Effective, efficient, and safe delivery of healthcare is dependent on the timely identification and treatment of a deteriorating patient condition. Failure to rescue patients in the early stage of physiological deterioration can result in permanent organ injury, extended medical treatment, increased recovery time, or death. These avoidable adverse events drive healthcare costs up and quality down.

The primary indicator of failure to rescue is unsuccessful cardiopulmonary resuscitation. The American Heart Association created a national registry of cardiopulmonary resuscitation (NPCPR) in 2000 as a voluntary evidence-based patient safety initiative. A review by Peberdy and colleagues of 14,720 cases of cardiopulmonary arrest from the NPCPR database collected between 2000 and 2002 shows the following breakdown of physiology, immediate cause, and discovery.

First Pulseless Rhythm
25% Ventricular fibrillation/ventricular tachycardia (VF/VT)
30% Pulseless electrical activity (PEA)
36% Asystole
9% Unknown by documentation

Immediate Cause(s) of Event
49% Arrhythmia
37% Acute respiratory insufficiency
32% Hypotension
10% Acute myocardial infarction or ischemia
10% Metabolic/electrolyte disturbance
3% Acute pulmonary edema
2% Acute pulmonary embolism
2% Airway obstruction
1% Toxicological problem

Discovery at Time of Event
86% Witnessed and/or monitored
66% Witnessed and monitored
11% Witnessed and not monitored
9% Monitored and not witnessed
14% Not witnessed or monitored

The immediate cause of cardiopulmonary arrest present one hour prior to the event suggests that no single vital sign has sufficient sensitivity to detect a deteriorating patient. The most common locations of these events were the intensive care unit or ICU (48%), inpatient (32%), and emergency department or ED (11%).

In a more recent publication, investigators reported the impact of monitoring or witnessing a cardiopulmonary event based on NRCPR data. Results showed that witnessed and/or monitored patients were twice as likely to survive to discharge with no measurable neurological deficit as compared to patients who were neither monitored or witnessed.

The Institute of Medicine (IOM) 1999 publication *To Err Is Human* estimated that up to 98,000 deaths per year are caused by preventable medical error. The Institute for Healthcare Improvement (IHI) 100,000 lives campaign launched in 2004 stimulated the broad adoption of Rapid Response Teams.
Signs of deterioration occur hours before cardiopulmonary arrest.

The Medical Early Response Intervention and Therapy (MERIT) study, however, reported mixed results across hospitals that deployed rapid response systems. A consensus amongst rapid response researchers is that the early sensing component (afferent limb) of the rapid response system is essential in improving outcomes.

The Agency for Healthcare Research and Quality (AHRQ) has developed key patient safety indicators (PSI) to measure improvement in patient safety. The Healthgrades 2010 report covering data from the U.S. Centers for Medicare & Medicaid Services (CMS) between 2006 and 2008 identified 958,202 patient safety events including 96,402 avoidable deaths.

Together these PSIs represent over 8.9 billion dollars of expense to the Medicare system. The highest rates of avoidable incidents were failure to rescue, decubitus ulcer, postoperative respiratory failure, and postoperative sepsis.

Early detection of the deteriorating patient is essential to improving patient safety outcomes and reducing the cost of care. Late detection also often results in an escalation of care to higher cost-of-care settings. Eliminating such escalation in care optimizes the utilization of costly ICU beds and lowers overall length of hospital stay.

Signs of deterioration occur hours before cardiopulmonary arrest. Routine vital signs are insufficient to detect these subtle changes. The consensus amongst rapid response researchers is that the following core vital signs should be continuously monitored: heart rate, blood pressure, respiratory rate, temperature, pulse oximetry, and level of consciousness.

The rapid response consensus group agreed that all patients should be monitored continuously if such a system was practical and affordable. However, they expressed concern that current technology is clinically inadequate due to high false positive and negative alarm rates, suboptimal ease of use, and patient acceptability.

Continuous Vital Signs Monitors
Multi-parameter continuous vital signs monitors have been available in the intensive care setting since the early 1960s. These medical devices have been significantly improved upon through the advent of microprocessor technologies in the 1970s. Moore's Law (which estimates that the number of transistors on integrated circuits doubles every two years), and advancements in signal processing. Efforts to monitor NASA astronauts stimulated the creation of electrocardiogram (ECG) telemetry systems in the mid-1970s.

The creation of these technologies was geographically bound by the hospital setting. ICU monitoring assumed a use case in which patients were tethered to a permanently mounted monitor. Cardiac telemetry allowed patients to ambulate on a patient floor supported by a proprietary antenna system.

The invention of liquid crystal displays during the 1980s allowed bulky fixed multi-parameter monitors to be packaged into portable units that could be used for transport. These devices assumed a one-to-one association between continuous vital sign viewing and a skilled clinician. Telemetry devices allowed a relaxation of the number of clinicians at patient bedside by allowing a trained monitor watcher to view multiple patients in a single location.

These use models prevailed until the concept of flexible monitoring was invented by a multidisciplinary team at Massachusetts General Hospital in the late 1980s. Flexible monitoring allowed portable multi-parameter monitors to be brought to a bedside and connected to a general purpose IT network. This concept of merging medical monitors with IT networks expanded in 2000 with the creation of Institute of Electrical and Electronics Engineers (IEEE) 802.11 wireless standards.

Concurrently, the U.S. Federal Communications Commission (FCC) creation of the Wireless Medical Telemetry Service radio frequency (WMTS RF) spectrum has allowed proprietary wireless telemetry systems to expand in hospital settings. In spite of all these technological advances, monitoring on the general care ward and alternate care settings has been limited.

The primary reason for this has been the high incidence of nuisance alarms and cost. The high occurrence of nuisance alarms has created a patient safety issue due to the desensitization of clinicians to clinically relevant conditions in a cacophony of non-clinically relevant alarms.

Reducing nuisance alarms is a fundamental requirement to improving patient care. The Association for the Advancement of Medical Instrumentation (AAMI), Emergency Care Research Institute (ECRI), American College of
Clinical Engineering (ACCE), U.S. Preventive Health Care Task Force (HCTF), and other organizations have brought a focus on this serious limitation of medical devices. A multi-disciplinary team at The Johns Hopkins Hospital has been able to reduce the occurrence of alarms of multi-parameter monitors by up to 47% by tailoring alarms to care areas, relaxing settings, and adding alarm delays; but the number of alarms per patient per day remains at approximately 200. A study from Dartmouth Hitchcock Hospital reported a dramatic decrease in alarm occurrences to 4 alarms per patient per day for a pulse oximetry study based on a significant relaxation of threshold settings and alarm delays.

Continuous Vital Signs Monitoring For Mobile Health
Mobile health monitoring to detect physiological deterioration requires technology that can alert a first responder capable of reversing the condition in a timely manner, and be broadly deployed throughout the continuum of care. Costs for deploying such innovations can be reduced by leveraging existing IT and telecommunications infrastructures.

Patient acceptance and mobility become essential requirements because ambulation is an important element of the healing process. Fortunately, Moore’s law forecasts continuous improvements in miniaturization, and the low power needs of microprocessors allow on-body wireless sensors.

Such innovation had led both academic institutions and new ventures to create new solutions in mobile on-body sensing. For example, Asada describes a prototype ring sensor developed by researchers at Massachusetts Institute of Technology (MIT) that continuously measures pulse rate and oxygen saturation.

However most innovations are limited to a subset of the full complement of vital signs recommended by the consensus of rapid response experts. Existing multi-parameter monitoring companies have introduced expanded versions of existing telemetry and wireless portable monitoring by re-factoring existing legacy technologies. However, alarm management, cost efficiency, and wearability are additional criteria to consider.

We discuss here the development of one example of a wireless on-body digital architecture, Sotera’s ViSi mobile system (an early warning indicator of patient deterioration), that enables ambulatory continuous vital signs monitoring, to highlight the possibility of designing for alarm management, cost efficiency, and wearability.

The device continuously measures ECG/heart rate, respiration rate, noninvasive blood pressure, temperature, and oxygen saturation; and consists of four primary components: on-body sensors, IEEE standards-based wireless communications, a central appliance-server, and remote viewing devices.

The main sub-components of the on-body network are a chest sensor, upper arm accelerometer, wrist transceiver, and thumb sensor. These sub components are connected to each other by a digital bus (Figure 1). The system is designed to strengthen the afferent limb of rapid response systems.

Each sub-component has a three-axis accelerometer and specialized components for directly converting analog physiologic signals to
Digitization of biological signals close to the sensors eliminates analog signals traversing cables found in traditional monitors that can cause artifact nuisance alarms. The on-body consolidation of all routine vital signs also reduces or eliminates the “spaghetti factor” found in current multi-parameter bedside monitors that impede patient comfort and mobility.

Transceiver

A transceiver serves as the hub of the on-body digital network. In this case, a wrist transceiver supports the capture, storage, display, and alarming of all components. It also hosts the pulse oximetry measurement and provides wireless connectivity.

Ideally, a transceiver allows for submersion for cleaning and disinfection between patient uses. Measured vital signs with access to waveforms can also be displayed on a screen for clinician viewing.

In this system (Figure 2), a connector at the distal end facing the hand provides connection to a thumb sensor for pulse oximetry measurements or specialty plugs for biomedical service and shipping. Three digital bus connectors on the opposite end provide digital connection to the chest sensor (measuring ECG and posture), non-invasive blood pressure (NIBP), and future parameters. A speaker is incorporated to provide alarm annunciation.

The Wi-Fi 802.11b transceiver supports bidirectional communications to a dedicated appliance-server located in the IT datacenter. TCP/IP protocols are used for all data, and the maximum data rate generated by the device when all parameters and waveforms are active is less than 20kbs.

In all such devices, security is an important design consideration. In this case, data security is ensured with Wi-Fi Protected Access 2 - Pre-Shared Key (WPA2/PSK) encryption.

Pulse Oximetry

The pulse oximeter for a mobile system is ideally optimized for low power. When motion is present it is detected by the accelerometer which causes measurements to suspend and thereby avoid false alarms.

Pulse oximeters can be finger-based. In this case, a thumb sensor is placed around the base of the thumb, capturing the princeps pollicis artery to provide a signal resistant to changes in peripheral vascular resistance.

Chest Sensor

The chest sensor (for either three- or five-lead ECG monitoring) is attached to the patient’s upper torso near the midline. The back of the sensor incorporates a skin surface temperature sensor: Although skin surface temperature will differ from core body temperature, upward trends may indicate a rising fever.

Independent ECG channels are sampled at 500 Hz to detect pacemakers, leads-off, and impedance respiration. A microprocessor detects beats and calculates heart rate (HR). Resulting waveforms, HR values and status (such as leads-off) are communicated to the wrist transceiver via the digital bus. The accelerometer provides measures of motion and three axis posture. Motion is used to suspend HR calculations in presence of motion artifact to reduce false alarms.

Upper Arm Sensor

This sensor is used primarily for the detection of posture changes and to correct for hydrostatic pressure used in the determination of continuous non-invasive blood pressure. It also serves as a mechanical anchor to the cable from the wrist transceiver to the chest sensor.

NIBP

In this example, the NIBP function is contained in a cuff module (without display) that directly connects to a cuff. The module includes an integrated battery, dual microprocessors, and a digital bus connector. Blood pressure measurements are determined during the cuff inflation cycle rather than the deflation cycle.
Measurements taken during inflation avoids over-inflation, a patient safety concern, and lowers overall power consumption and measurement time. Measurements are passed to the transceiver for display.

**Continuous NIBP, cNIBP**

Non-invasive blood pressure is the last remaining core vital sign not continuously measured on a routine basis. As a result, spot check measurements are made on general care floors that are labor intensive and may not detect early physiologic deterioration.

The time it takes for a pulse ejected from the left ventricle of the heart to arrive at a peripheral detection point is inversely related to blood pressure. The commonly used method for measuring pulse transit time (PTT) is to measure the time between an ECG R-wave and the associated peripheral pulse plethysmograph (PPG) from a finger pulse oximeter probe.

Accelerometers attached to the upper arm and contained within the wrist provide dynamic adjustments to hydrostatic pressure changes associated with arm movement and posture changes. The unique thumb sensor provides peripheral pulse detection that is proximal to terminal peripheral vascular beds, ideally reducing measurement errors associated with changes in peripheral vascular impedance.

In this example, cuff inflation permits correlation of oscillometric blood pressure measurements with PTT determinations. Cuff inflation also modifies the transluminal pressure of the brachial artery, resulting in a unique calibration between measurement methods specific to a patient’s cardiovasculature.

**Posture**

Patient falls and hospital acquired decubitus ulcers are considered “never” events for which Medicare does not reimburse hospital expenses. Decubitus ulcers accounted for $726 million in avoidable cost to the healthcare system between 2006 and 2008.

Accelerometers embedded in the system allow real time monitoring of posture changes. Warning messages are posted on system when posture changes indicate changes that may result in patient fall, torso elevation changes, or when the patient remains in a static posture for too long a preset time.

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Alarm Management

Alarm management should be an important consideration in the design of continuous vital signs monitors. In the example described here, alarms originate from the wrist transceiver. Visual icons and audible annunciation conform to the IEC 60601-1-8 standard.

Threshold alarms are set at factory default values but may be reconfigured at installation. Audio alarm annunciation can be delayed based on alarm type, severity, and preconfigured time. Audio alarm delays allow filtering of short duration nuisance alarms.

Alarm delays have been shown to reduce nuisance alarms by adding a simple rule of persistence to the vital signs value. In the case of repeat and closely spaced, short duration alarms, each successive alarm delay is shortened, so that clinicians are alerted to this physiologic pattern. Ease of use, or human factors, is another important consideration in alarm management. For example, nursing work flow can be simplified if all alarms can be changed at one time by the clinician.

In this case, activating autoset changes all alarm parameters to new set points depending on the patient’s current condition. The degree of change depends on the current patient value compared to default alarm limits. If the current vital sign value is close to the default limit, the autoset function will cause a limited change in the threshold value.

Remote alarm annunciation is provided through a third party interface on the system server. A bidirectional interface ensures the system server receives an acknowledgment of a posted alarm. An application programming interface supports waveforms as well as alarms, so remote viewers which support higher graphics content can display both waveforms and alarm values as well as provide an interface for a clinician to silence an alarm.

Remote Viewing Display

Data originating from patient-worn devices are similar to requirements for voice over Internet Protocol (VOIP) telephony applications. In the ViSi Mobile system, data is captured in the appliance server which acts as an enterprise hub. The appliance is dedicated hardware installed in the IT datacenter for secure network connectivity and emergency power backup.

Electronic medical records (EMR) interface is enabled from the appliance in Health Level Seven (HL7) and other formats. Additional interfaces such as supplementary alarm notifications are available as well. A secure virtual private network (VPN) connection allows remote service support and software updates.

Clinical data from up to 32 patients can be displayed on a single remote touch screen. Patients are admitted to the system through the remote viewing display either manually or through an ADT feed. Bedside audio alarms are annunciated at the central station as well as the wrist transceiver (Figure 3). Alarm settings on the wrist transceiver can be changed from the remote viewing device as found in other types of multi-parameter monitoring systems.

Clinical Performance

Finally, it is important to test the clinical performance of devices that will perform critical patient vital sign measurements. In our example, volunteer testing under the Institutional Review Board (IRB) was conducted to measure patient comfort and the incidence of alarms in an ambulatory setting.

Fifteen healthy adult volunteers were recruited to take a system home and wear the on-body monitor during the evening and overnight. All
Finally, it is important to test the clinical performance of devices that will perform critical patient vital sign measurements.

data was collected on a portable PC that integrated the appliance and remote viewer. Waveforms and alarm data were extracted and compiled. Volunteers also completed a questionnaire to elicit feedback on wearability.

The average overnight use was greater than seven hours, during which less than five alarms per patient per day were calculated. The major contributor to false alarms were poor sensor placements for either the ECG electrodes or thumb sensors. The low incidence of alarms was made possible by the motion sensing of the embedded accelerometers and the on-body digital architecture. Participants found wearability to be acceptable throughout the use period.

Discussion
The effectiveness of rapid response systems is based on a reliable early warning system. Patient deterioration occurs hours before a rescue event becomes necessary. No single parameter is sensitive enough to detect the common causes of deterioration.

In addition, events such as patient falls and decubitus ulcers are not detected by traditional vital signs. The system described here was designed specifically to address these avoidable adverse events, and we envision the development of many other mobile wearable devices as technology continues to evolve.

References