QUERI

Technology Assessment: EarlySense for Monitoring Vital Signs in Hospitalized Patients

May 2016

Prepared for:
Department of Veterans Affairs
Veterans Health Administration
Quality Enhancement Research Initiative
Health Services Research & Development Service
Washington, DC 20420

Prepared by:
Evidence-based Synthesis Program (ESP)
Coordinating Center
Portland VA Healthcare System
Portland, OR
Mark Helfand, MD, MPH, MS, Director

Investigators:
Mark Helfand, MD, MPH, MS
Vivian Christensen, PhD
Johanna Anderson, MPH

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

PREFACE

The VA Evidence-based Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of particular importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. QUERI provides funding for four ESP Centers, and each Center has an active University affiliation. Center Directors are recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Centers. The ESP is governed by a Steering Committee comprised of participants from VHA Policy, Program, and Operations Offices, VISN leadership, field-based investigators, and others as designated appropriate by QUERI/HSR&D.

The ESP Centers generate evidence syntheses on important clinical practice topics. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The ESP disseminates these reports throughout VA and in the published literature; some evidence syntheses have informed the clinical guidelines of large professional organizations.

The ESP Coordinating Center (ESP CC), located in Portland, Oregon, was created in 2009 to expand the capacity of QUERI/HSR&D and is charged with oversight of national ESP program operations, program development and evaluation, and dissemination efforts. The ESP CC establishes standard operating procedures for the production of evidence synthesis reports; facilitates a national topic nomination, prioritization, and selection process; manages the research portfolio of each Center; facilitates editorial review processes; ensures methodological consistency and quality of products; produces "rapid response evidence briefs" at the request of VHA senior leadership; collaborates with HSR&D Center for Information Dissemination and Education Resources (CIDER) to develop a national dissemination strategy for all ESP products; and interfaces with stakeholders to effectively engage the program.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP CC Program Manager, at Nicole.Floyd@va.gov.

Recommended citation: Helfand M, Christensen V, Anderson J. Technology Assessment: EarlySense for Monitoring Vital Signs in Hospitalized Patients. VA ESP Project #09-199; 2016.

This report is based on research conducted by the Evidence-based Synthesis Program (ESP) Center located at the **Portland VA Healthcare System, Portland, OR**, funded by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Quality Enhancement Research Initiative. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

TABLE OF CONTENTS

INTRODUCTION

The EarlySense Monitoring System has been developed to provide continuous monitoring of heart rate (HR), respiration rate (RR), and bed motion for patients in medical/surgical, oncology, orthopedics, isolation, post-partum, skilled nursing facilities, long term acute care**,** and rehabilitation settings.

The VA Office of the Deputy Under Secretary for Health for Policy and Services (10P) requested an independent evaluation from the VA Evidence-based Synthesis Program (ESP) to help guide the field as to EarlySense's monitoring capabilities, benefits and harms, impact on nurse staffing, and the overall effectiveness of the system. The USH seeks to better understand how this technology is being used in similar hospital settings in the US, what kinds of VA patients would be best served by it, and whether there are particular types of units or distribution of beds within those units for which this technology would be best suited.

The ESP review team searched for and critically appraised relevant studies and systematic reviews and interviewed key informants, including VA nurses who have experience with the EarlySense system. In addition, we requested a Product Brief from the ECRI Institute,[1] which is intended to serve as a companion to our report.

WHAT IS EARLYSENSE?

EarlySense is a *low-acuity continuous monitor.* As shown in the figure below, EarlySense consists of (1) a sensor that is placed under the patient's mattress, (2) a bedside monitor, (3) a central display station, and (4) proprietary analytic software that runs on a PC (not shown). The system is based on a piezoelectric sensor, sensitive to applied mechanical strains. The system differs from other patient monitoring systems in that it is a contactless device which eliminates the use of telemetry leads. While the patient is lying flat in bed, the system continuously records heart rate (HR), respiration rate (RR), and bed motion. Low-acuity systems do not provide cardiac waveforms (rhythm strips). They can display oxygen saturation if that is monitored using a separate system. EarlySense does not interface with the electronic medical record.

Every 0.5 seconds, an updated HR reading is established based on analysis of the heart pulse pattern for the last 8 seconds, and an updated RR reading based on analysis of the last 1 minute of the respiration pattern. The system provides alerts if any of the parameters exceed predefined thresholds, which can be customized. Alerts can also be sent directly to nurses' mobile phones or pagers. EarlySense also provides bed exit alerts for patients at risk of falls, and includes a timer

to remind nurses to turn patients (to help prevent the development of pressure ulcers). EarlySense can monitor up to 40 beds at one time.

EarlySense received FDA 510(K) clearance as a Class II device based on demonstration that it was equivalent to devices that are used to monitor vital signs in patients undergoing sleep studies and in ambulatory patients. FDA clearance permits marketing in the US but does not mean that the FDA has found the device to have clinical efficacy. Rather, clearance means that EarlySense is equivalent to older devices in its ability to measure respiration rate and heart rate.[2]

PREDICTING CLINICAL DETERIORATION

Research conducted in the 1990s suggested that, among patients on general hospital wards, delays in treatment can lead to clinical deterioration and changes in vital signs and mental function that precede deterioration are often missed.[3,4] These observations led to the development of "rapid response teams" (RRTs) that are activated when a patient fulfills predefined criteria.[5] The criteria are based on vital signs checks and assessment of mental status. Some systems also include decreased urinary output, oxygen saturation, difficulty breathing, increase in supplemental oxygen dose, and subjective concern detected by the nurse at the bedside.

The Early Warning Scoring Systems (EWS), Modified EWS (MEWS), and the National EWS (NEWS) are commonly used sets of criteria. These systems are widely used in VA. In addition to indicating when to call the RRT, the systems also incorporate recommendations for the frequency of bedside assessment. In 2014, a systematic review from the VA Evidence-based Synthesis Program found that EWS/NEWS have strong predictive value for cardiac arrest and patient death and their use increases RRT calls, but the impact of EWS/NEWS on preventing patient mortality, transfers to the ICU, or length of hospital stay is uncertain.[6]

The ability to predict which patients are most likely to deteriorate has not been established. DeVita et al (2010)[7] argue that while analyses of cardiac arrests and deaths indicate that most are preceded by vital signs lying outside normal ranges, most studies are retrospective, and because the total number of clinical deteriorations has not been determined, the ability of physiological abnormalities to predict risk of a serious event is unknown. Thus, in many circumstances, clinicians cannot predict which patients are most likely to deteriorate. In addition, lack of data prevents any estimate of how often severe deterioration leads to clinically adverse outcomes. In a study examining the association of delays in transfer to ICU, morbidity, and mortality,[8] 11 physiological and laboratory markers of clinical instability were observed as having high sensitivity (88%) in identifying patients who were transferred to the ICU. These markers, however, lacked specificity (13%) and had very low positive predictive value (8%). This study suggests hospital staff cannot rely on markers alone to identify patients most at risk of deterioration without using considerable resources and incurring a high cost-benefit ratio.

Because of the limitations in predicting patients at highest risk of a serious event, the ability of intermittent or continuous monitoring systems to detect severe physiological abnormalities in order to provide a true estimate of risk or to determine optimum response triggering values has not been fully established.[3,6,7,9,10] Qualitative research suggests that nurses' worry or concern often precedes deterioration in vital signs, suggesting that better characterization of "concern"

might lead to detection of deterioration at an early stage when intervention to prevent adverse events may be more effective.[11]

RATIONALE FOR CONTINUOUS VIAL SIGN MONITORING

The rationale for continuous vital sign monitoring is that suboptimal vital sign monitoring prior to an RRT referral may contribute to suboptimal patient outcomes. A more specific rationale for the *EarlySense* monitoring system is that alerts based on vital sign *trends* rather than just threshold parameters may add predictive ability to that of MEWS criteria and lead to earlier, more effective RRT calls. On busy wards, the frequency and accuracy of vital sign checks may be insufficient to detect deterioration, especially at night.[3] Factors that may contribute to suboptimal patient monitoring include adverse working conditions, heavy workloads, lack of education and training, lack of experience and failure to recognize clinical urgency, errors in calculating EWS, communication deficits between doctors and nurses, cultural influences and intra-professional hierarchies, and lack of compliance.[12]

WHAT ARE THE ALTERNATIVES TO EARLYSENSE?

Standard nurse-led monitoring in conjunction with EWS or MEWS is the most commonly used alternative to continuous vital sign monitoring.

Other low-acuity systems are also alternatives to EarlySense. They are similar to EarlySense but require leads attached to the patient, and some require cables to connect with the display. All of these systems capture respiratory rate and heart rate, and some capture blood pressure, oxygen saturation, temperature, and ECG. Most contribute vital sign data directly to the electronic medical record. The market for low-acuity monitoring systems is growing rapidly, leading to intense technological development.

Bedside monitors have sensors that are attached to the patient and connected via cables or leads to a display panel near the patient's bed and on remote displays. Manufacturers include Covidien, Masimo, Welch Allyn, and Zoe Medical. A major assumption underlying EarlySense is that these systems may be less safe than a contact-free low-acuity monitoring system because of cable management issues.

Wearable monitors have sensors that attach to a small, lightweight display unit that enables monitoring even when the patient is out of bed. It is not known to what extent the need for contacts is a disadvantage for nursing staff or for patients. Few if any data are available about the use of these systems on general medical-surgical wards. For example, a search by ECRI found no clinical trials of GE Carescape or Nihon Kohden BSM-6000 bedside monitors. Philips and Sotera also manufacture wearable monitor systems.

Medium-acuity telemetry systems are widely employed in the general medical and surgical wards. They are more expensive than EarlySense. An example is Intellivue (Phillips). This system uses ECG leads (wires) attached to the patient and to a small mobile device that fits into the patient's pocket. It records cardiac waveforms so that heart rate and rhythm are easily visualized. More expensive (and bulkier) models also monitor respiratory rate via the telemetry leads. Like EarlySense, these systems provide alerts if any of the parameters exceed predefined thresholds, which can be customized. Unlike EarlySense, the wearable sensors can monitor the

patient in or out of bed, enabling continuous distant ECG monitoring. Continuous output can be viewed at the bedside and from a central monitoring system and text alerts are provided to nurses on mobile devices.[13] The systems can analyze the ECG output to diagnose many cardiac arrhythmias. They are often used in conjunction with pulse oximetry (oxygen saturation monitoring) and, especially in post-operative patients, capnography.

WHAT ARE POSSIBLE ROLES FOR EARLYSENSE IN VA?

Monitors such as EarlySense are intended to fill the niche between periodic vital sign monitoring protocols (EWS) and higher-acuity monitors such as pulse oximetry and telemetry.[1] As discussed later, clinical evidence does not support specific patient groups or indications for EarlySense.

However, some of the studies of EarlySense have focused on certain groups of patients. Possible target patient groups include:

- PEG feeding and other patients at risk for aspiration.
- Post-operative pain, patient-controlled analgesia, and other patients with pain. The heart rate alerts could be useful to detect pain and the respiratory rate monitor could be useful to detect respiratory depression.
- Surgical patients who are expected to be in bed continuously.
- Patients at increased risk for respiratory failure, including those who have an admitting diagnosis of pneumonia, congestive heart failure with pulmonary edema or congestion, and other patients who have tachypnea or need supplemental oxygen on admission.
- Patients who are at high risk of falls.
- Spinal cord injury patients.

In addition to patient groups, other goals for deploying EarlySense might include facility- and ward-level considerations. For example, EarlySense might reduce demand for telemetry where telemetry beds are in short supply. It might also be deployed on night shift where the number of patients per nurse is higher, or on wards that have higher ratios of patients to nurses. Another approach would be to deploy EarlySense on wards that have high rates of patient deterioration, unplanned ICU transfers, or falls. There is, however, no evidence to guide whether these strategies are practical. In particular, it is unknown whether the factors that lead to poor performance would also prevent successful implementation of EarlySense monitoring.

WHAT IS THE ACCURACY AND PREDICTIVE ABILITY OF EARLYSENSE?

The accuracy of EarlySense has been examined in one small feasibility series.[14] Heart rate and respiratory rates recorded by sleep laboratory monitoring equipment and EarlySense were compared in 16 adults and 41 children who were referred for sleep studies and in 42 ICU patients. Accuracy was calculated by comparing the average one-minute measurements of both

systems on a minute-to-minute basis. Among adult sleep lab patients, the EarlySense system had an RR accuracy of 93.1% and an HR accuracy of 94.4%. Among ICU patients, the EarlySense system had an HR accuracy of 94% and the RR accuracy ranging from 75-82% depending on whether patients were intubated and connected to an ET CO_2 module. The absolute relative error rate (aRE), calculated as (Reference-EarlySense)/Reference, ranged from 0.03 to 0.08.[14]

In the sleep lab, HR and RR were measured with the Embla Sleep Lab System, which uses abdominal and chest belts with respiratory inductive plethysmography technology. In the ICU arm, HR was measured by standard ECG monitoring and RR was measured by an end-tidal CO_2 (ET CO_2) module for ventilated patients and manually by trained research assistants for non-ventilated patients.

Presumably the sleep laboratory and ICU settings were selected because they use "gold standard" methods to measure vital signs, but it is unclear how well these results apply to patients seen in VA general medical and surgical beds. The accuracy of EarlySense may depend on how much time the patient spends in bed and whether they lie flat, and may also depend on other factors such as body habitus or laying still. There are no published studies of the factors that affect the accuracy of EarlySense readings in a general medical setting.[1]

The ability of EarlySense to predict patient deterioration was explored in one noninterventional feasibility study carried out in medical units of 2 academic medical centers.[15] This study evaluated 149 patients with an acute respiratory condition. Of these, 36 patients were excluded because the duration of monitoring was less than 30 hours. Of the remaining 113 patients, 9 deteriorated, as defined by (1) transfer to an ICU, (2) intubation and mechanical ventilation, or (3) cardiac arrest. Data were analyzed retrospectively to select criteria for potential threshold and trend alerts to predict deterioration within 24 hours. The sensitivity and specificity of the derived alerts in predicting clinical deterioration were 82% and 67% respectively for HR, and 64% and 81% respectively for RR using threshold alerts. For trend alerts, the sensitivity and specificity of the EarlySense system in predicting clinical deterioration were 78% and 90% respectively for HR, and 100% and 64% respectively for RR.

A sub-analysis of this study assessed the utility of the EarlySense system as a risk assessment tool for pressure ulcer development.[16] All patients were assessed for pressure ulcer risk upon admission using the Norton scale. Patient motion data from the EarlySense system were analyzed and an EarlySense motion level score (EML) was calculated for each patient. Using the Norton scale as the gold standard reference, the EML had a sensitivity of 85% and a specificity of 93% in assessing patient risk for developing pressure ulcers.

Promotional material from EarlySense describes the study as a "clinical study" and cites it in support of the statement that the EarlySense Monitoring System "accurately predicts patient deterioration." The study doesn't support this claim. This study and the substudy were "noninterventional," that is, the EarlySense results were not used in clinical decision making. The estimates of predictive ability were based on a retrospective analysis that sought criteria providing the best possible prediction. The alerts were also virtual – there were no actual alerts or alarms, but the authors estimated how many alerts might have occurred using different

[1] The Boise VA team collected data comparing EarlySense readings with the nurses' manual vital signs at various time points. The data are not published but were provided to our team.

criteria. Such studies almost always lead to higher estimates of predictive ability than studies in which the criteria for a positive test are defined in advance. Another limitation is the lack of a control intervention. Without a comparator, it is difficult to interpret whether the hypothetical alarm rate is higher or lower than it would be using nurse-led monitoring or telemetry with MEWS.

WHAT IS THE THERAPEUTIC IMPACT OF EARLYSENSE?

To date there is no evidence from well-controlled studies that EarlySense improves patient outcomes compared with a well-defined alternative approach. Only one published study has evaluated the effect of EarlySense in clinical use. Results from this study were described in a white paper and in a journal article.[17] The white paper, an interim report, describes it as a pre-post study conducted on a 33-bed medical-surgical ward in a community hospital in California. The journal article compares the outcomes of 9 months of use of EarlySense for all admissions to the intervention-group ward with 1) results in an earlier 9-month period on the same ward and 2) results on another 33-bed medical-surgical ward in both time periods. The wards had a 1:5 nurse to patient ratio. Data for EarlySense were collected prospectively, while pre-EarlySense data were collected retrospectively. It is unclear whether any data on the control ward were collected prospectively.

For the intervention ward, key findings were:

1. The rate of transfer to the ICU did not change before and after implementation of EarlySense. ICU days per 1000 patients fell (120.11 to 63.44) but did not reach statistical significance ($p = 0.10$). Code blue events were reduced (6.3 vs 0.9, $p < 0.01$). After adjustment for sex, age, comorbidities, and primary diagnosis, ICU length of stay was lower in the postintervention period than in the preintervention period, but whether this difference was statistically significant is not clear.[2]

2. There were 2.2 HR and RR alerts per 100 recording hours in the intervention period (less than 1 alert per nurse per 12 hour shift). Since the pre-intervention group did not have alerts, there is no comparison group for this measure. The frequency of RRT calls is not reported. Rates of "Turn Patient" and "Bed Exit" alerts were also not reported in the journal article.[3]

Comparing the control unit to the intervention unit in the post-implementation period, there were no significant differences in medical-surgical unit length of stay (LOS), ICU transfers, APACHE II score, LOS in unit before transfer to ICU, or code blue events. There were no differences in unexpected deaths among any of the patient groups.

From the viewpoint of effectiveness, this body of literature represented by this study is of poor quality. Some key outcomes are not reported, and measurement of other outcome measures was not blinded and was subject to bias. In particular, the study failed to describe the mechanisms in place for the utilization of RRTs and whether there were any differences between the 2 study

[2] A significant p value is provided for the comparison of the intervention ward to that of the intervention ward before the intervention and to that of the control group. As discussed below, the validity of using the nonintervention ward in this comparison is low.

[3] In the interim report these rates were 0.7 and 0.4 alerts, respectively, per nurse per 12 hour shift, but the rates for these alerts depend on how often the bed alerts are turned on and that is not reported.

groups in the number of calls made and RRT response times.

Perhaps most important, both control groups – the preintervention results on the ward that implemented EarlySense, and the control ward – are inadequate. There were dramatic differences between the wards. For example, in the preintervention period, the intervention ward had 6.3 code blues and 120.11 ICU days per 1000 patients, versus 3.9 and 32.69 in the control ward. On the control ward, ICU days per 1000 patients increased from 32.69 to 85.36, versus a drop from to 63.44 in the intervention ward. The large fluctuations in the rates of this and the other outcomes on both wards make it difficult to determine what role EarlySense played in the results.

OTHER STUDIES

The experiences of other wards that have implemented EarlySense have been published in conference abstract and poster formats (see Appendix). These reports are tabulated in the ECRI report on EarlySense. The posters and abstracts provided insufficient information to assess the quality of these studies and analyses. Of some concern, several studies registered in ClinicalTrials.gov have not been reported or published, including a study of post-operative patients requiring patient-controlled anesthesia that was scheduled to be completed in 2010 (NCT00640718).[4]

WHAT ARE IMPLEMENTATION ISSUES OF EARLYSENSE IN THE VA SETTING?

We are aware of two VA facilities currently using EarlySense. The Boise VA Medical Center (VAMC) uses the monitoring system on a general medical/surgical ward, and a VA Spinal Cord Injury (SCI) Center at the Tampa VAMC uses EarlySense in their medical/surgical unit. Results from these centers have been presented in abstracts and marketing materials, but the data they have collected have not been presented in a scientifically rigorous manner.

In order to better understand potential feasibility and implementation issues for EarlySense in the VA setting, the ESP Coordinating Center conducted a series of informal interviews with medical staff who currently use the system. In addition, we contacted two VA facilities that are not using the system in order to better understand how EarlySense compares to other monitoring systems that are currently in use within the VA healthcare system.

The Boise VAMC (VISN 20) piloted EarlySense in 20 beds for one year and currently uses the system for all 27 beds in their medical/surgical ward. Patients in the medical/surgical ward are most often admitted for general surgery, orthopedic and spine surgeries, pulmonary and cardiac diagnoses, as well as multisystem admissions. The current patient-to-nurse ratio in the Boise medical/surgical ward is 4 to one during the day and 6 to one at night. During normal unit operation, nurses take vital signs every 4 to 6 hours and round on even hours, while aides round on odd hours.

The Tampa VA SCI Center has used EarlySense in its 30-bed medical/surgical unit for over a year and plans to implement the system throughout the rest of its SCI units. The SCI medical/surgical unit consists primarily of patients with UTIs, pneumonia, wounds, and patients

[4] NCT00361426, NCT00382746, NCT00361608, NCT01978340, NCT00640718, NCT01774708

in for their annual exams. The current patient-to-nurse ratio in the SCI medical/surgical unit is 3 to one during the day and four to one at night. Vital signs are taken once per shift and more frequently if needed.

PERCEIVED ROLE OF EARLYSENSE

During our interviews, nurses from both facilities described the EarlySense system's ability to track trends in patient vital signs as extremely helpful. However, they clearly stated that EarlySense should be viewed as an aid to, rather than a replacement for, nurses and other providers. According to Boise nurses, EarlySense helps them to determine which patients may be at increased risk for deterioration, as well as to assess patient RR and HR status, and to determine necessary next steps if a patient shows a trend towards decline (*eg*, call the ward physician or RRT). Similarly, nurses from the Tampa SCI unit described how EarlySense helps to identify cases where "something more is going on," even when a patient is not complaining or showing visible signs of deterioration. At both centers, EarlySense assists when deciding whether a patient should be transferred to the ICU. Nurses from both centers also commented that EarlySense's trend-tracking ability "acts as another set of eyes on patients" and "fills in the gap" when signs of patient deterioration might otherwise be missed. EarlySense, then, is seen as having the ability to "bring the nurse to the patient's bedside more often and with purpose." Nurses at the Boise VAMC suggested that patients with the highest acuity scores, patients who have a known infection, and patients who are placed in single rooms would likely benefit most from EarlySense.

Tampa nurses described the unique monitoring needs of spinal cord injury patients as "generally stable, but [having the potential to] develop infections and become septic fairly quickly, without clear symptoms." In addition, patients with an injury above T6 tend to be more susceptible to abrupt changes in blood pressure. Tachycardia (an abnormally rapid heart rate) was a major concern. Both conditions can increase the risk of cardiovascular symptoms. EarlySense has been viewed as especially helpful for patients with tachycardia. As one nurse stated, "EarlySense is early detection, it's the early warning system."

LIMITATIONS AND CHALLENGES OF EARLYSENSE

Although nurses from both centers view EarlySense as a helpful tool, there have been challenges with "buy-in" among nursing staff, issues with false alarms, and problems integrating EarlySense into existing communications systems. Nurses at the Boise VAMC, for instance, mentioned that the initial acceptance of the system was poor. Similar comments were made by nurses at the Tampa SCI unit, as one nurse remarked. "With the buy-in, that's something that, even here, we struggle with, that we have to make sure they're looking at the trends, looking at everything, and taking everything seriously." The centers suggested that having a few of the nursing staff receive additional ongoing training from EarlySense would enable "EarlySense champions" or "super users" to promote utilization of the technology, and to help educate other nurses to better understand how to use the system. The Tampa SCI unit also described the need for IT and biomedical departments to be involved in the initial system implementation.

For the Tampa SCI unit, experiences with false alarms have been viewed as a hindrance to acceptance, as it made nurses more hesitant to trust the system. One nurse mentioned that, "It made some people think it was not accurate all the time." The center is currently tracking the rate

of false alarms in order to address these concerns, but noted that once a patient is discharged or transferred from the unit, staff cannot retrieve the data from the bedside monitors. Instead, EarlySense has to retrieve the data for them, which is viewed as an additional barrier. In addition, nurses from the Boise VAMC noted problems with false alarms for patients on air mattresses. They noted that EarlySense has a tendency to "double read" heart rate due to vibrations of the air mattresses. They are continuing to work on this issue with EarlySense.

Integrating EarlySense into existing communications systems such as Vocera has also been an issue. The Tampa SCI Center had cases in which "sometimes it was working and sometimes it was not," which caused concern that nurses might not receive all of the alerts. This may be dependent on the type of communication system that is in use during the implementation of EarlySense. For the Boise VAMC, nurses did not have a pager system prior to the implementation of EarlySense and therefore did not have to integrate the system into an existing communications framework.

Boise nurses also spoke of their experiences with the limitations of EarlySense's vital signs detection. The system cannot detect vital signs once a patient leaves his or her bed, nor for patients who use air mattresses, nor in some instances for patients who are positioned on their sides.

Lastly, the technology of EarlySense is changing rapidly. For instance, a nurse in the SCI Center mentioned that "over the course of time the tool evolved. From when we first saw it to when we actually got it, it had changed several times." It is unknown what the impact of constant changes in the product is having regarding the uptake and usability of EarlySense.

ORGANIZATIONAL CULTURE

Nurses from the Boise medical/surgical ward describe themselves as a cohesive group with supportive nursing leadership. It is important to note that their experiences with EarlySense are dependent on the specific working conditions, culture, patient load, and complexity of their ward, as well as the performance of the hospital as a whole. Boise nurses felt that the implementation of EarlySense could be quite challenging in poor-performing units. Similarly, the Tampa SCI medical/surgical unit is viewed as well-staffed and well-supported. The organizational structures at the Boise VAMC and the Tampa SCI unit represent ideal test cases in which the implementation of EarlySense still posed some initial, and in some cases ongoing, challenges. It should also be noted that neither of the groups that we interviewed had access to other monitoring systems, such as telemetry, at the time that they implemented EarlySense.

In addition to our interview with the Boise and Tampa nursing staff, we consulted with one of the authors of the publication described above which examines the therapeutic impact of EarlySense,[17] and learned during our conversation that EarlySense is best suited for nursing staff who work well with prespecified protocols. It remains unclear how best to integrate decision support systems with the EarlySense system and the extent to which EarlySense monitors would need to be individualized by the VA due to differences in patient population and staffing.

Comparison Centers

In order to better understand how EarlySense may compare to other monitoring systems, the ESP Coordinating Center contacted medical staff at two VA centers who currently do not use the

product. The ESP CC had informal conversations with nursing staff at the Portland VAMC, a general medical/surgical ward, and medical staff from the Milwaukee VAMC, a medical/surgical spinal cord injury (SCI) unit that houses 32 beds. Nurses at the Portland VAMC currently use IntelliVue and telemetry. They described their experience with IntelliVue as positive, and liked that alarm thresholds which can be customized for each patient. They further remarked that portable telemetry units tend to work well for VA patients who are accustomed to leaving their rooms. Moreover, Portland nursing staff on wards that have met performance targets for reducing falls are hesitant to change their current practices for fall prevention.

The Milwaukee VMAC SCI unit uses pulse oximetry, which nurses described as working well for their patient population. Each patient room has its own machine, enabling continuous monitoring. The Milwaukee VMAC SCI unit does not currently use telemetry. Staff remarked that although their caseload may be high at times, they feel their monitoring system has not been an issue. One nurse remarked: "our rapid response rate is quite low. We might do such a good job of monitoring before [patients] get that way."

WHAT ARE THE CONTRACTING CONSIDERATIONS AND COSTS OF EARLYSENSE?

ECRI Institute has offered the following advice regarding contracting for low-acuity monitors:

- Monitoring system purchases should be carefully planned and coordinated for the entire facility. Such purchases should be part of a long-range strategic monitoring acquisition and management plan that considers the hospital's resources, expected patient population, and current technology base.[1] Other considerations include whether the monitoring system can be easily interfaced with other devices and whether the system support for software is likely to be discontinued.

- Clinical evaluations (including a full evaluation of alarms) and consultations with clinical staff regarding their needs and desired performance should be performed before purchase to encourage staff acceptance.[1]

- Other factors to consider when purchasing a physiologic monitoring system include utilization demands in monitored areas, number of patients, patient care objectives, number of monitors and telemetry transmitters, alarm coverage protocols, additional alarm notification equipment, system configuration, general ese of monitor's use, implementation plan and staffing adjustments, staff training, and the ability to expand capabilities with clinical needs, utilization requirements, and technology advancements.[1]

COST

The return on investment (ROI) analysis of EarlySense estimated that EarlySense is cost-saving.[18] However, the assumptions used in the analysis are based on the results from the intervention group in the Brown et al study.[17] The annual ROI was 292.8% using the base model and 92.5% using the conservative model with net benefits of $710 per patient and $224 per patient, respectively. The largest cumulative cost savings came from reduced LOS in both models. There is little doubt that, if the results of Brown et al were reliable, then use of

EarlySense would be cost-saving. However, these assumptions, based on a pre-post analysis of a single, flawed study, are not reliable enough to produce any confidence in the results of the cost analysis. In addition, because the ROI is based on a study in which little is known about the specific methods for monitoring patients in the control groups, a cost comparison of EarlySense to other monitoring devices or to a specified nursing protocol for invoking RRT has not been addressed.[17]

The initial acquisition costs of patient monitors do not accurately reflect the total life-cycle costs of operating a patient monitoring system. For example, sensors for the EarlySense system must be replaced annually. Hospitals must take into account ongoing maintenance, operational costs, service support, and standardization with existing equipment.

A review of a FY2013 VISN 20 Equipment Justification for a 2-year contract with EarlySense for 27 beds the Boise VA Medical Center showed a total cost of $212,613. The total costs for the system included a $175,473 contract fee ($6499 per patient bed), one Gateway computer $825, second year sensor replacement $22,275 ($825 per patient bed), and an annual quality maintenance program of $14,040 ($520 per patient bed).

SUMMARY OF KEY POINTS

1. Based on evidence that vital sign monitoring is often deficient, there is a strong rationale for low-acuity monitoring in general. Although there are no data about which patient groups are most likely to benefit, the rationale is strongest for certain groups of patients, including those who are at high risk of falls.

2. According to VA end users, EarlySense has been implemented successfully in at least 2 medical/surgical units, with one being a SCI medical/surgical unit, within the VA system. It is not known whether implementation has been attempted and failed at other locations.

3. The evidence base regarding the clinical benefits and cost of the EarlySense system is poorly developed. There are only 3 peer-reviewed journal articles and these have focused on clinical deterioration; as yet, there is no evidence supporting an effect on the rate of ICU admission. The peer-reviewed studies have not focused on fall prevention, an important potential advantage of EarlySense because low-acuity monitors and intermittent vital sign measurement by a nurse do not reliably detect attempts to get out of bed.

4. There are no prospective, well-controlled studies of the benefits and costs of EarlySense in comparison to a viable alternative. Viable alternatives include (1) nurse-led monitoring with a well-executed protocol for calling a RRT and (2) other low-acuity monitors, particularly those that measure blood pressure. In particular, the comparative effectiveness of EarlySense on alarm frequency and effective use of Rapid Response Teams has not been demonstrated adequately.

5. Technology and competition for low-acuity monitoring systems are changing rapidly.

IMPLICATIONS FOR FUTURE RESEARCH

A study comparing EarlySense to other strategies currently used in the VA medical/surgical ward setting is warranted to assess the true cost/benefit and therapeutic value of implementing EarlySense in selected spinal cord and general medical/surgical units that meet certain criteria. It is particularly important to determine through an independent assessment whether EarlySense is likely to improve outcomes in poor-performing facilities, and what it adds for units that have sufficient access to telemetry beds. It would be important for such a study to begin collecting data, with audit, in advance of the implementation of EarlySense, and to select concurrent controls with careful attention to baseline similarity in clinical spectrum and utilization patterns in order to accurately determine the impact of EarlySense on patient outcomes.

It remains unclear how EarlySense will affect patient health outcomes, unplanned ICU transfers, ICU LOS, and LOS in the medical/surgical ward. While there is enthusiasm among nurses in the medical/surgical unit in the Boise VA Medical Center, research is needed to determine the types of units and patients within these units that would be best served by EarlySense, and how best to integrate the system into existing nursing organizational structures. For instance, it is unclear how using EarlySense would impact patients who would ordinarily be encouraged to be mobile.

We also suggest a more in-depth evaluation on the impact of EarlySense, either through a qualitative study which could include participant observation or an observational study, would better inform the impact EarlySense may have on nurse satisfaction, work environments, and nursing practice (*eg*, frequency of patient visits, use of RRTs), and to determine the necessary elements that are required for successful implementation of this type of monitoring system within the VA. It is likely that organizational factors such as the availability of appropriately skilled staff, awareness and support of the system, and access to monitored or critical care beds will impact the ability of nursing staff to successfully use EarlySense.

REFERENCES

1. ECRI Institute. *EarlySense System (Early Sense Ltd.) for Noninvasive Continuous Patient Monitoring*: ECRI;2016.
2. U.S. Food and Drug Administration. 510(K) Summary: EarlySense ES-16 System (510(K) Number K070375). 2007; https://www.accessdata.fda.gov/cdrh_docs/pdf7/K070375.pdf. Accessed February 5, 2016.
3. McGaughey J, Alderdice F, Fowler R, Kapila A, Mayhew A, Moutray M. Outreach and Early Warning Systems (EWS) for the prevention of intensive care admission and death of critically ill adult patients on general hospital wards. *Cochrane Database Syst Rev.* 2007;3.
4. ECRI Institute. *Low-Acuity Continous Monitoring: An Introduction*: ECRI 2014.
5. Jones DA, DeVita MA, Bellomo R. Rapid-response teams. *New England Journal of Medicine.* 2011;365(2):139-146.
6. Smith MB, Chiovaro JC, O'Neil M, et al. Early warning system scores for clinical deterioration in hospitalized patients: a systematic review. *Annals of the American Thoracic Society.* 2014;11(9):1454-1465.
7. DeVita MA, Smith GB, Adam SK, et al. "Identifying the hospitalised patient in crisis"— A consensus conference on the afferent limb of Rapid Response Systems. *Resuscitation.* 2010;81(4):375-382.
8. Young MP, Gooder VJ, Bride K, James B, Fisher ES. Inpatient transfers to the intensive care unit. *Journal of general internal medicine.* 2003;18(2):77-83.
9. Cardona-Morrell M, Prgomet M, Lake R, et al. Vital signs monitoring and nurse–patient interaction: A qualitative observational study of hospital practice. *International Journal of Nursing Studies.* 2015.
10. Vlayen A, Verelst S, Bekkering GE, Schrooten W, Hellings J, Claes N. Incidence and preventability of adverse events requiring intensive care admission: a systematic review. *Journal of evaluation in clinical practice.* 2012;18(2):485-497.
11. Douw G, Schoonhoven L, Holwerda T, van Zanten AR, van Achterberg T, van der Hoeven JG. Nurses' worry or concern and early recognition of deteriorating patients on general wards in acute care hospitals: a systematic review. *Crit Care.* 2015;19:230.
12. Odell M. Detection and management of the deteriorating ward patient: an evaluation of nursing practice. *Journal of clinical nursing.* 2015;24(1-2):173-182.
13. Philips. IntelliVue Information Center. 2016; http://www.usa.philips.com/healthcare/product/HCNOCTN171/intellivue-information- center-piic-ix, 2016.
14. Ben-Ari J, Zimlichman E, Adi N, Sorkine P. Contactless respiratory and heart rate monitoring: validation of an innovative tool. *Journal of medical engineering & technology.* 2010;34(7-8):393-398.

15. Zimlichman E, Szyper-Kravitz M, Shinar Z, et al. Early recognition of acutely deteriorating patients in non-intensive care units: Assessment of an innovative monitoring technology. *Journal of hospital medicine.* 2012;7(8):628-633.

16. Zimlichman E, Shinar Z, Rozenblum R, et al. Using continuous motion monitoring technology to determine patient's risk for development of pressure ulcers. *Journal of patient safety.* 2011;7(4):181-184.

17. Brown H, Terrence J, Vasquez P, Bates DW, Zimlichman E. Continuous monitoring in an inpatient medical-surgical unit: a controlled clinical trial. *The American journal of medicine.* 2014;127(3):226-232.

18. Slight SP, Franz C, Olugbile M, Brown HV, Bates DW, Zimlichman E. The return on investment of implementing a continuous monitoring system in general medical-surgical units*. *Critical care medicine.* 2014;42(8):1862-1868.

19. *EarlySense for Heart and Respiratory Monitoring and Predicting Patient Deterioration*. London, UK: National Center for Health and Care Excellence; 2016.

APPENDIX A. CONFERENCE ABSTRACTS

- *Using Piezoelectric Sensor for Continuous-contact-free Monitoring of Heart and Respiration Rates in Real-life Hospital Settings*
- *Using Continuous Motion Sensing Technology as a Nursing Monitoring and Alertign Tool to Prevent In-hospital Development of Pressure Ulcers*
- *Effect of Contactless Continuous Patient Monitoring in a Medical-Surgical unit on Intensive Care Unit Transfers: A Controlled Clinical trial*
- *The Effect of Contact-free Patient Monitoring System on Reducing Falls and Re-hospitalizations in a Rehabilitation Center*
- *Impact of Nursing Safety Initiatives on Patient Outcomes*
- *Effect Of Contactless Continuous Patient Monitoring In A Medical-Surgical Unit On Intensive Care Unit Transfers: A Controlled Clinical Trial*
- *Evaluation of EarlySense Device for Automatic Detection of Nocturnal*
- *Cost Savings Attributable To A Continuous Monitoring System In A Medical-Surgical Unit*
- *Recognizing Specific Respiratory Patterns Preceding In-Hospital Clinical Deterioration: a Multi- Center Study*
- *A Continuous Nocturnal Monitoring Device for Predicting Asthma Exacerbation in Children*
- *Anticipating Bed Exit in Hospitalized Patients*
- *The Effect of a Continuous Patient Monitoring System on Reducing Falls and Hospitalization in Skilled Nursing Facilities*
- *Contact-Free Under-the-Mattress Monitoring for Early Recognition of End-of-Life in Med/Surg Units*
- *Contact-Free Under-the-Mattress Monitoring for Early Recognition of and Response to Clinical Deterioration in Medical/Surgical Units*
- *A Novel Monitoring Device for Predicting Asthma Exacerbation in Children*
- *Prediction of Post-Extubation Respiratory Failure by Identifying Non-Reassuring Waveforms*
- *Early Detection of Patient Deterioration Using Novel Monitoring System*