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SMART—An Integrated Wireless System for Monitoring Unattended Patients

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Abstract Monitoring vital signs and locations of certain classes of ambulatory patients can be useful in overcrowded emergency departments and at disaster scenes, both on-site and during transportation. To be useful, such monitoring needs to be portable and low cost, and have minimal adverse impact on emergency personnel, e.g., by not raising an excessive number of alarms. The SMART (Scalable Medical Alert Response Technology) system integrates wireless patient monitoring (ECG, SpO_2), geo-positioning, signal processing, targeted alerting, and a wireless interface for caregivers. A prototype implementation of SMART was piloted in the waiting area of an emergency department and evaluated with 145 post-triage patients. System deployment aspects were also evaluated during a small-scale disaster-drill exercise.

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Introduction

Continuous monitoring of unattended patients is desirable in a number of settings where patients cannot be well monitored after triage. One such setting is an overcrowded emergency department (ED), where there is always the concern that a patient in the waiting area may deteriorate suddenly without being noticed. Similarly, at a disaster site, where patients far outnumber caregivers, some monitoring of post-triage patients could be useful. In these situations, it is desirable to have a system to monitor patient status and location, and to alert one or more caregivers of significant events in an efficient way.

Building a continuous monitoring system for an overcrowded emergency room or disaster site has many challenges:

- Selecting vital signs and location sensors that are low cost, low power, accurate and able to communicate with other components.
- Selecting a lightweight, low cost platform that incorporates wireless communications, can be integrated with the sensors, and has a long battery life.
- Devising a packaging of the sensors and platform that is acceptable to patients and convenient to handle.
- Guaranteeing that the wireless system can support the concurrent monitoring of a large number of patients.
- Analyzing the data from the sensors and presenting alerts and data to appropriate caregivers in a way that does not overload them.
- Integrating these components into a workable system that can be quickly deployed at a disaster site, that is familiar to disaster personnel, and that will scale to monitor large numbers of patients.

Given our goal of providing patient monitoring both in overcrowded EDs and at disaster sites, we designed SMART (Scalable Medical Alert Response Technology) to address the above challenges. The SMART system integrates wireless patient monitoring (ECG, SpO_2), geo-positioning, signal

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processing, targeted alerting, and a wireless interface for caregivers.

This paper describes the design of SMART and the experience with the initial evaluation of it in the waiting area at Brigham and Women's Hospital's Emergency Department in Boston, MA.

A prototype implementation of SMART was piloted in the waiting area of the Brigham's emergency department and evaluated with 145 post-triage patients. System deployment aspects were also evaluated during a citywide disaster drill exercise on eight patients. Because of IRB (Internal Review Board) limitations, full integration with ED protocols was not attempted.

Background

Vital sign monitoring via portable devices is currently available. There is one commercial system offered by Welch Allyn®, the Micropaq® Monitor,[1] that monitors patient electrocardiogram (ECG) signals and is used in certain hospital wards. Both SMART and two other research systems for vital sign monitoring were developed for disaster environments (WIISARD[2-4] and AID-N[5-7]). These two systems were implemented during the same time-frame as the SMART system. There are three systems developed for military applications (Artemis,[8] BMIST-J,[9] and TAC-MEDCS[10]), as well as two systems for physiological monitoring developed by researchers: Telcordia® T2[11] and a system developed at National Taiwan University.[12] Also related to our efforts is ER-One,[13] a collection of specifications for disaster response. With the exception of the Welch Allyn® commercial system, evaluation of these systems in a significant number of real patients has been limited. A framework for comparing these systems and SMART should include the following issues:

1. Which vital signs are monitored?
2. Are the patient's vital signs monitored continuously?
3. Can the system monitor the location of people and equipment?
4. Is there a tunable alarm system? Can it alert individual caregivers?
5. Is there a mobile caregiver component?
6. Is the system open to modification to accommodate local needs?

Commercial Systems

The Welch Allyn® Acuity® LT Central Monitoring Station[1] is a commercial system that wirelessly collects data from sensors on a patient. This system monitors pulse oximetry (SpO_2) and ECG signals and its alarms are based on thresholds. We considered basing SMART on this system, but this would have precluded local adaptation of the patient monitoring component, the alarm system, and the monitoring station. SMART extends the capabilities of this system by providing an open platform for modifying the system and by adding a mobile component for the caregiver. SMART's location system allows patients, providers, and equipment to be continuously monitored.

Disaster Management Systems

The goal of disaster management systems is to improve the management of mass casualty incidents by introducing more accurate victim tracking and enhancing situational awareness. This is largely achieved by replacing systems based on paper and interpersonal verbal communications with electronic components. Two main paper components are replaced: records filled out by first responders and paper triage tags. Verbal communications include reports from first responders to incident commanders and transportation specialists and vice-versa.

WIISARD (Wireless Internet Information System for Medical Response in Disasters),[2-4] was developed at the University of California at San Diego. At a disaster site, responders start by deploying a wireless bubble of communications infrastructure. There are several levels of caregivers and the caregivers receive appropriate computing devices for their roles. The first responder assesses each victim and logs the victim into the WIISARD system. The responder then gives the victim an electronic tag. This tag helps responders know where the victim is: at the site, in transport, or at a hospital. The nurses in charge of coordinating transport of victims to hospitals have laptops or tablet computers that allow them to see where the victims are. The disaster command and control centers have software that allows the site commanders to see the activities of the victims, responders, and coordinators. Some of the tags given to victims monitor the patient's SpO_2 level. In addition to SpO_2 measurement and location monitoring, SMART extends the vital signs monitoring by collecting and analyzing ECG signals to generate and direct alarms to individual providers. Like WIISARD, SMART is designed to accept inputs from indoor or outdoor location subsystems.

The Advanced Health and Disaster Aid Network (AID-N)[5-7] is another research project focused on improving disaster response. It was developed at the Johns Hopkins University Applied Physics Laboratory. Like WIISARD, it is focused on managing a mass casualty incident and provides support for first responders, monitoring victims, and incident commanders. The first responders carry tablet PCs to record patient information. They give each patient an electronic tag and download patient information to that tag. In addition to the electronic tag, the first responder may give the victim an SpO_2 sensor and/or a blood pressure sensor. These Mote-based[14] sensors, developed by the Code Blue Project[15] at Harvard University and Boston University, independently report their readings to the first responder's tablet PC, which then uploads the information to a central database when the network is available. The incident commander can monitor the status of the response via accessing the central database. AID-N uses a location subsystem based on Motes and a research-based mesh network is used to provide the communications infrastructure. SMART substitutes commercially available network gear for the research-based mesh network for more reliable collection of data. It also extends AID-N by collecting and analyzing ECG data.

One conceptual difference between SMART and other disaster response systems such as WIISARD and AID-N is that the former was conceptualized so that it could potentially become part of regular ED operations that could extend to field work when necessary. The rationale was that, in disaster situations, scaling up a familiar system would be preferable to implementing a new system. So while the other systems' evaluations were based primarily on disaster drills

with actors and computer simulations, ours was based on at-risk patients in a real ED, since the expectation is that the system can be utilized on a continuous basis inside an ED and be extended to a disaster site and transport units when necessary. The utilization of the same system inside and outside the hospital increases the potential for seamless integration of care and decreases time spent on patient "hand-off," which is critical in overloaded EDs.

Military Systems

ARTEMIS[8] (Automated Remote Triage and Emergency Management Information System) is an application developed for the military. This system focuses on providing remote triage capabilities in order to help upper level resource management and coordination of efforts. It includes a commercial SpO_2 sensor. Patients can be triaged into one of five possible NATO severity categories by a fuzzy logic algorithm driven by physiological measurements and responder evaluations. An outdoor positioning system keeps track of the patients' locations and can guide the provider to the patient. A mesh network with dynamic routing tables provides connectivity among units and the central server. ARTEMIS relies heavily on self-assessment by the soldier or on an external caregiver to change the triage level. Only a very serious condition such as a severe SpO_2 or heart rate change and no response from the subject would trigger a critical alarm. SMART builds on this approach by monitoring ECG, in addition to SpO_2. SMART does not rely on self-assessment by the soldier/patient and, while SMART currently does not change triage levels automatically, it provides information to caregivers so that they can adjust triage levels.

BMIST-J[9] Battlefield Medical Information System Tactical - Joint is a medical information system implemented and currently in use by the military. The mobile PDA units, used exclusively by caregivers, can be pre-loaded with medical records for all the soldiers in the field. Data can be stored on the PDAs until the data can be uploaded to a central server. It contains information about allergies, medications, and treatment and is compatible with other systems such as the one used by the Veterans Health Administration, so there is a seamless transition between care centers. SMART expands on this approach by providing on-line monitoring of the soldiers/patients vital signs and by providing a geo-positioning system.

TACMEDCS (Tactical Medical Coordination System)[10] was developed by the Naval Aerospace Medical Research Laboratory. The main components of the system are a PDA carried by the medical corpsman and an RFID tag that is given to the patient. The corpsman collects information about the patient, loads it onto the patient's RFID tag, and uploads it, when possible, to a central database. SMART extends this approach by continuously monitoring the patient's ECG and SpO_2.

Vital Signs Monitoring Systems

Telcordia® Technologies of Piscataway N.J. has a prototype system, T2,[11] for analyzing streams of data from "Bio-Sensors." In this system, a patient has an ECG sensor and an accelerometer—the latter used to ignore false high heart rates derived from ECG data that correlate with high rates of acceleration. The ECG sensor uses a BioRadio® from CleveMed[16] to communicate readings to a PC. The accelerometer is on a Mote from Crossbow®.[14] The Mote uses Bluetooth to communicate to a Pocket PC PDA which uses 802.11 to forward the data to a PC. SMART extends this approach by adding location and integrating data from other vital signs such as SpO_2, as well as providing a targeted alarm system.

National Taiwan University[12] has been developing a wireless PDA-based telemonitoring system. This system monitors heart rate, SpO_2, and ECG signals. The designers' rationale is that portable units alleviate the problems of large and unwieldy monitoring systems and the need for caregivers to be in constant proximity to patients, which is helpful in cases of radioactive agents and airborne pathogens, such as SARS. SMART expands on this approach by providing location tracking information and decision support to distribute targeted alarms.

In addition to the physiological monitoring systems above, the ER One[13] Project provides a set of recommendations for implementing an "all-risks-ready" ED. SMART complies with many of the relevant recommendations from this project: The SMART caregiver has a PDA to wirelessly access information stored at the SMART Central computer. The PDA has dashboard displays of the roster of patients and per-patient access to vital signs, current location and other data. Vitals signs data from the patients are automatically logged at the SMART Central computer, as are the continuously tracked locations of patients, caregivers, and equipment. The SMART Central software runs on a laptop and so is portable to disaster sites. SMART Central monitors the network's connections with Patients' and Caregivers' PDAs and sends alerts when a connection is lost.

Design Objectives

In designing SMART, the primary desiderata are the following:

- Open platform hardware and software for ease of modification.
- Inexpensive commodity components whenever possible.
- Robust geo-positioning to track patients, caregivers, and equipment, so that the SMART system can alert an appropriate caregiver. Appropriateness can be defined by geographical location, qualification, or availability, depending on the situation. The geo-positioning can also help locate both the patient and the nearest, relevant available piece of equipment. The system should be flexible enough to integrate a variety of commercially available location systems for both indoor and outdoor use.
- Sufficient wireless network capacity for reliably delivering data from the Patient PDAs to a central computer, data from the location detectors, alerts from the central computer to the Caregiver PDAs, and other data requests/responses between the Caregiver PDAs and the central computer.

System Description

The SMART system consists of a patient monitoring device, a geo-positioning subsystem, a wireless networking subsystem, decision support and logistic support subsystems (SMART Central), and a caregiver module. The system also has a logging subsystem. Figure 1 shows the main components of the SMART System architecture: A geo-positioning

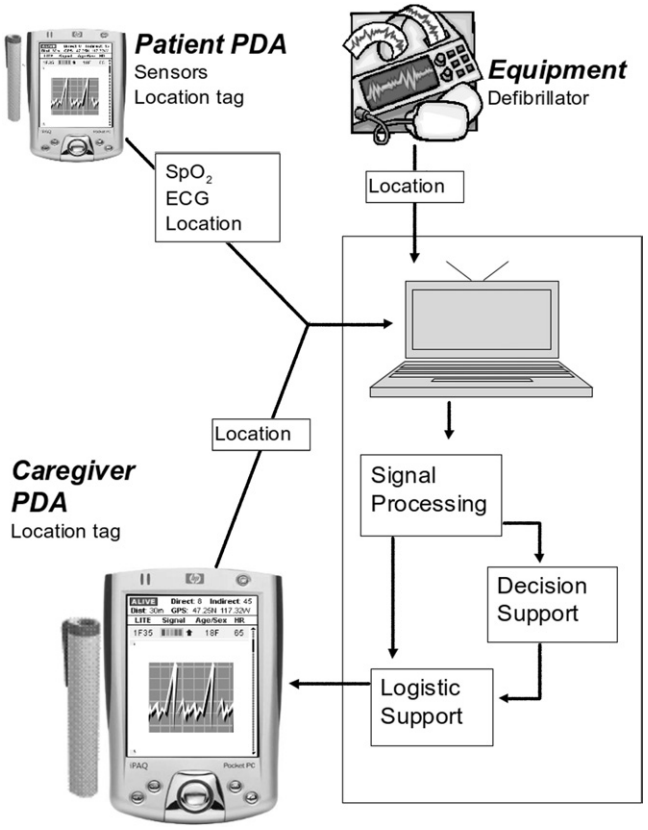

Figure 1. SMART components: Caregiver PDAs, location sensors and patient PDAs with ECG and SpO_2 sensors are wirelessly connected to SMART Central where all data are processed.

system based on active tags and detectors provides location information for patient and caregiver PDAs. Patient data such as ECG signals, SpO_2 readings, and location information flow into SMART Central. The Streaming Data Manager inside SMART Central receives all the streams of data from the patients and caregivers, processes them and makes them available to other modules for further analysis.

Patient Monitoring Device

In the test bed implementation evaluated in this article, the patient monitoring device is a waist pack containing a PDA and a sensor box, as shown in Figure 2. It weighs about two pounds. The sensor box (Figure 3) collects oxygenation level and a single-lead ECG (Lead II). The SpO_2 sensor is available from Nonin®[17] and the ECG sensor was developed at MIT. The PDA is an HP® iPAQ® running Linux®. The PDA forwards data collected from the sensors to SMART Central. Communications between the Patient PDAs and SMART Central are not currently encrypted since they contain no identifiers such as name, SSN, date of birth, etc. The PDA stores no patient identifying data and only limited raw data so it cannot compromise patient confidentiality by being stolen.

Geo-Positioning System

For this pilot study, we deployed the Indoor Positioning System (IPS) from Sonitor®[18] for geo-positioning. This ultrasound-based system consists of active tags worn by patients and caregivers and detectors on the walls. SMART Central collects messages from the detectors and computes the location of the patient or caregiver.

Wireless Communication

Standard wireless networking technology (802.11b) is used to connect the Patient PDAs and the Caregiver PDAs to a wireless router. Wireless bridges are used to connect the location detectors and two remote areas to SMART Central. To decrease the possibility of wireless messages interfering with each other, SMART Central is connected directly (wired) to the wireless router.

The standard available bandwidth from an 802.11b network (11 Mbps) covers the communications needs, which are estimated at about 0.5Mbps for 10 patients (10 ECG messages per second + 3 SpO_2 messages per second + < 1 location message per second + <1 battery message per second where a message has a maximum of 400 bytes * 8 bits/byte). The traffic for a Caregiver PDA is significantly less than that for a patient and there are only two Caregiver PDAs in the basic system evaluated here.

SMART Central

The heart of the system is SMART Central, which runs on a commodity PC, using the Linux® Operating System. SMART Central contains a Streaming Data Manager, and two decision support components: a patient-specific Decision Support Module and a Logistics Support Manager. The Streaming Data Manager receives the real-time patient data, processes it, and forwards it to the Decision Support Module. The Decision Support Module then analyzes the data and triggers alarms. The Logistic Support Manager matches alarms to the environment to dispatch relevant information to the appropriate caregiver. All data and alarms are logged for later review and analysis.

The Streaming Data Manager receives the SpO_2, ECG, and location data streams. The SpO_2 data stream provides both the patient's oxygenation level and the patient's heart rate. The ECG sensor provides waveform data. The location data stream shows the tag id, status and signal strength of each tag transmission received by the location system detectors. The Streaming Data Manager provides access to raw data and derived measurements via a simple query mechanism. This module also incorporates a computation module for detecting heart beats from the ECG waveform data using a modified version of the SQRS algorithm,[19,20] a real-time algorithm for QRS detection. The algorithm is able to report QRS complexes and QRS-like artifacts, and warns about no beats detected in the last 3 seconds

SMART Central's Decision Support Module subscribes to the Streaming Data Manager's data streams for the ECG waveform, the detected heart beat positions (times), the SpO_2 sensor information, and location information. In the Decision Support Module, the data are combined and new higher level data are generated. A robust heart rate is obtained by using a median filter to mask missed or extra beats detected by the Streaming Data Manager. The Decision Support Module monitors and generates alarms about a patient's cardiac status by evaluating the SpO_2, ECG, and heart rate data streams. Other intermediate parameters obtained from the ECG waveform and the heart beat positions by the Decision Support Module are:

Figure 2. Patient wearing SMART monitoring gear: SpO_2 and ECG sensors, and a waist pack with sensor box and HP® iPAQ®. (this photo is used at http://csail.mit.edu/events/news/2006/smart.html)

- Skewness: The histogram of a normal ECG's data has a distribution with most of its data around the basal depolarization voltage. Skewness under 0.5 (symmetric distribution) of this data in a two second window is considered abnormal.
- Width: If the width of a QRS complex is over 120ms, the beat is marked as abnormal.
- Irregularity: If the standard deviation of successive time differences between normal beats in an 8 second window is over 0.4 seconds, the series is marked as irregular.
- Saturation: If the measured ECG voltage changes rapidly between its maximum and minimum possible values for this sensor, the data are marked as saturated.

The Decision Support Module analyzes streams of data to detect alarm conditions and uses a rule set to generate alarms. Alarms are divided into two categories: technical and medical. Technical alarms are caused by electrodes that have fallen off, loose lead wires, etc. The rules for detecting alarms are described in Table 1.

The Decision Support Module also combines location data from different location detectors to compute the position of the patient. A large room typically has several detectors, and the location within the room is based on the amplitude of the signals from each detector.

The Logistic Support Manager is responsible for dispatching alarms to the appropriate personnel or system for notification. Unlike the Decision Support Module, which deals with patient-specific data that are independent of the environment, the Logistic Support Manager is highly environment-dependent, and incorporates workflow rules. These rules indicate that the alarm should be sent to the nearest available and appropriate caregiver. The rules also describe an escalation procedure in case a caregiver does not respond to an alarm. Currently, if a caregiver "responds" to an alarm, re-notification of most alarms is suppressed for ten minutes. The exceptions are AWOL (Away WithOut Leave) and battery. The Logistic Support Manager matches alerts to the appropriate caregiver and sends the alert information to that Caregiver PDA. A summary of outstanding alerts is also available on the SMART Central display.

Caregiver Module

There are two main caregiver interface modules in SMART: the user interface associated with SMART Central, and the interface for the Caregiver PDA.

SMART Central provides a basic monitoring interface. This interface displays the list of registered patients with their current vital signs and their most recent alarm. It also displays a list of recent alarms and a map of the locations of patients and caregivers. When a patient is selected from the list, additional detail about that patient can be shown, including the patient's vital signs readings, other demographic and medical data, and the live ECG waveform, as seen in Figure 4. "HR" indicates heart rates calculated by the SpO_2 sensor. SMART Central uses a second screen to display location information.

The Caregiver PDA interface has three distinct modes. The first shows the roster of patients. When a caregiver clicks on a patient in the roster, the second mode shows the detailed vital signs, as depicted in Figure 5. When an alert arrives, the Caregiver PDA buzzes audibly and vibrates and enters the third mode for handling alarm conditions. In this mode, the window (see Figure 6) displays the identity of the patient with the problem, his or her location, and the type of alert (e.g., bradycardia). Then the caregiver can indicate to SMART Central that he will respond to that problem, by tapping on the "Respond" button. Other responses include indicating that the caregiver is busy, via the "Unavailable" button, forwarding the alarm to another caregiver via the

Figure 3. Inside the patient waist pack: SpO_2 and ECG sensors, sensor box and HP® iPAQ®.

Table 1 ■ Rules for Generating Alarms

Alarm	Condition that triggers the alarm
Oximeter Medical Alarms	
High HR	Heart rate from oximeter sensor above patient-specific threshold (default threshold is 100bpm)
Low HR	Heart rate from oximeter sensor below patient-specific threshold (default threshold is 60bpm)
Low SpO_2	Oxygen saturation below patient-specific threshold (default threshold is 90%)
ECG Medical Alarms	
Asystole	No beat detected in 3 seconds
Ventricular Fibrillation	ECG shows artifacts, abnormal skewness, wide waves or no waves, lacks QRS complexes, and the SpO_2 heart rate is missing or below 20bpm or above 150bpm
Ventricular Tachycardia	ECG has wide QRS complexes and heartrate is over 100bpm
Tachycardia	ECG heart rate above patient-specific threshold (default threshold is 100bpm)
Bradycardia	ECG heart rate below patient-specific threshold (default threshold is 60bpm)
Irregular	ECG QRS complexes are irregularly spaced
Technical Alarms	
Mismatch	ECG diagnosis inconsistent with SpO_2 heart rate: (a) if ECG indicates asystole and oximeter heart rate is between 20bpm and 150 bpm, or (b) if ECG indicates ventricular fibrillation and oximeter heart rate is between 20bpm and 150 bpm
Noisy	Artifacts and normal skewness in ECG signal
Leads Off	ECG lead is off (signal is saturated)
No Signal	No ECG data received
Technical SpO_2	Oximeter sensor removed from finger
AWOL (away without leave)	No communication between PDA and SMART Central
Battery	Low battery (below 20%)

"Forward" button, and delaying a response for a short time via the "Defer" button. These latter responses result in forwarding the alarm to another provider.

The Caregiver PDA locks up when unattended (lack of input) and requires a password to regain access. It stores no data locally and un-refreshed data ages and disappears, so a stolen Caregiver PDA will not reveal any confidential information. Wireless communications between SMART Central and the Caregiver PDAs are encrypted via SSL (Secure Sockets Layer).

SMART Central also deals with the situation when the caregiver does not respond at all. In this case, the re-alerting behavior is governed by the Logistics Support Manager rule set: typically another caregiver will be alerted promptly.

Data Management

SMART Central has web pages for entering patient demographic information and caregiver registration. Smart Central logs all raw data received from patients in a database. It also logs derived data: calculated ECG heart rate, locations

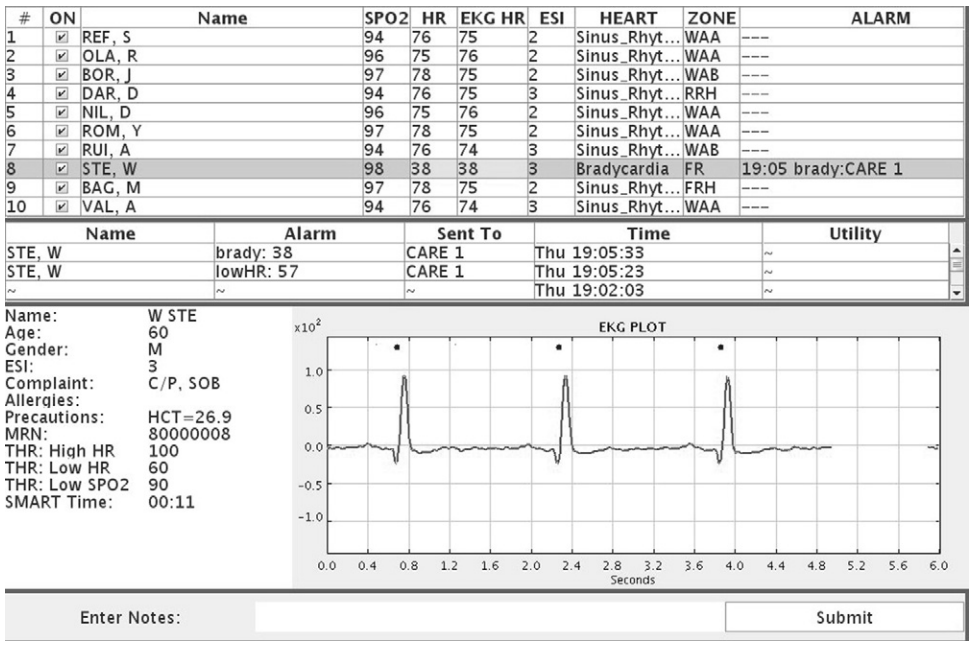

Figure 4. User interface for SMART Central. Yellow highlighting indicates abnormal values relative to patient-specific threshold settings.

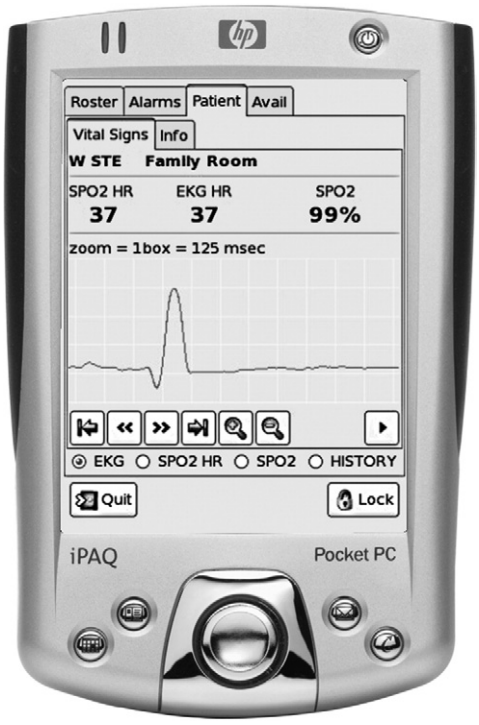

Figure 5. Caregiver's view of a patient.

computed from detector data, alarms sent, responses to alarms, and buttons clicked on Caregiver PDAs.

Status Report

Pilot Study

The pilot study reported here began on June 19, 2006, in the Waiting Area of the ED at the Brigham and Women's Hospital in Boston and ended on March 30, 2007. We conducted our pilot study there because it provided a controlled environment with ambulatory patients in whom the expected rate of real events was higher than normal. Only patients with intermediate severity statuses, based on triage, were eligible for the study.

Workflow

This study was approved by the IRB of the Brigham and Women's Hospital, which required that an individual with ACLS training (a paramedic who we will refer to as "SMART Operator") would monitor the SMART Central station at all times. This prevented us from testing the direct response of other caregivers to alarms, since they knew of the SMART Operator's role in filtering out false alarms and communicating directly with a triage nurse. While away from SMART Central, the SMART Operator carried the caregiver device and hence we could verify its functionality. The fact that no patients were being monitored in the waiting area of the ED before our study began did not preclude the IRB from demanding human mediation in SMART, because, once patients are monitored, the hospital is responsible for adequately responding to detected abnormalities. Caregivers knew that they would be alerted only if the SMART Operator deemed the alarm significant.

The ED workflow was as follows: Initially a triage nurse interviewed the patient and assigned an Emergency Severity Index (ESI).[21,22] Those deemed most severe (Category 1) were immediately admitted to the ED, while others went back to the waiting area. This process did not change at all with SMART. The SMART Operator had access to the ED census and chief complaints via the EDTrack system, the electronic patient tracking system in the ED. Patients eligible for the SMART study included those triaged in ESI categories 2–5 and presenting with cardiovascular or respiratory complaints. When the SMART Operator noticed that an eligible patient had been triaged, he approached the patient for consent. He provided a description of the study and answered any questions about it. He explained, among other things, that participation in the study would not change the patient's waiting time. After obtaining consent, he gave the patient a SMART waist pack and placed the ECG electrodes and the SpO_2 sensor on the patient. Heart rates were measured redundantly by the oximeter and the analysis of ECG waveform.

Each waist pack had a unique number. The SMART Operator then enabled alarms for that waist pack at SMART Central and entered the demographic information. The process of enlisting an eligible patient and outfitting him with the SMART waist pack took about two minutes. At the end of the monitoring session, when a bed was available and the patient was admitted to the ED, the SMART Operator collected the waist pack and survey information from the patient. When the SMART Operator noticed that a patient was having a problem, he located a triage nurse to evaluate the situation. Although the capability existed, as explained above, in this study, other ED personnel did not carry PDAs.

Patient Population

During the study period, the SMART Operator approached a convenience sample of 189 eligible patients, of whom 151

Figure 6. Caregiver's view of an alarm. Clicking on "Respond" indicates that the caregiver will handle the alarm.

Table 2 ■ Alarms Detected

Alarm	Total	True Positive	False Positive	Unclear	Comment
High HR (SpO_2 sensor)	79	75	1	3	Occasionally reported HR value did not exceed threshold
Low HR (SpO_2 sensor)	21	15	3	3	Occasionally reported HR value did not exceed threshold
Low SpO_2	44	35	5	4	Occasionally reported SpO_2 value did not exceed threshold
Asystole	79	0	79	0	No SpO_2 sensor present + noise or no signal
Ventricular Fibrillation	46	0	46	0	No SpO_2 sensor present + noise
Ventricular Tachycardia	0	0	0	0	
Tachycardia (ECG)	124	61	31	32	Noise often mistaken for tachycardia
Bradycardia (ECG)	18	12	5	1	Occasionally reported HR value did not exceed threshold
Irregular rhythm	116	43	34	39	Noise often mistaken for irregular
Mismatch	59	59	0	0	
Noisy	59	47	12	0	
Leads Off	56	49	2	5	Noise sometimes mistaken for leads off
No Signal	0	0	0	0	
SpO_2 sensor off	86	85	1	0	
AWOL	329	309	16	4	Occasionally periodic battery message from PDA lost
Battery	16	15	1	0	

Unclear indicates that the alarm condition may or may not have been true, e.g., when a signal showing tachycardia is noisy, it can be difficult to see tachycardia. In other situations involving readings vs. thresholds, the reported number was near the threshold, but not over it, indicating either a race or a software bug in the reporting mechanism.

patients consented to participate. Six were then excluded: one withdrew; two were admitted into the ED before having a chance to receive the device, and three withdrew after starting to wear the waist pack (reasons: "got tired," "wait was too long," "device was irritating"). The 145 included patients wore the waist pack between 5 minutes and 3 hours, with an average of 47 minutes each. Ninety-four (65%) of the participants were surveyed. Respondent ages ranged from 18 to 87 years (average 49.5, 12 omitted their age). There were 38 males and 49 females (7 omitted their gender). 65% of the patients felt safer wearing the monitoring system. 93% of the patients responded that they "would wear" or "probably would wear" the monitoring system again.

Location

The pen-sized location tags were attached to lanyards around the patients' necks, since in this position the transmitter did not get covered by clothing. In analyzing the logged location data, we computed the "track" of each patient. The track is the succession of zones that the patient entered and the time spent in each zone. The average track had four zones. The main waiting area contained three zones, and these are where patients spent most of their time, as expected, but there was significant patient movement. The maximum number of zones in a track was 21. Some of the tracks showed "discontinuities," indicating that the location system had "missed" the patient as he or she moved from zone to zone. The discontinuities were limited to skipping one zone at a time.

Decision Support and Logistics Modules

Between June 19th, 2006 and August 15th, 2006, several changes were made to the SMART alarm subsystem. Table 2 shows the alarms the SMART system detected between August 15th, 2006, and March 30th, 2007. The classification of each alarm was based on a majority vote of a panel of three judges. The judges, a subset of the authors, were a paramedic, a computer scientist, and an electrical engineer. There were no reports of patient problems that would lead us to believe that there were any false negatives.

Reportable Episodes

During this initial period, most of the patients showed no abnormalities. SMART did provide sufficient ongoing monitoring so that some patients were re-triaged: The first case was a 30-year-old female with chest pain, triaged in category 3. SMART Central reported a series of irregular rhythms alternating mainly with tachycardia. These alarms led the SMART Operator to notice that the patient was having a series of premature ventricular contractions (bigeminy). He notified the triage nurse, and the patient got a 12-lead ECG and was admitted to the ED.

The second case involved a 70-year-old female who had passed out while sitting in a hot car. The SMART System detected bradycardia. The SMART Operator asked the ED staff to review her situation. She was admitted to the ED and then to the hospital for further monitoring.

The third case concerned a 64-year-old male who was sent from his primary care physician's office because of a pulse rate of 120 bpm without symptoms, a past history of hyperthyroidism, and "irregular heartbeat." The SMART Operator noticed that his SpO_2 heart rate and his ECG heart rate differed significantly. Suspecting atrial fibrillation, he notified the ED staff. The patient was admitted to the ED and the 12-lead ECG showed junctional tachycardia.

Disaster Drill

We participated in the Poseidon Drill[23] in Boston, on September 17, 2006. This citywide disaster drill included 150 healthy individuals acting as patients, about 20 of whom were transported to BWH. On arrival, we set up the SMART system in about five minutes, by turning on a laptop and setting up a wireless hub. We monitored seven patients who arrived with life-threatening symptoms. As each patient arrived, the SMART Operator placed a SMART monitoring pack on the victim and entered demographic information into the SMART system. The Caregiver PDA was not used in the drill as all the monitored patients and the SMART Central computer were all in one small room. The SMART

system and the SMART Operator freed other hospital staff from having to monitor these patients.

Discussion

With respect to the SMART system design objectives, almost all of the SMART components are affordable, off-the-shelf, portable, easy to deploy, and un-tethered. The only exception is the ECG waveform board, which we designed and built ourselves, because we could not find a commercially available board that met our needs. The patient monitoring device provided with the SMART system meets our design objectives. One shortcoming is that the battery life is about three hours. This was sufficient for our tests, but in a future deployment we would reconfigure the Patient PDA to extend the battery life. The geo-positioning subsystem in SMART was able to track patients adequately. We did not track caregivers or equipment, because of limited integration with the ED operations. The geo-positioning subsystem is flexible because, in addition to the integration with the Sonitor® IPS reported on in this paper, we have integrated SMART with two other geo-positioning subsystems, Cricket[24] and the Global Positioning System (GPS).

The Caregiver PDA is intended to be used for detecting alerts when a caregiver is attending to patients. While the Caregiver PDA operated as intended during tests on healthy volunteers, it was not used by ED personnel and only minimally by the SMART Operator during the pilot study. The SMART Operator reported that he preferred watching ECG signals on the large display of the SMART Central workstation. We also did no equipment tracking during the testing period.

With respect to the networking components, the throughput of the wireless system was never a problem, perhaps because the number of patients monitored simultaneously was never greater than four. The lower-than-expected volume of patients presenting concurrently with cardiovascular or respiratory problems prevented us from addressing questions of scaling. This kept us from understanding how many patients a single SMART Operator could monitor well. Pushing data wirelessly to Caregiver PDAs was shown to be feasible in some demonstration situations, but was not used in the pilot study.

The SMART Decision Support and Logistics Modules received and analyzed the data and generated, for the most part, appropriate alerts. Recognizing that some medical conditions, such as atrial fibrillation, would cause almost continuous alarms, we allowed alerts related to irregular heart rates to be disabled by the SMART Operator. We also delayed alerts for technical SpO_2 problems, because these are usually caused by the patient moving the sensor from one finger to another. The literature contains many articles[25,26] concerning the problems caused by too many alarms in the Intensive Care Unit, and the ED is a similar environment—but SMART was deployed in the waiting area of the ED. This is an area without audible alerts, and we chose to keep it that way. In three cases, alarms were deemed serious enough to request reprioritization of patients. In all three cases the medical staff accepted the reprioritization.

The data management and logging subsystems performed well enough to allow us to replay and analyze the data recorded from the patients. Registration of caregivers is not supported at this time, due to lack of integration with ED operations.

An important limitation of the current study is that we were not able to measure the system utilization by ED personnel, given that they knew that a paramedic would be responsible for monitoring all study subjects. Although we received positive feedback from some of the nurses, a systematic study on the impact of the system on the ED workflow is needed.

Lessons Learned

The deployment of an experimental system for monitoring previously unmonitored patients within a high-functioning organization, such as an urban ED, requires an intermediary, in our case, the SMART Operator. This requirement originates from two main concerns:

1) Hospital liability: a failure to detect an event in monitored patients in the ED waiting area could lead to a lawsuit (even if the risk for not detecting an event in this system was the same as if the patients had not been monitored, as in the current standard of care).
2) Relatively high number of false positives: false alarms might unnecessarily distract ED personnel from their existing cases, which would indirectly pose an additional risk to the patients already admitted to the ED.

Selection of a location system was challenging, inasmuch as the technology is changing rapidly in this area. Although the location system we chose provided sufficiently accurate data about the location of patients, it proved more time-consuming than expected to manage: we had to regularly survey whether its various components were working and make arrangements to replace failed components.

Both redundancy in the vital signs monitoring and the provision of single lead ECG tracing proved useful. The redundancy allowed us to detect "suspected atrial fibrillation" in one patient and the single-lead ECG tracing allowed the SMART Operator to detect bigeminy in another.

Before beginning the pilot study of the SMART system in the ED waiting area at BWH, we used the SMART system on healthy volunteers and recordings from synthetic patients. These tests were quite useful in testing the whole system. One side effect, however, derived from the fact that the "volunteers" were either technically or medically savvy. As a result, they tended to request features (such as much lighter waist packs) that turned out to be irrelevant to actual patients. Although the volume of eligible patients was low, it was not due to "refusals;" in fact, the patients were more accepting of the system than expected and perceived the monitoring to be useful.

Future Work

Our future plans include refining our algorithms to reduce the number of false positives, increasing the integration of the SMART system with the ED, exploring ways to manage multiple SMART systems, integrating data collected from patients in moving vehicles, and assessing usage of wireless networking in large areas.

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