-San Bernardino unit. These two agencies include over 100 providers with a wide range of experience and backgrounds.
Approximately 100 of these providers will participate in the study. The two agencies are representative of typical EMS systems in southern California. Together they represent municipal agencies, commercial transport systems, and first responders.

A convenience sample will be used such that whenever that researcher is available for data collection, the EMS providers will be eligible for participation. Inclusion criteria include 1) that the subject is a licensed EMS provider and 2) consents to participate in the study. There are no exclusion criteria. Potential subject candidates will be those available at change of shift at AMR or SBCFD. Subject recruitment will occur through contact with the above-mentioned agencies.

Procedure/Protocol Design: Changes in the EMS providers' satisfaction with the record keeping systems will be reported. Measures will be made before and three months following the replacement of a paper medical record documentation system with an electronic medical record documentation system. Since there is no currently validated survey instrument for EMS satisfaction with various data collection modalities, one was development for this purpose via a panel of emergency physicians, EMS Medical Directors and Prehospital care personnel. Questions were designed to reflect the logistical challenges of data collection in the prehospital environment. The survey attempts to measure the durability, portability, accuracy, and ease of use of the different data collections systems. Each EMS provider will complete a 17 single item satisfaction survey regarding the written record and then later complete a similar satisfaction survey regarding the written record and then later complete a similar satisfaction survey regarding the electronic record. The survey instruments have not been pilot tested due to the requirement for HSRRB approval prior to implementing this study. Differences will be compared using the Wilcoxon signed rank test. Descriptive statistics will be used to illustrate differences in skill level and years of experience. Based on out previous experience, approximately 70% of EMS providers will complete the survey (Corbett 1998). In the absence of any previously published data regarding variance in this type of survey we are unable to do a sample size calculation. Nevertheless, descriptive data should be useful in this size sample population.

Research Interventions that the Subject will Experience:

1. For their own convenience, EMS providers will be consented by the researcher at the EMS agency (AMR or SBCFD) around the time of all their shift changes. There are no clinical assessments or evaluations made prior to entry in the study.

2. The EMS provider will complete a questionnaire regarding their opinions of the current paper medical record data collection system. This will take approximately 10 minutes of their time and will immediately follow the informed consent process. Completed survey will be collected immediately.

Approximately three months later, (at the EMS agency) after installation of an electronic data collection system, the EMS provider will complete a second questionnaire regarding their satisfaction with the electronic data collection system. This will take an additional 10 minutes. The completed surveys will be collected immediately by the research assistant.

Description of the Informed Consent Process: Written informed consent will be obtained from the EMS providers prior to their participation. The consent process will take place at the EMS agency, and will be administered by the qualified researcher. An independent third party will be present. This third party will be another EMS provider, not participating in the study, and they will also serve to witness the event. Adequate time will be provided for the consent process including time for decision-making and questions. One copy of the Informed Consent Document (ICD) will be given to the subject. The researcher will keep a second copy.

California Experimental Subject's Bill of Rights: The study does not involve an experimental clinical procedure and the California Experimental Subject's Bill of Rights does not therefore apply.

HIPAA considerations: The data being collected are not part of the subject's Protected Health Information (PHI) and therefore the provisions of the Health Insurance Portability and Accountability Act (HIPAA) do not apply.

Risks/Benefits:

There is no benefit for the subject to participate in this study.

The main inconvenience of subjects participating in this survey relates to the time required to complete the questionnaires (approximately 10 minutes apiece).

Risks are also related to the confidentiality of the data. The data will not be shared with anyone and will be kept in a locked and secure location. Specifically, the EMS agencies (AMR and SBCFD) will not have access to the data. They will only see the published results in aggregate without individual or agency identifiers. After data collection is complete, the date base will be purged of individual identifiers.

Questionnaires completion will expose these subjects to minimal risk

Adverse Events:

There are no foreseeable adverse events associated with participation in this study. Nevertheless any serious or unexpected adverse events will be immediately reported to the

Principal Investigator, Lea Lynch, MD by calling 909-558-4000 and asking the hospital operator to page Dr. Lynch at 4505. They will also be reported to the local IRB (IRB administrator, Office of Sponsored Research, 11188 Anderson Street, Loma Linda, CA 92350).

Adverse events that are both serious and unexpected will be immediately reported by telephone to the USAMRMC, Deputy for Regulatory Compliance and Quality (301-619-2165) and send information by facsimile to 301-619-7803. A written report will follow the initial phone all within three working days. The written report will be addressed to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ, 504 Scott St., Fort Detrick, Maryland 21702-5012

Disposition of Data: A complete data set will be kept for a period of one year or until the data collection is complete. The raw data, consent forms, and electronic storage media will be kept in a locked file cabinet in Suite 220 (primary investigator's office) of the Loma Linda University Medical Center, 11155 Mt. View Avenue, Loma Linda, CA 92354. A de-identified set of data and consent forms will be kept for an additional period of two years. The DISCOVERIES project authorized personnel (Lea Lynch, Stephen Corbett, Brett McPherson, Hal Marlow) will maintain the data.

Protocol Modifications: Any protocol modifications will be simultaneously submitted to both the local IRB (Loma Linda University Medical Center) and when approved, will be forwarded to the HSRRB for review and approval before the modification is implemented.

Protocol Deviations: Protocol deviations will be immediately reported to the Principal Investigator by calling 909-558-4000 and asking the hospital operator to page Dr. Lynch at 4505. They will also be reported to the local IRB (IRB administrator, Office of Sponsored Research, 11188 Anderson Street, Loma Linda, CA). In addition to notifying the local IRB, the project Human Subject Research Review Board (HSRRB) will be notified of any protocol deviations.

As a part of the U.S. Army Medical Research and Materiel Command's (USAMRMC) responsibility to protect human subjects in research, representatives of the USAMRMC may review research records.

Roles and Responsibilities of the Study Personnel:

Elizabeth Lea Lynch, MD: Principal Investigator, Project Oversight

Stephen W. Corbett, MD, PhD: Research Coordinator, experimental design, data analysis, manuscript preparation.

Brett McPherson, RN: Project Manager, consent and recruitment of subjects, data collection, data entry, records maintenance.

Harold J. Marlow, PhD: Research Manager, consent and recruitment of subjects, data collection, entry, and analysis, manuscript preparation, records maintenance.

Gwyneth Zimmerman, PHD: Statistical Support and consultant, experimental design.

Bibliography:

Corbett SW, Grange JT, Thomas TL: Exposure of prehospital care providers to violence. Prehosp Emerg Care 1998;2(2): 127-131.

DISCOVERIES Project
Center for Prehospital Care
Loma Linda University Medical Center

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DISCOVERIES Project- Experimental Protocol

Title: The effect of telemedicine on prehospital care of nursing home patients

Principal Investigator (PI):

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The effect of telemedicine on pre-hospital care of nursing home patients

Project Manager (PM):

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Principal Investigator, Nursing Home (NHPI):

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Research Assistant (RA):

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Locations of study:

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Reche Canyon Rehabilitation and Health Care Center, Inc.
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Colton, CA 92324
Contact: Fred Frank, Administrator (see attached letter)

Time Required to Complete: 3/1/2007 to 3/1/2008

DISCOVERIES Project- Experimental Protocol

Hypothesis: Introduction of an emergency department-based telemedicine system will improve care and reduce unnecessary emergency transports of nursing home patients.

Materials: A skilled nursing facility, Reche Canyon Nursing Home, will be equipped with tele-video examination suites connected to the Loma Linda University Medical Center Command Center. This will permit real-time tele-video examination of nursing home patients by emergency department physician consultants.

Patient Selection: All adult patients requiring transport from the nursing home to the emergency department for evaluation will be eligible to participate. Some patients may be enrolled more than once if they require transport more than once during the study period. During a 1-year period emergency department tele-video consultation (EDTC) will precede transport. The consultation will be requested at the time the 911 or transport request call is made and will continue no longer than it takes for the ambulance to arrive. Loma Linda University Medical Center Emergency Department is the automatic destination for transports from these facilties in the event of an emergency.

The target population is the population of adult nursing home patients. We hope that these results from this typical southern Californian nursing home will be generalizable to that population. Inclusion criteria will be prior consenting adult patients who require emergency transport to the Loma Linda University Medical Center Emergency Department during the study period. Exclusion criteria will be those that do not wish to participate, are non-English speaking, and those that arrive by elective or routine transport. Patients that aren't able to provide informed consent will also be excluded from the study.

Procedure: Study related training and orientation would be conducted with nursing facility staff and EDTC physicians prior to implementation of this study. After making the 911 or transport request call, the nursing home caregiver will initiate a telemedicine consultation with an EDTC physician at the Loma Linda University Medical Center Emergency Department. These consults may be initiated 24 hours per day and any day of the week. Consults will only be initiated by the nursing home caregiver on patients that have a complete informed consent in clearly marked colored envelope at bedside. If this colored envelope isn't immediately available at bedside, then a telemedicine interview will not be conducted with that patient. The EDTC physicians will document the time at which they determined that emergent ambulance transport was indicated (the 911 transport request call was appropriate) or the time at which they determined that emergent ambulance transport was unnecessary (elective transport in the next 24-36 hours would suffice). If they have not decided by the time the ambulance arrives, they will be asked to record whether they felt transport was justified or unnecessary at that time. The EDTC physician will also indicate what treatments, if any, they would start for the patient. Since EDTC physician intervention has never been proven to help, no actual intervention or change in the standard of care will be implemented at this time. The time these treatments would have been administered will also be noted. A second emergency

physician located in the LLUMC ED will assess and treat the patient in the usual manner after their arrival to the hospital. They will be blinded to the results of the EDTC, and will determine patient disposition in the usual manner. They will indicate whether, based on their evaluation, the patient needed emergent or non-emergent (elective transport in the next 24-36 hours) transport from the nursing home. Blank data forms will be kept in the locked telemedicine consult room for both the EDTC and ED physician. Completed forms will be stored in locked drop box in locked telemedicine consult room. Only the primary research investigators will have access to the locked drop box and it will be routinely checked. Current physician staffing in the emergency department is such that there is always a physician available for radio and telemedicine consultation.

Privacy will be maintained during the telemedicine consult by using a secure line for transmission. The telemedicine network uses a dedicated point-to-point T1 line for the nursing home site. We control access to the T1 line by having control lists at the router and switch level to ensure that only the approved hardware (such as the televideo unit) is connected. For wireless connectivity at the far end, we use an encryption algorithm (WEP 128) and a non-broadcast wireless access point (SSID) to secure the televideo units. In addition, the EDTC will occur in a secure room used only for radio and telemedicine communications. On the nursing home side, the use of private rooms and education of staff will assure privacy. The EDTC will not be recorded.

Previous work has suggested that telemedicine might decrease transports by 15%. Based on a sample size calculation, approximately 100 patients will need to be entered during the study period. If this estimate is correct, adequate numbers of cases should be present in each category to allow for calculation of confidence intervals.

Inter-observer reliability of the EDTC exam will be determined by having two EDTC physicians each perform an examination on the same patient. These paired exams will be done on 10 patients and a Kappa (κ) score will be calculated.

Primary Outcome Measures: The proportion of 911 or transport calls in which the EDTC physician felt that transport was unnecessary will be used as an indicator of how many emergent transports might be eliminated in this system. Descriptive statistics will be used (mean and median with interquartile ranges).

Secondary Outcome Measures: The second emergency department physician performing an independent evaluation of the patient in the emergency department will serve as a *gold standard* for the accuracy of the EDTC. Patients in whom the second ED physician felt that transport was justified would be viewed as positive cases. Patients in whom the second ED physician felt that transport was unnecessary would be viewed as negative cases. The accuracy, sensitivity, and specificity of EDTC in determining the need for emergent transport to the ED could thereby be calculated along with 95% confidence intervals.

An additional outcome measure will be the amount of time required for the EDTC physician to reach a decision about the need for transport, to assure that the process does

not create undue delays in care delivery. *A Priori* it would seem that decisions made in less than the Event-Treatment Interval were unlikely to affect care. Descriptive statistics will be used.

Any interventions or treatments suggested by the EDTC physician will be considered *definitive treatments* if the same treatments are instituted later in the patient's care. The time between the EDTC proposed treatment and the actual receipt of that treatment would be presented as an interval in which benefit from earlier treatment might be realized. Descriptive statistics will be used.

Finally, the number of days of admission and the final disposition on discharge will be noted for each patient transported to the ED (see attached data forms).

Implementation at the Nursing Home: The nursing home principal investigator (NHPI) will be responsible for identification and recruitment of the subjects for the study. To ensure that the subjects are appropriately informed the NHPI will be certified in human subject's training. The process will be witnessed and the ICD signed by a RN from the nursing home staff that will administer the Mini Mental State Examination to insure that the subjects have the mental capacity to consent. The NHPI will also be responsible for the process by which study participants are identified and the telemedine consultation is initiated.

The NHPI, Co-Investigator (Co-I), Project Manager (PM), or Research Assistant (RA) will conduct in-service training for the nursing home staff. These will take place at the nursing home before the protocol is initiated on several occasions for the convenience of the staff. They will be repeated as needed so that all staff will be familiar with the experimental protocol, familiar with patients that have consented to participate, understand their roles in the protocol, and understand the voluntary nature of participation in the project. Additional in-services will be given after the start of the project if new staff are added, if the staff request clarification about the project, or if the investigators feel that additional training is needed.

The in-service content will emphasize the following topics:

1. The means by which study participants will be readily identified.
    a. Each participant will have a colored packet at the bedside containing the ICD, a copy of the protocol, and a flow diagram summarizing the protocol (Appendix A).
    b. Prior to initiating a telemedicine interview, nursing home staff will verify that the consent document correctly identifies the patient, is signed, and had the correct date.
2. The mechanism to ensure that the tele-video interview maintains patient privacy.
    a. Nursing home staff will be reminded that the telemedicine interview requires the same safe-guards for patient privacy that exist in any medical encounter.

   b. Audio and video must be placed in such a way that privacy is ensured.
3. Assuring that the staff understands the protocol especially with regard to initiation and termination of the tele-video assessment.
   a. The tele-video interview is not initiated until the 911 call has been made.
   b. The tele-video interview is not initiated until a staff member not involved in patient care has been identified.
   c. The tele-video interview will be terminated at the patient's request
   d. The tele-video interview will end when EMS arrives at the bedside.
4. Identifying team members responsible for the experimental protocol so that this process does not interfere with ongoing patient care.
   a. Nursing home staff designated to initiate the experimental protocol cannot be involved in patient care.
   b. If a staff member is not available to fill this role the protocol will not be initiated.
   c. The designated staff member must know how operate the equipment.
   d. The designated staff member must understand and review the ICD.
   e. The designated staff member must understand the need to protect patient privacy during the interview.
   f. The designed staff member must understand the voluntary nature of the protocol, especially with regards to the patients' rights to terminate the protocol at any time.
   g. The designated staff member must understand that the EDTC physician is not directing or influencing ongoing care in any way.
   h. The designated staff member must understand that the tele-video ends when EMS arrives for patient transport.

An algorithm to facilitate implementation of the protocol at the nursing home is found in Appendix A.

Description of the Informed Consent Process: Since the patient population being studied here is finite and fairly constant, we will obtain written informed consent on each patient during the admission process prior to any requests for transport. The PI, Co-I, PM, or RA will obtain informed consent at the nursing home during usual visiting hours. A nursing home RN will serve as a witness and insure the subject's ability to consent. Adequate time will be provided for the consent process including time for decision-making and questions from the patient or family members/friends. All researchers obtaining consent will be certified in human subject's training in order to assure that subject participation is voluntary and informed. Only patients providing informed consent will be included.

All patients will be re-consented at intervals no longer than three months by the PI, Co-I, PM, or RA. Patients may withdraw from the study at any time, even during the tele-video interview. One copy of the Informed Consent Document (ICD) will be given to the subject, one copy with be placed at the bedside, and one copy will be kept by the researcher.

Other than the inconvenience of the tele-video examination (without any physical contact) and the risk of disclosure of protected health information (PHI) there are no harmful aspects of the study. We assume that participating will expose the patients to minimal risk.

The EDTC physicians might also be viewed as experimental subjects in this study. For this reason they will also be consented prior to initiation of the study. Consent will be obtained in the emergency department with another staff member serving as witness. The PI, Co-I, PM, or RA will obtain consent and a copy of the ICD will be given to the participating physician. The researcher will keep a second copy. There will be approximately 30 participating physicians due to the number of full time ED physicians currently on staff. All full-time ED physicians will be recruited as possible subjects during their regularly scheduled staff meetings. Neither the PI, Co-I, PM, nor RA have any supervisory role over the physicians.

Potential harmful aspects of this study include: enrolling an unconsented patient in the study, diversion of nursing staff from clinical duties, not intervening in potentially beneficial patient care, inconvenience of the tele-video examination (without any physical contact) and the risk of disclosure of protected health information. Otherwise there are no harmful aspects of the study. The above risks will be minimized via training of nursing staff to only Initiate a telemedicine interview with patients who have colored envelop visible at their bed and to assure that patient care takes priority over study procedures. We assume that participating will expose the patients to minimal risk.

California Experimental Subject's Bill of Rights: The California Experimental Subject's Bill of Rights will also be provided to each nursing home participant (see attached). Since the study does not involve an experimental clinical procedure with regard to the telemedicine physician, the California Experimental Subject's Bill of Rights does not apply.

HIPAA considerations: Some of the data being collected is part of the subject's Protected Health Information (PHI) and therefore the provisions of the Health Insurance Portability and Accountability Act (HIPAA) apply. The subjects will therefore also sign an Authorization for use of Protected Health Information (see attached). One copy of the Authorization will be given to the subject. The researcher will keep a second copy.

Research Interventions that the Subject will Experience:

1. Nursing home residents will be consented at the nursing home by the PI, Co-I, PM or RA prior to any data collection. There are no clinical assessments or evaluations made prior to entry in the study.
2. In the event that the patient requires transport to the hospital, a portable tele-video unit will be brought to the patient's bedside. A 5 to 15 minute interview will take place between the subject and the EDTC physician located in the Emergency Department. This interview will stop upon arrival of the ambulance. The telemedicine encounter will not be used for clinical decision-making and the

telemedicine physician will not intervene in nursing home patient care under any circumstances.

3. The subject will be eligible to participate for a period of three months after which time they will need to be re-consented to participate in the study.

Adverse Events:

There are no foreseeable adverse events associated with participation in this study. Nevertheless any serious or unexpected adverse events will be immediately reported to the Principal Investigator, Elizabeth Lea Lynch, MD by calling 909-558-4000 and asking the hospital operator to page Dr. Lynch. They will also be reported to the local IRB (IRB administrator, Office of Sponsored Research, 11188 Anderson Street, Loma Linda, CA 92350).

Unanticipated problems involving risk to volunteers or others, serious adverse events related to participation in the study and all volunteer deaths should be promptly reported by phone (301-619-2165), by email (hsrrb@amedd.army.mil), or by facsimile (301-619-7803) to the Human Subjects Research Review Board. A complete written report should follow the initial notification. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZB-P, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

Disposition of Data: A complete data set will be kept for a period of one year or until the data collection is complete. A de-identified set of data and consent forms will be kept for an additional period of two years. A patient identification code will be used on each data form rather than a name to maintain subject confidentiality. The DISCOVERIES project authorized personnel will maintain the data. The raw data, consent forms, and electronic storage media will be kept in a locked file cabinet in room A235 of the Loma Linda University Medical center, 11234 Anderson Street, Loma Linda, CA 92354. Representatives of the U.S. Army Medical Research and Material Command are eligible to review research records as part of their responsibility to protect human subjects in research.

Protocol Modifications: Any protocol modifications will be simultaneously submitted to both the local IRB (Loma Linda University Medical Center) and the HSRRB for review prior to implementation. Continuing local IRB reports will be forwarded to the HSRRB when available.

Protocol Deviations: Protocol deviations involving risks to subjects or others, or those that affect the scientific integrity of the study, will be immediately reported to the Principal Investigator by calling 909-558-4000 and asking the hospital operator to page Dr. Lynch. They will also be reported to the local IRB (IRB administrator, Office of Sponsored Research, 11188 Anderson Street, Loma Linda, CA). These will also be reported promptly to the HSRRB.

Scientific Review: This study was reviewed for scientific merit by the statistical and design support consultant, Gweneth Zimmerman, PhD. In addition, an independent panel comprised of faculty and staff members of the LLUMC and the LLU School of Medicine acted in a scientific review function. This panel made additional useful recommendations with regard to hypothesis testing, design, and analysis. Finally, the LLUIRB routinely considers scientific merit in order to make a balanced risk-benefit assessment.

Roles and Responsibilities of the Study Personnel:

Elizabeth Lea Lynch, MD: Principal Investigator, project oversight.

H. Bryant Nguyen, MD, MS: Co-Investigator, project oversight, IRB primary contact, consent and recruitment of subjects, data collection and database design, data entry, data analysis, manuscript preparation, records maintenance.

Stephen W. Corbett, MD, PhD: Co-Investigator, experimental design, data analysis, manuscript preparation.

Brett McPherson, RN, BSN, MICN: Project Manager, consent and recruitment of subjects, data collection, data entry, records maintenance.

Karla Lavin-Santamaria, MPH: Project Manager, consent and recruitment of subjects, data collection, data entry, records maintenance.

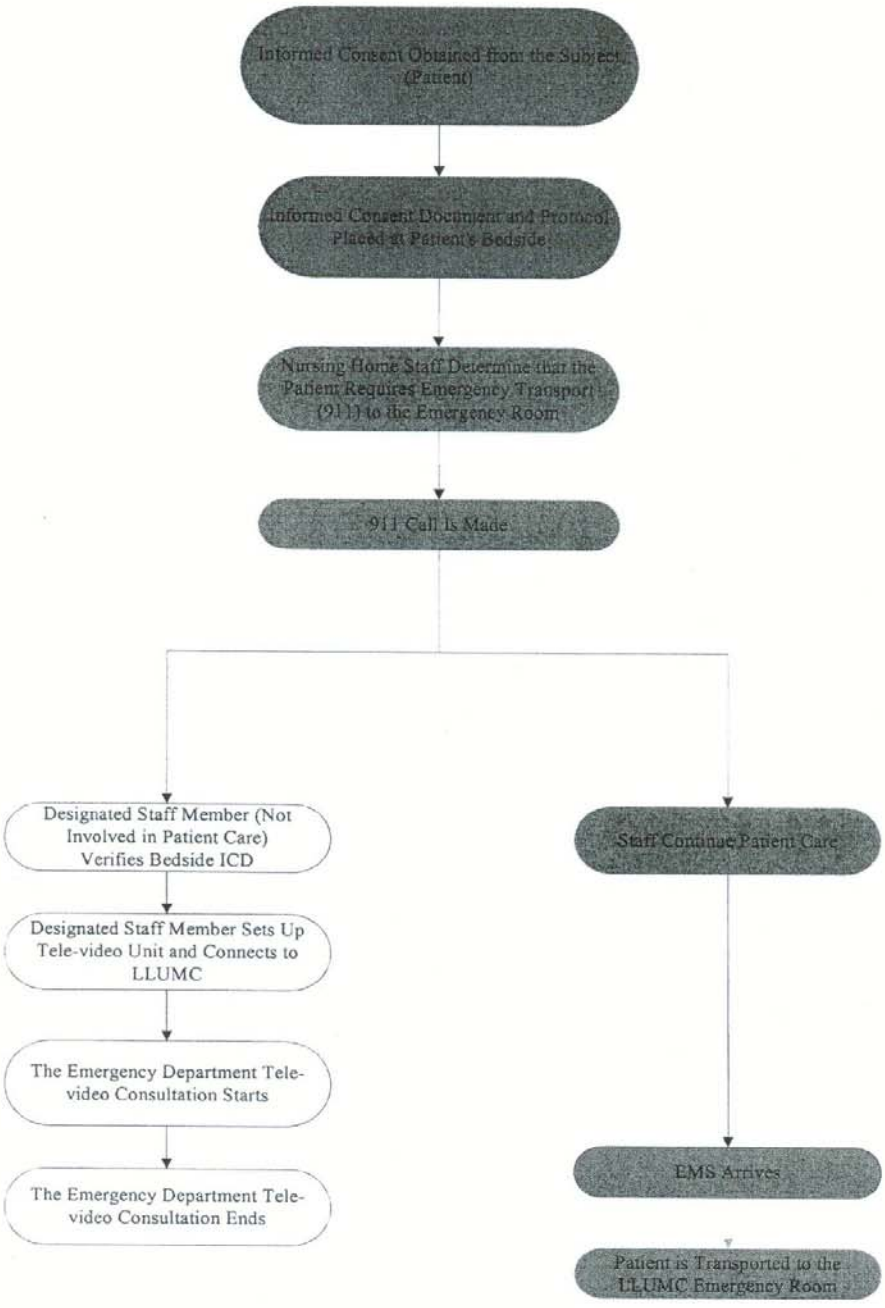
Kristy Burroughs, BS: Research Assistant, consent and recruitment of subjects, data collection, data entry, records maintenance.

Gwyneth Zimmerman, PhD: Statistical support and consultant, experimental design.

Fred Frank: On-site investigator for Reche Canyon Rehabilitation and Health Care Center, Inc. providing protocol oversight, staff education, and oversight of consent processes.

Appendix A (next page): The Effect of Telemedicine on Pre-Hospital Care of Nursing Home Patients, Loma Linda University Medical Center

Nursing Home Protocol Algorithm:
Orange (protocol activities taking place before the 911 call)
Blue (Standard nursing home procedures)
Yellow (tele-video protocol activities)


Informed Consent Obtained from the Subject (Patient)
Informed Consent Document and Protocol Placed at Patient's Bedside
Nursing Home Staff Determine that the Patient Requires Emergency Transport (911) to the Emergency Room
911 Call is Made
Designated Staff Member (Not Involved in Patient Care) Verifies Bedside ICD
Designated Staff Member Sets Up Tele-video Unit and Connects to LLUMC
The Emergency Department Tele-video Consultation Starts
The Emergency Department Tele-video Consultation Ends
Staff Continue Patient Care
EMS Arrives
Patient is Transported to the LLUMC Emergency Room

DISCOVERIES Project
Department of Emergency Medicine
Loma Linda University Medical Center

11155 Mt View Avenue, Suite220
Loma Linda, CA 92354
Tel. (909) 558-7611

The effect of telemedicine on pre-hospital care of nursing home patients

Purpose and Procedures

You are invited to participate in this research study because you are an emergency physician at the Loma Linda University Medical Center. Dr. Elizabeth Lea Lynch, Principal Investigator for this Department of Defense funded research project is conducting a study to determine whether telemedicine could be used to improve the health care of people living in nursing homes. Approximately 30 other emergency physicians will also be participating in this study.

This study will look at the use of telemedicine in patients that need to be sent from Reche Canyon Rehabilitation and Health Care Center to the emergency department. In these cases you may be asked to conduct a telemedicine interview and complete a data form on patients awaiting transport to the Loma Linda University Medical Center Emergency Department. The data will include demographic information, chief complaint, vital signs and treatments you would consider at various times in the interview. You will not be directing medical care during this interview. The interview is for research purposes only and will not appear in the patient's medical record. When the ambulance arrives to take the patient to the hospital, the telemedicine interview will stop. It is therefore reasonable to expect these interviews to take lass then 10 minutes. The telemedicine equipment will be located in a secure area so that your (and the patient's) privacy will be maintained. If you are providing medical care for a nursing home patient that has arrived in the emergency department following a telemedicine interview, you will be asked to complete a data form after treatment is complete.

These unscheduled telemedicine interviews will continue for a period of one year. Your participation will continue throughout this time and you may be involved in none or several interviews as the need requires.

Risks

The IRB (Institutional Review Board) at Loma Linda University has determined that participation in this study exposes you to minimal risk. The patient will be receiving standard medical care whether or not you participate in this study. All experimental data forms will be kept secure and confidential.

Benefits

There are no benefits to you for participation in this study. There may be benefits to others in the future if telemedicine is shown to improve care of nursing home patients.

Participant's Rights

You do not have to participate in this research project if you do not want to. If you do decide to participate, you may stop at any time. If you decide to stop participating, your data will not be used for this research project. There is no penalty or loss in benefits to which you are otherwise entitled if you decide not to participate or withdraw from the study.

Confidentiality

In order to protect your privacy, your name will be removed from the data forms at the completion of the study. The data will not be available to anyone (including yourself) until it has been published. The published data will only appear in aggregate. Research project personnel will maintain the data in a secure location at the primary investigators office. Access to the data will be restricted to research project personnel. The de-identified data will be maintained for two years after completion of the study, until the study is closed, or until the study is published, whichever comes first. Representatives of the U.S. Army Medical Research Materiel Command could review research records as a part of their responsibility to protect human subjects in research.

Additional Costs

There is no cost for you to participate in this study. No compensation will be provided to any research subjects.

Research-related Injury

Should you be injured as a direct result of participating in this research project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the

principal investigator before you enroll in this study. In the event of research related injury you should discuss this issue with the Principal Investigator, Dr. Lynch (909-558-7611) if you have any questions about medical care related to a research related injury.

Impartial Third Party Contact

If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647 for information and assistance.

Consent

I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may contact Elizabeth Lea Lynch, MD by dialing 909-558-4000 and asking the hospital operator to page him if I have additional questions or concerns. I have been given a copy of this consent form.

Signatures

Signature of Subject	Printed Name of Subject	Date
Street	City	Zip code
Signature of Witness	Printed Name of Witness	Date

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator	Phone Number	Date

DISCOVERIES Project
Department of Emergency Medicine
Loma Linda University Medical Center

11155 Mt View Avenue, Suite220
Loma Linda, CA 92354
Tel. (909) 558-7611

The effect of telemedicine on pre-hospital care of nursing home patients

Purpose and Procedures

You are invited to participate in this research study because you are a guest of the Reche Canyon Nursing Home. Dr. Elizabeth Lea Lynch, Principal Investigator for this Department of Defense sponsored research project is conducting a study to determine whether telemedicine could be used to improve the health care of people living in nursing homes. All English-speaking guests of Reche Canyon that are able to consent and agree to participate are eligible to enroll in the study.

Telemedicine is when a television and a video camera are used to allow a patient and a doctor to see and talk to each other even though they are not in the same place. The doctor can interview a patient such as yourself in the nursing home even though the doctor is in the hospital. We will see if getting the doctor to the bedside sooner by using telemedicine will result in better and more efficient medical care for patients in the future. Essentially, you will see a doctor on a television screen and he will be able to talk to you via the television and video camera. He will ask you questions and be documenting your answers about you, your medical history and your current condition. We will attempt to determine whether or not telemedicine can improve patient care.

The telemedicine doctor in the hospital will not be directing your care in this study. In other words, although the doctor will be interviewing you, they will not be providing any treatments or therapies. For this reason the care you receive will be the same whether or not you decide to participate. Because we have no way of knowing if you will ever need to go to the ED for treatment, we are asking for your permission to include you in the research study now. You may be enrolled in this study more than once if you need to go

to the hospital more than once or you may never be enrolled if you don't require transfer to a hospital.

This study will look at the use of telemedicine in patients that need to be sent from the nursing home to the emergency department. If you need to be transported to the emergency department (ED) for any reason, the telemedicine doctor will immediately interview you using a camera and a television. You will be able to see and hear the doctor and he (or she) will be able to see and hear you. When the ambulance arrives to take you to the hospital, the telemedicine interview will stop.

The telemedicine interview will be viewed only on a secure television so that your privacy will be maintained. Security of the video transmission is achieved in several ways. First of all, the line used to transmit the video is dedicated for this purpose. Second of all, the information is scrambled so that unauthorized people will be unable to view or hear any of the transmissions.

On some occasions, two doctors may perform the telemedicine interview. This is for research purposes only, and will not otherwise change the care you will be receiving. Approximately 100 other nursing home patients will be participating in this study. This research project will last for a period of one year.

There is no way to know if you will need to go to the emergency room in the next year. It is possible that you may never need emergency care, and that you will not participate in the study at all. It is also possible that, months from now if you need to go to the emergency room, you might not recall everything we are discussing with you today. For this reason, we will ask you if you want to continue to participate in this study every three months. Please remember that you may ask any time to be reminded about your role in this study. Please also remember that you may change you mind about being in the study at any time, even if the telemedicine interview has already started. If you have any questions about your involvement in this study over the next year, now would be a good time to ask.

Risks

You will be receiving standard medical care whether or not you participate in this study. The telemedicine interview with the doctor will not delay or change your care in any way. Loss of privacy and confidentiality of your health information is potential risk of participating in this study.
Any information from your medical record that appears in the study will be kept locked up. We will not report any information that could be used to identify you personally. The IRB (Institutional Review Board) at Loma Linda University has determined that participation in this study exposes you to minimal risk.

Benefits

There are no benefits to you for participation in this study. There may be benefits to others in the future if telemedicine is shown to improve care of nursing home patients.

Participant's Rights

You do not have to participate in this research project if you do not want to. If you do decide to participate, you may stop at any time. You will receive standard medical care whether or not you decide to be in the study. There are no consequences for withdrawing from this study and your data will not be utilized if you request to withdraw from this study. If you do decide to withdraw, you will not lose any benefits or rights that you are otherwise entitled to. The investigators may withdraw you from the study if you have trouble understanding the project because of confusion or some other problem.

Confidentiality

In order to protect your privacy, your name will be removed from the data forms at the completion of the study. The data will not be available to anyone (including yourself) until it has been published. The published data will only appear as a group. In other words, your individual data will not be reported in any way. Research project personnel will maintain the data in a secure location at the primary investigators office. Access to the data will be restricted to research project personnel. The data (without your name on it) will be maintained for two years after the completion of the study, until the study is closed, or until the study is published, whichever comes first. Representatives of the U.S. Army Medical Research Materiel Command could review research records as a part of their responsibility to protect human subjects in research.

Additional Costs

There is no cost for you to participate in this study. You will not receive any compensation for participation in this study.

Research-related Injury

Should you be injured as a direct result of participating in this research project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study. If you have questions about medical care, you should discuss this issue with the Principal Investigator, Dr. Lynch (909-558-7611).

Impartial Third Party Contact

If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647 for information and assistance.

Consent

I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may contact Elizabeth Lea Lynch, MD by dialing 909-558-4000 and asking the hospital operator to page him if I have additional questions or concerns. I have been given a copy of this consent form.

Signatures

Signature of Subject	Printed Name of Subject	Date
Street	City	Zip code
Signature of RCNH RN	Printed Name of RCNH RN	Date

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator	Phone Number	Date

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI)

OSR#54075

Per 45 CFR §164.508(b)

OFFICE OF SPONSORED RESEARCH
Loma Linda University • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)

TITLE OF STUDY:	The effect of telemedicine on pre-hospital care of nursing home patients
PRINCIPAL INVESTIGATOR:	Elizabeth Lea Lynch, MD
Others who will use, collect, or share PHI:	H. Bryant Nguyen, MD; Steve Corbett, MD; Brett McPherson, RN; Karla Lavin-Santamaria, MPH; Kristy Burroughs, BS
Research Sponsor:	U.S. Army Medical Research and Material Command

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: your name, age, and medical record number. Medical information from your nursing home transfer form, medical information from your emergency department report, and medical information from your discharge summary will be used in this research study. Specific examples of information taken from your medical record will be vital sign measurements, medical treatments, number of days of hospitalization, and final diagnosis.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) of Loma Linda University, and its affiliates, and with representatives of the U.S. Army Medical Research and Material Command.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may

are with others if they are required by law, and they may share it with others who may not ed to follow the federal privacy rule.

ubject to any legal limitations, you have the right to access any protected health information eated during this study. You may request this information from the Principal Investigator amed above but it will only become available after the study analyses are complete.

his authorization expires three months from the date below and if you wish to continue with e study you will be requested to reauthorize the use of your medical information. You may hange your mind about this authorization at any time. If this happens, you must withdraw our permission in writing. Beginning on the date you withdraw your permission, no new ersonal health information will be used for this study. However, study personnel may ontinue to use the health information that was provided before you withdrew your ermission. If you sign this form and enter the study, but later change your mind and ithdraw your permission, you will be removed from the study at that time. To withdraw our permission, please contact the Principal Investigator or study personnel at 909-558-4000 nd ask the operator to page Dr. Elizabeth Lea Lynch.

ou may refuse to sign this authorization. Refusing to sign will not affect the present or ture care you receive at this institution and will not cause any penalty or loss of benefits to hich you are entitled. However, if you do not sign this authorization form, you will not be ble to take part in the study for which you are being considered. You will receive a copy of is signed and dated authorization prior to your participation in this study.

---

agree that my personal health information may be used for the study purposes described in is form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
Approved 3/21/07 Void after 4/26/2007
#54075 Chair R L Ritschard MD

Version 03/07

Appendix B

EMS Provider Satisfaction Survey – Paper Data Collection

DISCOVERIES Project – Department of Emergency Medicine
Loma Linda University Medical Center
Investigators: Jeff T. Grange, MD

Name (print please)			
Date			
Agency (circle one)	AMR	SBCFD	
Skill Level (circle one)	EMT	EMT-I	Paramedic
Years of Experience in Pre-hospital Care			

Instructions: please indicate how strongly you agree or disagree with the following statements about the pre-hospital run sheet by circling the appropriate number next to the statement.

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
1. The pre-hospital run sheet is easy to read.	1	2	3	4	5
2. The pre-hospital run sheet works equally well in dark and light conditions.	1	2	3	4	5
3. The pre-hospital run sheet works equally well in all weather conditions.	1	2	3	4	5
4. Pre-hospital run sheets are easy to locate (they are accessible).	1	2	3	4	5
5. Pre-hospital run sheets are easy to carry around (they are portable).	1	2	3	4	5
6. The order in which things are presented on the pre-hospital run sheet makes sense.	1	2	3	4	5
7. I seem to spend more time doing the documentation than I do taking care of the patient.	1	2	3	4	5
8. I feel that errors are rare collecting information using the pre-hospital run sheet.	1	2	3	4	5
9. It is easy for me to figure out what went on when I look at a pre-hospital run sheet.	1	2	3	4	5
10. It is easy to transfer care from one caregiver to another using the pre-hospital run sheet.	1	2	3	4	5
11. The pre-hospital run sheet makes it easy to find out what happened to my patient.	1	2	3	4	5
12. I never have to search for a pencil or a pen to fill out the pre-hospital run sheet.	1	2	3	4	5
13. I have no trouble filling out the pre-hospital run sheet correctly.	1	2	3	4	5
14. It is always possible to complete the documentation using the pre-hospital run sheet.	1	2	3	4	5
15. The pre-hospital run sheet helps me get my job done.	1	2	3	4	5
16. The pre-hospital run sheet helps improve patient care.	1	2	3	4	5
17. Overall, I am satisfied with the pre-hospital run sheet.	1	2	3	4	5

Survey Question

Last Name	First Name		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Anderson	Carson		1	2	2	4	2	4	1	4	5	5	5	5	4	4	5	5	5
Archer	Marc		2	2	2	3	2	4	4	4	2	5	4	4	4	4	4	4	5
Arias	Jose EMT																		
Armstrong	Nathan EMT																		
Chastain	Graig NE																		
Edwards	Sean EMT																		
Falkingham	Rebecca		2	2	2	4		5	2	2	4	4	4	4	2	4	4	3	4
Galicia	Alberto		3	4	4	2	4	5	1	4	4	5	4	4	5	3	4	3	5
Gibbons	Thomas		1	1	4	2	3	3	4	3	1	4	3	2	1	1	3	3	1
Green	James		1	4	4	2	1	3	4	3	2	2	2	3	1	4	2	3	1
Groff	Nick		2	4	2	2	2	4	1	4	5	4	5	4	4	5	3	5	5
Honeter	Jamie		4	3	5	4	3	4	4	5	5	5	4	4	4	2	3	4	3
Isiordia	Gabriel EMT																		
Josephson	Ashley	NE																	
Kendall	Holly		4	3	5	4	5	4	1	5	2	4	3	1	5	5	5	5	5
Larkin	Michael		1	1	1	1	1	1	4	1	2	1	1	1	1	2	1	3	1
Linn	Adrienne	EMT																	
Lopez	Raphael																		
Magallanes	Ben		5	3	3	5	4	5	1	2	3	5	5	4	4	4	5	4	5
Nassetta	Joe NE																		
Ohlson	Kyle NE																		
Orosco	Greg EMT		4	2	3	4	3	5	2	3	4	5	4		3	3	4	4	4
Paladini	Dave		2	2	2	2	2	3	3	4	5	5	4	2	3	2	3	3	4
Palkewicz	Jeff		5	5	2	2	2	5	1	5	5	2	5	2	4	5	5	5	5
Rocha	Lorenzo NE																		
Rodesky	Mac		2	3	2	2	2	3	2	3	3	3	3	3	3	3	3	3	4
Rollins	Tom		2	5	5	3	2	5	1	5	5	5	5	1	5	5	5	5	5
Sanchez	Leo		4	4	2	2	2	4	1	4	3	3	3	2	4	5	4	4	5
Statham	Robert																		
Stawniczy	Adam		4	2	2	4		4	1	3	2	5	2	4	2	4	3	5	4
Stuart	Tatitiana																		
Vindiola	Lindsay		4	5	5	3	5	5	1	4	5	5	5	2	3	4	5	5	5

Strongly Agree			4	2	1	1	2	1	10	1	1	1	1	3	3	1	1	0	3
Agree			6	6	9	8	8	0	3	2	5	2	2	5	2	3	1	0	0
Niether Agree or Disagree			1	4	2	3	3	4	1	5	3	2	4	2	4	3	6	7	1
Disagree			6	4	3	6	2	7	5	7	3	4	6	7	7	7	5	5	5
Strongly Disagree			2	3	4	1	2	7	0	4	7	10	6	1	3	5	6	7	10

Strongly Agree	Agree	Neigher agree or disagree	Disagree	Strongly Disagree
2	3	0	5	7
0	5	1	9	2
0	0	0	0	0
0	0	0	0	0
0	0	0	0	0
0	0	0	0	0
0	6	1	8	1
1	1	3	8	4
6	2	6	3	0
4	5	4	4	0
1	4	1	6	5
0	1	4	8	4
0	0	0	0	0
0	0	0	0	0
2	1	2	4	8
13	2	1	1	0
0	0	0	0	0
0	0	0	0	0
1	1	3	5	7
0	0	0	0	0
0	0	0	0	0
0	2	5	7	2
0	7	5	3	2
1	5	0	1	10
0	0	0	0	0
0	5	11	1	0
2	2	1	0	12
1	4	3	7	2
0	0	0	0	0
1	5	2	6	2
0	0	0	0	0
1	1	2	3	10

NE = Not Employed
EMT = EMT not using device

PREHOSPITAL EMERGENCY TELEMEDICINE: CHALLENGES TO IMPLEMENTATION IN A PROSPECTIVE RESEARCH STUDY

ABSTRACT

The prehospital environment represents an area of opportunity for telemedicine to expand the reach of emergency physicians' expertise and also provide earlier evaluations for conditions in which time is a critical factor. We designed a prospective, controlled research project to determine the accuracy of emergency physicians' prehospital patient assessments by means of telemedicine. However, we encountered a number of challenges in implementing this study which we report here. These obstacles included those that are common to all disciplines employing telemedicine as well as one particular to emergency care research. These issues should be addressed in future research involving prehospital emergency telemedicine.

INTRODUCTION

Telemedicine is the use of communications and information technology to distribute medical knowledge and skills to areas in need. As such, telemedicine's primary application historically has been in expanding specialty and subspecialty care to rural, underserved areas. Successful telemedicine programs in the specialty of Emergency Medicine have been established upon this model of distribution to need.[1, 2]

The prehospital environment is also arguably an area in need of specialty knowledge and care, and emergency physicians currently provide specialized skills while using a rudimentary form of telemedicine whenever Emergency Medical Service (EMS) providers make base station contact for medical direction. When prehospital EMS

providers need medical direction the current common practice is to make audio contact with a physician at a base station through radios or mobile telephones. If interactive video was added to this prehospital contact, it is reasonable to consider whether the inclusion of this dimension would confer an advantage in terms of more rapid and/or accurate assessments of the patient's diagnosis. By "reinventing the house-call," telemedicine could be integrated into daily EMS encounters, with the promise for expanding the ability of physicians to evaluate and initiate treatment of patients in austere environments and under conditions such as disaster relief and battlefield medicine. It may also help EMS and base-station physicians make more appropriate destination and resource decisions according to the medical needs the patient has.[4] Several institutions have reported in the literature their experiences with prehospital and emergency telemedicine.[1-4] However, there have been no controlled prospective studies to evaluate whether in fact the use of telemedicine would translate into a benefit in terms of facilitating earlier and/or more accurate diagnosis, or be able actually to affect assessments and care.

In the application of telemedicine there are notable challenges that are shared in common among disciplines.[5] Our experience of the challenges in attempting to apply prehospital telemedicine in a prospective, controlled research project is reported here, specifically, the evaluation of patients in a skilled nursing rehabilitation facility (SNRF) before transport to the ED.

METHODS

The DISCOVERIES Project (Demonstrating Innovative Solutions to Care for Others Via Electronic Real Time Information and Emergency Services) at Loma Linda University (LLU) has been investigating ways to use telemedicine in acute care medicine, including earlier patient evaluation as they first enter the emergency care system by EMS. Sponsorship came primarily through the Department of Defense.

The study we report here was a component of DISCOVERIES designed to evaluate the potential effect that telemedicine might have on prehospital patient assessments made by emergency physicians. Specifically, regarding the accuracy of those evaluations: would physicians' assessments of patients via telemedicine before transport to the ED lead to different conclusions than face-to-face examination in the ED? The study population was comprised of the faculty emergency physicians who practice in the study site: a tertiary, acute care, academic medical center, where a minimum of two faculty emergency physicians are always on duty in the adult component of the ED.

Both the LLU and US military Institutional Review Boards (IRB) approved the study. The faculty emergency physicians who comprised the study population were consented to participate. The patients of the SNRF were also consented to participate in the telemedicine evaluations as was required by the military IRB.

In order to control for and minimize the effect that variations in telemedicine equipment and diverse presenting illnesses would have on these assessments a site was needed where telemedicine equipment could be installed permanently and where there was a relative uniformity of patients. A SNRF, not affiliated with LLU, is located within a few miles of the medical center, and EMS frequently transports patients from there to the ED. After meetings with the administration of the SNRF, standardized

videoconferencing equipment and the necessary high bandwidth connections were installed at their site. In order to minimize time and effort spent on moving patients to a telemedicine suite,[2] the equipment was mounted on a mobile pole cart which could be wheeled from room to room in order to assess patients via telemedicine before transport. Teleconferencing equipment was installed in the "radio room" in the LLU ED. Emergency physicians were already accustomed to interacting with prehospital EMS contact calls in the "radio room" through radio equipment and telephone calls, which made this arrangement a natural extension of their daily practices.

If the SNRF nursing staff recognized a need for acute care treatment of a patient, their standard procedure was to make a 911 telephone call, thereby activating an EMS response. The patient was then transported to the ED after EMS personnel complete their prehospital assessment and necessary procedures. For this study nurses at the SNRF were asked to initiate a telemedicine evaluation after they activated emergency services and while waiting for EMS personnel to arrive. During the study period, a faculty emergency physician in the ED was to evaluate the patient over the telemedicine connection and fill out a standardized form regarding their assessment of the patient.

Once the patient arrived in the ED, the other attending faculty physician on duty was to care for the patient and fill out another standardized form describing their evaluation. To control for the bias related to the prehospital evaluation, the telemedicine physician and treating physician were not to be the same individual. The two forms would then be compared to see if field telemedicine evaluation rendered different conclusions from face-to-face assessment in the ED. This study was intended to be purely observational and designed to avoid any change in, or the timing of, standard

prehospital assessments, prehospital treatments, transport, ED assessments, or ED treatments. The only outcome to be evaluated was whether there were differences between the faculty emergency physicians' telemedicine assessments made before EMS transport and their subsequent in-person bedside assessments made in the ED. The telemedicine evaluations were to be limited in time, and terminated upon arrival of EMS personnel so as to ensure no delays in patient care or transport.

RESULTS

The study was conducted from January 2007 to March 2008, with no activations of the telemedicine consultation process and no physician assessments enrolled. The SNRF continued to send patients to the ED on a daily basis, and during the course of the study period we encountered a number of barriers to the use of telemedicine in the acute care setting. The following challenges to the implementation of telemedicine in a prospective emergency prehospital were identified during the course of the study:

The first obstacle encountered was fundamental to any application of telemedicine, that is, the challenge of adopting the technology itself.[3, 5] Once decisions were made about which videoconferencing equipment offered adequate resolution to perform medical examinations, pole cart assemblies were arranged to mount the required equipment. Unlike a standard telemedicine clinic, in which patients are brought to a suite where the videoconferencing equipment is stationary, the equipment had to be relatively mobile in order to go to the bedside of a patient.[2, 3] In order to ensure this portability, a wireless data connection was chosen, along with an appropriate level of encryption to prevent dissemination of private healthcare information. Installing this wireless network

required extensive negotiation and eventually an inter-institutional agreement between LLU and the SNRF regarding use of the equipment, patient data confidentiality, and security issues involved in connecting our two data networks to each other.[5]

Furthermore, the attitudes of the healthcare workers at the SNRF towards the technology presented a challenge. The absence of telemedicine consult activations combined with a high staff turnover rate meant that the nurses and technicians at the SNRF were either uninformed about the study or felt insecure about being the first one to make a telemedicine connection. Additionally, the time required to bring the telemedicine pole cart to the patient's bedside was an extra burden, even if small, added to a common daily task. Instead of simply waiting for EMS personnel to come and transport the patient away, the staff would now have to go through the extra, alien steps of using a piece of unfamiliar technology to talk with a stranger. This mixture of social apprehension and small new tasks were too much to overcome without institutional commitment and leadership to motivate the staff. Unfortunately, there were no identifiably responsible parties at the SNRF to "champion" the telemedicine project to the SNRF workers. The lack of institutional commitment meant both that there were no negative motivators for the staff at the SNRF (no "stick"), and no benefit offered for activating the telemedicine equipment (no "carrot").

In an attempt to provide motivation for the SNRF staff, gift cards were offered to thank them for participating in the study if a telemedicine consult was activated. It was hoped that their negative feelings towards unfamiliar technology would be countered by this measure of appreciation. Further, the research study staff increased efforts to personally demonstrate the pole cart to the SNRF workers, both so they would become

more familiar with the way it worked, and as a way of humanizing the experience. It was thought that if they could see the faces at the other end of the connection they might feel less unease about a potentially awkward social interaction. However, due to the lack of a "homegrown" telemedicine champion at the SNRF and the high staff turnover rate, each of our attempts to familiarize the nurses and technicians at the SNRF was a novel one which could easily be ignored.

Obtaining patient consent for this prospective study presented an obstacle in this experience. In addition to consenting the physicians who were participating in the study, the military IRB required consent of the patients undergoing telemedicine evaluations. Many of the patients in the SNRF with altered mental status, however, could not be consented to participate in the study. Only a very few patients were consented early in the study, and those who could consent were often the least likely to develop any conditions requiring transport to the ED while they convalesced. As a result, the SNRF staff usually activated EMS for patients who were not consented to participate in a telemedicine evaluation.

DISCUSSION

Healthcare workers tend to be adverse to change, and understandably so. There is a natural reluctance to embrace novel technologies or approaches because they are unproven, and healthcare workers are accustomed to abiding by the dictum, first and foremost, to do no harm. Even though the equipment looked like something universally familiar—a television set with a remote control—the idea of using it to speak with another human being in real time was unfamiliar. A number of the nursing staff at the

SNRF voiced their unease with the equipment and openly stated they would never use it. There has been some evidence to suggest that people are comfortable with robots and adapt to them quickly.[6, 7] One area of future investigation is healthcare workers attitudes toward telemedicine and whether they would respond more positively to anthropomorphized telepresence robots.

Our experience confirms the need for "champions" who can encourage their colleagues to adopt the process in implementing prehospital telemedicine, a principle that has been discovered in other fields. A respected individual comfortable with the application of telemedicine, and identified as a responsible party at the SNRF, would have solved a great deal of the motivational problems. Telemedicine's well-established history demonstrating the need for a local "champion" who can motivate those around them operates without regard as to which discipline is involved.[5]

Finally, we experienced, even in this setting of minimal risk, an ethical challenge that affected our research. The irony is that the actual study population was the faculty emergency physicians performing the telemedicine assessments. However, given that the patients would receive no material benefit from the study but face some risks involved with the technology (such as public transmission of their images), albeit minor, this ethical question could not simply be ignored. The issue of consent and the identification of which parties need to be consented in order to perform studies of this nature may represent a barrier to prospective research in emergency telemedicine and warrants further exploration.

CONCLUSION

Our investigation in to the accuracy of prehospital emergency telemedicine's assessments confirmed that a number of the obstacles that face the successful implementation of telemedicine are shared across disciplines, including the associated technical issues as well as the need for local "champions". We also discovered an ethical challenge that, along with a number of other ethics issues in emergency and resuscitation research requires further investigation and discussion. These challenges, both those that are common to all telemedicine disciplines, as well as the ones unique to emergency medicine, must be addressed in order to perform future prospective research in prehospital emergency telemedicine.

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