1. TECHNICAL DISCUSSIONS

A. Statement of Work

A.1 ABSTRACT

Communications constitute the weakest link in most disaster responses, in particular, immediate tracking of victims. Disasters are best managed not with novel equipment and approaches but with scaled-up use of the equipment and emergency routines already known to emergency medical services. We propose to combine existing and new technologies to develop SMART: Scalable Medical Alert and Response Technology, a system for patient tracking and monitoring that begins at the emergency site and continues seamlessly through transport, triage, stabilization, and transfer between external sites and health care facilities as well as within a health care facility. The system is based on a scalable location-aware monitoring architecture, with remote transmission from medical sensors and display of information on personal digital assistants, detection logic for recognizing events requiring action, and logistic support for optimal response. Patients and providers, as well as critical medical equipment will be located by SMART on demand, and remote alerting from the medical sensors can trigger responses from the nearest available providers. The emergency department at the Brigham and Women's Hospital in Boston will serve as the testbed for initial deployment, refinement, and evaluation of SMART. This project will involve a collaboration of researchers at the Brigham and Women's Hospital, Harvard Medical School, and the Massachusetts Institute of Technology.

A.2 OBJECTIVES

A.2.1 Overview

Increasing attention is being focused on the optimal response to and most effective delivery of health care in disaster situations. Disasters magnify issues involved in response to individual emergency medical problems. Those problems, arising at random and unpredictable intervals, require not only specific medical action but also attention to regional requirements for coordination of logistics (e.g., closest EMT, nearest emergency department (ED) that has available capacity, appropriateness of the ED trauma center rating for the level of problem, and whether beds are available for admission if necessary). It is generally agreed that, in disaster situations, efforts should be aimed at scaling up current processes, rather than introducing new procedures or devices that might actually decrease providers' productivity because of unfamiliarity, and thus hinder the provision of efficient care for the patients. Therefore, it is critical to identify non-scalable processes in the current model of care, replace these processes by scalable and adaptable ones, and introduce any necessary technical innovations, keeping in mind whether they would be useful in situations of mass casualties due to natural or other causes.

A key issue in achieving this goal is to develop a scalable approach to monitoring of patient status and managing the logistics for an appropriate response in a resource-constrained, highly dynamic environment. This proposal aims at building a scalable model of emergency medical care, by establishing a dynamic infrastructure that efficiently puts together the triad of: patients, providers, and material resources (such as monitors, defibrillators, and other critical care devices). The aim is to foster: (1) identification and location of available resources, (2) decision support for their appropriate allocation, and (3 integration of such capabilities with those of the current emergency health care system.

The project will test the use of wearable personal sensors integrated with personal indoor and outdoor locators, and wireless networking, to recognize and respond to medical emergencies. Medical personnel and material resources will be tagged, in an effort to identify closest available responders and suggest a plan for best resource allocation. This technology has considerable application on a personal level in the community, for accidents, cardiac events, seizures, and other acute medical problems, while it should also be applicable to larger-scale events, in which its full potential would be realized. Sensors are becoming ever more powerful, miniaturized, and unobtrusive, and can be worn, carried, or even ultimately implanted. We plan to test this model in the controlled environment of the Brigham and Women's Hospital (BWH) Emergency Department (ED), in Boston, Massachusetts. Specifically, the focus of SMART (Scalable Medical Alert and Response Technology) will be the design, implementation, and infrastructure deployment for provision of services at the BWH ED that will serve as a testbed network for exploration of relationships among the following capabilities:

(a) Continuous and on-demand active and passive indoor and outdoor location of patients, providers, and critical material resources.
(b) Continuous and on-demand monitoring of patients' essential vital signs, with alerts for critical values transmitted wirelessly to a system that will filter and broadcast information to providers.
(c) Mobile support for health care providers to facilitate optimal care practices given the available resources. This will include decision support for resource allocation (e.g., criteria for prioritizing cases given the available resources, criteria for requesting additional resources, and criteria for referral to specialized procedures, such as radiological examinations).
(d) Portability of the infrastructure to other environments.

The testbed population for SMART will be the patients and the staff of the BWH ED. The BWH is a key academic medical center of the Partners Healthcare System, Inc. (PHS), and an affiliated hospital of Harvard Medical School. The BWH ED's patient population is representative of that of EDs serving highly dense urban communities. It serves as an ideal testbed because of several factors: (a) this is a well-known environment for the investigators, who have already identified areas in which advanced network infrastructure could be used to make processes more efficient; (b) The BWH ED is well-delimited in terms of procedures and geography: patients are expected to be in specific areas, and the workflow is well defined, allowing the refinement of methodologies for evaluation of various technology developments; and (c) the PHS administration has high interest in and commitment to a concerted health care initiative that is scalable to other hospitals and other environments.

The approach we adopt to implementation of SMART is a component-based strategy. This involves methodologies for integrating a distributed set of tools and services that are designed as modular, reusable components, and communicate via standard message protocols. Integration relies on inputs (from sensors, patients, providers, location devices), databases, vocabulary services, and knowledge resources. This project will consist of a proof-of-concept that the system we will develop is feasible, reliable, and scalable. In the BWH ED testbed, the focus is on monitoring patients in and around the ED and waiting room, and those in transit to the CT, MRI, or vascular labs for special procedures, to develop a decision support system that will dynamically suggest appropriate allocation of resources. The project will be a combined effort of BWH's Decision Systems Group (DSG) and its ED, the Laboratory for Computer Science (LCS) at the Massachusetts Institute of Technology (MIT), the Center for Integration of Medicine and Innovative Technology (CIMIT), and PHS Information Systems.

The hypotheses to be tested include the following:

(a) It is feasible to track location of patients, providers, and materials both indoors and outdoors on a continuous basis.
(b) It is feasible to continually monitor untethered patients' vital signs, and give providers appropriate warnings of critical values.
(c) It is possible to implement, in consultation with experts, algorithms that dynamically suggest the best allocation of resources for the ED and to provide a mobile interface for their deployment.
(d) The infrastructure developed is reliable and can be scaled to a large number of patients, and ported to an ad-hoc environment rapidly.

Note that some of these hypotheses have been tested independently[1], mostly outside the domain of medicine, but there have been few reports on these technologies working together in a critical system. The project will focus on three aspects: (a) system architecture and infrastructure development; (b) implementation at the BWH ED, and (c) assessment. Data security and preservation of patient and provider privacy will be major issues for this project.

Products resulting from this work will include the model SMART system, a functioning testbed, a set of component tools and services, and an evaluation of viability and impact of the approach as well as its scalability and adaptability to other environments.

Phase I will have a duration of 12 months, and will be aimed at refining the methodologies and distribution/setup of resources for SMART services, as well as collection of baseline data. Phase II will be for 20 months, and will be aimed at testbed deployment and formative evaluation of SMART at the BWH ED. Phase III will be for 4 months and will consist of evaluation of the operational testbed and analysis of results, reporting, and future plan development.

[1] See section A.2.2 "Background" for a brief review.

A.2.2 Background and rationale

The advent of technological innovations that permit precise indoor and outdoor tracking of location of individuals and materials, remote sensing of status, wireless communication via different media, and adaptive algorithms for resource allocation have the potential to modify the role of information systems considerably. The full circle of locating the patient, transporting him or her to the ED, and having him or her triaged by providers and referred to special services needs to be addressed by an information system that makes the continuum of emergency medical services efficient. This system needs to be scalable to situations of disaster.

In this proposal, we interpret the word *disaster* both in its narrow (a sudden calamitous event bringing great damage, loss, or destruction) and broad definitions (a sudden or great misfortune or failure)[2] and refer to emergency situations in which it is essential to provide the best *feasible* care to many individuals, which may need to be a compromise relative to the best possible care, due to resource constraints. Just as with the allocation of medical resources, deployment of technology will need to be based on what is feasible or practical, not necessarily ideal. Feasibility of sensors and other devices depends heavily on their acceptance by patients and providers. For example, although it would be desirable to have every chest-pain patient immediately and continuously monitored with a 12-lead EKG (which requires that a bed be available in the ED) it is feasible to have the patient monitored with a single-lead or possibly 2-lead EKG while he or she is still in the waiting room. Although it would be best to display monitoring status and alerts on a 21-inch high-resolution display, a mobile device that fits into a provider's pocket or clip to a belt may be more feasible. Although complex algorithms to detect abnormalities in vital signs can be constructed, simple ones based on predefined cutoffs may be sufficient. The ED triage personnel are highly qualified to establish priorities given a patient's condition at presentation, but there are some cases in which the patient deteriorates rapidly without evident signs. For these cases, simple devices might be sufficient to monitor the patient's status, and serve as a useful tool for the busy and highly mobile ED providers.

In the following paragraphs, we review some applications of remote sensors, location devices, hospital and health care-related wireless networks, and decision support systems for emergency care. A recent review led by one of the investigators [Teich 2002] contains more details.

In the health care context, sensors that transmit measurements to a central or remote processing unit are traditionally found in the realms of epidemiology and telemedicine. For epidemiology, systems like RODS (Real-Time Outbreak and Disease Surveillance, University of Pennsylvania) and LEADERS use resources such as laboratories found in hospitals as "sensors". Other more focused uses are telemedicine systems that monitor a small pre-selected group of individuals during a particular event [Harnett 2001]. For geographical data, these systems rely on implicit knowledge of the locations of the data acquisition devices. A step up in integration is made by systems that include geographic sensing devices. One such system is the ACADA/911 system [Miller 1997] that combines sensor devices, a cell phone and a GPS (global positioning system) device. On a larger scale, Thie [Thie 1998] describes a pan-European social alarm system, SAFE 21, using a neck-worn speech-pendant combined with a cell phone and GPS device. These systems can be seen as steps towards a patient-centric health care network (PCN) based on simple, inexpensive, non-invasive, and unobtrusive wireless sensors linked to an intelligent infrastructure; in addition to offering the possibility of monitoring, decision support and telepresence, such systems also offer logistic support such as resource location tracking, allocation, and scheduling.

We propose to build a system that integrates several existing technologies into a functioning application that has the potential to improve the provision of emergency care. Special emphasis will be given to the privacy and confidentiality of human subjects involved in this project, the patients, their families, and providers. At the same time, access to the data needed for patient care, and the aggregation of data useful for assessing the system or specific aspects of health care practice, must be facilitated without undue obstacles. Technical solutions are available to provide adequate security but they sometimes impose considerable additional burden on the users. Appropriate methods must include not only well designed protection, but an understanding of the necessary management and control to administer it, assign privileges, and monitor the process [Andreae 1996; Safran 1995].

A.2.3 The SMART model

We will build a secure scalable system to provide information and decision support in emergency situations. While our testbed focus is the ED, we emphasize that the long-term goal of the approach is

[2] Webster dictionary. http://www.webster.com/cgi-bin/dictionary

considerably broader. The SMART model has potential application across a spectrum of settings, both common and less common but serious, as illustrated by the following scenarios:

Nursing home: An elderly man who is full-code status experiences a sudden acute myocardial infarction at early dawn in a nursing home. His initial call for help is unheard; he rapidly succumbs. The nurse does not discover this patient until several hours later when she rounds to record vitals. Had this man been equipped with a monitor, an alert would have been received by the staff who could have then immediately responded by knowing exactly where the patient could be found, his code status, and where the nearest defibrillator and code cart could be found. Additionally, the system could have called the EMT while the nurse attempted to resuscitate the patient.

Isolated at-risk patients living at home: A 60-year-old woman with debilitating multiple sclerosis lives with her husband, who is currently at work, in their suburban home. Due to her difficulty walking, she trips and falls in the bathroom, hitting her head and losing consciousness. When she regains consciousness, she discovers she has broken a hip yet is unable to walk or crawl to the phone to call for help. When her husband returns from work that evening, she is unconscious, in shock, and is later discovered to have rhabdomyolysis. Had she been equipped with a monitor, an alert would have been sent which would reveal her location, vital signs, and critical information about her medical diagnosis to her husband and to the EMT.

Assisted-living community: An elderly widower with brittle diabetes and coronary disease lives in an assisted-living center. During a birthday celebration, he indulges in dessert and alcohol and then forgets to take his insulin. During the night he loses consciousness, and hours later, develops a fatal ventricular arrhythmia. He is discovered the next afternoon after missing breakfast. A personal monitor could have detected early abnormalities, alerting appropriate providers of his location, his diagnoses of diabetes, and the location of defibrillators and code carts.

Fire in elderly apartment complex: An old high-rise apartment complex serving hundreds of low-income elders experiences a boiler room fire that sends noxious smoke throughout the building's circulation system. The fire department evacuates residents with some difficulty. Most residents need to be evaluated for smoke inhalation; some have severe burns; several are in respiratory distress. The two local EDs are put on alert. Use of personal monitors would help to expedite the evacuation by facilitating the locating of residents during the fire alarm and locating spaces with high and low levels of smoke to recommend safe exit paths. Simultaneous alerts by these monitors would signal notification and initiate coordination of a large fire rescue operation, helping to identify locations of empty beds and emergency personnel, and tracking patients, to be able to advise concerned family members.

Prevention of car accident: A smart sensor detects the onset of a seizure while a 25-year-old female with epilepsy is driving on a major highway. The system alerts the person to pull over, contacts a nearby EMT with precise location of the patient, and activates a repeating recorded message to bystanders alerting to the patient's status and making recommendations to keep the patient seated with the seat belt fastened to avoid trauma given that the patient's oxygen saturation is normal.

Airplane crash at landing: An airplane that is landing at the busy Logan airport in Boston collides with a smaller plane that is wrongly positioned. Rescue teams evacuate dozens of people with severe burns and smoke inhalation. The victims lay on the floor while medics provide basic care, place monitors, and code the priority of each case. As ambulances arrive, victims are selectively routed to trauma centers or regular EDs, given occupancy rates and available resources. EDs monitor the patients from the ambulance, and reassign priority codes as needed.

Monitoring intermediate priority ED patients en route to the radiology department: A 74-year-old man, O-, with abdominal pain following a mild car accident, is taken to the radiology department by a nurse assistant for assessment of internal bleeding. In the elevator, the patient's heart rate rises abruptly. An alert is sent and the closest CPR provider and closest defibrillators are located. The ED provider is notified and rushes to the scene. Blood is ordered from the bank. Surgeons are called and the OR is prepared.

In our testbed, we will be focusing on situations similar to the ones in the last scenario. For sensors, we will focus on pulse oximeters and two-lead EKGs, since these will provide simple but critical information about patient status as an early warning system. For location devices, we will focus on the Cricket technology developed at MIT for precise indoor location. This technology is based on active beacons for radio frequency and ultrasound that are fixed in the environment and received by mobile listeners. The listeners can determine the location by analyzing the signals received from the transmitters. For outdoor location, the technology used is geographic positioning systems (GPS). The precise location of an object or person can be continuously tracked by these two technologies, and this information can be transmitted to remote

monitors continuously or on demand. For clinical decision support and logistic support, we will focus on simple decision methods that integrate geographical models and expert domain knowledge to recommend appropriate actions.

The various scenarios above illustrate the long-term goal of our proposal. We aim to build a model of emergency care which we call SMART, that integrates necessary components (sensors, location devices, databases, vocabulary services, and knowledge resources) to facilitate optimal allocation of patients, providers, and material resources in a cohesive framework. Its goal is to enable decision makers to put together what is needed for an emergency response in a timely and efficient manner, given the constraints imposed by the case load and mix.

An important design strategy underlying SMART is its reliance on component-based software methodologies [Grimes, 1995; Bernstein, 1996]. Applications can be designed by integration of distributed, separately developed components. This has several consequences: (1) Applications can be readily adapted, customized, modified, or extended by changing the way components are integrated and visually presented, the sequence in which they are invoked, or the particular set of components offered. This means it is relatively easy to build applications for particular kinds of user requirements, and to repurpose and reuse components in different contexts. (2) Since components are invoked by well-defined protocols, they can be interchanged with others that have the same message interface. Thus components can compete in the marketplace on the basis of their functionality, quality, and cost. (3) Evolution of legacy systems can be accomplished by encapsulating aspects of their functionality as components. Thus new applications can potentially utilize "best-of-breed" services from either new or legacy systems in a transparent fashion, and the legacy systems can gradually as needed be replaced by more modular components that replace these functions. Some related components that have been developed by the team members in the past can be adapted to this project and are outlined in the next section.

A.2.4 Previous work

The proposed project involves the need for expertise in several areas involving location devices, sensors, wireless networks, databases, medical decision making, human-computer interfaces, decision support systems, software engineering, and emergency medicine. Through collaboration with PHS IS, CIMIT, and MIT LCS, BWH's researchers from the DSG and ED have assembled a team that has documented experience in all those areas. Information about these groups is described in Section 2.A of the Technical Proposal, Other Considerations, and in the subcontract Technical Proposal from MIT. We highlight in this section those activities most relevant to SMART.

The DSG's biomedical informatics research began in 1980, and has spanned several areas of relevance to this project: (1) structured medical data capture, (2) controlled medical terminologies and medical information standards, (3) knowledge representation, (4) guideline automation, (5) patient-centered computing, (6) mobile computing, (7) medical pattern recognition, (8) medical decision support, and (9) protection of privacy in medical data.

Researchers from the DSG are working with the MIT Media Lab in the development of an open-source handheld-based EMR with decision support for paramedical health workers delivering care at patients' homes [Anantraman 2002]. The system is currently deployed on a pilot basis in northern India and is being used by four health workers who cover a population of approximately 30,000 people. The handheld device provides access to patient records, forms for clinical documentation, and decision support in the form of guidelines and alerts. The mobile EMR system is a Linux-based PDA designed for extensibility and easy adaptation to different platforms and settings, and uses a MySQL database. The system uses a CLIPS-based rule engine for implementation of WHO guidelines [Ray 2000]. The SMART system will use a similar PDA platform for users.

Knowledge representation for decision support has long been an important part of DSG work. The Guideline Interchange Format (GLIF) is an activity of the InterMed collaborative project of researchers at the DSG, Stanford and Columbia, to foster sharing of executable knowledge in the form of a common standardized guideline representation [Ohno-Machado 1998; Greenes 1999, 2001]. The InterMed team is working actively within HL7 to foster convergence on a standard. The Guideline Expression Language Object-oriented (GELLO) [Ogunyemi 2002] which is used in GLIF version 3 to represent queries and expressions, is currently being considered by the HL7 Clinical Decision Support Technical Committee as a candidate for standardization and is expected to be balloted by the TC in the fall, 2002. GELLO will be used in this project for encoding decision rules.

An important part of the GLIF and GELLO work is the use of controlled vocabularies. The DSG has developed tools for vocabulary mapping to UMLS terminology sources for guidelines and also is carrying out work related to patient information retrieval needs, mental models, and vocabulary usage [Zeng 2001, 2002].

DSG work in decision support includes an ED application involving assessment of penetrating trauma injuries [Ogunyemi 2002]. Other related work includes the use of machine learning models in a variety of clinical settings, including diagnosis of myocardial infarction given symptoms and EKG findings [Dreiseitl 1999; Wang 2001], and for prognostication of patients undergoing angioplastic procedures [Resnic 2001].

Work on patient-centered computing at the DSG has focused on information resources for patients, in the HealthAware project [Boxwala 1999], selection of appropriate clinical trials for patients based on clinical data descriptors [Ohno-Machado 1999; Ash 2001], and the development of risk assessment tools for patients [Col 2002], and models and tools for shared patient/doctor decision making [Col 1997].

Protection of privacy and confidentiality is also an active area of research essential to this proposal. Researchers at DSG are investigating algorithms to quantify the "anonymity" of disclosed data, as well as developing and refining a theoretical framework for their development. [Ohno-Machado 2001; Vinterbo 2001; Dreiseitl 2001].

The BWH ED has recently undergone re-engineering of its triage, registration, and patient tracking processes. Patterns of resource utilization have been recently reported [Stair 1999]. All providers are active users of electronic information systems.

Partners Information Systems has a long history of development and evaluation of clinical systems to improve patient care. The BICS (Brigham Integrated Computing System) is one of the most comprehensive patient computing systems [Teich 1999], combining EMR, computerized patient order entry, alerts and reminders [Kuperman 1997], a large number of knowledge resources and decision aids, and many capabilities aimed at facilitating information transfer and continuity of care (e.g., a resident sign-out application). The Partners Information Systems environment extends BICS capabilities to the other medical centers in the Partners network, provides an ambulatory longitudinal medical record (LMR), and supports patient-centered information access capabilities. In addition, the system supports a Clinical Data Repository (CDR) with data feeds from legacy systems and ancillary services, and a Research Patient Data Repository (RPDR) to support investigator queries. The Partners IS environment is particularly recognized for the seminal work of Dr. David Bates and colleagues, which demonstrated the effectiveness of error checking in medication order entry as a means of reducing adverse events as well as reducing costs [Bates 1995].

The MIT LCS has focused on the invention, development and understanding of information technologies which are expected to drive substantial technical and socio-economic change. LCS members and alumni have been instrumental in the development of the ARPANet, the Internet, the Ethernet, the World Wide Web, time-shared computers, RSA encryption, and dozens of other technologies. Currently, LCS is focusing its research on human-machine communication via speech understanding; designing new computers, operating systems, and communications architectures for a networked world; and automating information gathering and organization.

Of particular relevance to the current proposal, LCS recently launched the Oxygen project[3], an integrated collection of eight technologies: handhelds, wall and trunk computers, a novel net, built-in speech understanding, knowledge access, collaboration, automation and customization. Taken together, these human-oriented technologies will forge a new computing metaphor that it is hoped will mark an important shift from the desktop icons of today. This five-year research program, being done in conjunction with the MIT Artificial Intelligence Laboratory, draws upon some 60 research projects that the LCS is currently pursuing (see MIT subcontract technical proposal for details). Several technologies proposed for SMART are part of the Oxygen Project.

CIMIT has a variety of projects focusing on biomedical engineering and information technology innovations, particularly in minimally invasive surgery. Of relevance to this proposal is its focus, in collaboration with LCS, the MIT Media Lab, and Draper Laboratories, is on wearable and implantable sensors ("Body LAN") for monitoring patient status. The emphasis is on miniaturization, convenience, and reliability of these devices.

[3] http://oxygen.lcs.mit.edu/

A.3 APPROACH

The goal for SMART is a scalable system in which users and critical materials can be located and put together when needed, in a way that maximizes the probabilities of successful outcomes. Our intent is to provide access to information resources and decision support tools for emergency care providers that cover the whole continuum of care: identification, transporting, triaging, admission, and referral to special services. Selection of information resources and development of on-line decision support assistance are key components of our system. In the ED testbed, this translates into the need to allocate providers and material resources to patients in a logical manner, subject to the many constraints and demands occurring in this highly dynamic environment. To do this, it is necessary to track where these providers, patients, and material resources are, what their status is, and in which situations they are needed. Interface to the existing information resources, and integration of their inputs and requirements must also be considered.

A desirable endpoint for this work would be the conduct of a rigorous multi-center prospective randomized clinical trial that could statistically demonstrate the advantages of using SMART, when compared to the current infrastructure, in the various scenarios described in Section A.1.3 (and other unanticipated ones). While we are several years away from that possibility, in this proposal we aim to make a significant step toward that goal. We will design a scalable infrastructure to support practical wireless networks for emergency medical care that can handle data securely and reliably and implement a system that integrates sensors and location devices using this infrastructure. Instead of attempting to do a superficial analysis of the system in several settings, we will use the limited and relatively controlled environment of the ED as a testbed to perform an evaluation of our approach in a functioning operational mode, working out issues of usability, workflow, clinical appropriateness and effectiveness, reliability, security, and logistics. An independent evaluator will provide continuing advice and feedback throughout the design and deployment, and will assess the operational testbed, in the form of a trial with historic (baseline) controls.

The overall design is a client-server architecture with dynamically recognized and reconfigured clients, in the form of wireless PDAs connected to various sensors and locator devices. The control structure consists of a monitoring hub and underlying database, an Alert Module (AM) and logistics module (LM) with their corresponding knowledge bases. The AM will determine when alerts should be triggered and the LM will determine to whom they should be routed. Technical details about the proposed infrastructure and implementation in our testbed are given in Section A.4. ("Methods").

Our proposal addresses key points of the BAA: SMART aims at developing a scalable, wireless network technology and corresponding decision support system that integrates geographical and medical information focusing on the management of health emergencies. This technology can be extended to provide information for research on early detection of unusual patterns of ED visits, and therefore has both direct clinical impact and indirect effect on public health and surveillance programs. We propose a testbed network to demonstrate a revolutionary application for responding to emergency situations rapidly and effectively. The application is scalable and utilizes self-optimizing wireless network technology. Its evaluation in a busy ED testbed will provide insight into the biomedical and social value of proposed services. The project will provide insight into the direct value of the technology for health delivery, and potential value for disaster management and public health. It will also advance the body of knowledge in networking technology.

A.3.1 User roles in the proposed testbed

We describe here the specific roles for each of the users of the system in our testbed, as they are essential for an understanding of the approach we have chosen. In particular, it is necessary to understand these user roles to assess the adequacy of our proposed evaluation.

All critical mobile devices that are considered important to locate in the ED will get a physical location tag. The devices that **personnel** will carry consist of PDAs with attached location tags and wireless communication capabilities. Our groups have experience with these devices and their flexibility in terms of addition of capabilities such as sensors and wireless communication [Anantraman 2002]. For certain

patients, vital sign sensors (such as a pulse oximeter or two-lead EKG) will be interfaced to PDAs. Display capabilities will allow users (patients and providers) to see information in numeric or graphical form, with the capability or scrolling the measures back in time. **Material resources** such as EKG machines, defibrillators, or oxygen units, will have location tags that can transmit their location to the information system. More details about this hardware and software, as well as the rationale behind them are given in Section A.4.

A.3.1.1. ED providers

The ED providers will carry the PDAs with locating devices. The PDA will have a GUI that allows providers to see a list of patients and their current status in a single panel, and to look at details for specific patients. The patient display will show the chief complaint, vital signs from the sensors (for those patients who have been selected to be monitored), location, and key information such as current illnesses, allergies, and medications. Patients can be searched by ID, priority level, time from registration into the system, location, and type of assistance anticipated (e.g., Mandarin translator, or waiting for lab results). The SMART system will have an interface to the clinical information system so that lab results and other data are sent to the provider PDAs as soon as they become available. A provider can elect to signal a patient's PDA to have the patient come to the ED in case he or she is in the waiting room or other areas. Or an alert can be triggered on the provider's PDA indicating that vital signs or other data of any of the patients are abnormal, and simultaneously, a display of information about that patient will be provided. Additionally, an alert could be triggered on the provider's PDA indicating that he or she is needed in a particular treatment bay, with information about the patient displayed. Acknowledgement of the message will be requested from the providers. A lack of response will be dealt with by repeating the alert and/or relaying the alert to another provider.

A.3.1.2. Patients

Patients will be provided with a locating badge as soon as they register in the ED. Those that fall into Emergency Severity Index (ESI) triage priority 1 (need for immediate attention) will not be part of the system until they convert to less urgent levels. Those patients have severe conditions and will be seen by several providers immediately. For those at priority 5 whose chief complaint does not warrant monitoring (e.g., minor cut that will require a few stitches), no sensors will be provided. For those whose chief complaint does not rule out the need for monitoring (e.g., asthma patients, chest pain), vital sign sensors will be placed and connected to the PDA. All patients will be locatable at all times. Any patient can be signaled at any time to come to the ED in case he or she is in the waiting room or other areas.

A.3.1.3. Family members

Family members will have location tags and alphanumeric beepers. They can be signaled at any time to return to the ED area for news about or request from the patient, or for signatures and other administrative questions. The providers will just need to select the appropriate option and the system will alert family members and keep track of their location.

The user roles just described can be modified to fit other testbeds, while the proposed infrastructure would remain the same, as it is designed to be adaptable to other environments.

A.3.1.3. Coordinator

Initially, a nurse will be assigned to oversee the alerts and recommendations of the decision support system, as well as make sure that there are responses from the appropriate providers. This will be necessary to decrease the burden of false alarms and minimize the possibility that pertinent recommendations do not result in actions. We expect this function to be one of system supervision and that it will be decreasingly needed once the appropriate thresholds for alerts are well established and the confidence in recommendations is high.

A.3.2. Sensors, locating devices, and decision support in the proposed testbed

The base technologies used to build the SMART system will include (1) the Patient Centric Network (PCN), the Cricket System, and Intentional Naming System (INS) [Balazinska 2002] developed at MIT LCS; (2) existing technologies of radio-frequency identification (RFID) [Finkenzeller 1999], and global positioning systems (GPS); and (3) a decision support system and logistic support system that makes appropriate recommendations based on the patient status, location, and resource availability.

The PCN focuses on collecting sensor data from each patient and using appropriate algorithms to alert providers. We will begin with the implementation and testing of pulse oximeters and two-lead EKGs

connected to PDAs, as they are the simplest sensors, and their interface to the PDA has already been developed and implemented by the MIT LCS. Other sensors might be added at a later stage, but they will not be a focus of the proposed evaluation. The Cricket System provides indoor location information for both patients and providers. INS provides a location database for patient location information, provider location information, and equipment information. The RFID system provides indoor location information for equipment. GPS provides location information outdoors. These systems are all inherently scalable. We will refer to the integration of sensor and location information as the scalable location-aware monitoring (SLAM) sub-system.

To demonstrate feasibility of SMART and reliability of the network infrastructure, and to collect data to evaluate SMART, we have limited the types of sensors, locating devices, and decision support services we will initially provide. Other sensors and services may be added if time and budget permit.

We will initially limit decision support to simple alarms regarding low levels of oxygen saturation, and potential arrhythmias, and to simple expert-based rules for resource allocation given existing constraints. Providers will be able to check these signals remotely, however, and we will store signals to create a database that may serve as a basis for pattern recognition in the future. We will keep track of whether recommendations for action are subsequently actually followed.

A.3.3 Evaluation: baseline versus post-intervention data

Several aspects of our testbed implementation are amenable to evaluation, including qualitative and quantitative measurements of (a) network reliability; (b) hardware and software reliability; (c) adequacy of alerts to providers; (d) time needed to locate providers, patients, and family members; (e) waiting times until a patient is seen by an ED provider (other than triage nurse); (f) provider, patient, and family member satisfaction regarding usage; and (g) adequacy of the allocation of providers and materials to patients, given the ED's load and mix. Some of these measurements will need to be adjusted to seasonal trends, biases of selection, and other important factors. However, certain simple measurements can provide important insight regarding what the impact of such an integrated emergency information system can be, in terms of benefit to both patients and providers. We will focus our evaluation efforts on factors (a) through (e), but will gather data for exploratory analysis of (f) and (g), inasmuch as data for these two factors are expected to be less complete, given their high dependence on the other items. For all cases, we will collect baseline and post-intervention data for matched individuals (e.g., match a chest pain case with another with similar ESI, age range, and gender).

Based on experience from information systems implementation at BWH, it is usually infeasible to randomize providers into an intervention and a control arm, especially when they work in the same unit. Therefore, we have not designed our evaluation in the form of a prospective clinical trial, but rather as a study with a prospective intervention arm, the measurements of which will be compared to those for matched historic controls. We will utilize a phased approach: collect baseline information in the beginning and select controls, conduct formative evaluation and refine the system, and perform summative evaluation of the system. The main endpoints are outlined below.

A.3.3.1. Feasibility

We will assess whether the system is capable of being used effectively. Although during development we will elicit extensive feedback from providers, we are not electing to use questionnaires to assess the perceived usefulness of the system, as the information would tend to be highly biased and of little value, given that the ED providers are excited about the project and are a superset of the investigator team. Instead, we will measure which modules (location, remote sensing, decision support) are used most often vs. shut down, as an indirect indicator or proxy for their perceived usefulness. We also do not want to impose extra burden on the patients, as would be needed by asking them to fill out forms assessing their interest in the system. These provisions are in conformance with the Paperwork Reduction Act outlined on the BAA. We will fully inform the patients that the use of the device is voluntary, and make them aware that the standard of care is not to use it. If they elect to use the device and continue to use it until their discharge from the ED or admission to the hospital, we will count this as a success. Otherwise, we will record the time spent with the device and the reasons to remove it. Patients, providers, and family members may elect not to use the system before trying it out. We will distinguish this category from those who gave up using it.

A.3.3.2. Reliability

Reliability of the network will be sampled once the system is implemented, and every episode of disruption will be recorded. We will utilize secure protocols for data transmission, as well as extend our work on protecting patient confidentiality outlined in Section A.2.4 to the data disclosed for investigators of this project. Identifiable data will not be made available to other parties. Reliability of the sensors will be measured by utilizing dual monitoring (e.g., 12-lead non-mobile EKG and 2-lead mobile EKG) in certain patients who are in the ED and in healthy volunteers. Location technology will be tested against known positions of stationary and moving people and objects. The decision support component will be tested in terms of adequacy of recommendations in specific settings. A panel of three ED physicians will evaluate the system's recommendations.

A.3.3.3. Scalability

Scalability of the system in terms of higher patient load (higher number of patients, more sensors per patient, increased number of providers); geography (adaptability to changes in the physical environment, outdoor environments); and settings (other user roles, different applications) will be assessed by porting the system to work in the Brookline EMS context (providers carry the equipment in ambulances and place the monitors in the field, and signals and location can be monitored from the BWH ED prior to arrival at the hospital). An important future issue is to determine how long it would take to set up the whole system and train personnel in another ED, or perhaps even in an improvised ED at a disaster scene in which providers would be familiar with the system, but not with the environment.

Details of the proposed evaluation, which are expected to change given the input from an independent evaluator, are provided in Section A.4.4.

A.3.4 Limitations and response to potential problems

Our aim is to show that the availability and efficient use of an integrated emergency care delivery system that encompasses the whole mission of emergency care (from location of patients to appropriate allocation of resources for their treatment) promotes better provision of care than the current system. Our ultimate goal is to show that new technologies that can be used for regular care can scale up to disaster situations. In this initial step towards that goal, we will introduce new technology to an ED and monitor the changes in care.

From a research point of view, we want to demonstrate that we can, using advanced wireless self-adaptable networks, transmit, securely and reliably, information gathered from remote sensors to mobile units that can provide decision support for providers. From an emergency care system point of view, we want to demonstrate that, using the same tools and the same infrastructure, we can provide an information support resource that is both convenient and highly efficient, and which integrates with and complements existing information system capabilities. The infrastructure and tools we develop will interface with existing information system, to obtain or serve data. Patients should benefit from SMART by being more actively monitored and shortening their waiting times in the ED. Providers should benefit by having more information about their current and future patients, and by being able to respond in more timely and effective fashion when required. Researchers in medical informatics, computer science, and emergency medicine will be able to learn which factors influence the usage of an integrated emergency care delivery system, thereby being able to focus on enhancing positive aspects of their experimental research, and avoiding strategies that we discover to be suboptimal.

We expect that providers and patients will be interested in different aspects of SMART. There are several reasons for anticipated diversity of interest and response to the system:

(a) The usefulness of SMART may not be appreciated in periods of light load at the ED. Furthermore, the system may work well for certain ED teams, and not for others. We will monitor the use of the system and adjust to the case mix and team composition at the ED. Although it is critical that the system be perceived as useful in heavy load situations, we want it to be used in routine care so that its operation is fully mastered, should a disaster of large proportions occurs. We will try to determine the factors that influence the system's acceptance.

(b) Although the BWH ED already has a wireless access point that does not interfere with instruments, there is a small probability that instruments may be affected by the increasing load of wireless transmissions. All hardware and protocols will be submitted for approval by the hospital's engineering team, as well as the IRB.

(c) Although the PHS administration encourages the use of computer technology in all aspects of care delivery, and there are several "champions" in the BWH ED, there are likely to be some individuals

who are resistant to changes brought by information technology and who will less amenable to using SMART for assistance. We will make a concerted effort to have these individuals actively participate in the process of refining the system according to their feedback.

(d) Although the target population is large, and the sensors and decision support approach we propose are general, we expect that the number of individuals who actually will use the system will be small. We have determined that patients at either end of the triage priority range should not use the system, given that they are too severe not to be admitted and treated immediately, or are too "healthy" to warrant the monitoring.

(e) Matching patients to historical controls is a difficult and time-consuming task. We will use propensity score matching as described in [Rubin 2000].

(f) The relatively short time frame to perform an adequate longitudinal study may hinder our ability to show statistical significance in terms of health outcomes of individuals.

We do not believe that any of these problems will be insurmountable. In terms of statistical significance in this proof-of-concept project, we expect that, for each of the three main functions of the system (location, sensing, and decision support), and two main categories of chief complaints (cardiovascular and respiratory), we will get enough participants to be able to unequivocally demonstrate the usefulness of the system from the viewpoint of both the providers and the patients. We believe that, in the worst-case scenario, this experiment will provide a valid exploratory analysis of the advantages and disadvantages of establishing an integrated emergency information system in a reasonably controlled population. Even in this situation, the results of this experiment will set the stage for larger and longer studies reaching out to a broader community, and the tools developed in this project will be useful in such future endeavors. In the best case scenario, we will statistically demonstrate the usefulness of our system and its full acceptance by patients and providers at the BWH ED, and provide a sound basis for projecting its use into other broader settings.

A.3.5 Management strategy

A.3.5.1. Phased approach

We have opted to use a phased approach to our study because that allows for (a) gradual development and integration of different capabilities, with early deployment of the capabilities that require only small adaptations, (b) initial testing and feedback from users, with emphasis on feasibility and reliability, and (c) field testing with evaluation of a stable system. This is described in Section A.4.4. Briefly, phase I (12 months) will focus on infrastructure design and usability testing of devices, and baseline data collection for subsequent evaluation. Phase II (20 months) will involve development, pilot deployment, and formative evaluation in the ED environment. Phase III (4 months) will focus on operational testing, with evaluation by an external evaluator.

A.3.5.2. Project management committee

Dr. Ohno-Machado and Dr. Greenes will head the project management committee, composed of Drs. Boxwala, Ogunyemi, and Col from the DSG; Dr. Middleton from Partners IS (who is also on the DSG faculty); Dr. Mezrich from CIMIT and the Department of Radiology; Drs. Stair, Teich, McAffee, and Ms. Morrissey from the BWH ED, and Profs. Balakrishnan and Guttag from the Laboratory for Computer Science, MIT. Responsibilities will include defining and assigning tasks, monitoring progress, coordinating and producing reports, and establishing policy as issues arise. Co-investigators of the BWH will meet bi-weekly to report on development of applications, and at least one meeting monthly with an MIT representative is expected during the course of this project.

A.3.6 Possible extensions

The results of these experiments will help us define critical features for the success of an integrated emergency care delivery system in a limited setting. We intend to extend the breadth of services provided and the populations targeted. Through our relationship with other Harvard-affiliated hospitals, we have the opportunity to cover other similar environments. The next step in that direction would be to give all EDs in Partners the same capabilities as those that we will implement at BWH. We could in the future provide services for other institutions.

It is important to emphasize that the main contribution of our experiments will be the development and evaluation of an infrastructure and methodology for providing timely and effective response in emergency situations. We will publish our infrastructure, methodology, and results in widely distributed journals,

emphasizing lessons learned and our assessment of critical factors for success. This methodology can be used by other researchers to develop similar systems all across the U.S.

A.4 METHODS

A.4.1 Characterization of our testbed: the BWH ED

The Emergency Department (ED) at the Brigham and Women's Hospital is a Level I, Harvard-affiliated trauma center that offers a full spectrum of emergency and trauma care 24 hours/day, 365 days/year to patients over the age of 14. The ED sees over 55,000 patients a year, providing trauma care, acute and urgent care, fast-track care, observation medicine, and patient and family services. The BWH ED has WiFi 802.11b wireless LAN installed for bedside registration with interface to clinical information systems, and has one physician laptop connected to this system. Providers at the BWH ED consist of a group of 24 attending physicians, 2 fellows, 52 residents, 75 nurses, and 30 emergency services assistants (ESAs). Each 8-hour shift is staffed, on average, by 1 to 2 attending physicians, 1 to 3 emergency medicine residents, 12 nurses, and 6 emergency services assistants. Residents in internal medicine supplement ED staffing as they complete rotations in emergency medicine.

BWH is located in the middle of two highly contrasting neighborhoods in greater Boston: Roxbury, a poor urban neighborhood with high indices of criminality and low average educational level, and the town of Brookline, a wealthy neighborhood with a highly educated population that houses a large proportion of Harvard Medical School-affiliated staff, faculty, and students. The BWH ED has a high volume of cases, with a distribution that is indistinguishable from that of other academic hospital EDs in the greater Boston. Table I displays the main statistics related to BWH ED discharge diagnoses in 2001. Of note, chief complaints are currently not entered in structured format in BWH's information system at the time of the visit. We plan to change this situation by allowing the triage nurse to select from a menu of most frequent complaints, as well as add any information she deems necessary in free text, which will be matched to controlled vocabularies via a semi-automated process.

Table I. Top diagnoses at BWH ED FY 2001

Principal Diagnosis	Visits	Principal Diagnosis	Visits	Principal Diagnosis	Visits
786.59 CHEST PAIN NEC	1676	486 PNEUMONIA, ORGANI	504	789.00 ABDOMINAL PAIN	293
786.50 CHEST PAIN NOS	1143	079.99 UNSPEC VIRAL I	502	682.6 CELLULITIS OF L	283
847.0 SPRAIN OF NECK	1031	786.05 SHORTNESS OF B	454	525.9 DENTAL DISORDER	261
784.0 HEADACHE	944	789.09 ABDOM PAIN, SP	442	787.01 NAUSEA WITH VO	261
729.5 PAIN IN LIMB	833	845.00 SPRAIN OF ANKL	441	724.5 BACKACHE NOS	253
599.0 URIN TRACT INFE	777	789.06 ABDOM PAIN, EP	426	723.1 CERVICALGIA	252
724.2 LUMBAGO	717	428.0 CONGESTIVE HEAR	425	640.03 THREATEN ABORT	250
V58.3 ATTEN-SURG DRES	680	780.4 DIZZINESS AND G	420	729.81 SWELLING OF LI	241
462 ACUTE PHARYNGITIS	614	276.5 HYPOVOLEMIA	406	789.01 ABDOMINAL PAIN	241
780.6 FEVER	585	578.9 GASTROINTEST HE	404	427.31 ATRIAL FIBRILL	240
789.03 ABDOMINAL PAIN	575	411.1 INTERMED CORONA	368	782.0 SKIN SENSATION	233
493.92 UNSP ASTHMA W/	567	789.07 ABDOM PAIN, GE	359	998.59 OTR POSTOPERTV	232
780.2 SYNCOPE AND COL	567	789.04 ABDOMINAL PAIN	355	785.1 PALPITATIONS	226
648.93 OTH CURR COND-	554	780.39 OTHER CONVULSI	349	577.0 ACUTE PANCREATI	211
847.2 SPRAIN LUMBAR R	547	780.09 OTH ALTER CONS	343	490 BRONCHITIS NOS	203
883.0 OPEN WOUND OF F	530	959.01 HEAD INJURY,UN	330	782.1 NONSPECIF SKIN	203
465.9 ACUTE URI NOS	510	558.9 NONINF GASTROEN	296	522.0 PULPITIS	191

Patients referred to the BWH ED show a great disparity of educational and socio-economic conditions, and a typical mix of ethnicity and gender. Table II displays the patient demographics for 2001.

For this project, we will limit our system to patients presenting with cardiovascular and respiratory complaints. These patients constitute about 13% of total cases, with an expected average of 20 cases per day. We expect that 80% of these patients will accept participation in this study. See Section 2.C. "Human Subjects" on p. 87 for expectations of targeted enrollment.

Table II. Demographics at BWH ED FY 2001 for 54,434 total visits

Race	Visits	%
American Indian	64	0.1
Asian	970	1.8
Black	15453	28.4
Hispanic	10450	19.2
White	26053	47.9
Other	1231	2.3
Refused	5	0.0
Unknown	194	0.4

Age	
< 14	101
14 - 21	4325
22 - 40	21397
41 - 60	16498
61 - 80	9335
> 80	2773

Sex	Visits	%
Female	33024	60.7
Male	21408	39.3

ED Severity Index	Visits	%
1	205	0.4
2	12116	22.3
3	25362	46.6
4	12496	23.0
5	4254	7.8

Destination	Visits	%
Admitted	10961	20.1%
Death	47	0.1%
ED Observation	4407	8.1%
Home - Routine	35646	65.5%
Left Against Medical Advice	300	0.6%
Referral within Hospital Clin	167	0.3%
Transfer	1516	2.8%
Walkout	1374	2.5%

A.4.2. System design

A.4.2.1 Overview of functionality

Figure 1 displays the main components of the system. Patients with complaints compatible with cardiovascular or respiratory problems who consent to participate in the study receive two-lead EKG sensors, a pulse oximeter, and a cricket location-aware "SMART" PDA that receives inputs from the sensors. Participant family members receive alphanumeric pagers. Providers who agree to participate receive cricket location-aware PDAs. Equipment receives radio-frequency identification tags.

Data are transmitted from the patients' PDAs according to a frequency predetermined for each kind of patient: (1) only on demand or in the case of an alert; (2) 5 minute samples every 15, 20, 30 minutes; or (3) continuously. Handling of body sensors, including the fusion of signals from sensors (e.g., heart rate as measured by oximeter and by EKG sensors), is done via the Patient Centric Network. The PCN contains self-contained algorithms to discern certain types of false positives (e.g., when heart rate from EKG is zero and from oximeter is 80/sec). SMART's Alert Module (AM) has a knowledge base that contains more elaborate algorithms which consider other clinical and sensor data. SMART Central is the application that serves as an Event monitor and Router. It receives information about patients from the PCN and location devices. In addition to the above data from patient PDAs, SMART receives continual data inputs from the Partners Clinical Data Repository (CDR) regarding laboratory results, and essential information such as important co-morbidities. Additionally, SMART Central receives information about provider and equipment locations (via the Cricket system and RFID, respectively), and interacts with the AM and a Logistics Module (LM).

The AM determines whether alerts should be triggered for interesting events originating from the PCN (e.g., declining O2 levels). If an alert is triggered, the AM issues a message to SMART Central, which can invoke the LM. The LM can suggest allocation of resources according to pre-determined rules. SMART Central can verify whether resources are moving to the recommended location.

All relevant data from sensors, location devices and clinical sources are stored in the SMART Repository, according to pre-determined policies from the ED (e.g., a 1-minute sample every 10 minutes in addition to the last 5-minute stream). The data are removed from the active system upon the patient's discharge, and stored for documentation and analysis.

Provider SMART PDAs display lists of patients with highlighted information about status, and aggregated data for each patient, transmitted and updated via SMART Central. The same information is also made

available on the ED workstations. When alert conditions arise, messages are sent to the provider PDA that may trigger audible and visual alerts (with modifiable characteristics). In addition to alert messages, SMART may issue recommendations on appropriate resources and their availability. The provider may choose to accept or reject a recommendation. In case he or she accepts, the recommended providers and nurse assistants receive alerts from their PDAs so that the necessary resources are assembled at a particular location.

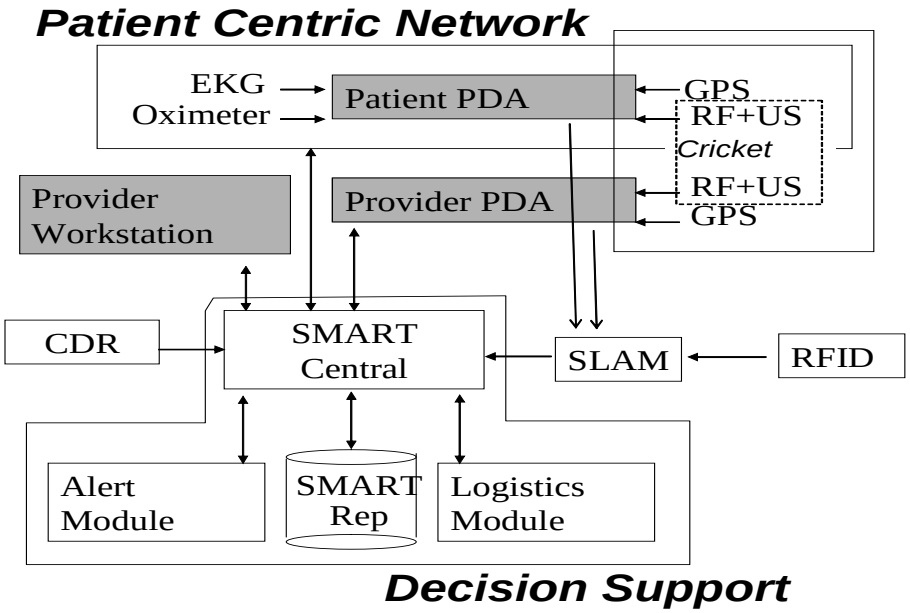

Figure 1. Architecture of SMART. RF: Radio frequency. US: ultrasound. RFID: Radio frequency identification (for equipment). CDR: BWH clinical data repository. SMART Rep: SMART Repository.

The following scenario illustrates the capabilities of the system in our testbed:
After dinner on a Saturday evening, a teacher experiences mild chest pain and mentions this in passing to his relatives. They are concerned that this might warrant medical attention, and accompany the patient to the BWH ED. Because of a multi-car accident, the ED is faced with an unusual number of trauma cases, and no beds are available. The triage nurse places on the patient a pulse oximeter and a two-lead EKG connected to a SMART PDA, after giving information on the study and obtaining written informed consent. The patient and his family stay in the waiting room area for twenty minutes. The patient's relatives get bored and decide to grab a quick snack in the cafeteria. After ten more minutes of waiting, the patient decides to go to the cafeteria to join his relatives. On the way to the cafeteria, he suddenly collapses to the floor. Sensor readings from the pulse oximeter indicate rapidly decreasing oxygen levels, while the EKG indicates a cessation of electrical activity, confirmed by the lack of heart beat from the oximeter.
The SMART system triggers an alert to the most appropriate ACLS provider's SMART PDA[4], with location of the patient and the defibrillator that can be grabbed on his way there. The provider confirms via his

[4] In the initial phase a nurse coordinator will filter SMART's alerts and recommendations, but the ultimate goal is to have SMART send alerts directly to the most appropriate provider. Appropriateness will be determined by a combination of location, availability, and importance of the alert. For potential cardiac arrest as in the scenario, location would have a high weight, while in a less severe situation availability might have a high weight. SMART will be designed to avoid alerting unnecessarily large numbers of providers for a given case. If a provider does not respond (or the location system determines that he or she is not moving toward the patient) within a defined amount of time, the next most appropriate provider will be called, and if this one responds and reaches the scene, the first one is notified and his alert is canceled. In case the second most appropriate provider does not respond, the third most appropriate will be alerted, and

PDA that he is responding to the alert. His relocation to the patient's location confirms this. The nearest available stretcher is located, and an alert is issued at the closest nurse assistant's PDA to take the stretcher to where the patient is. The provider arrives at the scene and successfully resuscitates the patient, who remains unconscious and is taken back to the ED. Relatives are quickly located based on information provided by SMART, and asked to return to the ED to sign consent for an emergency angioplasty.
The scenario illustrates the main components of the SMART architecture:
(1) A location system that indicates where patients, providers, and resources are.
(2) A monitoring system that can fuse data from different sensors and location inputs (SLAM).
(3) A control program that receives inputs from SLAM and from the CDR, detects events, passes events to an alert module, and if triggered, to a logistics module, updates the provider and patient PDAs and workstations with appropriate messages, receives and responds to user inputs, and logs all events and actions (SMART Central).
(4) An alert module (AM) that determines when to trigger an alert for a given case.
(5) A logistics module (LM) that makes specific recommendations on available resources.
(6) Knowledge bases containing rules used by the AM and LM.
(7) A database for storing data from sensors, locations, laboratory data, important co-morbidities and medications, as well as tracking of system use by providers (SMART Repository).
(8) GUIs and alerting mechanisms in PDAs and workstations to display patient data and recommendations, and support entry of requests.

Providers will interact with this system via user applications that will allow:
(1) Data display of different patients, with possible sorting according to ESI or complaint category. Data to be displayed include sensor, location, lab-generated information, and important co-morbidities; alerts will also be shown, with visual and audible cues.
(2) Acknowledgement of a particular alert and intention to respond.
(3) Acceptance or refusal of a particular resource allocation recommendation.
(4) Display of instantaneous summary data and statistics of the ED for the present shift: occupancy, number of triaged patients waiting to be seen (by ESI and complaint) and for how long they have been waiting, discharged patients and destination, and ED patients currently out for exams or procedures and their locations.

A.4.2.2 Component architecture

There are substantial technological challenges in the implementation of the proposed system. The LCS team at MIT will work with the BWH and CIMIT teams to develop and adapt to the ED setting a system that integrates the MIT SLAM sub-system with SMART's alert and logistics modules via an application named SMART Central. SLAM consists of three main components: (1) the Patient Centric Network, which integrates data from multiple sensors in a wearable PDA, (2) the Cricket location system, which uses radio frequency and ultrasound for indoor location; and GPS for outdoor location, and (3) the INS which facilitates data management coming from (1) and (2). The event monitor in Smart Central receives information from the Clinical Data Repository (CDR) and SLAM and transmits them to the Alert Module. Alert messages are sent to the Logistics Module via SMART Central to determine optimal responders and resource allocations. SMART Central is responsible for issuing alerts to specific providers, tracking responses, and issuing further alerts if necessary.
The event monitor of SMART Central listens to streams of incoming data for *new* events. It contains a knowledge base for defining what constitutes an *interesting* event for the AM. The AM and the LM will each contain:

- A knowledge base
- A rules interpreter that will evaluate the rules against present data and recommend actions.
- An action manager that will handle dispatch of messages to SMART Central.

In addition to the above, we will provide user interfaces on both PDAs and SMART-enabled clinical workstations for viewing summaries of patients and their status, for viewing clinical data for any patient currently under care, for viewing alerts, and for responding to them. The emphasis will be to make sure that solutions for the BWH ED are also scalable, and that any particular adaptations that are made necessary for

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so on. The system may make calls such that the code team is alerted via the hospital overhead paging system in case there are no ED providers nearby.

this environment are fully justified and documented. In particular, the decision support system based on domain knowledge of ED operations will have to be developed with close collaboration of technical and medical participants.

Our current plan in terms of hardware and software platforms, which may change given the acceptance of new standards and the development of cheaper and more powerful hardware, is as follows:

We will use Linux-based Compaq iPAQs given our group's experience with these devices in terms of application development and ease of integration with sensor hardware. The open-source operating system facilitates development and decreases the overall software costs, but currently limits the hardware to somewhat expensive devices. It is our expectation that these devices will become cheaper in a couple of years. These devices have a distinct advantage in terms of computational power and storage space. They allow greater expansibility using the industry-standard Compact Flash expansion or the PCMCIA slot expansion which allows addition of more storage devices (such as Compact Flash memory) as well as other peripherals (GPS, Crickets, and sensors). For our prior work, the Compaq iPAQ™ 3760 series was used. We will use for this project a newer version that incorporates Bluetooth capabilities for wireless connection to sensors. Among the Pocket PC-based devices, the iPAQ is one of the few that runs a stable Linux kernel. Linux allows good control of system resources unlike other operating systems for handheld devices such as Pocket PC and Palm OS. The operating system can be compiled for optimal usage of memory and space (which are crucial when using a PDA in which the memory resources are extremely limited). Also, the run-time overheads of the operating system such as the number of running processes can be controlled. We plan to use the Qt development system, as it provides an elegant C++ API with cross-platform development tools. The native C APIs are encapsulated in a set of well-designed, fully object-oriented C++ classes. Qt/Embedded is a version of Qt designed for resource-constrained embedded systems. It provides full GUI functionality without requiring X11 or Motif on the target system. This substantially reduces the memory and CPU demands of the embedded software. The alternative to Qt is to use Java. This is possible using the commercially available Java Virtual Machine such as Jeode™, however one of the key disadvantages of Java in a PDA is the additional resources that the byte-code interpreter consumes in an already resource-crunched system.

We will use HL-7 for clinical data message interfaces to the CDR, and we will use GELLO [Ogunyemi 2002] as a rule expression language, assuming expected progress in adoption by HL7. If undue delays occur, by June, 2003, then we will use Arden Syntax for rule interpretation.

A.4.2.3 Security and confidentiality

SMART system security will need to provide a satisfactory level of communication protection while supporting information delivery in a user-friendly manner. The security issues for the project will be explored and solutions implemented during the initial months of the project period. These include issues of system protection to prevent breaches into it, a tracking and trending protocol, and a provision for secure communication. Strong encryption underlies all active communication in this system, especially since wireless 802.11b communication is inherently insecure otherwise.

At times, the technical solutions that would permit each of these activities to occur with minimal opportunity for a security breach impose significant impediments for the user. Above all, patient privacy and confidentiality of the patient/provider communication must be maintained without obstacles while providing a user interface that encourages necessary interaction by the users. The methodology to be used for SMART will include the development of a management system to control security and role-based access to reduce the risk of down-time, intrusion, tampering, data loss, hacking, data theft, and other security risks.

We will develop a complete set of tools for authoring/editing of permissions and monitoring strategies for users of SMART. The development of security protocols will include a methodology to ensure that those information requests that need to be tracked over a period of time can be done with discrete user-specific yet encrypted identifiers, and which will assure security and privacy of data communication. Log data will be stored off-line and will be retrievable only by authorized persons who have a legitimate need for such access. The issues that we plan to address in the security mechanisms of the system are summarized as follows.

Access control: Control of the access to (i) the physical entities of the system, and (ii) the information stored in the system. Securing the physical entities will be left to the health care provider. The usage of the system and access to the information will be regulated by a configurable access control system that supports both role (group) and individualized access control lists for each item in the system.

Authentication: Confirmation of the identity of an entity wanting to access resources in the system. The system will use an authentication mechanism based on encrypted passwords. This will be required once for the PDAs at the start of the shift and at every session on the workstation, with appropriate time-outs as determined by the ED policy.
System and information integrity. System integrity issues are (i) ascertaining the system's adherence to functional specifications, and (ii) ascertaining the correctness of the data stored in the system. System correctness with respect to the functional specification will be addressed in both the design and implementation phases by rigorous documentation and testing procedures which will be continuously monitored, and by built-in self testing routines while in operation. Mechanisms for ensuring correct data entry will be implemented in order to minimize data entry errors.
Auditing: Auditing of use of the system and tracking of information transfers to ensure that procedures are followed, and to detect breaches. A configurable audit system will be implemented that allows the implementation of audit profiles that can be used for testing, regular operation, and when attacks are believed to happen.
Fault tolerance: System robustness in case of partial malfunction. The system will be designed with redundancy in mind, such that several redundant systems can operate simultaneously.
Disclosure control and privacy: Guarding against the improper disclosure of (i) patient data, and (ii) resource and personnel locations. The system will be able to function in two contexts: one within an institutional circle of trust, where it is allowed to query institutional resources such as hospital information systems; and another outside of this circle of trust, where it cannot rely on the security of the information obtained. The policy of tracking personnel only on demand will be supported in order to minimize compromise of individual privacy. The system will adhere to the HIPAA privacy rules when dealing with patient data. All communication will be done using secure channels and only with authenticated peers. The communication within the system can be divided into two classes, stemming from either (1) passive location tag reflections, or (2) active communication devices. Underlying active communication is strong encryption. The system will use this to implement authentication, digital signatures, and secure communication channels to deal with interception, modification and nonrepuditation issues. The system will be equipped with sensors to identify and located denial of service type of attacks.

A.4.3 Phases of development

A.4.3.1. Phase I (12 months)

This phase will be devoted to a thorough analysis and development of detailed specifications for the system envisioned, with particular emphasis on our testbed implementation at BWH ED. We will develop the infrastructure for assuring that the location devices and remote sensors are well tolerated by patients and providers, and that they work at the BWH without interference with any critical instruments. Specifically, geometric models of the BWH ED, waiting room, and travel routes to imaging services located outside the ED, as well as the vascular lab, will be constructed. Indoor active locating devices will be strategically positioned in rooms, hallways, elevators, and other critical locations in a cost-effective manner, by using algorithms based on the geometric models. We will also focus on design and usability testing of the PDA devices for providers and patients, and on the component design for the system as described in Section A.4.2.
We will refine our evaluation plans and modify them according to the recommendations of an independent evaluator, Dr. Richard Friedman of Boston University. Baseline data related to resource allocation will be collected, as well as data related to patient age/gender/ethnicity and presenting complaints for later comparison with data collected in phase II. We will also identify problem areas and create contingency plans for anticipated problems. A milestone for this phase will be the deployment and use of some devices and preliminary demonstration of their reliability.

A.4.3.2 Phase II (20 months)

During phase II, we will conduct a phased implementation of our capabilities. We will develop the algorithms that integrate the information provided by sensors and locating devices, as well as existing information systems data sources, and develop the PDA-based interfaces to provide decision support for providers. Different types of decision support are envisioned: (a) alerts from remote sensors based on critical values for pulse and oxygen levels and location sensing of material resources or patients outside the expected areas; and (b) integration of information from sensors, locating devices, clinical databases, and case load to suggest optimal allocation of resources given the current situation.

We will start by studying the floor plan of the ED and radiology suites that most often receive ED patients. We will also determine possible travel routes for patients going from the ED to the radiology suites or vascular laboratories and back, including elevators. We will study the spaces adjacent to the ED where patients are often located: waiting rooms, BWH main lobby, cafeteria, and nearest restrooms, telephone and ATM areas, newsstands, and near outside areas where smokers often go.

We will then determine algorithms for best positioning of stationary location devices (cricket beacons), and decide whether certain assets should receive radio frequency identification (RFID) tags[5]. We will also investigate the insertion of RFIDs into the current BWH badges that employees use at all times, as well as on wrist labels currently given to patients for identification. We will attach location devices (cricket listeners) to the PDAs as well. This apparent redundancy may be necessary to locate devices in case they are lost or inadvertently leave the hospital premises. (We can set up monitoring sensors at the exit points, to alert the guards at the entrance/exit to the ED, for example.)

In parallel with the "location" team pursuing the above issues, a medical sensor team will be testing the remote transmission of the pulse oximeters and two-lead EKGs. Protocols for response to false alarms will be put in place, as this is anticipated to be a major problem in the beginning of this implementation. The most feasible solution will likely be to have a nurse communicate with the patient whose signals are suddenly interrupted by asking the patient to press a button to acknowledge a message such as "please reposition the device on your finger".

Also in parallel, a logistics team will devise optimal ways to determine that a device, provider, or new lab results are available. The latter requires integration with the laboratory information system portion of BICS, and is expected to be accomplished by creating output data "services" from the Partners Information System CDR, which is fed by BICS. We will investigate latency issues to be sure that the CDR receives this input in a timely fashion, and methods to "push" the results to the decision module when they arrive. Identifying the location of a device may be the most feasible way to determine its availability, although better methods will be investigated. The same applies to providers.

Knowledge acquisition from ED experts, to develop recommendations regarding appropriate combinations of patient/provider/material resources, will be conducted in phases I and II. A specialist in graphical interface and human computer interaction will work with ED providers on best ways to display the information they need, for simple displays of location and vital signs to more complicated recommendations on what to assemble regarding a specific patient. Options for calling the providers with the touch of a button will be considered.

The main thrust of phase II will be continuous evolution of the system based on users' feedback. The system will be continually evolving based on recommendations and formative studies. We will document every element of feedback. A milestone for this phase is the actual use of the system, with acceptance by ED providers of the alerts and recommendations given by the system.

A.4.3.3 Phase III (4 months)

In phase III there will be no further refinements of the system, and we will assess the value of the testbed system in a summative evaluation and compare the data against the baseline data collected in phase I. Dr. Friedman, the independent evaluator, will assist in data analysis and interpretation of results. Also during this phase, we will also conduct preliminary implementation of SMART's first logical extension: We will add 5-10 devices to each ambulance in Brookline to monitor patients en route to the hospital. We will attach one device to each victim in each multi-casualty event (e.g., car accident, fire, building collapse, riot) to improve identification, tracking, ED pre-arrival planning, and monitoring. We will use this system instead of traditional red/yellow/green/black triage tags during the next disaster drill. A milestone for this phase will be the completion of the summative evaluation, analysis of results, and production of a report summarizing our conclusions about impact, scalability, and issues for future work.

Details of the timeline are given in Section A.5 "Schedule". Given our emphasis on the assessment of the system in this real setting, rather than on the technology per se, we emphasize next the key aspects of the planned evaluation studies.

A.4.4 Evaluation studies

All identifiable individuals participating in our experiments will be asked to give us written permission to utilize their data. As the study protocols are finalized, approval by the Project Officer and by the internal

[5] See subcontract Technical Proposal for more details on location devices and tags.

review boards of BWH will be sought. Participation in these experiments will always be voluntary. Certain endpoints of this study may change, given input from the independent evaluator, but the basic goals of the evaluation are expected to remain the same. Although feasibility and reliability are highly interrelated concepts (unreliable systems are impractical if not infeasible), for evaluation purposes we plan to divide the measurements as follows.

A.4.4.1 Feasibility of location devices and sensors

We hypothesize that providers, patients and family members will be able to use the system for remote monitoring of vital signs and location.
We will compute the proportion of eligible patients and providers who used the system, and report 95% confidence intervals for the proportion. Partial use will be accounted for. Reasons to stop use will be recorded. We will record whenever an inquiry about a patient signal or location was entered into the system.

A.4.4.2 Reliability of location devices, sensors, and decision support

We hypothesize that providers will be able to trust data provided by the system, as well as its recommendations.
Reliability of location devices will be tested in two ways: By randomly sampling the system, and comparing the system's information with that of a complete inventory of location and count of material resources and people at given points in time, and by recording the episodes in which the system failed (via provider complaints entered into the PDA directly). Reliability of the sensors will be tested using dual monitoring (stationary sensors such as 12-lead EKGs compared to two-lead remote sensing) for patients admitted to the ER and healthy volunteers.
The decision support component will be tested once the system is stable. Three ED providers consisting of at least one attending physician and one nurse will critique the system's alerts for hypothetical situations. The logistic support component will be critiqued by the same team, in terms of recommended allocation of resources for hypothetical situations given actual resource locations at randomly sampled times. We will also compare recommendations made by the system in real situations with the actions, by checking whether recommended resources were moved to the suggested area.
We will time the random samplings such that all four components (location devices, sensors, decision support and logistic support) are tested simultaneously, to verify the overall reliability of the integrated network.

A.4.4.3 Scalability of location devices, sensors, and decision support

We hypothesize that the system will be scalable to situations of unusual high load in the ED.
The BWH ED serves an average of 150 patients/day. Each 8-hour shift is staffed, on average, by 1 to 2 attending physicians, 1 to 3 emergency medicine residents, 12 nurses, and 6 emergency services assistants. Additional physician, nursing, and assistant staff are called in when the ED exceeds capacity, defined by meeting the following conditions:

((100% of RN-staffed ED beds are occupied)
and
(Seven additional patients are in the waiting area, where at least one is category 2 in the Emergency Severity index (ESI) and has been waiting longer than 15 minutes))
or
((Fifteen additional patients of any triage category are in the waiting area)
and
(Four or more patients are in hall stretchers in the Acute Unit))

We will test whether our solution scales up to those situations in which additional staff are called, when there would be substantial increase in the number of people needing location devices. We expect the decision support system to be more useful in these unusual situations. We will test whether the system is still usable under these circumstances. We will also develop simulations to test higher volume and more complicated scenarios.
We will test whether the system can be easily adaptable to another environment. We will do this by extending this model (in Phase III) to cover patients in ambulances served by the Brookline EMS. We will

have five ambulances equipped with the system. Instead of indoor location devices and local wireless networks, these devices will interface with GPS and cell phones.
We will develop simulations to test the possible scenario of creating an ED at a disaster scene.

A.4.4.4 Comparison with baseline data

We hypothesize that the system will improve patient care as measured by proxies related to decreased overall:

(1) time from registration and triage to ED examination and treatment (from the current average of 30 minutes);
(2) length of stay in the ED (from the current average of 3 hours for discharged patients and 6 hours for patients transferred to other units of the hospital);
(3) personnel utilization, adjusting for case mix.

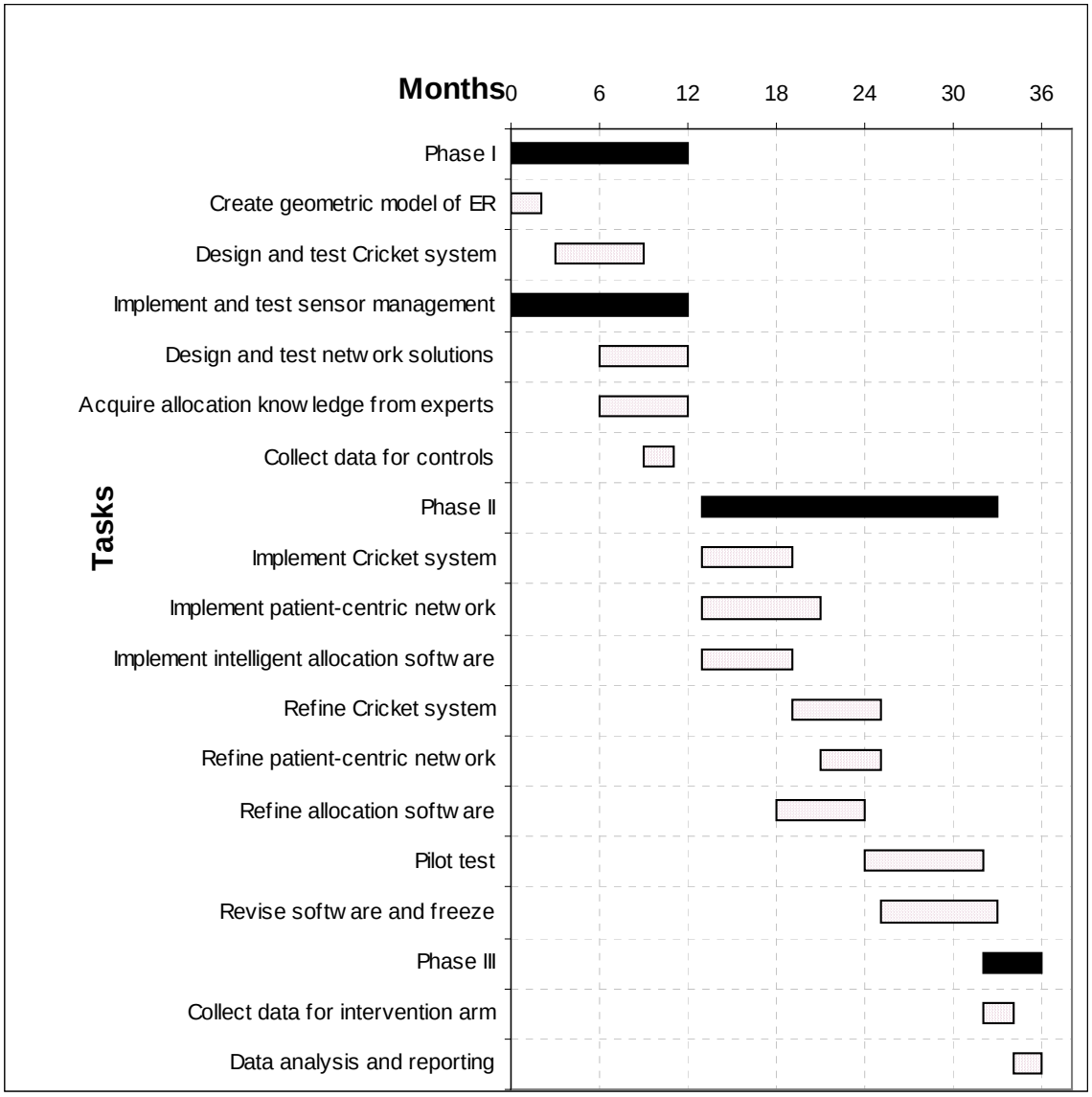
Table III shows the detectable standardized effect size for a two-tailed t-test with $\alpha = 0.05$ and $\beta = 0.8, 0.9$. The expected target enrollment of 1920 patients for the evaluation phase is detailed under the Section "Human Subjects" on page 89, and corresponds to an average enrollment of 16 patients per day. In addition to these endpoints, others may be suggested by the independent evaluator.

Table III. Sample size calculations

Power	Standardized effect size	Number per group	Total number
0.8	0.1	1570	3140
	0.15	698	1396
	0.2	393	786
	0.25	251	502
	0.3	175	350

Power	Standardized effect size	Number per group	Total number
0.9	0.1	2102	4204
	0.15	934	1868
	0.2	526	1052
	0.25	336	672
	0.3	234	468

A.5 SCHEDULE


Months
0
6
12
18
24
30
36
Tasks
Phase I
Create geometric model of ER
Design and test Cricket system
Implement and test sensor management
Design and test network solutions
Acquire allocation knowledge from experts
Collect data for controls
Phase II
Implement Cricket system
Implement patient-centric network
Implement intelligent allocation software
Refine Cricket system
Refine patient-centric network
Refine allocation software
Pilot test
Revise software and freeze
Phase III
Collect data for intervention arm
Data analysis and reporting