

Surveillance Monitoring of General-Care Patients

An Emerging Standard of Care

PART ONE

A CALL TO ACTION

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PART ONE: A CALL TO ACTION

“Modern hospitals service patients of increasing complexity and co-morbidity. Despite advances in technology and the best efforts of hospital staff, several studies have demonstrated that 6% to 17% of all hospital admissions are complicated by serious adverse events. These events are often unrelated to the patient’s underlying medical condition and in approximately 10% of cases they will result in permanent disability and even death”¹

“The Internet of Things is the network of physical objects accessed through the Internet, as defined by technology analysts and visionaries. These objects contain embedded technology to interact with internal states or the external environment. In other words, when objects can sense and communicate, it changes how and where decisions are made, and who makes them.”²

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Introduction

Perhaps the most interesting objects connected on the “internet of things” are all of us. With the advent of inexpensive sensors best exemplified by consumer-oriented fitness trackers, coupled with the communication, location, and computational power embedded within smartphones, we are experiencing the first steps towards connecting all of us in a way that says ‘who we are,’ ‘where we are,’ and ‘how we are’ all the time. Information gathered from consumer devices (heart rate, weight, glucose levels, activity levels, sleep patterns, caloric intake and more) can provide part of a person’s ‘health’ picture (the ‘how we are’), but it is best understood within the context of more formal data collected from traditional health-care sources.

Despite increasingly widespread use of sensors to monitor physiologic indicators and wellness activities of healthy individuals, the majority of acutely ill hospitalized patients remain unmonitored, even though **approximately half of all hospital deaths occur in the unmonitored population.**³

Early detection of patient deterioration is essential to intervene early or respond rapidly, but the standard for routine rounding

and vital sign measurement has not kept pace with increasing patient acuity. This is particularly true in lower acuity areas, where the majority of hospitalized patients receive care, and where continuous vital signs monitoring is currently not the clinical standard. Outside of an intensive care unit (ICU), physiological assessment is typically performed only every four to eight hours.⁴ No system focuses on protecting general-care patients when they are not under direct observation.

Cardiac telemetry, although widely used, has been shown to have no significant clinical value in patients who do not have a preexisting abnormal electrocardiogram (EKG) or diagnosis of a specific cardiac disorder.⁵⁻⁸ Currently available telemetry systems provide only a sub-set of the core vital signs, still mandating the need to spot-check other parameters. Traditional, continuous patient monitors, typically found in high-acuity areas (e.g., ICU), lack mobility, wear-ability and cost effectiveness to enable their use in ambulatory hospital areas. As a result, there has been increasing interest in exploring other monitoring options for hospitalized patients who are not traditionally monitored, especially in what is known as surveillance monitoring.

Whereas traditional condition monitoring refers to the allocation of monitoring resources for a patient identified as being at risk for problems (a patient with known cardiac disease is placed on telemetry), surveillance monitoring refers to the use of monitoring resources for patients who have not been identified as being at specific risk (Table 1). The terminology comes from the anesthesiology literature, where it contrasts the global monitoring found in high-acuity, intensive care settings (condition monitoring) with that found in general-care settings (surveillance monitoring).

dict, deterioration episodes.⁹ The development of systems that can be used outside of the ICU to detect patient deterioration prior to an event has become a 'holy grail' of sorts and is the subject of intense study.

In this article, we present evidence of the need for continuous patient surveillance monitoring in general-care areas; the call for multi-parameter, continuous surveillance monitoring as a new standard of care; desirable characteristics of an effective surveillance monitoring system; new monitoring technologies and opportunities for research.

Failure to Rescue, Failure to Recognize

Failure to rescue (FTR) is the failure to prevent a clinically important deterioration such as death or permanent disability from a complication of an underlying illness or medical care. In-hospital mortality studies show that patients frequently manifest signs of deterioration six to 12 hours prior to a clinical 'event.'¹⁰⁻¹² The failure to recognize such signs is obvious. Institute for Healthcare Improvement (IHI) data show that 25% to 75% of non-do-not-resuscitate (DNR) hospital deaths in U.S. hospitals occur in unmonitored settings outside of the ICU.³ A 1999 United Kingdom study showed that 66% of non-DNR deaths took place outside of the ICU,¹³ and an Australian study showed that 285 of 392 hospital deaths (73%) took place outside of the ICU.⁴

All too often, FTR is the result of failure to recognize. In their 2011 review article on rapid-response teams, Jones, DeVita, and Belomo identified the following issues as contributing to FTR¹⁴:

1. Failure to monitor. Vital sign measurements identify clinical deterioration in many patients; however, studies have shown that measurements may not be

Table 1: Types of Patient Monitoring

Condition Monitoring	Surveillance Monitoring
• Patient has risk factors	• Environment has risk factors
• Monitoring as ordered	• Monitoring as standard of care
• Specialized monitoring	• General monitoring
• Targeted measurements (cardiac telemetry for cardiac patients)	• Multi-parameter measurements (HR, RR, BP, SpO ₂ , etc.)
• Higher-risk population	• Lower-risk population
• Special wards	• General care wards

Taenzer *et al.* note that the use of continuous vital sign monitoring systems in the general care setting represents a more proactive approach to identifying patient deterioration, based upon the premise that physiologic changes can indicate, and perhaps pre-

The purpose is to help hospitals recognize the need for and benefits of improved patient monitoring, and to provide independently established criteria to help in the evaluation of potential solutions.

performed predictably, accurately, or completely. The cost of staffing and automated monitoring equipment is a major impediment to providing adequate monitoring.

2. Monitoring technology is used only in the ICU or step-down units.

3. Hospital-ward monitoring is only intermittent.

4. Intervals between measurements can easily be eight hours or longer.

5. Regular visits by a hospital-ward nurse vary in frequency and duration.

6. Visits by a unit doctor may occur only once a day.

7. When vital signs are measured, they are sometimes incomplete.

In 2004, to make health care safer and more effective and to ensure that hospitals achieve the best possible outcomes for all patients, IHI launched its “100,000 Lives Campaign.”¹⁵ The campaign identified six steps to help hospitals reach the goal of saving this many lives; one was to deploy rapid response teams (RRTs) at the first sign of patient decline. In 2006, having exceeded that goal, IHI introduced a “5 Million Lives Campaign,” which again included rapid response teams as a recommended core component.¹⁶

Rapid Response: The Critical Role of Recognition and Reporting

In 2010 a report from an international consensus conference on rapid response emphasized the need to concentrate on a rapid response system (RRS) rather than a rapid response team (RRT).¹⁷ An RRS comprises an “afferent limb” (the means of detecting patients at risk and triggering a call for assistance), an “efferent limb” (a means of responding to calls for assistance), and administrative and data analysis limbs. The report cited studies that have repeatedly revealed widespread deficiencies in acquiring and acting upon abnormal vital signs—errors that must be overcome to improve FTR statistics.

Successfully rescuing a patient includes **Recognition** that the patient requires acute intervention, **Reporting** that knowledge to appropriate personnel, and an effective **Response**. Failure in any of these areas will lead to FTR. Surveillance monitoring is key to both recognizing and reporting physiological instability. The consensus conference defined a core set of vital signs that should always be monitored: heart rate, blood pressure, respiratory rate, temperature, pulse oximetry, and level of consciousness. There was agreement that,

“...if practical and affordable, all patients should be monitored continuously.”

Evidence in Support of Surveillance Monitoring

The fundamental assumption of surveillance monitoring is that early identification of deteriorating patients will lead to clinical benefit. This can occur through two mechanisms: early identification of deterioration with subsequent stabilization on the existing ward, and early identification of deterioration with subsequent early transfer to a more appropriate level of care. Over the past decade, a growing body of evidence has documented the benefits of early identification in both circumstances.

• A retrospective study by Young *et al.* examined whether or not a delay in ICU transfer after physiologic deterioration is associated with increased morbidity and mortality.¹⁸ The study evaluated 91 consecutive non-cardiac patients transferred to the ICU at a community hospital. Specified physiologic and laboratory criteria indicated physiologic instability. They retrospectively identified the time when each patient met one or more of the criteria prior to transfer to the ICU; this became time-0. The timing of ICU transfer was defined as the interval between time-0 and

arrival in the ICU. They evaluated two groups: rapid transfers (<4 hours after time-0) and slow transfers (>4 hours after time-0). They tracked APACHE II scores at two points: at time-0 and again during the first 24 hours after admission to the ICU. They used the difference in the two APACHE II scores as a measure of deterioration or improvement.

Results showed a crude in-hospital mortality of 41% for slow transfer patients versus 11% for rapid transfer patients. Median hospital length of stay (LOS) after ICU discharge was significantly longer for slow transfers than rapid (14 days v 9 days, respectively). Median hospital costs were \$34,000 for slow transfers and \$21,000 for rapid transfers. In multivariate analysis slow transfer to the ICU was a significant predictor of death, discharge in a functionally dependent state, and higher costs. Much of this was attributed to documented deterioration which took place due to delays in ICU transfer; by the time slow transfer patients were admitted to the ICU they had significantly higher APACHE II scores (21.7 v 16.2).

- Taenzer *et al.* surveilled post-operative patients with pulse oximetry and compared the outcomes with those of other post-operative units at the same medical

center.¹⁹ In the monitored units, rescue events decreased from 3.4 to 1.2 per 1000 patient discharges, and ICU transfers from 5.6 to 2.9 per 1000 patient days, whereas the comparison units had no change. They concluded that early detection of deterioration of physiologic parameters (SpO₂ and heart rate) in the unit led to fewer rescue events and a decreased need to escalate care. Taenzer estimated a savings of approximately 135 ICU days annually from that 36-bed unit alone.

- In a follow-up analysis, Taenzer and Blike²⁰ found a potentially dramatic cost savings associated with continuous surveillance. They found that the average hospital cost for a patient without an ICU transfer was \$17,585 vs \$76,044 with an ICU transfer. For patients receiving continuous surveillance who required transfer to the ICU, LOS was reduced by almost 2 full days, and total hospital stay by 3.5 days. They estimated the annual cost savings of reduced ICU use at almost \$1.5 million, but cautioned that these results depended heavily on the pre-implementation ICU transfer rate.

- Brown *et al.* evaluated continuous monitoring of heart rate and respiratory rate in a medical-surgical unit and found an unchanged rate of transfer to the ICU, but a

significant decrease in total hospital and ICU LOS for transferred patients, as well as lower “code blue” (emergency) rates.²¹

- Cardoso *et al.* evaluated 401 patients admitted to the ICU: 125 were immediately admitted and 276 were delayed.²² Delay in ICU admission was associated with a significant increase in ICU mortality, despite initiation on the general ward of intensive-care treatments such as hemodynamic drips and ventilation. Each hour of waiting was independently associated with a 1.5% increased risk of ICU death.

- Chalfin *et al.* looked at the impact of delayed transfers from the ED to the ICU.²³ They looked at two groups, those transferred within 6 hours of a decision to admit to ICU and those transferred more than 6 hours afterwards. Demographics, ICU procedures, LOS and mortality were analyzed. The median hospital stay was longer in the delayed population by one day (7 days v 6 days), ICU mortality was higher (10.7% v 8.4%), and in-hospital mortality was higher (17.4% v 12.9%).

A New Standard of Care

In response to the documented need and supporting evidence, continuous, multi-parameter surveillance monitoring is

emerging as a new standard of care for the general medical/surgical population. The 2010 report from the international consensus conference on rapid response systems listed the desirable characteristics of an effective surveillance monitoring system (Table 2).¹⁷

**Table 2:
Surveillance
Monitoring Systems:
Desirable Characteristics¹⁷**

- 1 Accurate
- 2 Evidence-based
- 3 Sensitive
- 4 Specific
- 5 Continuous
- 6 Ability to trend in real time
- 7 Does not hinder patient mobility
- 8 Does not impair patient comfort
- 9 Multimodal (multi-parameter)
- 10 Automated alert/alarm
- 11 Directed alert/alarm to specific clinician
- 12 Cost effective
- 13 Upgradable at low cost
- 14 Low maintenance
- 15 Interfaces to electronic health record
- 16 Failure mode recognition (detects when it is not working)
- 17 Default modes
- 18 Simple display in room and outside it

As noted above, cardiac telemetry systems do not address the full complement of vital signs recommended by the consensus

conference of rapid response experts.¹⁷ Similarly, a prototype ring sensor developed by researchers at the Massachusetts Institute of Technology (MIT) continuously measures only pulse rate and oxygen saturation.²⁴ A new, multi-parameter, wearable, patient monitoring system has been developed based on a completely new, wireless digital architecture.

The ViSi Mobile® Patient Monitoring System

Introduced in 2013, the ViSi Mobile® Patient Monitoring System is an innovative platform for comprehensive physiological monitoring. It is designed with the patient's mobility and comfort in mind and to meet the goal of keeping clinicians connected with their patients anywhere, anytime. Worn on the body, it allows freedom of movement and accurate, continuous monitoring of all vital signs, including beat-to-beat, noninvasive blood pressure in a majority of patients.^a Unlike traditional monitoring systems which require bulky, expensive monitors fixed to specific bed locations and are tethered to patients by wires, ViSi Mobile is worn on the wrist and communicates wirelessly for full integration with the hospital's electronic health record (EHR), using the

hospital's existing Wi-Fi network. The ViSi Mobile solution is the only Food and Drug Administration (FDA)-cleared monitor that permits continuous monitoring of heart rate (HR), pulse rate, respiratory rate (RR), oxygen saturation (SpO₂), skin temperature, and noninvasive cuffless blood pressure in a small device that can be worn by the patient. Blood pressure is measured using an FDA-cleared pulse arrival technique and does not require the ongoing use of a brachial pressure cuff. Vital signs data can be easily interfaced to the patient's EHR, thus avoiding time-consuming, error-prone manual entry. The nurse validates and documents the vital sign values in the EHR at intervals consistent with hospital policy. The vital sign data in the EHR is available whenever and wherever needed, and can be viewed on the patient's wrist monitor, at the nurse's station, via a central monitor, and on remote viewing devices. The flexible platform has been engineered to accommodate new sensors, new physiological measurements, and additional future functionality.

Qualitative benefits

There are expectations of 'soft' benefits which may be difficult to quantify but are nonetheless potentially significant:

1. The platform is wearable, com-

portable, and because the oximetry sensor is placed at the base of the finger, it allows full use of fingers, unlike traditional oximetry monitoring.

2. Using ViSi Mobile's ability to assess continuous noninvasive blood pressure without a cuff, the need to arouse patients at night due to brachial cuff inflation is minimized. This allows patients to sleep at night, in contrast with routine vital signs checks which periodically wake the patient.

3. Patients and families receive additional satisfaction knowing that monitoring is taking place even when a nurse is not in the room. Patients feel safer.

4. Improved patient satisfaction scores on the Hospital Consumer Assessment of Hospital and Provider Services (HCAHPS) survey may result from patients' greater feeling of safety.

5. Mobility is preserved.

6. With EHR integration, ViSi Mobile provides an optimal nursing and physician experience: data is timely and accurate.

7. The raw vital signs data can be leveraged for advanced predictive analytics (trend analysis coupled with activity information from the accelerometers is one example).

8. Reduced nursing stress – no patient is unmonitored.

9. Reduction in practice variation related to vital signs management.

10. Reduction in errors of transcription while entering vital signs into the EHR.

High-fidelity data

ViSi Mobile data is stored independently of protected health information. Data (HR, pulse rate, systolic/diastolic/mean BP, RR, oximetry, skin temperature, and waveforms) can be aggregated 'in the cloud,' analyzed, and used as an invaluable tool to help customize alarm settings for a hospital, a unit, or an individual patient (see Part 3). The data is also available for ongoing research and development, a major focus of activity at Sotera Wireless.

Conclusion

Surveillance monitoring represents a critical opportunity to improve the delivery of high quality, safe, effective healthcare. With ViSi Mobile, multi-parameter continuous monitoring, as envisioned by the Consensus Conference on the Afferent Limb of Rapid Response Systems, is now available in an FDA-cleared, patient-friendly system. Through the use of technology to improve recognition and reporting of physiological deterioration, hospital resources can be brought to bear earlier and more effectively, saving money and lives.

For further information about ViSi Mobile, please contact Mary Savoy, Clinical Director of Marketing at Mary.Savoy@soterawireless.com

Footnote

a. As of publication, continuous non-invasive blood pressure (cNIBP) technology had not been validated during patient ambulation.

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