

Opioid Safety & Patient Monitoring *Conference Compendium*

The National Coalition to Promote
Continuous Monitoring of Patients on Opioids
November 14, 2014 | Chicago, IL

AAMI FOUNDATION

Author

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Dedicated to

Lewis Blackman
Amanda Abbiehl
Leah Coufal
John LaChance
Matthew Whitman

And all those who have been harmed or lost their lives due to preventable adverse medical events.

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About the AAMI Foundation

The AAMI Foundation is the 501(c) (3) charitable arm of AAMI, whose mission is to “promote the safe adoption and safe use of healthcare technology.” The AAMI Foundation works with clinicians, healthcare technology professionals, patient advocates, regulators, accreditors, industry, and other important stakeholder groups to identify and address issues that arise from today’s complex medical environment and have the potential to threaten positive patient outcomes.

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National Coalition to Promote Continuous Monitoring of Patients On Opioids *Co-Convening Organizations*

American College of Clinical Engineering (ACCE)

Anesthesia Patient Safety Foundation (APSF)

Armstrong Institute for Patient Safety and Quality

Consumers Advancing Patient Safety (CAPS)

ECRI Institute

Healthcare Technology Foundation (HTF)

International Society for Rapid Response Systems (ISRRS)

Institute for Safe Medication Practices (ISMP)

The Joint Commission (TJC)

Leah's Legacy

Mothers Against Medical Error

National Patient Safety Foundation (NPSF)

Patient Safety Movement

Physician-Patient Alliance for Health and Safety (PPAHS)

Premier Safety Institute

San Diego Patient Safety Council

United States Department of Veteran Affairs National Center for Patient Safety

Conflict of Interest

The AAMI Foundation expresses gratitude to its industry partners for providing financial support allowing for the stakeholder meeting and deliverables to be offered free of charge to all participants. None of the co-convening organizations were involved in any way in seeking, discussing, or otherwise participating in these partnership agreements. All of the costs associated with this project were managed by the AAMI Foundation. Prior to attending the stakeholder meeting on November 14, 2014, all participants were asked to sign the AAMI Foundation's Conflict of Interest Form (COI), stating they had disclosed any potential conflicts on the form. A verbal announcement was made at the in-person meeting by AAMI leadership that all COI forms were available for review by the public. Each speaker was asked to disclose any potential conflicts to the audience, and these disclosures are noted in the conference proceedings.

Thank you to our valued partners for making this coalition possible!

DIAMOND LEVEL



PLATINUM LEVEL



GOLD LEVEL



BRONZE LEVEL



San Diego Patient Safety Council



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Opening Letter

The AAMI Foundation is pleased to present conference proceedings from the first kick-off meeting of the National Coalition to Promote Continuous Monitoring of Patients on Opioids, which was held November 14, 2014, in Chicago, Illinois. Sixty-four stakeholders committed to eliminating patient harm and death due to opioid-induced respiratory depression attended this historic meeting.

For patients in pain, opioids can be essential to their healing and overall well-being. However, opioid use presents serious risks. Hospitalized patients receiving opioids for pain control can suffer respiratory depression that leads to brain injury or death. Lying in bed behind closed doors or at the end of a long hallway, these patients can stop breathing without anyone noticing. Two-thirds of these patients cannot be resuscitated.

Although risk assessment models exist, they may not accurately predict which patients will have adverse reactions to opioids. Periodic monitoring or “spot checks” of these patients on general care floors, performed as infrequently as every two to four hours, will not detect the early onset of problems.

The AAMI Foundation, with the support of key industry partners and other patient safety organizations, has launched a multiyear initiative to highlight this potentially catastrophic patient safety problem and to make the case for a solution that can save lives: continuous electronic monitoring (CEM). Let’s harness the knowledge of clinicians and the power of technology to save lives. **CEM isn’t the only answer, but it’s a fundamental part of any meaningful solution.**

In these conference proceedings, you will read about four families who suffered the death of a loved one due to undetected respiratory depression, as well as the harrowing experience of a patient who narrowly missed becoming another statistic. Individuals from each of these families attended the November 14 meeting, expressing a sincere desire to help others learn from their tragedies and inspiring all of us to make a difference.

Simply put, no family should have to suffer these preventable tragedies.

The good news? CEM to detect the early onset of respiratory decompensation is being used successfully at many hospitals. These hospitals are saving lives by integrating technology as a tool to support the work of clinicians. These conference proceedings highlight solutions that have been proven to not only save lives, but are also cost-effective, creating a return on investment by reducing patient injuries, follow-up care, and ICU transfers. These innovations are freeing up space in operating rooms and ICU suites for new patients rather than victims of in-hospital respiratory arrest.

Many organizations have worked diligently over the last decade to improve opioid safety. We are grateful for their efforts and pleased to partner with them. We want these stakeholders to share their experiences and to work together for solutions. The AAMI Foundation will facilitate the work of the coalition, urging multidisciplinary cooperation to enhance the power and promise of individual organizations to generate change.

Please join us as we rally the healthcare community to share data and successful strategies that advance CEM of patients on opioids as standard operating procedure. We look forward to partnering with all stakeholders to work toward a comprehensive solution to achieve the goal of achieving zero patient deaths due to opioid-induced respiratory depression.

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Introduction

Why this Coalition, Why Now?

An unintended side effect of opioids is that they affect the part of the brain that controls breathing and can cause ventilation to slow or the airway to obstruct, resulting in insufficient oxygen to the lungs. Despite these risks, opioids remain the first choice of analgesic drugs used to manage moderate to severe pain in hospitalized patients. The use of opioids for pain management has always carried risks, but several factors over the past decades have contributed to a rise in adverse events for in-hospital patients receiving opioids.

Background

In 2001, The Joint Commission responded to scientific data suggesting widespread undertreatment of pain by recommending more aggressive pain management.¹ Patient pain ratings are now used to evaluate hospital quality, and in some cases to control reimbursement. Predictably, the use of opioids for pain management has increased. One study examining the impact of this pain therapy standard found that the incidence of opioid-related adverse drug events more than doubled after the standards were established.²

Further, a rise in the use of patient-controlled analgesia (PCA) machines has introduced additional opportunities for adverse drug events. These machines allow patients to self-administer pain medications intravenously by using a computerized pump. They achieve the well-intentioned goal of providing patients more control in managing their pain, but they also introduce risks associated with mistakes in programming or the possibility that someone other than the patient is pressing the button for delivery of pain medication (“PCA by proxy”), both of which can result in fatal respiratory depression.

In addition, patients on general care floors of most hospitals today are often older, overweight, medically complex, and likely to suffer from undiagnosed conditions, such as obstructive sleep apnea. These risk factors increase the chances of adverse events from opioids. Although risk assessment tools have been developed to help clinicians triage patients to appropriately monitored care settings, these tools are not universally implemented, nor are they fail proof. Patients without risk factors may still experience critical respiratory compromise due to opioids.

There have been many efforts to focus attention on this issue and to encourage continuous electronic monitoring (CEM) of patients on opioids to reduce the risk of adverse events from respiratory depression. In 2011, the Anesthesia Patient Safety Foundation (APSF) hosted its second conference on this topic, after first raising awareness of this issue in 2006. While consensus was reached that CEM should be recommended for all patients, it was noted that more

evidence on the safety benefits was needed, including data on how CEM support would affect nursing workflow, alarm fatigue, and demonstrate the return on investment for hospitals implementing this policy. In 2012, The Joint Commission published, *Sentinel Event Alert #49*, which outlines which patients on opioids, at a minimum, should be monitored. In 2013, the Centers for Medicare & Medicaid Services (CMS) proposed a quality measure stating that patients on PCA pumps should be monitored every 2.5 hours by a healthcare worker; in 2014, CMS published stronger guidance to promote electronic monitoring of patients.

Formation of the Coalition

Despite these efforts to increase awareness of preventable harm from opioids, adoption of CEM of patients on opioids on general care floors has been slow. In 2014, the AAMI Foundation decided to bring together a group of stakeholders and organizations that believe 1) preventable harm from opioids is a sizeable threat to patient safety, and 2) evidence supporting the benefits of CEM of patients on opioids, although incomplete, suggests CEM is a viable strategy for reducing preventable harm from opioids (alongside other strategies to reduce opioid prescribing, such as multimodal analgesic techniques). The purpose of the meeting was to highlight institutions and organizations that have overcome barriers to adoption of CEM, with particular emphasis on demonstrating the business case for supporting their capital and workforce investments in the technology, as well as patient and provider acceptance.

On November 14, 2014, AAMI Foundation convened this group of patient-safety focused healthcare professionals, patient advocates, industry partners, professional societies, and regulators to share knowledge, data, and experience on this topic. The meeting marked the formal kick-off of the National Coalition to Promote Continuous Monitoring of Patients on Opioids.

The experts included industry professionals familiar with the technology of CEM, clinicians affected by the workflow changes that such monitoring creates, and researchers who have studied the return on investment accompanying various types of monitoring systems. It is worth emphasizing that the intent of this meeting was not to debate additional scientific evidence required to gain *unanimous* consensus on CEM, nor the merits of continuously monitoring all patients on opioids. The majority of stakeholders agree that CEM must be made available to ALL patients on parenteral opioids and not just those meeting risk criteria.

The presenters illustrated how different CEM technologies were chosen and implemented within their institutions. They discussed utilization of successful strategies to

“Postoperative patients are subjected to significant harm or death while receiving sedating medications without appropriate monitoring and intervention.”

—San Diego Patient Safety Council

overcome barriers and demonstrated various ways implementation can be achieved without causing undue financial burden on hospitals and additional alarm fatigue for front-line caregivers. Most important, they presented the impact of CEM on outcome metrics related to patient safety and value-based, high-quality care.

How Frequently Are Adverse Events Occurring?

The statistics tell the story: Opioids are involved in almost half of all deaths attributed to medication errors.³ Approximately one-third of code blue arrests in hospitals are from respiratory depression,⁴ and about 0.3% of postoperative patients receive naloxone rescue, which reverses the effects of opioids, accounting for up to 20,000 patients annually.⁵

Approximately 350,000 to 750,000 in-hospital cardiac arrests occur annually.⁶ Experts believe that patients suffering unrecognized opioid-induced respiratory arrest on the general care floor may make up a significant proportion of these deaths. The odds of survival for patients suffering in-hospital arrest are not good; only one in five will survive to hospital discharge. Patients in “unmonitored” beds—currently the majority of postsurgical patients on opioid analgesics—are twice as likely as those in monitored beds to receive delayed treatment. Patients arresting at night have only a 15% chance of survival until discharge.⁷ Economic costs are equally high. One study of 40 million hospitalized patients found that U.S. healthcare costs associated with post-operative respiratory failure total \$2 billion.⁸

What Are the Problems with the Current Standard of Care?

Current monitoring protocols at most hospitals call for “spot checks” of patients receiving opioids on general care floors. Spot checks are intermittent electronic monitoring of a patient’s breathing rate and oxygen saturation, typically performed every two to four hours if the patient has no risk factors.

Recognized risk factors include such conditions as obesity, low body weight, sleep apnea, chronic obstructive pulmonary disease, asthma, advanced age, and the concurrent use of other medications with sedative effects, such as sleeping pills, muscle relaxants, and anti-anxiety pills.

Patient safety experts have identified several problems with this approach. First, patients with no known risk factors have suffered critical respiratory depression and died, so called ‘dead in bed.’ They believe none of the risk-prediction models are sufficiently accurate to prevent what the APSF has called a “zero tolerance for preventable harm from opioids.” The APSF concluded, “Risk stratification was shown to be insufficient to eradicate post-operative opioid-induced respiratory depression.”⁹

The literature has shown that more than three-quarters of people with moderate to severe sleep apnea are undiagnosed, with a 7-22% prevalence.¹⁰ With those realities, clinicians cannot accurately identify which patients have which risk factors.

Spot checks assume that patients will show signs of deterioration at the precise moment the clinician is in the room. They do not account for the fact that the spot checks themselves often arouse patients, temporarily spurring their breathing and making them seem more alert, even though patients could fall back into a dangerous state once the clinician leaves their room. Plus, spot checks can only detect respiratory depression once it is in progress. As one researcher said, “Patients having vital signs checked every four hours are left unmonitored 96% of the time.”¹¹

Why Continuous Electronic Monitoring?

Continuous respiratory and other vital sign data from electronic monitors can identify subtle changes in respiration, detect trends, and provide clinicians with actionable information to prevent respiratory depression that is not readily apparent from a two- or four-hour spot check of vital signs. Studies find that in most cases of respiratory arrest, a progressive decline in patients’ vital signs precedes the arrest but is missed. As one researcher says,

“... respiratory depression that culminates in respiratory arrest is an insidious, gradual event, which will escape the notice of the casual observer of intermittent vital signs. Spot checks of ventilatory parameters, such as respiratory rate, SpO₂, or EtCO₂, may miss the gradual deterioration of ventilatory efficiency. CEM, combined with trend analysis and interpretation, will likely detect a patient about to cross the threshold from stable respiratory depression to respiratory decompensation and arrest.”¹²

Reviews of the literature show that adverse events are typically preceded by a period of physiologic instability of

six to eight hours. Researchers have pointed to rapid identification of patient deterioration as the primary determinant of the success of early intervention with medical emergency teams.¹⁴ As stated by one researcher, “Monitoring systems can help facilitate timely interventions for these high-risk patients. They can provide an added layer of care by continually observing hospitalized patients and drawing attention to those who show signs of deterioration.”¹⁵

It should be noted that both CEM, as well as electronic analysis of intermittently acquired vital sign data (with decision-support software), can identify patients at risk for death, and result in reduction in mortality. However, the latter method relies on deterioration that takes place over time, so that staff has the opportunity to perform vital sign measurements during the deterioration process. The tools used in this methodology do not have the capability to detect sudden, random, or episodic deterioration except by serendipity. Therefore, only patients that are continuously electronically monitored will be protected from deterioration over time and from infrequent events like opioid dosing errors or rapid-onset of allergic reactions.

Early Successes

By implementing CEM for respiratory parameters for all patients receiving opioids, several hospitals are seeing dramatic improvements in patient safety, saving money, and accumulating valuable data that can be mined to ultimately improve care for all patients.

St. Joseph's/Candler Health System in Savannah, GA adopted CEM more than 10 years ago and has succeeded in significantly reducing morbidity, mortality, and costs for hospitalized patients receiving opioids. Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire implemented a patient surveillance system based on pulse oximetry with nursing notification of alarms via wireless pagers and saw rescue events decrease from 3.4 to 1.2 per 1,000 patient discharges; ICU transfers dropped from 5.6 to 2.9 per 1,000 patient days.¹⁶ A multi-site study conducted by Eyal Zimlichman, MD, of Sheba Medical Center in Israel, found that by implementing CEM of vital signs (3-lead ECG, SpO₂, ETCO₂) on medical-surgical units the average length of stay per patient was reduced from 4 days to 3.6 days, ICU transfers were reduced by 47.2%, and stage two and above pressure ulcers decreased from 6/1,000 patient to 2/1,000 patients.¹⁸ This resulted in cost savings of \$3,268,000–\$9,089,000, given an 80% prospective reimbursement rate and a net benefit of between \$2,687,000 (\$658,000 annualized) and \$8,508,000 (\$2,085,000 annualized) respectively.¹⁹ Hospitals like these are finding that with increased monitoring, patients have significantly fewer rescues and transfers to

Calls to Action through the Years

July 2003, April 2012—Institute for Safe Medical Practices identifies safety issues with PCA and recommends monitoring patients receiving sedatives with continuous monitoring, using pulse oximeters and capnographers.

April 2004—The Joint Commission issues Sentinel Event Alert 33 warning against “patient-controlled analgesia by proxy,” in which family members and/or healthcare professionals administer drugs for the patient. Also recommends careful monitoring. “Oximetry and/or capnography monitoring may be appropriate in some cases.”

2006, 2009, 2011—Anesthesia Patient Safety Foundation (APSF) recommends that all patients receiving PCA should be monitored continuously.

September 2011—Pennsylvania Patient Safety Authority reports that it had received approximately 4,500 event reports associated with PCA pumps between June 2004 and May 2010.

August 2012—The Joint Commission issues Sentinel Event Alert 49, warning of the risk of adverse events for patients receiving opioid analgesics, “the most serious effect being respiratory depression” which can be caused by inadequate monitoring. “In addition to monitoring respiration and sedation, pulse oximetry can be used to monitor oxygenation, and capnography can be used to monitor ventilation.”

December 2012—Centers for Medicare & Medicaid Services (CMS) releases quality measures under consideration, including a call for “appropriate monitoring” of patients receiving an opioid via an IV PCA device, in proposed quality measure 3040.

Figure 1. Calls to Action through the Years¹⁷

the ICU and better survival if in-hospital arrests do occur. They are also seeing increased bed capacity and revenues from new patients in hospital operating rooms and ICUs.

Developing the Vision Statement

The long-term vision of the AAMI Foundation's National Coalition to Promote Continuous Monitoring of Patients on Opioids is for all “non-do-not-resuscitate (DNR),” patients receiving parenteral opioids, regardless of their risk category, to be continuously electronically monitored to reduce the risk of adverse events and death due to respiratory depression. The coalition recognizes that hospitals providing care to patients face significant barriers to implementing CEM of patients on opioids. These barriers range from hospital-level issues, such as competing financial priorities, to environment of care issues. These environment of care issues may include a shortage of nursing resources and lack of education for nurses regarding the following: the physiology of the vital signs being monitored; how to configure the equipment for individual patients; and how to interpret the data from the technology. Additionally, alarm fatigue is an ongoing concern that must be addressed before additional alarm noises are added to the environment. The education coming out of the AAMI Foundation's National Coalition for Alarm Management Safety will benefit this initiative, providing hospitals with the resources and tools they need to manage their clinical alarm systems.

Vision Statement

We recommend improving the safety for non-DNR*, patients receiving parenteral opioids by supplementing ongoing assessments of sedation level and respiratory status with continuous electronic monitoring and opioid sparing strategies (i.e. multimodal analgesia) for timely detection of respiratory decompensation. Experience from early adopters demonstrates that continuous respiratory monitoring combined with education, culture change, and process improvements—including effective management of clinical alarms—increases the quality of patient care in a financially sustainable manner.

Staging the approach: Hospitals may implement this vision by using a staged approach to address the necessary components, cited above, that are key to success, and by implementing continuous electronic monitoring for patients included under The Joint Commission's Sentinel Event #49 (www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf).

**When deemed appropriate by hospital policy.*

Endorsed

After reviewing these conference proceedings, if your organization would like to sign onto the vision statement, please e-mail **Sarah Lombardi** at slombardi@aami.org.

American College of Clinical Engineering (ACCE)
American Association of Nurse Anesthetists (AANA)
American Association for Respiratory Care (AARC)
American Society for Pain Management Nursing (ASPMN)
Anesthesia Patient Safety Foundation (APSF)
A Promise to Amanda
Consumers Advancing Patient Safety (CAPS)
Hospital Quality Institute (HQI)
Infusion Nurses Society (INS)
Institute for Safe Medication Practices (ISMP)
Leah's Legacy
Mothers Against Medical Error
Physician-Patient Alliance for Health & Safety (PPAHS)
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San Diego Patient Safety Council

The focus of this initiative over the next 24 months is to understand and overcome the barriers hospitals and healthcare professionals face to implementing CEM of patients on opioids. The AAMI Foundation will share and promote scholarly and white paper publication of data from hospitals that have successfully overcome the barriers to implement CEM. The coalition will help hospitals take a graduated approach to expand monitoring of the patient population on parenteral opioids in order to detect declines before an adverse event takes place. Each institution should adopt and adapt the vision statement (left), based on its own resources and capabilities, with the goal of overcoming the barriers to full implementation. It is important to collect baseline data, as well as ongoing data once CEM is implemented, in order to measure the clinical and financial metrics and encourage ongoing process improvement. The coalition will provide the knowledge, tools, and strategies to overcome the identified barriers to help hospitals implement policies to improve outcomes for patients on opioids.

Why 'Parenteral Opioids' in the Vision Statement?

After receiving feedback from clinical and professional societies, the AAMI Foundation recognizes that continuously electronically monitoring all patients on all opioids may be very difficult for some hospitals at this time due to the complexity of the environment; particularly, resource constraints, competing priorities and mandates, and alarm fatigue. In the future, the Foundation would like to see all patients on all opioids monitored, but for the purposes of this initiative the focus is on all those receiving parenteral opioids (i.e. patient-controlled analgesia, neuraxial opioids, etc.) as evidence shows they are particularly at an increased risk for adverse events.¹³

In addition, the vision statement offers an approach for those hospitals that may need to move towards the vision of monitoring all patients on parenteral opioids in phases. The Foundation recommends, as a first step to reaching the vision goal that hospitals, at a minimum, continuously monitor those patients that fall under The Joint Commission's Sentinel Event Alert #49.

During Phase II of this program, the AAMI Foundation will release Safety Innovation white papers, as well as host patient safety seminars and regional events to gradually introduce hospitals to the concept of electronically monitoring patients on opioids. The Foundation also will guide hospitals on implementation with a focus on how to overcome the barriers.

Latest Evidence: Opioids and Cardiopulmonary Arrest

Frank J. Overdyk, MSEE, MD

National Coalition—Chair

Overdyk consults on respiratory monitoring for Covidien, Hospira and Q-Core Medical, Ltd. He was not compensated for his time moderating this conference.

Cardiopulmonary arrest is the most serious adverse event that can occur in the hospital. Despite our best efforts over the last 30 years, outcomes have not changed: more than 70% of patients who have an in-hospital cardiopulmonary arrest (IHCA) suffer an anoxic brain injury or die.

Opioid-induced respiratory depression is commonly accepted as one of the causes of IHCA, and we are now seeing increased attention to the safety risks associated with opioids. We wanted to study the risks of IHCA in patients receiving opioids for analgesia. Unlike initiatives that use chart abstraction of reported adverse events, such as the Get With The Guidelines program, we used a billing database with procedure and diagnosis codes to obtain incidences and risk factors for IHCA, analyzing adult admissions from 2008 to 2012.

Our study found that more than 90,000 patients suffered an IHCA, respiratory arrest, or cardiopulmonary resuscitation (CPR), during that period; patients receiving opioids in addition to medications with sedative properties had a three times greater risk of cardiopulmonary arrest or respiratory arrest over patients who received neither. More than 10,000 of these patients suffered an IHCA on the general care floor, which is where patients with relatively stable conditions are placed. Providers do not expect these patients to have life-threatening events such as IHCA. We were surprised by the size of the increased odds of IHCA for a patient receiving opioids.

When analyzing patients who had a respiratory arrest only (stopped breathing) versus those with a full-blown IHCA (had no pulse and were not breathing), patients in respiratory arrest did somewhat better, with higher survival

“Let’s stop spending money on the treatment of in-hospital arrests and start preventing them instead.”

—Frank Overdyk, MSEE, MD

rates and less brain injury. Because we postulate that earlier detection of problems on the general care floor may prevent patients from progressing from respiratory arrest to IHCA, efforts to improve detection and limit opioid prescribing by combining opioids with other analgesic techniques and drugs should reduce the burden of IHCA.

Many of today’s presentations will focus on hospitals that have successfully reduced complications leading to IHCA by implementing continuous electronic monitoring of patients.

Finally, our economic analysis of the data quantified the annual economic cost of patients suffering an IHCA, expressed in additional length of stay and cost of care. Our study results support the need for education on proper prescribing and monitoring of patient response to opioids and sedating co-medications, along with the use of opioid-sparing analgesic techniques for hospitalized patients.

Let’s stop spending money on the treatment of in-hospital arrests and start preventing them instead.

Summary of Hospital Case Studies

Dartmouth-Hitchcock Medical Center, Lebanon, NH

Making the Business Case for Continuous Patient Monitoring

George Blike, MD, MHCDS

Chief Quality and Value Officer

Professor Anesthesiology

Dartmouth-Hitchcock Medical Center

Blike presented data from a before-and-after study at Dartmouth-Hitchcock Medical Center, which in December 2007 installed Masimo's Patient SafetyNet system. Masimo has supported the Hitchcock Foundation, which helped to fund this research. Blike was not compensated for his time to present at this conference.

Patient safety advocates within a hospital can now make a strong patient safety and quality case to support implementing a continuous monitoring system for all hospital patients on opioids. However, a business case must also be made before hospital senior managers will support such a project. The cost of such a project can be a major barrier to adoption. To persuade senior management of the viability of the project, a sustainable business model must be presented.

Such an argument was successfully made at Dartmouth-Hitchcock Medical Center a number of years ago with excellent results. Our business case can serve as a model for project advocates looking to gain management support for such a system at other hospitals.

Dartmouth-Hitchcock Medical Center began using surveillance monitoring in 2006-2007. The system, initially implemented in a 36-bed orthopedic unit, uses continuous pulse oximetry to assist in early recognition of a patient's deterioration and to alarm for rescue interventions. Our goal was to create a system that could function as a "patient safety airbag," protecting patients from harm and cutting in-hospital deaths following adverse outcomes, such as post-surgical complications. The system has since been expanded hospital-wide; all medical and surgical patients at Dartmouth have been continuously monitored since 2010 with good results. We have seen institutional reductions in rescue events and ICU transfers. No patients have suffered irreversible severe brain damage or died as a result of respiratory depression from opioids since surveillance monitoring was instituted in the original study unit in December 2007.

If you are looking to persuade hospital managers about the viability of a continuous monitoring system, you must understand management cost accounting, the cost structure of the project, and be able to estimate the financial

impact of such a project on the hospital. Without these elements, it is unlikely that you will gain support for undertaking a pilot project or expanding such a project system-wide.

To achieve management buy-in on a project of this size, you must demonstrate the financial sustainability of the intervention. One mission for hospitals is to be around for generations to come. Although I lead quality and safety, I fully understand and respect that we need balance and that we need to have a sustainable business model behind our quality and safety interventions.

For our continuous monitoring project, we understood the process of patient deterioration, as well as the theoretical basis for our intervention and why it would work. We next used rigorous management cost accounting data to understand the cost structure of the process before an implementation versus the cost structure of the process after implementation. We were fortunate to have access to extremely detailed cost data to help us estimate the project impacts. We were not required to conduct a formal return on investment (ROI) analysis, but we did have to demonstrate the long-term financial viability of the project.

Opportunity Costs Annualized (30 patients avoid ICU care)

Year	Marginal Return per Patient	Annual Returns
Start-up Year	\$255	\$817,000
Subsequent Years	\$404	\$1,295,000

Figure 2. Opportunity Costs Annualized (30 patients avoid ICU care)

You must understand how your institution gets paid, how to do an ROI analysis, how to think about seven-year net present value, the weighted cost of capital for your institution, and how your financial leaders are thinking about investment decisions.

What are the key arguments you need to be able to present? You can demonstrate the financial viability of a project in two ways:

1. Show cost reduction or avoidance on either the materials or the salary side. Remember that two-thirds of healthcare costs for any process are people, so rarely can you have big impact without doing salary expense reduction. But in addition, material opportunities can be part of savings, too.
2. Show an opportunity for increased revenues. Sometimes this can be framed as an opportunity cost.

At Dartmouth, we were not able to show decreased costs with the new system because of first-year implementation costs and subsequent maintenance expenses. However, we were able to demonstrate that implementation of the system would result in significant revenue increases.

Capacity in Dartmouth's intensive care units (ICUs) and step-down units is extremely tight. A fair number of patients are diverted from Dartmouth to other nearby hospitals when our units are full, resulting in loss of potential revenues for the hospital. So, we were able to demonstrate that use of surveillance monitoring would result in fewer in-patient transfers into the ICU, thus leaving those spaces available for new patients, resulting in fewer diversions and increased revenues.

Initial implementation costs for our 36-bed pilot unit totaled \$167,993, plus annual maintenance costs of \$58,261. The surveillance system allowed 30 inpatients to avoid ICU care. Our annual opportunity cost savings due to this decreased ICU transfer rate amounted to \$1.4 million for the pilot unit. Since rollout to other units, we have found that cost effectiveness depends primarily on incidence of adverse events and reduction of event rates per unit.

Taking into account the net cost of capital and the investment options available to a hospital, your project will typically need to generate better than a 10% return on

"Clinicians must make the business case for continuous electronic monitoring. You're going to need the help of your finance department and you're going to need to work closely with them."

—George Blike, MD, MHCDS

investment before management will consider it. Using malpractice ("one lawsuit can pay for a system for 10 years") as an argument is not very strong in terms of a sustainable business case. Typically, medical malpractice costs are not actually going to change enough to justify a large expenditure.

Also note that how hospitals get paid matters. If you are able to cut infection rates, costs go down. But, in traditional fee-for-service arrangements, the insurer typically accrues most of those savings while the hospital incurs the costs. In traditional fee-for-service arrangements, safety is sadly really difficult to pay for. Dartmouth is now aggressively moving toward risk payment arrangements because we can create value and quality with projects and capture the cost savings under that structure.

To make a successful business case for your project, you have to understand your intervention, the process, and its impact on quality and safety. You must also be able to understand and present the financial impact of the project. Be aware that senior hospital managers must make difficult choices between many worthwhile projects when considering where to invest the hospital's money. You need to help them prioritize this investment. These are the points and concepts you are going to have to apply if you bring this proposal to senior leadership.

Sheba Medical Center, Tel Hashomer, Israel

Continuous Monitoring on General Floors for Early Recognition of Patient Deterioration

Eyal Zimlichman, MD, MSc (MHCM)

Deputy Director General and Chief Quality Officer, Chaim Sheba Medical Center, Israel

Zimlichman received a research grant from EarlySense to study continuous vital sign monitoring. He was not compensated for his time presenting at this conference.

Patients treated in hospitals have complex needs, but most are still hospitalized in a non-ICU setting. Research shows that 10-20% of hospitalized patients develop complications, and 5-8% of all patients die in hospital. However, 33-50% of these events may be preventable.

In reported studies, between 60% and 84% of patients who have developed cardiac arrest had instability within the eight-hour window preceding the event. Ideally, we would like a nurse to be beside every patient, but that is impossible. Instead, technology can be there. Using continuous vital signs monitoring on the general care floor allows earlier recognition of patient instability and provides an opportunity to intervene. An effective technology for monitoring these low-risk patients must meet several requirements: it must be easy to use by the staff; place few limitations on patients; have a low false positive rate to prevent alarm fatigue; and be cost effective.

We wanted to evaluate the EarlySense™ Monitoring System (EarlySense, Waltham, MA) for potential use as a continuous monitoring system. This system relies upon a piezoelectric-based sensor placed under a patient's mattress. It includes advanced mathematical modeling-based algo-

rithms intended to alert for clinical deterioration (respiration rate, heart rate), pressure ulcers (movement), and patient falls (movement).

A non-interventional prospective study was conducted on the EarlySense™ Monitoring System with medical ward patients at two academic centers.²⁰ Patients admitted with a diagnosis of an acute respiratory condition were monitored for heart rate and respiration rate under a “black box” study protocol with retrospective analysis of data only. For the 113 patients studied, we identified 10 major clinical events (e.g., cardiac arrest, death, or unplanned ICU transfer). The system was found to have a negative predictive value of 95% and a positive predictive value of 50%, which is a very high level of accuracy for any monitor. A 50% positive predictive value indicates that, if you are a nurse on this floor and you hear this system alarm, there is a 50% chance that the patient will either die, need to be transferred to an ICU, or will go through a cardiac arrest in the next 24 hours.

A major outcomes study was next conducted comparing a 33-bed medical-surgical unit (intervention unit) to a “sister” control unit for a nine-month pre-implementation and nine-month post-implementation period.²¹ All beds in the intervention unit were equipped with the EarlySense monitors, which allowed for continuous assessment of heart and respiration rate. Primary outcomes analyzed included transfers to ICU units and length of stay, both overall and ICU. Secondary outcomes included Code Blue events, mortality, and pressure ulcers. Return on investment was also investigated. Study authors hoped to see fewer transfers to the ICU or, alternatively, just as many transfers to the ICU but with lower acuity levels and less time spent in the ICU.

A total of 7,643 patient charts were reviewed (2,314 in the intervention unit and 5,329 in the control unit). Significant findings included the following:

- A significant decrease was seen in the average total length of stay in the intervention unit v. the control unit (from 4 days to 3.6 days).



Figure 3. Trends Screen—all hospitalization - taken from EverOn bed-side unit

Figure 3. Trends Screen—All Hospitalization from EverOn Bed-side Unit

- Total ICU days were significantly lower in the intervention unit (63.5 days per 1000 patients in the intervention unit post-implementation v. 120.1 days in that same unit pre-implementation and 85.36 days in the control unit).
- Rate of transfer to the ICU did not change.
- Rate of Code Blue events decreased in the intervention unit from 6.3 days per 1000 patients (pre-implementation) to 0.9 days (post-implementation).

The average number of alerts from the system was tracked for 73 patients.

There was an average of two alerts per 12-hour shift per nurse, with an estimated 0.6 false alerts per nurse per shift, which is close to the 50% positive predictive value found earlier.

Finally, a financial analysis was conducted to estimate the cost savings attributable to the implementation of the system and to determine the return on investment associated with its implementation. Data on cost and outcomes were obtained from the intervention unit in our study, before and after the intervention was implemented. Cost savings were derived from a decrease in the total hospital length of stay from 4.0 to 3.6 days per patient and a 47.2% decrease in total ICU days, as well as a reduction of stage-two and above pressure ulcers from 6 to 2 per 1,000 patients.

“One study found that monitoring technology pays for itself within 18 months.”

—Eyal Zimlichman, MD, MSc (MHCM)

System implementation costs totaled \$274,000 in capital costs, \$15,000 in one-time noncapital costs, and \$293 in ongoing operational costs to implement the system. The system saved between \$3.2 million (conservative model B) and \$9.1 million (base model A), given an 80% prospective reimbursement rate. This resulted in net benefit of between \$2.7 million (\$658,000 annualized) and \$8.5 million (\$2.1 million annualized). Given these outcomes, the investment in this continuous monitoring technology would be paid back in 0.5 to 1.5 years.

Overall, this intervention was found to be a cost-effective way to address three of the top patient safety failures that cost hospitals money: failure to rescue, pressure ulcers, and postoperative respiratory failure.

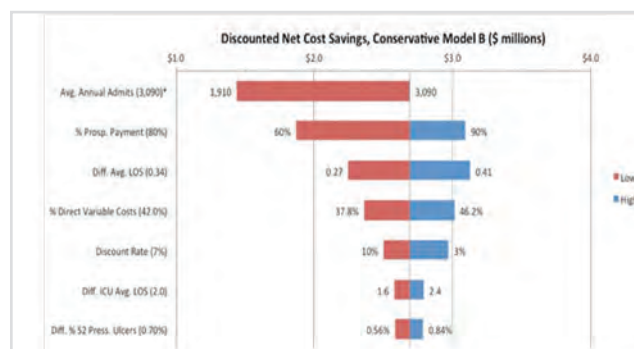
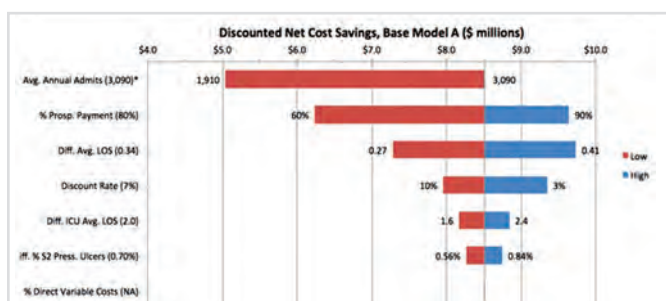


Figure 4. Discounted Net Cost Savings: Base Model A (left) and Conservative Model B (right).²²

Intermountain Healthcare, Salt Lake City, UT

Automated Detection of Sleep Apnea and Physiologic Deterioration Using Computer Decision Support Alerts

R. Scott Evans, MS, PhD, FACMI
 Medical Informatics Director, Intermountain Healthcare

Intermountain Medical Center (IMC) is a 456-bed teaching hospital and Level One trauma facility. It is part of Intermountain Health (IH), which has developed an integrated electronic medical record (EMR) that contains most clinical information including bedside charting by respiratory therapy. We maintain an extensive enterprise data warehouse (EDW) where most clinical and business information is updated every night from all inpatient and outpatient facilities across our system.

Large enterprise data warehouses provide the ability to monitor patient encounters over wide geographic areas, to automate analyses, and to generate decision support alerts. We recently undertook two projects to mine data from our EDW and our EMR to improve the early detection of conditions that can lead to serious patient injury or death. One study investigated whether our data systems could be used to detect hospitalized patients with previously

diagnosed obstructive sleep apnea.²³ The other reports the results of a four-year effort to use current data in our EMR to develop, implement, and evaluate a system to automatically detect physiological deterioration in hospitalized patients.²²

Obstructive sleep apnea (OSA) patients are at elevated risk for hypoxemia, cardiac arrhythmias, stroke, and death during hospitalization. While the condition affects up to 14% of males and 7% of females, it has been estimated that its diagnosis is missed in 82% of males and 93% of females. Further, OSA patients are frequently admitted to the hospital without reporting a previous diagnosis of OSA.

Our goal was to use previous documentation of OSA from our EDW in combination with current patient information from our EMR to find and treat hospitalized patients with OSA. In 2011, we developed and tested a computer application to identify such patients and send an

Category	Unit A intervention	Unit A pre-intervention	Unit B intervention	Unit B pre-intervention
Patients	3189	3423	3100	3169
Average age	59.9*	60.5*	51.3	51.1
Female, %	54*	55*	46	46
Average Charlson comorbidity (range)	2.04(0-12)*	2.07(0-13)*	.68 (0-13)	.76(0-12)
Average LOS, days	4.9**	4.4	4.3	4.1
Average cost of hospitalization, \$	12813***	11 509	15929	15700
MET calls	60#	29	21	11
Transferred to ICU (%)	163 (5.1)	146 (4.3)	72 (2.3)	71 (2.2)
Died (%)	84 (2.6)##	125 (3.7)	19 (.6)	17 (.5)
Average physiologic deterioration score (range), died	5.2 (4-16)*	-	7 (4-11)*	-
Average physiologic deterioration score (range), did not die	4.5 (4-8)	-	4.7 (4-11)	-
Average physiologic deterioration score (range), transferred to ICU	4.6 (4-8)	-	5 (4-7)	-
Average physiologic deterioration score (range), not transferred to ICU	4.6 (4-16)	-	5 (4-11)	-

Figure 5. Comparison of Patients and Outcomes in Unit A and Unit B during the Intervention and Pre-intervention Years²⁴

OSA patient alert via secure e-mail to our respiratory therapy supervisors. Identified patients who agreed to the treatment were placed on positive airway pressure (PAP) machines if they wore a PAP at home or if a PAP had previously been prescribed for them. Over a 20-month study period, we compared patients at IMC treated during the time before (2011) and after (2012) OSA monitor alerts were implemented. Our evaluation showed that significantly more of the OSA patients received respiratory therapy in 2012 compared to 2011, while significantly fewer OSA patients had an SpO₂ of less than 90% in 2012. The impact was greater for non-surgery patients compared to surgery patients. In summary, the computer alerts resulted in significantly more OSA patients receiving appropriate medical care and significantly fewer experiencing hypoxemia. The system has since been installed at all 22 Intermountain Health hospitals.

Our second study reports the results of a four-year effort to create an automated detection and alert system for

physiological deterioration using our EMR that meets nursing workflow requirements and gains their approval. The effort was launched to help nurses determine when to call our Medical Emergency Team (MET) due to deteriorating patient conditions.

After extensive development and testing, we implemented an automated system that polls our EMR every five minutes for data from each patient. The system relies upon a physiological detection model (similar to the Modified Early Warning Score [MEWS] system) that includes 11 patient parameters. Five of those parameters represent the patient's vital signs (systolic blood pressure, heart rate, temperature, respiratory rate, oxygen), and six represent different mental status scores charted by nursing staff (Rancho scale, nurse level of consciousness documentation, IH sedation score, Glasgow Coma Score, Confusion Assessment Method, and Richmond Agitation Sedation Scale). Each parameter is scored on a four-point scale, and an alert (a page sent to the charge nurse) is generated when a patient's total score reaches four or higher.

A graphical vital signs display of the physiologic deterioration alerts was also created to allow nurses to quickly evaluate patient status.

The intervention was tested for a one-year period on two different nursing units: Unit A and Unit B. We found that the computerized decision support system provided an effective way to constantly monitor patients and notify nursing staff of early physiologic deterioration. We saw a significant increase in appropriate MET calls and a significant decrease in mortality in Unit A, which had older patients with multiple comorbidities. No significant differences were found on Unit B.

Nurses reported that the positive predictive value of the alerts was 91% to 100%, depending on erroneous data present. High nursing acceptance of the system was achieved. Nurses reported that the graphical alerts helped them more quickly evaluate patients, and that the system helped them feel more comfortable about their assessment and more comfortable requesting help. The physiologic deterioration alerts have since been implemented in twelve other units at two other hospitals and will be installed in a third hospital by the end of 2014. We are currently ramping up capabilities to install them at all nursing units in all 22 IH hospitals.

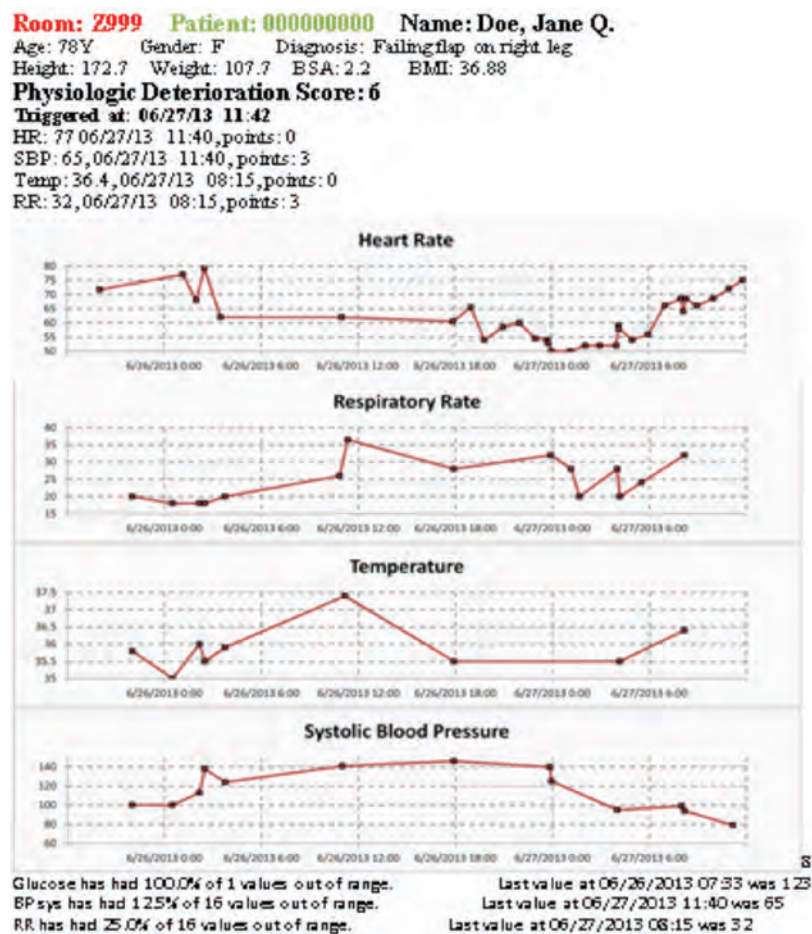


Figure 6. Automated Detection of Physiologic Deterioration in Hospitalized Patients²⁵

St. Joseph's/Candler Health System, Savannah, GA

Using Smart Pumps and Continuous PCA Monitoring: Results and ROI

Ray R. Maddox, PharmD, FASHP

Director, Clinical Pharmacy, Research & Pulmonary Medicine, St. Joseph's/Candler Health System

Maddox has received honoraria from CareFusion and Oridion for invited presentations at various professional clinical and pharmaceutical meetings concerning respiratory monitoring and opioid therapy. He was not compensated for his time presenting at this conference.

St. Joseph's/Candler Health System (SJCHS), a 644-bed, two-hospital health system in southeastern Georgia, has more than 10 years of experience with continuous respiratory monitoring of patient-controlled analgesia (PCA)



Figure 7. CareFusion Alaris Pump

patients. Several problems led to our investment in this technology. Prior to 2002, we had four different infusion devices for different areas of the hospital. We wanted to establish a single infusion platform to promote safety and staff familiarity throughout the hospitals. We experienced three critical events in young, healthy males over a six-month period related to sedation and PCA, and two pediatric patients experienced analgesia/anesthesia-related problems. As a result of these events and other industry safety alerts, we initiated an evaluation of infusion technology and decided to implement the CareFusion Alaris smart infusion technology in 2002.

To apply smart technology to PCA pumps, we first developed a “best practice” data set of dosing parameters. We were successful at averting several programming errors by implementing this technology. We next decided to implement a continuous respiratory monitoring system for patients on these devices. We evaluated pulse oximetry but decided that it had several limitations in this application, perhaps most significantly that it is a late detector of

	Fiscal 2002	Fiscal 2003	Fiscal 2004	Fiscal 2005	Fiscal 2006	Fiscal 2007	Total
Capital purchases ^a	(\$606,515)		(\$955,250)	(\$11,110)			(\$1,572,875)
Disposables saved ^b		\$28,193	\$29,039	\$29,910	\$30,807	\$31,731	\$149,680
Cost avoidance ^c		\$695,271	\$721,985	\$812,254	\$848,750	\$892,036	\$3,970,296
Totals	(\$606,515)	\$723,464	(\$204,226)	\$831,054	\$879,557	\$923,767	\$2,547,101
Cost per ADE assuming 6% inflation to 2006		\$7,725	\$8,022	\$8,374	\$8,750	\$9,196	
Count of ADEs averted (increase of 7 per year in fiscal year 2005)		90	90	97	97	97	471
IRR							81%
NPV ^d							\$1,866,973

^aAssumed capital bought at start of each fiscal year regardless of actual month of purchase; ^bDisposables savings spread evenly over 5 years and inflated 3% per year; ^cCost avoidance uses 2006 as base, deflated by Consumer Price Index Medical Care Component; ^dNet present value (NPV) discount rate used is 6%; ADE = adverse drug event; IRR = internal rate of return.

Figure 8. ROI of IV Smart Pump with PCA

respiratory depression. Capnography was determined to be a better indicator of drug-induced respiratory depression. We therefore made the decision to monitor all PCA patients with EtCO₂, and invested in this technology over the next five to six years.

Continuous electronic monitoring has made a tremendous difference in patient outcomes at SJCHS since it was implemented in 2004. We have had no serious outcomes associated with PCA therapy since that time. We have also seen a significant reduction in our liability self-insurance costs.

Wireless connectivity for the system was implemented in 2004. This technology increased ease of use and allowed timely system changes to prevent future errors.

Some of the key lessons learned during our decade of experience with this technology include the following:

- Undiagnosed sleep apnea is more prevalent than expected.
- Patients will comply with wearing a nasal cannula more easily when educated on the safety benefits.
- Nurses and physicians outside of critical care need education to interpret and utilize EtCO₂ data.
- Respiratory therapists have an important role to play; they have strong clinical assessment and intervention skills and are available around the clock.

Capnographic monitoring is now also used for all patients receiving epidural PCA, Dilaudid intravenous doses, and procedural sedation in nontraditional locations

like the emergency department, as well as for periodic monitoring of chronic obstructive pulmonary disease and asthma patients in some areas.

The net cost of the system over five years was \$1,423,195. Safety improvements resulting from the system allowed us to avoid 471 adverse drug events over that period, thereby avoiding costs of \$3,970,296. Investment in these systems provided a five-year return on investment (ROI) of \$1.87 million, with an internal rate of return of 81%.²⁶

“Continuous electronic monitoring has made a tremendous difference in patient outcomes at SJCHS since it was implemented in 2004. We have had no serious outcomes associated with PCA therapy since that time. We have also seen a significant reduction in our liability self-insurance costs.”

—Ray R. Maddox, PharmD, FASHP

SJCHS Policy for Continuous Monitoring

- All patients receiving IV PCA receive EtCO₂; some also receive SpO₂
- Patients receiving IV hydromorphone doses > 2mg intermittently
- Patients receiving hydromorphone doses more frequently than Q3H (i.e., 1mg IV Q2H)
- Postpartum patients receiving epidural administration require both EtCO₂ and SpO₂ for a minimum of 6 hrs after the last dose of epidural/intrathecal narcotic
- Procedural sedation in nontraditional locations (ED, GI, EP lab and bronchoscopy suite)

Vanderbilt University Medical Center, Nashville, TN

Bedside Monitoring at Vanderbilt: The Road to Implementation

Brian Rothman, MD

Assistant Professor, Anesthesiology, Medical Director, Perioperative Informatics, Vanderbilt University Medical Center

Failure to rescue—a hospital death following an adverse occurrence—is a key safety target for healthcare systems. Retrospective reviews demonstrate that adverse events are preceded by a period of physiologic instability six to eight hours prior to the event. Early recognition of such physiologic change prompts early intervention, potentially minimizing the occurrence of escalation of care and adverse events.

Most hospitals do not currently use continuous patient physiologic monitoring outside of intensive care units. At Vanderbilt, we are implementing a continuous physiologic monitoring system for general care floor patients. The system was designed to facilitate early recognition of deterioration and cue rescue interventions with notifications to a patient's nurse via pager when limits are violated, and escalation of those alerts if the nurse does not respond.

For our project pilot, we installed a Covidien Vital Sync monitoring platform with Nellcor pulse oximetry probes to measure patient vital signs and deliver values to a database. Algorithms were established within the Covidien platform that generates alerts and escalations, which are distributed via a Connexall system. Parameters initially monitored included pulse oximetry and heart rate. The system was piloted on two general care floors.

We had to establish a technical support model, governance plan, data retention policy, and alarm limits. We set the alarms for low thresholds and wide ranges, with sufficient latencies to offset artifacts and decrease false positives. Our goal was for nurses to know that when they received a system notification, they should immediately visit the patient. If the initial alert persisted for 15 seconds without response, a second alert was sent to the nurse/care partner. If the alert still did not result in a nurse at the patient's bedside after 15 seconds, an escalated alert was then directed to the charge nurse/staff leader.

In planning the project, we assumed that our facility's wireless infrastructure could support this increased use by new devices and the real-time data flow that would be required; that sufficient data center storage space was available; and that the technology would be scalable from the pilot's two floors to over 300 beds. However, we ran into Wi-Fi connectivity issues. Our connectivity was inconsistent. Monitors could not all be linked to patients or staff, and escalations of alerts did not occur when monitors were not connected. We originally thought the issue was vendor-based, but it turned out to be a hospital-wide configuration issue. By working to resolve the connectivity problems with our monitoring system, we were ultimately able to improve Wi-Fi performance hospital-wide. Other issues encountered during the pilot included data collection ceasing with server failure and the reporting function not always being available.

Nursing acceptance was another major barrier that had to be overcome. Nurses were concerned about connectivity; ergonomic impact; perceived unreliability of the system; usability of the software programs; lack of support; cleaning of machines; and that monitors were not available for all patients at risk. Further, the project did negatively affect patient satisfaction. Patients complained that the finger probes were uncomfortable, interfered with personal hygiene, impeded mobility, and resulted in too many false positives that brought nursing staff to their rooms. Yet, for all these complaints, nurses wanted the system to work, and when the pilot was over, they did not want the monitors to be removed.

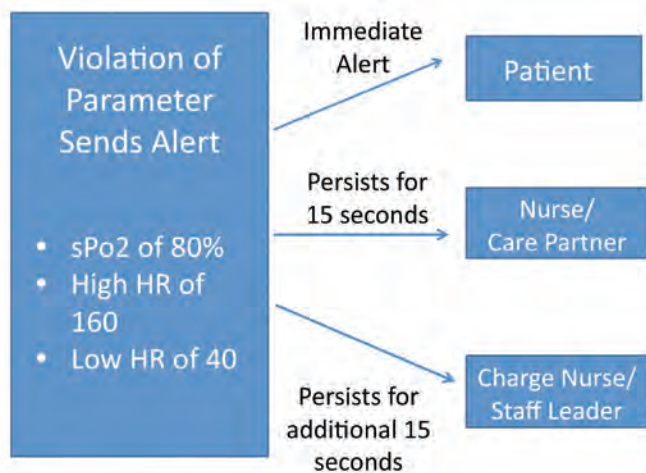


Figure 9. Alert Parameters and Escalation Pages

Adverse events were successfully avoided during and shortly after the pilot phase. A pulmonary embolism was identified early and treated in one patient with an excellent outcome. A case of hypoglycemia was treated with no ICU transfer, and a patient with new onset atrial fibrillation was transferred and rescued.

Our results were promising but inconclusive, with a positive trend that did not reach the level of statistical significance. We saw two patient saves and decreased rapid response team calls during the pilot, with fewer ICU admissions and shorter length of stay for patients without care escalation.

As we move forward, we aim to achieve the following milestones:

- Improved nursing satisfaction
- Decreased use of Narcan in units
- Decreased code rate on surgical units
- Better identification of patients at risk for obstructive sleep apnea
- Earlier interventions and increased awareness of risks with patient-controlled analgesia (PCA) and epidurals.

“Periodic monitoring of patients is akin to opening the refrigerator door to see if the light is on...not effective.”

—Brian Rothman, MD

In January 2015, we will begin to roll out continuous monitoring of postoperative patients hospital-wide, and further support the current continual monitoring of patients upon initiation of PCA, additions to basal narcotic rates, or continuous narcotic infusions.

CHI Health–St. Francis, Grand Island, NE

Capnography Monitoring for Patients Receiving Opiate Analgesia

Pamela Pohlenz, BS, RRT

Respiratory Clinical Educator, CHI Health–St. Francis

CHI Health–St. Francis is a 160-bed regional referral center and Level III trauma center in Grand Island, Nebraska with a 16-bed intensive care unit (ICU). Serious safety events led us to focus on risks to patients receiving narcotics via patient-controlled analgesia (PCA) machines. A review of our baseline narcotic reversal data for 2009 revealed that PCA delivery was involved in 50% of reversals for a total 13 surgical and six nonsurgical patients, far higher than any other cause that year.

“Our PCA reversals dropped from 19 in 2009 to only eight in 2010, our first year with continuous monitoring.”

— Pamela Pohlenz, BS, RRT

A multidisciplinary team was convened to examine our PCA process, with respiratory care, nursing, and pharmacy partnering with our anesthesia department. We reviewed the APSF recommendation to use capnography on patients and conducted a literature search, which found that the benefits of continuous capnography are many. It provides a continuous EtCO₂ waveform that changes from breath to breath. This waveform shape can be used to validate breathing and

airway integrity, offering the earliest indicator of hypoventilation, airway obstruction, or no breath.

Because our respiratory monitoring devices were in need of replacement, we decided to invest in a capnography monitoring system. PCA orders were revised to include capnography on a risk-stratified population. The Respiratory Care Department budgeted for 25 oximetry/capnography monitors. An education program was conducted for physicians, nurses, and respiratory therapists. The new process was implemented in June and July, 2010. We hoped to increase safety for our patients receiving narcotics by decreasing reversals, prevent the need to increase level of care, and maintain stable or improved pain scores.

Our results have been positive. Our PCA reversals dropped from 19 in 2009 to only eight in 2010, our first year with continuous monitoring. In 2009, eight patients saw an increase in level of care; in the four years since implementing continuous monitoring, only two patients experienced an increase in level of care. Our pain scores have remained stable. With continuous monitoring, we believe that we now have a more complete clinical picture of the respiratory patient. We have also raised awareness of the risks of respiratory suppression with narcotic use.

We did not originally see this as a cost-saving venture; we knew that it was going to be a benefit to the hospital on multiple levels. The Institute of Medicine estimates that the cost of managing a serious adverse drug event is \$8,750 per occurrence.²⁷ Using that figure, by avoiding eight such events per year, we would estimate cost savings of approximately \$70,000 per year.

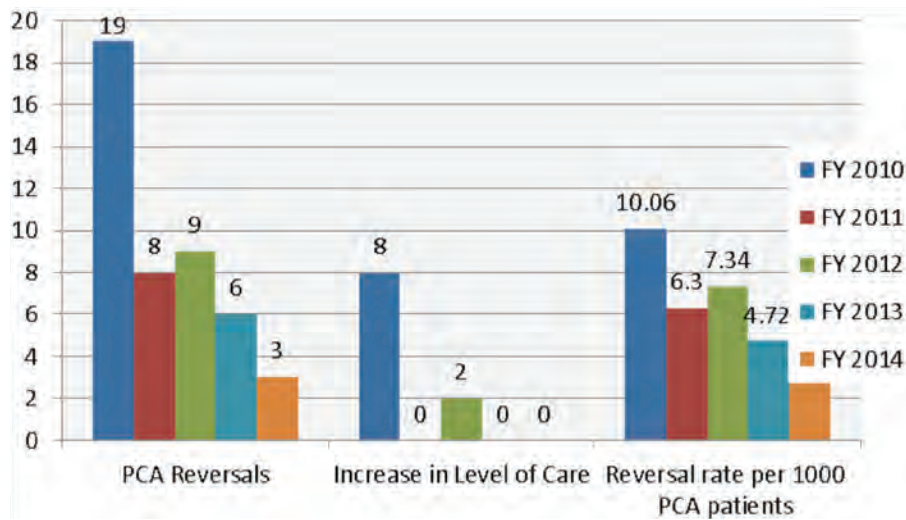


Figure 10. CHI Health—St. Francis—Results / PCA Reversals by Year

Factors critical to the success of this project included administration and budgetary support; physician approval of order set revision, including capnography; replacing basic oximetry monitors with capnography devices that monitor multiple respiratory parameters; staff education; and ongoing quality monitoring by pharmacy, respiratory therapy, and nursing. Critical factors to watch include the risk of alarm desensitization and the need for continual coaching regarding process improvement to both staff and patients. It is also very important to share successes with staff, continuing to motivate them toward a culture of change and patient safety.

We have since purchased 15 more capnography machines to support expanded uses. In October 2012, we narrowed the risk factors and added narcotic naïve to reach more of the population. As of November 2014, we have eliminated consideration of any risk factors and are now placing EtCO₂ on all patients receiving narcotics. Once we saw the benefits, we wanted that protection for all patients, regardless of risk stratification. The technology is now being used on all in-patient floors, as well as in the emergency room and interventional labs.

The Johns Hopkins Hospital, Baltimore, MD

Early Detection of Patient Deterioration Using Remote Patient Monitoring with Wireless Nurse Notification

Sue Carol Verrillo, RN, MSN, CRRN
Nurse Manager, The Johns Hopkins Hospital

Verillo was involved in a pilot project at Johns Hopkins Hospital to study the impact of surveillance monitoring. The general support, supplies, equipment and software for this project was supplied by Masimo. Verillo was not compensated for her work on that pilot study or for her time presenting at this conference.

In recent years, mounting evidence about the value of continuous patient monitoring has led the APSTF, TJC, and CMS to make announcements in support of the practice. At Johns Hopkins Hospital, we aim to be a high-reliability institution. Zayed 11 East is a 32-bed adult surgical general care unit that serves general orthopedics/spine, trauma, general surgery, and neuro patients and experiences significant daily patient turnover. We initiated a pilot of remote patient surveillance monitoring in February 2014 to determine if a noninvasive system could provide earlier detection of and response to patient deterioration. It was important to

integrate alarm management with the current nurse call system and develop a meaningful alarm notification algorithm that had a low false alarm rate.

From a nursing perspective, we already knew that the every four-hour vital signs checks on patients who had patient-controlled analgesia (PCA) systems were only giving a three-minute snapshot on a patient's condition. For the other three hours and 57 minutes, we assumed the patient was maintaining the baseline we saw in the vital signs and were expecting the continuous surveillance monitoring to show that dynamic. The data showed quite the opposite. We soon realized that the widely divergent and continuous information the surveillance monitoring was producing gave us the data we needed to intervene sooner, avert rapidly advancing clinical deterioration, improve patient outcomes, prevent failure to rescue, and better utilize our scarce higher level of care bed resources.

The pilot project used the Masimo Patient Safety Net system, which features a central view station that continuously displays and trends data, as well as remote bedside

- FDA approved Masimo Patient Safety Net System
 - Central View Station:
 - Continuously view and trend data
 - Remote Bedside Data Collection:
 - Motion and low perfusion pulse oximetry
 - Heart Rate Monitoring
 - Acoustic Respiratory Rate Monitoring



Figure 11. Data Collection System—Masimo Patient Safety Net System

data collection. An acoustic Doppler sensor picks up respiration rate and the fingertip sensor picks up heart rate and low perfusion pulse oximetry.

We spent three months providing education and training and went live with the full unit in February 2014. Since then, we have been collecting data. We set pre-determined alarm parameters that use a lower threshold in order to reduce delivery of self-correcting alarms. Alarms sound at heart rates of less than 45 or greater than 135 beats per minute; SpO₂ values less than 85%; and respiratory rates less than six or greater than 36 breaths per minute. Alarm notification was achieved by integrating Connexall middleware, which handles assignment management and executes a pre-determined alarm escalation, with our existing Ascom wireless communication system for alarm notification.

We wanted to ensure that the alarms were meaningful so nurses would pay attention to them and see the value of the system. Our alarms algorithm has two built-in delays: a 15-second delay from the monitor to the patient, to allow the patient time to self-correct; and a 30-second delay until the alarm is sent to the nurse on an Ascom phone. By setting these parameters and using these delays, we have significantly decreased our false alarm rate to about 10%. The nurses have bought into the idea that alarms on their Ascom phones are real and that they better go check their patient when they receive an alarm.

As a further step, we ask nurses to document actionable alarms in our clinical documentation system with an event marker and a notation about what they did in response to an alarm. This practice has greatly strengthened our data collection.

Approximately 500 patients have been monitored using the system since its implementation. Early on, we had an unexpected death due to a very unusual chemoembolization. The system alarmed repeatedly as the patient deteriorated. Although we were not able to save the patient, the nurses saw the value of the system. They saw that the system worked.

We have already learned many lessons from this pilot. Multi-system technical integration, software optimization, and connectivity are tough. Education was required to change staff perspectives on patient conditions. Alarm fatigue is a real issue, and it is essential to make wireless

“From a nursing perspective, we already knew that the every 4-hour vital signs checks on patients who had patient-controlled analgesia (PCA) systems were only giving a 3-minute snapshot on a patient’s condition. For the other 3 hours and 57 minutes, we assumed the patient was maintaining the baseline we saw in the vital signs and were expecting the continuous surveillance monitoring to show that dynamic. The data showed quite the opposite.”

—Sue Carol Verrillo, RN, MSN, CRRN

alarm messaging meaningful. Patient engagement was also challenging, as we saw resistance to wearing the required monitoring devices and complaints that the hard-wired devices interfered with activity/independence. Staff training was another ongoing challenge with the use of float staff and the onboarding of new staff.

This pilot study is underway, so we do not have comprehensive patient results or financial return on investment data yet. So far, we have seen 17 activations of our rapid response team and 10 ICU transfers. New onset arrhythmias were identified in five patients. There were four codes with two deaths on the unit, and two patients were transferred to a higher level of care. We are seeing more early intervention and more team management of conditions.

Planning is in the early stages to run a pilot with Sotera’s Visi Wireless continuous surveillance monitoring system. Our facility-wide surveillance monitoring policy is under development with rollout planned for January 2016.

Saint Agnes Hospital, Baltimore, MD

From Engagement to Implementation: Initiation of Continuous Pulse Oximetry in a Teaching Hospital

Kenneth P. Rothfield, MD, MBA

System Chief Medical Officer, Saint Vincent's Healthcare

Editor's Note: The following presentation was based on Rothfield's former employment at Saint Agnes Hospital

How can we build engagement in support of continuous monitoring? Many of us are still struggling with that challenge, even though over sedation and respiratory depression caused by opioids are now well-recognized causes of patient harm. Too often, patients at risk are not identified or monitored. The Joint Commission and others have now charged hospitals with preventing these injuries. The APSF got it right back in 2011 when it stated, "no patient should be harmed by opioid-induced respiratory depression." Importantly, the APSF realized that our ability to perform risk stratification is imperfect, and that we

should just be monitoring all postoperative patients.

Despite these recommendations, many healthcare organizations are not aggressively addressing the issue. Some are complacent. Some accept respiratory depression as the "cost of doing business." Some cite financial barriers, and others say there is no burning reason to make a change.

At Saint Agnes Hospital, a 400-bed community teaching hospital in Baltimore, our group critically re-evaluated our continuous monitoring policies. In 2010, we added more than 50 channels of continuous pulse oximetry. Unfortunately, the system received minimal use (10-20% of capacity) for monitoring for respiratory depression. During

Patients at Risk for Oversedation and/or Respiratory Depression	
<ul style="list-style-type: none">• Elderly (>65 yrs)• Pulmonary Disease• Obstructive Sleep Apnea (see STOP BANG tool on back to assess risk)• Obesity• Other sedating medications• ESRD/ESLD	
RDR STATUS ASSESSMENT	
GREEN all below present:	
<ul style="list-style-type: none">• Pulse ≥ 50 and ≤ 110, + stable• RR ≥ 10, and ≤ 20, + stable• No slurring of speech• RASS 0 or -2	
YELLOW any below present:	
<ul style="list-style-type: none">• Risk or known OSA, COPD• Mild slurring of speech• RASS -3• Mild lid ptosis but pupils OK	
RED any below present:	
<ul style="list-style-type: none">• P ≥ 120 or ≤ 50 or RR ≥ 30 or ≤ 10• RASS -4 or -5 concern• Severe lid ptosis or pinpoint pupils	<ul style="list-style-type: none">• ALOC or very slurred speech• Other RN discretion or

Figure 12. Respiratory Depression Risk Status Assessment

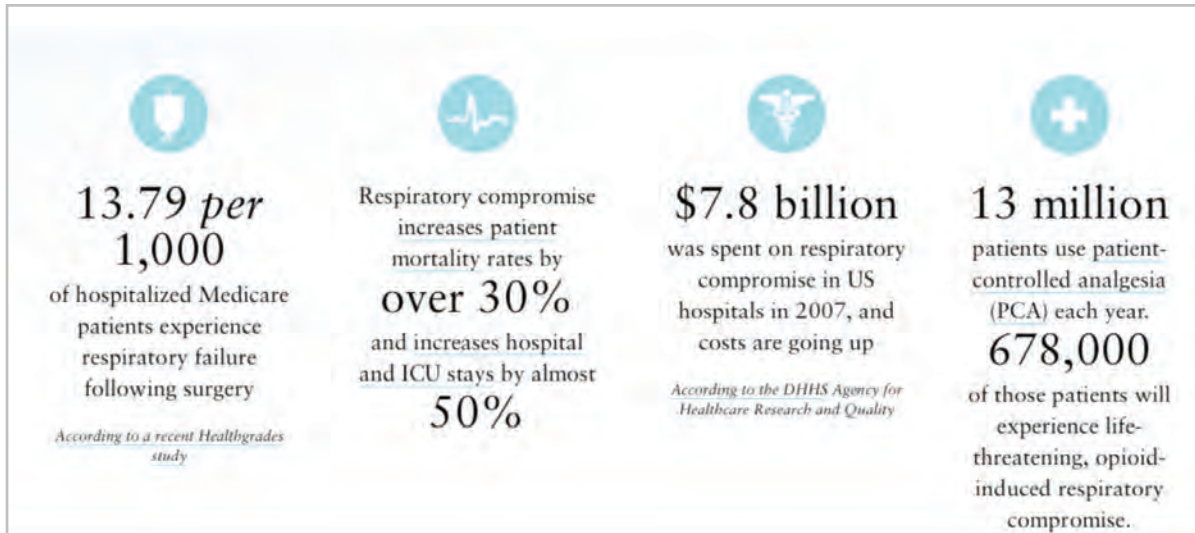


Figure 13. Physician-Patient Alliance for Health & Safety's Respiratory Compromise Institute

our re-evaluation, we put together a multidisciplinary stakeholder team including representatives from nursing, critical care/pulmonology, anesthesiology, respiratory therapy, and nurse educators. They were charged with revising the policy to address The Joint Commission's Sentinel Event Alert 49 on safe use of opioids in hospitals.

The committee called for automatic monitoring of all patients on patient-controlled analgesia (PCA) machines and all patients with a diagnosis or suspected diagnosis of obstructive sleep apnea (OSA). It recommended that the STOP-BANG questionnaire should be used to screen all surgical patients for OSA. The policy also called for improvements in nursing and medical staff education.

In addition, a Sedation Safety Committee was formed to regularly review all cases of pharmacologic reversal use, as well as complications of procedural sedation. These reviews are offering insight into over sedation when a nurse fails to assess patient level of sedation prior to opioid administration. In order to improve nursing skills in opioid safety, we placed an emphasis on bedside evaluation before administering an additional dose of opioid. We adopted training and education for nurses to remind them to look at patients' level of sedation, not just respiratory rate.

We have made things better at our hospital, but we still face many challenges. We continue to evaluate our alarm limits to avoid alarm fatigue. By making pulse oximetry mandatory with PCA, I worry that we have created the false

"No hospital should have a budget for allowable, preventable patient deaths."

—Kenneth Rothfield, MD, MBA

impression that PCA is dangerous, but bolus opioids are somehow safer, which of course is not the case. Getting away from the idea that PCA is the culprit is very important, and that will be a challenge for all of us to educate our peers.

To really create a burning platform for change in your own hospital, be sure to start the discussion from the individual patient perspective, using storytelling to illustrate the dangers to patients. While it is very important for leadership and for anyone else who wants to be a change agent to understand the business of medicine, the business side is not everything. No hospital should have a budget for allowable, preventable patient deaths. Although there may be other hospital investments that have a higher rate of return, opioid-induced respiratory depression is a problem that we cannot afford not to fix.

Stakeholder Perspectives

Westchester Medical Center, Valhalla, NY

The Clinical Voice: Is Continuous Monitoring the Answer?

Maureen Cooney, RN, DNP, NP-BC

Nurse Practitioner, Pain Management, Westchester Medical Center

In addition to my work as a nurse practitioner in pain management in an academic medical center, I work with other organizations to help them with their pain processes, and serve on the board of directors of the American Society of Pain Management Nursing (ASPMN). First, a question: Is continuous monitoring really the answer? I would say no, that what we really need is an integrated approach to assuring safety for our patients on opioid therapy. There is no one answer here. Education is important; a culture of vigilance and safety is important; and the ability to monitor our patients with relevant technology is important.

“Whatever we do with the technology, we have to do it in a way to make sure the data is meaningful.”

—Maureen Cooney, RN, DNP, NP-BC

In my clinical practice, I have found that it is very difficult to impart an understanding of EtCO₂ to the clinician at the bedside. Consistent efforts to educate the bedside floor nurse related to risk factors for respiratory depression and the use of EtCO₂ must be undertaken. Use of case studies and simulation exercises are necessary to assure competence in the care of patients receiving opioid therapy. There is often a knowledge gap, as the understanding and recognition of opioid induced advancing sedation and respiratory depression require high-level critical thinking skills to analyze the data and derive appropriate actions.

Patient education and satisfaction related to the use of monitoring devices are major problems. Nurses need to understand and recognize the need to educate patients about the value and benefit of this technology. Alarm noise is a source of patient complaints, but also an

education opportunity. Yes, alarms may be annoying, but much of the time, the alarm is what is waking the patient up and preventing some of the negative outcomes that we know exist.

In addition to monitoring, facilities have implemented several other measures that can improve opioid safety. Many avoid basal opioid infusions outside the ICU setting. Many have increased use of regional anesthesia techniques, and have been getting support from pharmacy to use multimodal agents to reduce overall use of opioids. The safety features built into “smart” pump systems like guardrails and dosing restrictions are also very helpful.

Another important safety measure is to use a standardized sedation scale for patients who are receiving opioids. Hospitals have revised policies to include use of sedation scales and to impress on our nurses how important it is to evaluate how patients are tolerating opioids.

Most hospitals struggle with identifying the appropriate time frames for monitoring and nursing assessment of patients on opioid therapy. When monitoring is intermittent there is always the risk that a patient’s untoward response to a dose of medication will initially be unrecognized. Even continuous technological monitoring does not identify the early indicator of increasing sedation and does not guarantee that someone will be watching the monitor. In some hospitals, for patients in the first 12 hours of PCA or opioid epidural, nurses are required to monitor vital signs, respiratory status, and sedation level every hour. After 12 hours, patients are monitored every two hours, and then if everything goes well, every four hours. However, despite this frequency of monitoring, there is the risk that the nurses are not getting back to the patient at the time they need to be there.

I am not certain that continuous monitoring is really where all the focus should be at this time. We need nurses to be able to exercise critical thinking to allow them to do something with the information that they are getting.

There are many difficulties and challenges related to continuous monitoring, including the following:

- Recognizing and prioritizing high-risk patients
- No universally recognized definition for respiratory depression
- Inconsistent use of tools to identify patients at risk for obstructive sleep apnea

- Routine use of supplemental oxygen, which artificially elevates oxygen saturation readings
- Vital signs monitoring delegated to support staff
- Lack of central monitoring
- Lack of skills to assess sedation levels

There is also a problem among nurses with the perceived usefulness of end-tidal CO₂ data. Having data can be great, but if nurses don't perceive it as being of value and easy to use, we've lost them. The interpretation of the waveforms has to be simple, applicable, and accurate. Correlating the data with the assessment findings is critical, as is intervening based on the assessment results. Modifying parameters to avoid alarm fatigue is important. And the technology must be affordable enough to be used on a wide patient population.

The ASPMN stands ready to work collectively with other stakeholders in this area. Nurses are very ready and willing to work as part of a multidisciplinary team, because it has to be a multidisciplinary effort to make sure our patients are safe.

ASPMN Membership Survey of Current Practice

ASPMN surveyed its members in 2009 and again in 2013 to see if increased awareness of opioid-induced respiratory depression was making a difference in practice.²⁸

The good news is that we are increasing our monitoring of patients, particularly with continuous pulse oximetry. End-tidal CO₂ monitoring usage has increased out of the single digits, but it still has a long way to go. When asked

about usefulness of monitoring practices, nurses said that they found the following most useful: Nurses' eyes on the patients; use of the sedation scale; and the screening for high risk in increasing monitoring strategies. Continual pulse oximetry was cited as useful by 76% of respondents, and EtCO₂ monitoring was found useful by 49% of respondents. If nurses don't perceive something as useful, they are not likely to use it, or they will gather the data, but it will be meaningless to them.

Less than half of nurses believe that pain management has improved with continuous monitoring, and 23% believe that clinicians are now more reluctant to administer or prescribe opioids or opioid-based treatments.

For EtCO₂ monitoring to be optimally effective, it must do the following:

- Be accurate/correlate with clinical status
- Be simple for providers to set up and use
- Be continuous and centrally displayed
- Be acceptable to the patient
- Be appropriate for patients of various ages
- Display RR and EtCO₂ reading clearly
- Permit visualization of trends
- Retain data even if tubing is temporarily removed (conversation or eating)
- Alarm loudly enough to wake the patient
- Display along with O₂ saturation readings when needed
- Permit individualization of alarm limits
- Be perceived by staff as valuable

Use of Electronic Monitoring				
	High Risk Only		All Patients	
	2013 (n = 102)	2009 (n = 90)	2013 (n = 102)	2009 (n = 90)
Intermittent Pulse Oximetry				
Epidural	30%	21%	38%	36%
IV PCA	36%	22%	42%	36%
Oral/IV opioid	34%	20%	40%	37%
Continuous Pulse Oximetry				
Epidural	41%	25%	37%	31%
IV PCA	41%	32%	28%	20%
Oral/IV opioid	17%	27%	5%	13%
End Tidal Carbon Dioxide				
Epidural	10%	6%	7%	2%
IV PCA	14%	8%	11%	2%
Oral/IV opioid	8%	-	1%	-

IV = intravenous; IV PCA = intravenous patient-controlled analgesia.

Figure 14. "Monitoring for Opioid Induced Advancing Sedation and Respiratory Depression: ASPMN Membership Survey of Current Practice"

ECRI Institute, Plymouth Meeting, PA

Low Acuity Continuous Monitoring: Trends and Challenges

Ramya Krishnan, MS
Senior Project Engineer, ECRI Institute

There is growing interest in systems that provide continuous vital signs measurements and central surveillance without the cost of high-acuity patient monitoring systems. Some of ECRI Institute's member hospitals have adopted such systems. In the past year, we have seen an increasing interest in solutions that help monitor non-critical patients, and we continue to get requests for such systems.

Some challenges our member hospitals have observed with the various monitoring modalities include the following:

- EtCO₂: Lack of centralized surveillance with monitoring, comfort issues with the nasal cannula
- SpO₂: A late indicator of respiratory depression; prone to false alarms, requires patients on room air
- Respiratory rate: Past problems with accurate, reliable monitoring, new emerging technologies
- High-acuity physiologic monitors: training, networking, cost

Hospitals considering purchasing a continuous monitoring system should involve front-line staff in developing the criteria for what the system should do. And, before purchasing a new solution, look at what capabilities your existing system includes. Could it meet your requirements, or could its use be expanded?

Ask yourself if your low-acuity areas are ready for such a system. Consider needs for staff training, networking infrastructure upgrades, and possible changes to workflow and policies.

Cost is another key factor. Consider both the implementation costs and the operational costs of the system, including disposables, software licenses, and maintenance agreements. Offsetting savings from improved patient outcomes should also be considered.

Alarm management policies are a key consideration. It is important to ensure accountability when it comes to alarms. These low-acuity care areas are typically not used to alarms; having an alarm ring in a care area with nobody noticing it is not going to help a patient. If you opt to use central station alarming, someone must be designated to watch for alarms. If alarms are being sent to pagers and phones, then you must have escalation policies in place and nursing assignments to ensure that every time an alarm rings, there is somebody to respond to it and take care of the patient.

There is interest in making sure these monitoring solutions talk to the electronic medical record (EMR). If EMR integration is a goal, consider workflow requirements. Even if you don't want to integrate these systems now, you may want to do so in the future. Consider if the solution you purchase has that ability.

Early warning scores are proving valuable in some hospitals today. Individual hospitals are building protocols to roll up multiple parameters into early warning score indices, providing an easier way to assess patient condition and deterioration. Some devices currently offer ways to roll up individual parameters into such scores. There are also third-party vendors who can help collect data from multiple devices and provide you with scores.

Our members have seen that there is no one-size-fits-all approach to continuous monitoring. A variety of different approaches can work. Sharing experiences, outcomes, and best practices will help all of us understand the benefits and challenges of this technology.

ECRI Institute: Key Procurement Considerations

How do you want to deploy low-acuity continuous monitoring?

- Consult clinical stakeholders on the monitoring needs of each care area, their desired clinical workflow, and their expectations of a new low-acuity continuous monitoring system.
- Develop and stick to clearly defined performance requirements that support this workflow, including items, such as parameters monitored and interconnectivity with mobile devices.

Are your low-acuity care areas ready to take advantage of monitoring?

- Understand clinical stakeholders' current usage of patient monitoring equipment and identify the needs for training and education to enable clinicians in low-acuity care areas to interpret and respond to continuous monitoring alerts and information.
- Some caregivers may not be familiar with all parameters you plan to monitor.
- Workflows will need to be changed to allow for surveillance at a central station in addition to other nursing tasks.
- Policies regarding alert response will need to be developed (for example, escalation schemes if a caregiver is unable to respond to an alert).

Do you need to buy new equipment?

- Before considering the purchase of a new monitoring system, assess the patient monitoring capability of your current inventory and evaluate the need and potential to cover more areas.

How much will this cost?

- Prices vary greatly among different models and approaches and your facility will need to find a solution that will best suit your needs and budget.
- Consider both the initial (e.g., implementation, installation, integration, training) and operational (e.g., disposables, software licenses, upgrades, maintenance) costs of each system in a life-cycle cost assessment.
- Consider the availability and appropriateness of acquisition pathways like leasing, lease-to own, and consumables agreements.
- While performing cost analysis for a system, consider cost savings from the potential for improved clinical outcomes and patient safety.

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Figure 15. ECRI Institute's Key Procurement Considerations Checklist

San Diego Patient Safety Council, San Diego, CA PCA Toolkit

James D. Harrell, RCP
Manager, Pulmonary Services, Sharp Memorial Hospital

The San Diego Patient Safety Council is a coalition of representatives from healthcare organizations in the San Diego area. Together, we developed a toolkit to provide evidence-based recommendations and best practices on safe and effective assessment, monitoring, and intervention of patients at risk for unrecognized respiratory depression outside of the intensive care unit (ICU). To date, the toolkit has been used successfully at several healthcare systems in San Diego County.

The toolkit organizes the recommendations for bedside caregivers into eight recommended steps for bedside caregivers:

1. Assess the patient for the presence of identified risk factors using standardized and validated tools.
2. Identify the risk level considering medication-related risk factors, as well as known or suspected obstructive sleep apnea (OSA)/sleep disorder risk factors.
3. Decide whether the patient should be monitored using the Respiratory Monitoring Prioritization Recommendations Based on Risk.
4. Determine the monitoring method. Options include EtCO₂ monitoring, pulse oximeter, multi-parameter monitor, or a transcutaneous CO₂ monitor.
5. Educate, engage, and coach the patient and the family/care partners before and during monitoring as well as when monitoring is discontinued.
6. Monitor the patient, ensuring adequate surveillance and that alarms are audible. Use appropriate alarm parameters.
7. Intervene as necessary, considering respiratory depression warning signs.
8. Document, evaluate, and communicate.

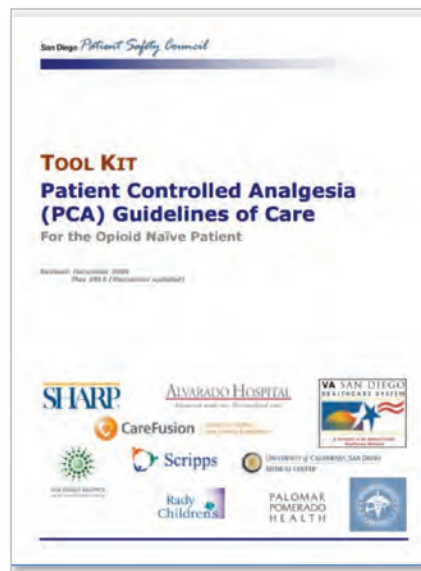


Figure 16. San Diego Patient Safety Council Toolkit; available here: www.carefusion.com/pdf/The_Center/2008-PCA-toolkit-disclaimer-updated-may-30-2014.pdf.

Alarm Parameters	
EtCO ₂	High – 60 mmHg Low – 10 mmHg
Respiratory Rate	High – 48 breaths per minute Low – 7 breaths per minute
No breath delay	30 seconds
Pulse Oximetry	<90 on room air

Figure 17. Alarm Parameters

Respiratory Monitoring Prioritization Recommendations Based on Risk ^a				
Risk Level ^b	Very Low Risk ^d	Low to Moderate Risk	Moderate to High Risk	Very High Risk
Monitor ^c	Recommend periodic monitoring with Pulse Oximetry ^e	Recommend continuously monitoring with Pulse Oximetry ^e	Strongly recommend continuous EtCO ₂ monitoring Recommend continuously monitoring with Pulse Oximetry ^e	Strongly recommend continuous monitoring EtCO ₂ and Pulse Oximetry ^e
Location	Bedside	Bedside	Remote/centralized and/or close proximity/high visibility	Remote/centralized and/or close proximity/high visibility

^aSDPSC acknowledges many hospitals are not fully equipped to offer EtCO₂ monitoring on patients that may benefit and that triaging the monitors for the most critical patients may be necessary (until the appropriate numbers of monitors are acquired).
^bAll risk factors identified apply to sedated patients outside the ICU (e.g., post anesthesia care unit, interventional radiology, endoscopy, catheterization laboratory, emergency).
^cSDPSC monitoring recommendations are inclusive of existing best practices and standardized protocol for pulse oximetry monitoring
^dAn example of a patient with Very Low Risk is a marathon runner in the emergency department with a broken wrist and no health risks.
^eWhen using supplemental oxygen, evaluate the patient for EtCO₂ independent of SpO₂ values.

Figure 18. San Diego Patient Safety Council: Respiratory Monitoring Prioritization Recommendation Based on Risk

The tools in this kit are available to be used by institutions as needed. The following key points should be kept in mind:

- Be aware of any potential co-morbidity when assigning risk for respiratory depression to the patient.
- Once risk is identified, monitor the patient appropriately per recommendations.
- Know the risk level to your patient and know their baseline condition.
- Engage the patient and their families or caregivers in the monitoring process.
- Intervene. If your monitor is alarming, there is a reason.
- Reassess risk as patient condition changes or improves.

Respiratory Depression Warning Signs

A – **Abnormal slowness of respiration** (<8 or <10 breaths/minute)

T – **Too long to arouse**

M – **Mental status change** or reduced level of consciousness

O – **Oxygen saturation is low**

S – **Snoring** or other noisy respirations

P – **Poor respiratory effect/quality** (i.e., paradoxical rhythm with little chest excursion)

H – **Hypoxia** (deficiency of oxygen reaching body tissues)

E – **Elevated level of carbon dioxide** in the circulating blood

R – **Rapid breathing**

E – **EtCO₂ alarming**

San Diego Patient Safety Council 2014

Figure 19. San Diego Patient Safety Council: Respiratory Depression Warning Signs

Summary of Breakout Groups: Barriers to Continuously Monitoring Patients on Opioids

BREAKOUT GROUP 1: FINANCIAL BARRIERS

MODERATOR

Eyal Zimlichman MD, MSc (MHCM), Deputy Director General and Chief Quality Officer, Sheba Medical Center

Suggested Discussion Questions:

1. Are we aware of any more evidence that supports financial justification for continuously monitoring patients on opioids?
2. With the evidence at hand, how can clinical, quality, and safety directors best approach decision makers so that policy allows for continuous monitoring of patient on opioids?
3. Do we think it is likely that the new payment models (e.g., bundled payments, value-based purchasing) would promote the business case for continuously monitoring patient on opioids? And how so?

Key Points from Summary

Key question: *How can we demonstrate to hospital management that investing in continuous electronic monitoring is a good idea?*

Suggested Approaches

- In terms of demonstrating ROI, one size does not fit all. One plan will not fit all institutions. Think of it as a recipe book: Not every recipe will work for every hospital. You have to tailor your business case to the size and requirements of the institution.
- Some hospital systems think it is critical that monitoring systems integrate with the electronic medical record (EMR), while others think requiring this would derail a proposed project—EMR integration instantly becomes a multi-year project, thus exploding costs. Know your audience. Sell as a phased approach to integrate with EMR, not as immediate.
- When you go to the C-suite, bring your clinical and administrative champions with you. Build consensus among people who are educated on the topic of preventable harm.
- New healthcare cost paradigms: we are heading to pay for quality, not pay for tasks done. Your hospital's cost paradigm will impact the business case for continuous monitoring.
- Come to the C-suite armed with metrics, both financial and clinical.
- Clinical metrics: show that monitoring will decrease ICU transfers and reduce ICU staffing burden. Show declines in reversals. Measure rescue and transfer calls. Show improvements as a result of best practices. Measure and report outcomes. Before and after studies can yield useful data.
- Hospital units that have the greatest use of high-dose opioids will yield the most positive results. Find the units that have the highest opioid use, the highest ICU transfers, the highest rapid response calls, and measure the impacts of continuous monitoring there first. If you try to measure results hospital-wide, ROI gets very diluted. Start small.
- Use the consumer angle. Continuous monitoring in hospitals is a selling point to patients. Sell it as a safety advantage. You can leverage that, and it would speak to folks in the C-suite.
- Come in with a readiness assessment. Evaluate the technical hurdles you may face in terms of wireless connectivity and clinician/patient adoption. Develop a 360-degree view of what this will take.
- A regulatory argument may also be persuasive to the C-suite: We expect CMS and TJC statements to become more strongly in favor of continuous monitoring as we have a bigger installed base and more data.
- While we do not need to develop research projects or level one clinical evidence, we may be able to develop

level two or level three clinical evidence based on all the data that we are gathering from these installed bases. Manufacturers could take ownership of that and help us do it.

- Zimlichman showed the group a spreadsheet that is a template for building a business case for continuous monitoring. If you enter your institution's variables, you will be able to develop a straightforward ROI in terms of real numbers and dollars. Charts can be customized to each hospital's needs.
- Clinical arguments in favor of CEM can go beyond the dangers of opioids. Detecting early symptoms of deterioration can lead to other care improvements as well. We may find more data in support of this argument as we get a bigger installed base.
- You should consider calculating the negative financial impacts of poor outcomes and building that into your business case. Consider the addition of penalties and fines when things go wrong, such as poor outcomes and readmissions. Penalties and fines avoided are an example of a positive ROI from CEM. Factor in cost of poor quality, reversal drugs, and rework.
- Also consider reimbursement changes. Payers are not going to continue to reimburse on failure to rescue, postop complications, or respiratory failure.
- As payment models shift from fee for service to capitated care, savings due to safety improvements will increasingly accrue to the hospital rather than the payer. This should strengthen the business case for safety improvements.
- The AAMI Foundation's report from this conference on the state of continuous monitoring should be helpful in making the argument for the value of monitoring.

Key Points from Broader Discussion

- The AAMI Foundation should provide education for hospitals on how to make the business case and calculate ROI. Not everyone has a business degree or understands ROI or the present value of money. This could be a huge benefit. The Foundation could create a toolkit for facilities to figure out how to calculate their ROI.
- ROI calculation tools should be risk-based. Hospitals should calculate savings of avoiding things that are critical to them. They should be able to make the case that, at a given level of risk, they need to start implementing continuous monitoring.

Key financial questions to answer are: How will this impact revenues of hospital? Expenses? Margin?

Suggested Approaches

- Very few hospitals have a visionary CEO and the financial resources to implement continuous monitoring instantly. With ROI based on risk/patient type, they can start small and deploy further later. Consider creating a profile of the patient population that could be helped.
- Arguments cannot just focus on financials. CEM is about quality care. This technology is never going to show the ROI that some others can. Don't spend too much detailed time and effort creating theoretical models of ROI. Focus on the broad sweep: how opioids cause harm.
- Most effective argument: CEM promises to free up ICU days, allow more surgical days, more revenue. This is the analysis that Dartmouth-Hitchcock used. Savings in ICU days allowed them to pull in more surgical procedures, increase revenues. With that argument, continuous monitoring went from one unit to hospital-wide in a year. ICUs are pressure points for hospitals. They have very thin margins. They are not getting more ICU beds, so they have to divert patients to other hospitals and lose revenue. If continuous monitoring frees up those beds, revenues will increase. Key CEO question: Show me how I can make my hospital more efficient. If I pay for this today, what is my return tomorrow? This is a good answer.
- Some would like to see an annual survey/status report of what's going on with continuous monitoring in hospitals across the country. We are early adopters, but we need to fit that into a story that has broader survey-based data across multiple hospitals. Survey representative acute care hospitals: what are you doing? Describe state of monitoring, impact, clinical results, financials.
- The AAMI Foundation could also develop a readiness assessment tool. If a hospital's culture/policy/staff is not ready for this technology, it will fail.
- Workforce argument: Every time a patient is harmed, we are harming our teams and ourselves. There is a cost of destroying the workforce by not having the right resources in place.

BREAKOUT GROUP 2: EDUCATIONAL BARRIERS

MODERATOR

Darin Correll, MD, Director, Postoperative Pain Management Service, Brigham & Women's Hospital

Suggested Discussion Questions:

1. Who are the groups of providers that need to be educated—is this the same everywhere?
2. Do you feel there is a “one size fits all” plan that can or should be developed?
3. What effect will EMR have on the effort—aid or hinder?
4. Is The Joint Commission statement from March 2014 really enough to drive practice change—are other regulatory interventions needed?

Key Points from Summary

Barriers/Challenges

- Time. Limited time is available to educate patients pre and postoperatively and for staff training and education.
- Lack of knowledge. People are not being educated on these topics within medical school and nursing school. How and when are we going to be able to educate them?
- Cost. Who is going to pay for it? Huge cost of education, lack of reimbursement.
- Patient understanding, receptiveness.
- Patient expectations. Need to be aware of these risks; that there is no gold standard for monitoring, but many variations in approach—no absolutely correct answer.
- Lack of reinforcement of training and education. Too often one-and-done policies—staff is educated when hired but not repeated.
- Lack of accountability for education. There is a lack of ownership—who is responsible for education and follow-up? Lack of acknowledgement of shared responsibility for education.
- Professional training. Only cursory treatment of pain management is provided in nursing/medical education.
- Expanding/evolving concept of healthcare teams.
- Who needs to be educated?
- Who should be doing the teaching?
- What should we be educated on.
- What are the best training modalities?
- What do we do about the lack of training policies.

Suggested Approaches

- Use simulation to implement education, although it can be problematic with respect to cost, access to systems/tools, time/staff availability.

- Provide flexibility in modality of education—e.g., text, audio, visual—and address different styles of learning.
- Demonstrate competency after training. Identify the best practices and the approach for your institution. Identify what competencies are most relevant.
- Clarify policies. Education is not enough. Policies from the institution are necessary to put some “teeth” into information.
- Get buy-in from key stakeholders in the broader policy environment.
- Get stronger, clearer statements from regulatory agencies like CMS and TJC. These would help force the importance of education and could provide strong leverage.
- Provide training for IT and informatics staff. Electronic order entry could use its forcing function to require users to, for example, implement monitoring for certain patients. However, right now, EMRs vary in their ability to support this function.
- Train hospital executives and administrators. They will be needed to support various policies.
- Provide tools to educate individual patients like clear, simple visual brochures and diagrams.
- Integrate educational efforts into the community, for example through churches, free clinics, VFW, beauty clinics, etc.
- Use the media and social media tools to get information out to the community so patients have seen these ideas and there is less education to be done.
- Design overall system to support monitoring, to track and educate.
- Educate on the need for monitoring capacity/ability across the hospital, not just in the ICU.
- Focus on empowerment, not fear. Empower and inform patients about the importance of their role in their own care.

BREAKOUT GROUP 3: CULTURAL BARRIERS

MODERATOR

Gina Pugliese, RN, MS, FSHEA, Vice President, Premier Safety Institute

Suggested Discussion Questions:

1. What is role of leadership support and teamwork to support a safer culture?
2. What are the biggest challenges to overcome to implement continuous monitoring?
3. What are the key departments that need to be involved?
4. How does the patient and family experience and beliefs impact on culture?
5. What is role of education for patient and staff?

Key Points from Summary

- Culture is the attitude and behaviors that characterize a group.
- Overarching challenges to achieving a culture of safety are leadership, teamwork, the need to promote the disciplinary teams, patient and family education, expectations, satisfaction, staffing issues.
- Accountability and a just culture are key.
- Sharing successes is important.
- Leadership culture is key.

Key Question: *How do you get a hospital's administrators to accept that you need continuous monitoring technology?*

Suggested Approaches

- Need a strong champion within an organization. Could be from any department.
- Patient stories are key. You hate to wait for something terrible to occur to provide impetus, but in some hospitals that is what happens.
- Share patient stories from other hospitals to open a discussion with administrators.
- Use the data you have available to you in your organization, like the number of transfers to ICU, the rescue data, and any other data that may help show there is a problem.
- It is important to manage the expectations of patients and to educate them. What kind of surgery? What kind of pain? What kind of drugs will you be on? What monitoring will you need?
- Educate patients that achieving a pain level of zero is not necessarily achievable.

Barriers/Challenges

- Organizations are working on so many patient safety issues that messages get diluted.
- There are so many performance measures and performance ratings that opioid safety can get lost in the noise.
- There needs to be a balance of accountability for all staff. It needs to be balanced with a just and fair culture, a non-punitive culture to really encourage people to come forward with solutions and recommendations to solve the problem.

Patient's perspective: *Why are we not using the technology that we have?*

- Recognize there is a difference between the daytime hospital and the nighttime hospital. At night, there are more patient transfers, but also less staff, less family, greater need for technology.
- Hospitals should be open to finding out what neighboring hospitals are doing, sharing best practices. What technologies and processes are others implementing?
- Bottom line: system redesign. Make it easier for people to do the right thing and more difficult to do the wrong thing.
- Need to identify, use best current technology that delivers reliable data on respiratory status.

BREAKOUT GROUP 4: WORKFLOW BARRIERS

MODERATOR

Greg Spratt, BS, RRT, CPFT, Director of Clinical Marketing, Medtronic

Suggested Discussion Questions:

1. Recognize that there are three basic monitoring models:
 - Bedside monitoring with no remote alarm annunciation (nurse call at door only)
 - Bedside monitoring with central station monitoring
 - Bedside monitoring with remote alarm annunciation (e.g., cell phone, pager, nurse call to central station)—Direct to clinician
2. With each of the three models:
 - What are the communication models for responding to alarms?
 - How are alarms communicated to the caregiver?
 - How are alarms escalated if the primary caregiver is unavailable?
 - How is alarm resolution communicated?
 - Workflow
 - What workflow challenges exist for each of these models?
 - How have you overcome these challenges?
 - What are the “best practices” learned from each of these models?

Key Points from the Summary

An alarm is really a message. It can be very simple—“there is something wrong”—up to a very detailed message that goes to a specific person at a specific time. It could be relayed to other people and it could have content related to what the alarm was and even what the response should be.

In every message, there are a number of parameters that create levels of complexity that have to be sorted out:

- Content
- A defined recipient
- Timeliness/urgency component
- Technology—how get message out
- Security, particularly if you use over-air messaging
- Analytic or decision support can be added
- Nothing at bedside, data and alarm go to central monitor elsewhere

Issues with bedside display and bedside alert only, no central monitoring

- Staffing ratios and their distribution within the unit: Size of unit, distance of caregiver from the patient that is

alerting is key. If a large unit, audibility of alarms may be a major problem.

- Getting the message to the right person: If an alarm sounds and a maintenance worker or housekeeper is there is very different from a clinician being in the room.
- You must ensure that the alarm will be heard, so volume is an issue. Are you trying to reach just people in the room, just people within 30 feet, or anybody who is in the unit?
- Educational requirements: Huge in this scenario, education required of many more people/professions. Whoever is there is going to have to do some critical clinical decisionmaking and decide how to respond to the alarm. That could be very complex.

Issues with bedside display and central display

- If the alert is recognized at the central display, how do you get it back to the bedside clinician? This can be very costly and difficult.
- This model is expensive. You need proper equipment, staffing at central station, and maintenance.
- Maintenance is also key—technologically it is much more difficult to have all the different bedside monitors coming into a central station and to keep it functioning well.

- Can be problems with bedside caregivers being available. This problem really applies to ALL models.
 - Vigilance—I may relax my diligence regarding patients I can't see because I know there is a central station backing me up. Need a method to maintain vigilance.
- Issues with bedside display and directed alert**
- Alert message goes to a specific caregiver—could be nurse, respiratory therapist, or others.
 - Major technological issues include: networking infrastructure, software to do algorithms, policies for messaging, maintenance.
 - Need policies for over the airway messaging.
 - Maintenance of system is very complex.
- Targeting of messages can be difficult due to staffing patterns—people taking breaks, changing shifts, etc. Staff continuously change.
 - Need to have a feedback loop, some way of getting message back, “Yes I got the message and I’m the correct person. Can be very complex.
 - Can overcome this problem by increasing redundancy—notify 2,3,4,8 people. Now, an individual caregiver is receiving their own messages as well as messages for others on their team. This can really increase alert fatigue.
 - This approach requires huge clinical buy-in. The technological questions may doom project.

Next Steps

Phase I of this 24-month project consisted of the November 14, 2014 stakeholder meeting; the conference proceedings are included in this compendium. Phase II of this project will continue through December of 2016. The deliverables will include:

Safety Innovation Series: A series of publications offered by the AAMI Foundation that highlight how a healthcare delivery system has solved a technology-related issue. This series of papers will include an in-depth look at the ways hospitals have implemented strategies to continuously monitor patients on opioids, identified and overcame barriers, and share “lessons learned.”

Patient Safety Seminars: A series focused on the specific strategies used by hospitals to implement continuous electric monitoring (approximately 7-10 webinars over 24-months).

Outreach: Each of the co-convening organizations will help to publicize the event and disseminate the findings to their membership and the broader healthcare community.

Regional Events: AAMI Foundation staff will facilitate an in-person panel presentation with experts, hospitals representatives and manufacturer partners in two to four major market regions to share the Coalition's knowledge with the broader clinical community.

Contact Us

To track the status of this project, please visit:
www.aami.org/opioids

To learn more about this program, get involved or share your story, contact:

Sarah Lombardi, MPH
Program Director, AAMI Foundation
slombardi@aami.org

Continue the discussion by visiting our LinkedIn page: www.linkedin.com/grp/home?gid=4284508

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Appendices

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Appendix A: Agenda for Kick-off Meeting

National Coalition to Promote Continuous Monitoring of Patients on Opioids

INVITATIONAL MEETING

Friday, November 14, 2014, 8:00 a.m.-4:30 p.m.

Location: Chicago, IL

MODERATOR

Frank Overdyk, MSEE, MD

Chair

National Coalition to Promote Continuous Monitoring of Patients on Opioids

AGENDA

7:30 a.m.	Continental Breakfast	10:05 a.m.	Coalition Diamond Partner: Medtronic
8:00 a.m.	Welcome & Introductions <i>Mary Logan, JD, CAE, President & CEO, AAMI</i> <ul style="list-style-type: none">• Antitrust Statement• Conflict of Interest	10:10 a.m.	Break
8:15 a.m.	Latest Evidence: Opioids and Cardiopulmonary Arrest <i>Dr. Overdyk</i>	10:20 a.m.	St. Joseph's/ Candler Health System <i>Ray Maddox, BS, PharmD, FASH, Director, Clinical Pharmacy, Research & Pulmonary Medicine</i>
8:30 a.m.	Patient Stories <i>Brian Abbiehl, Promise to Amanda</i> <i>Matt Whitman, Retired Michigan State Trooper</i>	10:40 a.m.	Vanderbilt University Medical Center <i>Brian Rothman, MD, Assistant Professor, Anesthesiology, Medical Director, Perioperative Informatics</i>
8:50 a.m.	Dartmouth-Hitchcock Medical Center <i>George Blike, MD, MHCD, Chief Quality and Value Officer, Professor Anesthesiology, Dartmouth-Hitchcock Medical Center</i>	11:00 a.m.	St. Francis Medical Center <i>Pam Pohlenz, BS, RRT, Respiratory Clinical Educator</i>
9:10 a.m.	Sheba Medical Center <i>Eyal Zimlichman, MD, MSc (MHCM), Deputy Director General and Chief Quality Officer</i>	11:20 a.m.	The Johns Hopkins Hospital <i>Sue Carol Verrillo, RN, MSN, CRRN, Nurse Manager</i>
9:30 a.m.	Intermountain Healthcare <i>R. Scott Evans, MS, PhD, FACMI, Medical Informatics Director</i>	11:40 a.m.	Panelist Question & Answer <i>Moderator: Dr. Vanderveen</i>
9:50 a.m.	Panelist Question & Answer <i>Moderator: Dr. Overdyk</i>	12:00 p.m.	Coalition Platinum Partner: Connexall
		12:05 p.m.	Lunch Break
		12:35 p.m.	Coalition Platinum Partner: Sotera Wireless

12:40 p.m. Westchester Medical Center
*Maureen Cooney, RN, DNP, NP-BC
 Nurse Practitioner, Pain Management*

**1:00 p.m. From Engagement to Implementation:
 Initiation of Continuous Pulse Oximetry
 in a Community Teaching Hospital**
*Kenneth Rothfield, MD, MBA, System Chief
 Medical Officer, Saint Vincent's HealthCare*

1:20 p.m. ECRI Institute
*Ramya Krishnan, MS, Senior Project
 Engineer*

**1:40 p.m. San Diego Patient Safety Council PCA
 Toolkit**
*James Harrell, RCP, Manager Pulmonary
 Services, Sharp Memorial Hospital*

1:55 p.m. Platinum Coalition Partner: Masimo

2:00 p.m. Panelist Question & Answer
Moderator: Dr. Overdyk

2:10 p.m. Coalition Diamond Partner: CareFusion

2:15 p.m. Break

**2:25 p.m. Breakout Sessions: Barriers to
 Continuously Monitoring Patients on
 Opioids**

- **GROUP 1**
 Business Case/Financial Justification
Moderators: Dr. Blike & Dr. Zimlichman
- **GROUP 2**
 Education
*Moderator: Darin Correll, MD, Director,
 Postoperative Pain Management Service,
 Brigham & Women's Hospital*
- **GROUP 3**
 Culture—Clinician & Patient
 Acceptance
*Moderator: Gina Pugliese, RN, MS,
 FSHEA, Vice President, Premier Safety
 Institute*
- **GROUP 4**
 Workflow
*Moderator: Greg Spratt, BS, RRT, CPFT,
 Director of Clinical Marketing, Medtronic*

3:25 p.m. Breakout Sessions
Report Out by Group Leaders

3:45 p.m. Vision Statement
Moderator: Dr. Overdyk

4:20 p.m. Closing Remarks & Next Steps
*Dr. Overdyk
 Marilyn Flack, MA, Executive Director,
 AAMI Foundation
 Sarah Lombardi, MPH, Program Director,
 AAMI Foundation*

4:30 p.m. Adjourned

Appendix B: Speaker Biographies

George Blike, MD, MHCDS
Chief Quality and Value Officer
Professor Anesthesiology
Dartmouth-Hitchcock Medical Center

George Blike, M.D., is Dartmouth-Hitchcock's Chief Quality and Value Officer, joining the leadership team on July 1, 2012. In the role of Chief Quality and Value Officer, Dr. Blike has responsibility for the Quality, Safety and Value initiatives for the Dartmouth-Hitchcock system across New Hampshire and Vermont. Dr. Blike is a graduate of Case Western Reserve University and the University of Cincinnati Medical College. While a student he worked at the NIH pain and neurobiology section in research as a visiting scholar. Dr. Blike completed a preliminary residency year in medicine at Hartford Hospital and his residency in Anesthesiology at Yale New Haven Hospital. During residency he became engaged in human factors research and has been an active member of the Human Factors and Ergonomics Society since 1990. After residency, he joined Dartmouth as a member of the Anesthesiology Division, with a clinical focus on High Risk Obstetric Anesthesia, Cardiac Anesthesia, and Pediatric Procedural Sedation. In addition, Dr. Blike served as a Faculty for the first Institute for Healthcare Improvement Collaborative of Patient Safety commissioned by the Veterans Affairs.

Dr. Blike is a Professor in the Departments of Anesthesiology and Community & Family Medicine. Dr. Blike's research and clinical practice career has been devoted to creating patient safety despite the complexity of modern healthcare, and he has performed collaborative systems research to improve the safety of pediatric procedural sedation and reduce the risk of pain management in the hospital. He has published extensively on topics related to quality in healthcare and regularly presents to national and international audiences. His many professional associations include board membership of the Foundation for Anesthesia Education Research, acting President of the Society for Technology in Anesthesiology, a founding member of the International Society for Medical Simulation, and member of the Research Committee of the National Patient Safety Foundation. He participates as a member of a national advisory panel on payment innovation convened by Wellpoint. Dr. Blike is also Medical Director of the Patient Safety Training Center and a 2008 recipient of the James W. Varnum, Quality Healthcare Award.

Maureen Cooney, RN, DNP, NP-BC
Nurse Practitioner, Pain Management,
Westchester Medical Center

Maureen Cooney is a Nurse Practitioner in Pain Management at Westchester Medical Center in Westchester County, New York. She received a Doctorate in Nursing Practice from Case Western Reserve University and Masters and Undergraduate degrees from Pace University. She is Board Certified as a Family Nurse Practitioner, and also in Pain Management, Palliative Care, and Critical Care Nursing. She is an adjunct associate professor at Pace University. Maureen is on the Board of Directors of the American Society of Pain Management Nurses (ASPMN), and is the Chair of the American Pain Society's Nursing Shared Interest Group. She has served in various positions on the Board of the NYC chapter of ASPMN and is an ASPMN Master Faculty member. She has authored and co-authored a number of pain related articles and has lectured extensively on pain management issues.

R. Scott Evans, MS, PhD, FACMI
Director, Medical Informatics,
Intermountain Healthcare

R. Scott Evans is Medical Informatics Director at Intermountain Healthcare and Professor of Biomedical Informatics at the University of Utah. He has a BS degree in Zoology and MS degree in Microbiology/Parasitology and a PhD in Medical Biophysics. He is a member of the American Medical Informatics Association, a Fellow in the American College of Medical Informatics and is on the AMIA Board of Directors and the Editorial Board of the *Journal of American Medical Informatics Association*. His experience and interests included the design, development, implementation and evaluation of computerized decision support tools for the selection and management of antimicrobial agents, computer methods to identify and reduce adverse drug events, adverse medical device events, and venous thrombotic events; computerized methods to identify patients needing isolation, obstructive sleep apnea, chronic obstructive pulmonary disease, ECG critical events; and computerized methods to identify and reduce hospital-acquired infections and report notifiable diseases.

James D. Harrell, RCP
Manager, Pulmonary Services, Pulmonary
Rehabilitation & Sleep Laboratory
Sharp Memorial Hospital

James D. Harrell, RCP is the manager of Pulmonary Services, Pulmonary Rehabilitation and Sleep Laboratory at Sharp Memorial Hospital in San Diego, California. James has been the manager at Sharp Memorial since 2008. James has been a Respiratory Therapist for over 34 years. He received his training as a Respiratory Therapist at California College of Health Science in San Diego, California. James is a named co-author of the “San Diego Patient Safety Councils Tool Kit: Monitoring for Respiratory Depression outside of the ICU.” James lives in Murrieta, California with his wife Renee. James enjoys spending time with his four children and two grandchildren.

Ramya Krishnan, MS
Senior Project Engineer, ECRI Institute

Ms. Ramya Krishnan is currently a senior project engineer with the Health Devices Group at ECRI Institute. Her primary responsibilities include evaluating and testing medical devices, investigating device issues, and providing consultation to ECRI hospital members on selection, purchase and appropriate use of medical equipment. More recently, Ms. Krishnan, in collaboration with ECRI Institute’s patient safety organization, has been analyzing the efficiency of Health-IT event reporting. Her areas of expertise include physiologic monitoring, medical device integration with EMRs, cyber security of medical devices and alarm notification/ integration systems. Since joining ECRI Institute, Ms. Krishnan has evaluated several monitoring systems and has authored multiple guidance articles on cyber security, medical device connectivity and EMR integration for the Health Devices journal. Before joining ECRI Institute in 2008, Ms. Krishnan completed her Masters in Biomedical Engineering from Drexel University.

Ray R. Maddox, BS, PharmD, FASHP
Dean, University of Georgia College of Pharmacy
Southeast Georgia

Ray R. Maddox, PharmD, completed the Doctor of Pharmacy degree and clinical pharmacy residency training at the University of Kentucky. He is the former Director of Clinical Pharmacy, Research & Pulmonary Medicine for the St. Joseph’s/Candler Health System in Savannah, Georgia. Dr. Maddox recently became the campus dean for the University of Georgia College of Pharmacy Southeast Georgia campus located in Savannah. He was also appointed Clinical Professor and Associate Department Head for the Department of Clinical and Administrative Sciences of the College.

He maintains an active involvement in clinical service development and research and has been an advocate and innovator in the implementation of hospital medication safety technology. This includes development of bedside medication barcode and system-wide implementation of IV “smart pump” technology for large and small volume fluids with patient controlled analgesia (PCA) that incorporates continuous respiratory monitoring with pulse oximetry and capnography has been implemented. Maddox has authored numerous manuscripts with collaborating authors and made presentations about these initiatives at regional, national, and international professional meetings.

Pamela Pohlenz, BS, RRT
Respiratory Clinical Educator, St. Francis
Medical Center

Pamela Pohlenz has been a registered Respiratory Therapist for the last 11 years and is currently the Respiratory Clinical Educator at CHI Health St. Francis in Grand Island, NE since 2006. She is a graduate of the University of Nebraska at Kearney where she received her Bachelors in Science. She is a green belt for Lean Six Sigma programs, teaches ACLS & PALS, and is a Safety First instructor, and works with many other committees and programs. An important aspect of her life is her family; her husband Christian and their two daughters, Lauren (7) and Kendall (4). In her spare time, she enjoys reading, scrapbooking, and playing in a weekly volleyball club.

Ken Rothfield, MD, MBA
System Chief Medical Officer, Saint Vincent's
HealthCare

Dr. Ken Rothfield is the System Chief Medical Officer at Saint Vincent's HealthCare in Jacksonville, Florida, part of Ascension Health. He previously served as Chairman of the Department of Anesthesiology at Ascension's Saint Agnes Hospital in Baltimore. Dr. Rothfield received his undergraduate degree from Harvard College, medical degree from the University of Rochester, and MBA from the Johns Hopkins Carey Business School. He completed his training in anesthesiology, as well as a fellowship in cardiovascular anesthesia and research, at the University of Pittsburgh. He is nationally recognized for his work in patient safety, including emergency airway management, opioid safety, and respiratory monitoring. He is a member of the Ascensions core patient safety steering committee. Dr. Rothfield is a faculty member of the Institute for Healthcare Communication, and in that capacity serves as a physician leader, lecturer, and trainer for the Ascension Health risk management disclosure program. Dr. Rothfield is the recipient of a Healthcare Heroes Award from the *Baltimore Daily Record*, as well as a Circle of Honor Award for Innovation in Patient Safety from the Maryland Patient Safety Center.

Brian Rothman, MD
Assistant Professor of Anesthesiology, Medical
Director of Perioperative Informatics, Vanderbilt
University Medical Center

Brian Rothman, MD, is Associate Professor of Anesthesiology and Medical Director of Perioperative Informatics at Vanderbilt University Medical Center. Dr. Rothman received his medical degree from the University of Cincinnati and completed his residency at The Johns Hopkins Hospital. He serves on the Electronic Media and Information Technology and Equipment and Facilities committees for the American Society of Anesthesiologists. He has served in the Society for Technology in Anesthesia (STA) as Treasurer and an At-Large Member of the Board of Directors. His current work focuses on the meaningful application of mobile technology to healthcare and further enhancing Vanderbilt's Perioperative EHR, VPIMS. The enhancements seek to improve patient safety, efficiency, and communication relying on accurate data acquisition and handling with delivery to the correct personnel at the appropriate time, recognizing the data's relative criticality in a provider's workflow.

Sue Carol Verrillo, RN, MSN, CRRN
Nurse Manager, The Johns Hopkins Hospital

Since February, 2013, Sue Carol Verrillo has been the Nurse Manager of the 32-bed Orthopedic/Ortho-Spine/ Trauma/ Neurosurgery unit at The Johns Hopkins Hospital. As part of the Professional Practice Model, Sue functions as co-chair of The Johns Hopkins Hospital Standards of Care Committee and sits on the Hospital Nursing Research Committee and Clinical Products Value Analysis Committee. Her previous experience was as the Nurse Manager of the Comprehensive Integrated Inpatient Rehabilitation Program located in The Johns Hopkins Hospital, from 2007- 2013. She is a member of Sigma Theta Tau and is a certified Rehabilitation Nurse. Sue is a graduate of the University of Maryland at Baltimore with a BSN degree and from The Johns Hopkins University School of Nursing with a Master's degree in nursing management. In 2003, Sue was The Johns Hopkins Hospital Evidence-based Practice Fellow and along with a Wilmer based team, conducted an EBP project in the Wilmer Eye Institute to investigate the cause of toxic anterior segment syndrome. Prior to that, Sue was a co-investigator on a funded IRB research project to see if negative pressure dressings were more efficacious in healing complex wounds, after cardiac surgery, than wet-to-dry dressings.

Eyal Zimlichman, MD, MSc (MHCM)
Deputy Director General and Chief Quality Officer,
Sheba Medical Center

Dr. Eyal Zimlichman is an internal medicine physician, a healthcare executive, and a researcher focused on healthcare quality improvement and patient safety. Dr. Zimlichman is currently Deputy Director General and Chief Quality Officer at Sheba Medical Center, Israel's largest hospital. Prior to this Dr. Zimlichman has held the position of Lead Researcher at Partners Health Care Clinical Affairs Department in Boston where he was involved in the efforts to bring about a strategic care redesign initiative. He is still a consultant to Partners Healthcare. For the past five years, Dr. Zimlichman is conducting research on implementing technology to improve healthcare quality and patient safety at Brigham and Women's Hospital and Harvard Medical School affiliated Center for Patient Safety Research and Practice. Dr. Zimlichman served as an advisor to the Office of the National Coordinator for Health Care Information Technology at the U.S. Department of Health and Human Services. He is a graduate of the Harvard School of Public Health Executive Health Care Management Master of Science program and earned his MD at the Technion Israel Institute of Technology in Haifa, Israel.

Appendix C: List of Attendees

Brian Abbiehl

Patient Advocate
Promise to Amanda

Cindy Abbiehl

Patient Advocate
Promise to Amanda

Lenore Alexander

Executive Director
Leah's Legacy

Mary Alexander, MA, RN, CRNI, CAE, FAAN

Chief Executive Officer
Infusion Nurses Society

Robert Allen, MD

Staff Physician
Fayetteville Pain Center

Arthur Auerbach, MD, MPH

Professor of Medicine in Residence
University of California

Bona E. Benjamin, RPh, BSPHarm

Director, Medication-Use
Quality Improvement
American Society of Health System
Pharmacists

Jim Bialick

President
Patient Safety Movement Foundation

George T. Blike, MD, MHCDS

Chief Quality and Value Officer,
Assistant Professor, Anesthesiology
Dartmouth-Hitchcock Medical Center

D. Hunter Burgoon, RN, PHN

Director of Biomedical Technology
Integration
Kaiser Permanente

Maureen Cooney, RN, DNP, NP-BC

Nurse Practitioner, Pain Management
Westchester Medical Center

Darin Correll, MD

Director, Postoperative Pain
Management Service
Brigham & Women's Hospital

Paul Coss

Vice President, Business Development
Respiratory Motion, Inc.

Akin Demehin, MPH

Senior Associate Director, Policy
American Hospital Association

Michael DeVita, MD, FCCM

Director, Critical Care
International Society for Rapid
Response Systems

Richard Dutton, MD, MBA

Executive Director
Anesthesia Quality Institute

R. Scott Evans, MS, PhD, FACMI

Medical Informatics Director
Intermountain Healthcare

Sarah Fanta Lombardi, MPH

Program Director
AAMI Foundation

Thomas Frederickson, MD, SFHM, FACP, MBA

Medical Director
CHI Health-Alegent
Creighton Clinic

Dave Giarracco

Vice President, US Marketing
Respiratory and Monitoring Systems
Medtronic

Carolyn Gooding

Senior Market Program Manager
CareFusion

Beth Hammer, MSN, RN, ANP-BC

Program Manager for Nursing
Excellence
American Association of
Critical Care Nurses

James Harrell, RCP

Manager Pulmonary Services
Sharp Memorial Hospital

Helen Haskell

President
Mothers Against Medical Error

Benjamin Kanter, MD

Chief Medical Officer
Sotera Wireless Inc.

Ramya Krishnan, MS

Senior Project Engineer
ECRI Institute

Patricia LaChance Knode

Patient Advocate

Geoffrey Lighthall, MD, PhD

Associate Professor, Anesthesiology,
Perioperative and Pain Medicine
Stanford University

Alan Lipschultz, CCE, PE, CSP

American College of Clinical
Engineering

Mary Logan, JD, CAE

President & CEO
AAMI

Sean Loughlin

Vice President, Communications
AAMI

Andrew Lyzenga, MPP

Senior Project Manager,
Patient Safety
National Quality Forum

Ray R. Maddox, PharmD, FASHP

Clinical Professor, Campus Dean &
Associate Department Chair
University of Georgia

Christina Matadial, MD

Anesthesiology, Miami VA Healthcare
System
VA National Center for Patient Safety

Lisa Mazzia, MD

Physician Consultant
VA National Center for Patient Safety

Patricia McGaffigan, RN, MS

COO & Sr. Vice President, Programs
National Patient Safety Foundation

Melinda Mercer Ray, RN, MSN
Executive Director
National Association of Clinical Nurse
Specialists

Kathleen Mika, MSN, RN
Associate Director, Standards
Development
The Joint Commission

Joseph Miller, MS
Senior Vice President
Society of Hospital Medicine

Jacque Mitchell
American Society for Healthcare
Risk Management

Julie M. Morath, RN, MSN, CPPS
President/CEO
Hospital Quality Institute

Marilyn Neder Flack, MA
Executive Director, AAMI Foundation
Sr. Vice President, Patient Safety
Initiatives, AAMI

Tim O'Malley
President
EarlySense

Frank Overdyk, MSE, MD
Chair, National Coalition to Promote
Continuous Monitoring of Patients
on Opioids

Veronica Petersen, RN, MSN, NE-BC
Assistant Vice President
North Shore LIJ Health System

Pam Pohlenz, RT
Clinical Respiratory Educator
St. Francis Medical Center

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Appendix D: Patient Stories

The number of patients who die in their hospital beds from undetected respiratory depression after receiving opioids for pain management has been the focus of medical conferences, examined in the medical literature, and featured in news stories. Yet, healthcare providers—following the standard of practice for their institutions—continue to miss the potentially preventable signs of respiratory depression. Patients die and their families are left distraught, wondering how such a thing could happen. In what follows, some of these families share their stories in the hope of limiting future tragedies.

Lewis Blackman Hospitalized for: Chest Surgery Risk Factors: None



Helen Haskell's son Lewis Blackman was a bright, active, healthy 15-year-old in November 2000 when his parents brought him to a hospital in Charleston, South Carolina for an elective medical procedure. He was undergoing surgery to correct a congenital defect of the chest

called *pectus excavatum*, a sunken breastbone.

The procedure involved a surgeon inserting a bar into his chest to place upward pressure on the sternum. Lewis was placed on a heavy narcotic pain regimen, with high doses of hydrocodone in an epidural plus adjunct injections of Toradol to control his pain. The surgery went well, and Lewis was initially monitored with pulse oximetry. However, his saturation levels kept dropping below 85%, and the monitor repeatedly alarmed. Nurses turned off the monitor.

On the third day after surgery, Lewis developed a sudden intense pain in his stomach. Nurses assumed that it was an ileus, an intestinal blockage, and Lewis's epidural narcotics were stopped. Ultimately, he went into cardiac arrest and died. Autopsy revealed a large perforated ulcer of a type

usually associated with NSAID overdose. The ulcer had penetrated an underlying artery and Lewis had lost 2.8 litres of blood and stomach contents into his abdominal cavity. "Losing Lewis was devastating," says Haskell. "We entered the hospital with two children and came out with one. Our son had slowly died from a severe medication reaction, while his nurses and residents seemed unable even to respond to our pleas for help. I was stunned at the disorganization we had witnessed, and felt that my son's death would be meaningless if we did not do all we could to change the situation."

Following Lewis' death, Haskell became active in the patient safety movement. She founded the group Mothers Against Medical Error and helped create a coalition of South Carolina health professionals and consumers to pass the Lewis Blackman Act, aimed at addressing the conditions that led to Lewis's death.

"These stories all involve people not paying attention," says Haskell. "I believe that continuous monitoring must be part of a system for rescuing deteriorating patients. Data must be trended, rolled up into a score, and evaluated by a critical care person who is not part of the original team. Respiratory depression is the key measure, and I believe that technology is the answer to get around toxic relationships in the hospital environment."

"Every patient deserves continuous monitoring," she says. "You never know what's going to happen, particularly with postoperative patients. Lewis is a prime example. He was a perfectly healthy child, which is why no one could believe that anything was wrong with him. You need an objective observer like a monitor."

Website: lewisblackman.net

Video: www.youtube.com/watch?v=yNsJaf8nONO

Leah Coufal

Hospitalized for: Chest Surgery

Risk Factors: None



In December 2002, Lenore Alexander's daughter Leah Coufal, a healthy 11-year-old girl, underwent elective chest surgery at a major medical center in Los Angeles, California to correct *pectus carinatum*, a deformity of the chest. "A lot of things went wrong that day," says Alexander.

Leah came out of surgery successfully. She was on an epidural with fentanyl for pain control. When her pain was not relieved, they increased her fentanyl dosing, ultimately to the highest dose. When Leah's parents insisted that they stop increasing her pain medication dosing, they gave Leah Ativan, an anti-anxiety medication, instead. Leah was not on any electronic monitors. Per hospital policy, nurses checked on her every few hours. Alexander stayed at her side that night but, exhausted, finally dozed in a chair next to Leah's bed. When she woke, Leah was dead, a victim of undetected respiratory arrest. An autopsy found that Leah's epidural had been inserted in the wrong place, into the intrapleural space of her left lung rather than to the epidural space in Leah's spine. This explained why she was feeling so much pain.

"That night at the hospital, I didn't know I needed to be ready to save Leah's life," says Alexander. "I didn't know she needed protection. But she did. This was so avoidable. Had she been on a monitor, they would have detected that her breathing was deteriorating and something would have triggered an alert. With no medical training, I could have saved my child's life that night." Ten years later, Alexander began speaking out about Leah's experience, advocating for what she calls Leah's Law: Continuous postoperative monitoring for patients on opioids.

"How many children will die this year because they're not on a monitor after surgery?" asks Alexander. "The way my daughter died 10 years ago, she would die today, just as likely. I think of all the families that have been torn apart and broken by the tragedy of losing a child, and it's because most things have not changed. We're not doing enough things differently. How many families will be told, 'Your child died from respiratory depression,' never understanding

that it was a lack of continuous monitoring that ended their child's life?"

"I want a standard of care that uses the existing technology to create a new standard of safety. Because medical errors happen to one person at a time, behind closed doors, it's easy for people not to pay attention. But medical errors are now the third leading cause of death. We no longer have the luxury of believing it could never happen to me. We need to be engaged, educated, and smart patients. My part in this is making sure continuous electronic monitoring for all patients on opioids is the standard of care in every hospital in America."

Website: leahslegacy.org

Video: www.youtube.com/watch?v=Kp_Jf65hp3M

Katie Couric interview: www.youtube.com/watch?v=m530yntLZFQ

John LaChance

Hospitalized for: Rotator Cuff Surgery

Risk Factors: Sleep apnea, previous problems with pain management



In March 2007, Patricia LaChance accompanied her husband of 27 years, John Michael LaChance, to a hospital in Fredericksburg, Virginia for routine rotator cuff repair surgery. He had re-injured his shoulder when he reached out to block a basketball from hitting Patricia during an event at their church.

Because he had experienced adverse reactions to pain medication with an earlier surgery for the same rotator cuff problem, his surgeon recommended a 23-hour hospital stay for pain management. In addition, John was previously diagnosed with sleep apnea. He and Patricia shared this information with the medical team prior to surgery, but a continuous positive airway pressure (CPAP) machine was not ordered for him to use after surgery.

To control his pain during surgery, he received a shoulder block, a form of local anesthetic. After surgery, doctors prescribed morphine through a patient-controlled analgesia (PCA) machine, along with monitoring via pulse oximetry. The morphine did not manage his pain but

instead caused extreme vomiting. John was removed from the PCA machine, as well as the supplemental oxygen he had been receiving and instead given an injection of Dilaudid for pain along with an anti-nausea medication. He was also removed from the pulse oximeter that had been monitoring his oxygenation levels while on the PCA machine.

“Shortly after, John seemed to be sleeping well, so I went home for the night with the intent of taking him home the next morning,” says Patricia. When she left at 10 pm, John was snoring. He was in a room by himself at the far end of the hallway. Patricia never got the chance to take him home. After a second dosing of Dilaudid sometime during the night, a nurse making rounds at 4:20 am found John unresponsive in his bed. The crash team worked on John for more than 40 minutes, but he died.

“Why was John removed from monitoring when they began administering stronger opioids?” asks Patricia. “That was the standard of care for post-orthopedic surgery patients. But now we’re finding out how important it is to remain monitored. His sleep apnea diagnosis was really a respiratory issue, and when mixed with opioids, that diagnosis puts patients at a much higher risk for respiratory depression. Each patient, each person, has different needs and issues. Blanket care orders don’t work for everybody.”

“I don’t want any other family to go through this,” she says. “I continue to be shocked as I learn of the deficiencies within our healthcare systems and in our healthcare providers when it comes to understanding the dangers of these drugs and the importance of continual monitoring.” “How can patients and their families be expected to understand and monitor these things when even our healthcare providers don’t?” she asks.

Video: www.youtube.com/watch?v=dH9agqZRdXw

Amanda Abbiehl

Hospitalized for: Severe Throat Pain

Risk Factors: None



In July 2010, Brian and Cindy Abbiehl brought their 18-year-old daughter Amanda to a hospital in Mishawaka, Indiana with a sinus infection and severely sore and swollen throat due to a virus. She was dehydrated, had lost weight, and was in a great deal of pain. Her physician admitted her to the

hospital with the goals of rehydrating her, administering antibiotics, and managing her throat pain.

Amanda was placed on a PCA machine that would allow her to control the amount of pain medication—hydromorphone, also known as Dilaudid—that she received. Her parents hoped that the stay would be short. Instead, in less than 12 ½ hours after being put on the PCA pump, Amanda was found unresponsive in her hospital bed and died.

The most likely cause of her death was respiratory depression caused by the pain medications she was receiving. Opioids can sedate the part of the brain that controls breathing, causing the lungs to slow and ultimately stop. The risk of respiratory depression increases with people who have apnea, are obese or have other problems, but Amanda had none of those risk factors.

“Amanda was on a general care floor and was not on any kind of electronic monitoring that might have alerted staff to her deteriorating condition,” her parents say. They are left to wonder, “Would an alarm signaling Amanda’s dropping levels have alerted caregivers to check on Amanda’s condition in time to save her?”

“Everyone can do everything exactly as the doctor prescribed, and the patient can still perish because of respiratory depression,” says Brian.

Amanda’s parents are working hard to raise awareness about respiratory depression. With the help of a local graphic arts design class and some dedicated healthcare providers, they have started, A Promise to Amanda Foundation, and launched a website. Their goal is to encourage all healthcare facilities to monitor patients on opioids with both oximetry and capnography to eliminate the possibility of respiratory depression as a cause of death. “Patients and

their families must be educated about the need for this monitoring,” they say. “Such monitoring needs to be done on all patients, not haphazardly. There is no way to know how any patient is going to react to these medications. Every patient is high risk.”

“We hope and pray that no one will ever have to feel the emptiness we have in our hearts,” they say. “The lack of will among hospitals to provide this monitoring today is shocking.” “If you have a safety net, why not use it?”—Cindy Abbiehl

Website: www.promisetoamanda.org/

Youtube: www.youtube.com/watch?v=gNZbvs3aByc

Matt Whitman

Hospitalized for: Neck Surgery

Risk Factors: None



In April 2003, Matt Whitman checked into a hospital in Indianapolis, Indiana to undergo the neck surgery his doctors had been recommending for years. As a state trooper, he was injured in 1990 when a drunk driver struck his squad car. He had returned to his job after undergoing six months of rehabilitation

and was eventually named a district Trooper of the Year. But, by 2002, doctors were warning that if he got hit again, he would be a quadriplegic.

The surgery went well. While in recovery, he was placed on a morphine pump to help manage the pain, but not monitored. “I was still in pain, so they upped the dosage later that night,” he says. Per hospital practice, a nurse monitored his vital signs every few hours. Late that night, a nurse had just checked him and proceeded to check other patients on the large hospital floor. But, when another patient needed something, she decided to go to the supply room to restock her cart. “Fortunately for me, her path to the supply room led her past my room,” says Whitman. “So, even though she had just checked on me 15 minutes earlier, she just so happened to be passing my room when she noticed I was not breathing and called a ‘Code Blue.’” Miraculously, Whitman survived. He had been without oxygen for six minutes. “I was a ‘near miss,’” he says. “And

if not for the grace of God, I would not be alive today. My doctor told me that only 4% of Code Blue patients live.”

“I was never electronically monitored. There was nothing that would have indicated to a nurse that I was about to experience respiratory depression and almost die. I was 39 years old and in terrific health. I was not a high-risk patient.” Whitman is now speaking out to encourage hospitals to electronically monitor all of their patients, not just the ones at high risk. “A human life is too valuable for you not to do this,” he says. “All hospitals need a technological safety net for their patients. All nurses and caregivers need that safety net too.”

Whitman has since retired as a trooper and is now a teacher. “As soon as I heard about the Amanda Abbiehl story, I contacted a reporter. I want to speak out. I strongly believe that a technology safety net would go a long way in reducing the many ‘near miss’ cases that continue to cause caregivers so much shame.”

“Like Amanda, I was not a high risk patient,” he says. “Continuous monitoring should be used with every single PCA pump, regardless of age, risk, operative status. These tragedies are so avoidable. I don’t understand why that monitoring is not done already.”

Website: ppahs.org/tag/matt-whitman/

Appendix E: Stakeholder Stances

Statements in Support of Continuous Monitoring for Patients on Opioids Stakeholder Organizations

1. American Association for Respiratory Care (AARC) Position Statement: Administration of Sedative and Analgesic Medications by Respiratory Therapists

The American Association for Respiratory Care (AARC) recognizes the fact that Respiratory Therapists are called upon to assist physicians with the administration of sedative and analgesic medications during diagnostic and therapeutic procedures and patient transportation.

“Sedation” and “analgesia” describe a physical state in which the patient is able to tolerate unpleasant procedures, while maintaining adequate cardiorespiratory function, and the ability to respond purposefully to verbal commands and tactile stimulation. This is commonly referred to as moderate sedation.

The AARC believes that Respiratory Therapists working under qualified medical supervision can assist physicians during diagnostic and therapeutic procedures and patient transportation, and help to minimize risks by administering prescribed medications and closely monitoring the patient.

The AARC recognizes and acknowledges the following:

The American Society of Anesthesiologists (ASA) has published the document “Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists.” Reference: *Anesthesiology*, 2002; 96: 1004- 1017

The purpose of the ASA document is to allow clinicians to provide their patients with the benefits of sedation and analgesia, while minimizing associated risks.

ASA Guidelines should be followed by all Respiratory Therapists called upon to provide this service. The clinicians and their facilities have the ultimate responsibility for selecting patients, procedures, medications, and equipment.

Respiratory care education programs approved by the Commission on the Accreditation of Allied Health Education Programs/Committee on Accreditation for Respiratory Care (or their successor organizations) provide appropriate pharmacologic and technologic training to enable Respiratory Therapists to safely administer sedatives and analgesics by following the ASA Guidelines.

Following successful completion of a specialized education and competency assessment program, the Respiratory Therapists must have the following competencies:

- Be knowledgeable about the techniques, medications, side effects, monitoring devices, response or untoward effects of medications, and documentation for any specific procedure
- Meet qualifications to be certified as competent, in accordance with her/his facility’s and Respiratory Care Department’s policies, to administer sedatives and analgesics under qualified medical direction.

The AARC affirms that Respiratory Therapists who have successfully completed a specialized education and competency assessment program on sedation and analgesia based on the ASA’s Guidelines, and who have been certified as competent by the appropriate medical director and department head or governing body, should be permitted to provide the service in accordance with ASA’s Guidelines, facility policies, procedures, protocols, and service operations, as well as with Joint Commission and state requirements and policies.

Source:

Effective 12/97

Revised 07/07

Position Statements | AARC.org | www.aarc.org

2. American Society for Pain Management Nursing

As the complexity of analgesic therapies increases, priorities of care must be established to balance aggressive pain management with measures to prevent or minimize adverse events and to ensure high quality and safe care. Opioid analgesia remains the primary pharmacologic intervention for managing pain in hospitalized patients.

Unintended advancing sedation and respiratory depression are two of the most serious opioid-related adverse events. Multiple factors, including opioid dosage, route of administration, duration of therapy, patient-specific factors, and desired goals of therapy, can influence the occurrence of these adverse events. Furthermore, there is an urgent need to educate all members of the healthcare team about the dangers and potential attributes of administration of sedating medications concomitant with opioid analgesia and the **importance of initiating rational multimodal analgesic plans to help avoid adverse events.**

- Nurses play an important role in the following:
1. identifying patients at risk for unintended advancing sedation and respiratory depression from opioid therapy;
 2. implementing plans of care to assess and monitor patients; and
 3. intervening to prevent the worsening of adverse events.
- Despite the frequency of opioid-induced sedation, there are no universally accepted guidelines to direct effective and safe assessment and monitoring practices for patients receiving opioid analgesia.

Moreover, there is a paucity of information and no consensus about the benefits of technology-supported monitoring, such as pulse oximetry (measuring oxygen saturation) and capnography (measuring end-tidal carbon dioxide), in hospitalized patients receiving opioids for pain therapy.

To date, there have not been any randomized clinical trials to establish the value of technologic monitoring in preventing adverse respiratory events. Additionally, the use of technology-supported monitoring is costly, with far-reaching implications for hospital and nursing practices.

As a result, there are considerable variations in screening for risk and monitoring practices. All of these factors prompted the American Society for Pain Management Nursing to approve the formation of an expert consensus panel to examine the scientific basis and state of practice for assessment and monitoring practices for adult hospitalized patients receiving opioid analgesics for pain control and to propose recommendations for patient care, education, and systems-level changes that promote quality care and patient safety.

Source:

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www.aspmn.org

Jarzyna D, Jungquist CR, Pasero C, Willens JS, Nisbet A, Oakes L, Dempsey SJ, Santangelo D, et al. *American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression*. *Pain Management Nursing*. 2011; 12(3):118–145.e10

3. American Society of Anesthesiologists

In 2009, ASA issued an updated report on its Task Force on Neuraxial Opioids Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration

Recommendation: All patients receiving neuraxial opioids should be monitored for adequacy of ventilation (e.g., respiratory rate, depth of respiration [assessed without disturbing a sleeping patient]), oxygenation (e.g., pulse oximetry when appropriate), and level of consciousness.

Source: <https://www.asahq.org/>

4. Anesthesia Quality Institute

AQI's mission is to be of value to practicing anesthesiologists for personal benchmarking, quality reporting, hospital credentialing, maintenance of licensure, maintenance of certification, and clinical research.

Source: www.aqihq.org/index.aspx

5. Brigham and Women's Hospital

Brigham and Women's Hospital policies require that "all patients on continuous opioid infusions, epidurals with opioids, or IV PCA must be on a centrally monitored continuous pulse oximeter."

Source: www.brighamandwomens.org

6. CareFusion's Center for Safety and Clinical Excellence

The CareFusion Center serves as an independent resource to help foster the development and dissemination of best practices, clinical insights, and innovations nationwide.

Source: www.carefusion.com/safety-clinical-excellence/

7. Centers for Medicare & Medicaid Services

On March 14, 2014, CMS issued guidance, "Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids."

This guidance recommends "at a minimum" [page 19] that hospitals "have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients receiving IV opioid medications, regardless of where they are in the hospital." [page 1]

In addition and more importantly, the CMS guidance necessitates monitoring for all patients receiving opioids when in hospital:

"Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all hospital settings in which

opioids are administered, to permit intervention to counteract respiratory depression should it occur.” [page 15] What does the CMS guidance mean by “appropriate monitoring”?

Does “appropriate monitoring” mean intermittent assessment, as was recommended in last year’s CMS proposed quality measure (#3040)?

Proposed measure #3040 provided that monitoring needs to be “documented” and the time between documentation must “not exceed 2.5 hours.” This means that a nurse or other caregiver must document the patient’s condition and do this in intervals of not greater than 2.5 hours.

In the report submitted after the CMS guidance was released by the National Quality Forum to HHS, the measure was not endorsed and it was decided that the measure “requires modification or further development.”

Robert Stoelting, MD, president of the Anesthesia Patient Safety Foundation, in commenting on proposed measure #3040 said: “The conclusions and recommendations of APSF are that intermittent ‘spot checks’ of oxygenation (pulse oximetry) and ventilation (nursing assessment) are not adequate for reliably recognizing clinically significant evolving drug-induced respiratory depression in the postoperative period. For the CMS measure to better ensure patient safety, APSF recommends that monitoring be continuous and not intermittent, and that continuous electronic monitoring with both pulse oximetry for oxygenation and capnography for the adequacy of ventilation be considered for all patients.”

Or does “appropriate monitoring” mean continuous electronic monitoring?

The CMS guidance provides two examples—one from the Institute for Safe Medication Practices and one from APSF—that could suggest that the guidance may be referring to continuous electronic monitoring. For example, the guidance provides the following from ISMP, which refers to monitoring for saturation of peripheral oxygen via pulse oximetry and end-tidal carbon dioxide via capnography.

Source: New CMS Guidance Recommends Monitoring of All Patients Receiving Opioids: What It Means for Healthcare Providers: www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-15.pdf

8. Covidien Professional Affairs and Clinical Equation (PACE)

Covidien’s PACE training is designed to help clinicians provide innovative solutions and improve patient care.

Clinical education and non-clinical education modules provide training related to the use of EtCO₂ monitoring with non-intubated and intubated patients in various clinical settings. These programs are designed to help provide safe and effective ventilatory monitoring of the patient.

Source: Clinical Education: www.covidien.com/pace/clinical-education

Source: Capnography Channel: www.covidien.com/pace/clinical-education/channels/capnography

Source, Respiratory Function Monitoring Channel: www.covidien.com/pace/clinical-education/channels/respiratory-function-monitoring

Clinical education and non-clinical education modules on oximetry, sensor use, respiratory rate, and capnography provide education on the safe and effective use of respiratory function monitors.

Source: www.covidien.com

9. United States Food and Drug Administration

FDA has issued information on drug safety applicable to the monitoring of patients on opioids.

Source: www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM277916.pdf

10. Institute for Healthcare Improvement Knowledge Center

The Institute offers tools, change ideas, measures to guide improvement, white papers, audio and video, improvement stories, and more.

Source: www.ihl.org/knowledge/Pages/default.aspx

11. The Joint Commission Safe Use of Opioids in Hospitals

While opioid use is generally safe for most patients, opioid analgesics may be associated with adverse effects,^{1,2,3} the most serious effect being respiratory depression, which is generally preceded by sedation.^{4,5,6} Other common adverse effects associated with opioid therapy include dizziness, nausea, vomiting, constipation, sedation, delirium, hallucinations, falls, hypotension, and aspiration pneumonia.^{4,7}

Adverse events can occur with the use of any opioid; among these are fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and sufentanil. While there are numerous problems associated with opioid use, including underprescribing, overprescribing, tolerance, dependence, and drug abuse, this Alert will focus on the safe use of opioids that are prescribed and administered within the inpatient hospital setting. The Joint Commission recognizes that the emergency department presents unique challenges that should also be addressed by the hospital, but may not be directly addressed in this Alert. This Alert will provide a number of actions that can be taken to avoid the unintended consequences of opioid use among hospital inpatients.

Opioid analgesics rank among the drugs most frequently associated with adverse drug events. The literature provides numerous studies of the adverse events associated with opioids. One study found that most adverse drug events were due to drug-drug interactions, most commonly involving opioids, benzodiazepines, or cardiac medications.⁸

In addition, a British study of 3,695 inpatient adverse drug reactions found that 16 percent were attributable to opioids, making opioids one of the most frequently implicated drugs in adverse reactions.⁷ The incidence of respiratory depression among post-operative patients is reported to average about 0.5%. Some of the causes for adverse events associated with opioid use include the following:

- lack of knowledge about potency differences among opioids;
- improper prescribing and administration of multiple opioids and modalities of opioid administration (i.e., oral, parenteral and transdermal patches); and
- inadequate monitoring of patients on opioids.^{9,10}

Of the opioid-related adverse drug events—including deaths—that occurred in hospitals and were reported to The Joint Commission's Sentinel Event database (2004-2011), 47% were wrong dose medication errors, 29% were related to improper monitoring of the patient, and 11% were related to other factors, including excessive dosing, medication interactions, and adverse drug reactions.*

These reports underscore the need for the judicious and safe prescribing and administration of opioids, and the need for appropriate monitoring of patients. When opioids are administered, the potential for opioid-induced respiratory depression should always be considered because:

- The risk may be greater with higher opioid doses
- The occurrence may actually be higher than reported

- There is a higher incidence observed in clinical trials¹¹

Various patients are at higher risk (see below), including patients with sleep apnea, patients who are morbidly obese, who are very young, who are elderly, who are very ill, and who concurrently receive other drugs that are central nervous system and respiratory depressants (e.g., anxiolytics, sedatives).^{5,11,1}

Source: www.jointcommission.org

12. Kelowna General Hospital (Kelowna, British Columbia)

KGH is the “first facility in Canada to implement continuous bedside capnography monitoring for postoperative patients with a history of OSA who are discharged from the recovery room to patient care wards.”

Source: ppahs.org/2012/04/05/improving-hospital-efficiency-and-patient-safety-bedside-monitoring-with-capnography/

13. Leah's Legacy

“Leah's Legacy is a not-for profit organization working to achieve zero preventable deaths from medical error through prevention, education, and advocacy, and to make continuous postoperative monitoring for all patients on opioids the law. Leah's Law.”

Source: leahslegacy.org/

Additional resources: leahslegacy.org/resources-3/

14. Mothers Against Medical Error/Empowered Patient Coalition

The Empowered Patient Coalition is a 501(c)(3) charitable organization created by patient advocates devoted to helping the public improve the quality and the safety of their healthcare. The coalition feels strongly that the first crucial steps in both patient empowerment and patient safety efforts are information and education. The public is increasingly aware that they must assume a greater role in healthcare issues but they need tools, strategies, and support to assist them in becoming informed and engaged medical consumers who are able to make a positive impact on healthcare safety.

Source: www.mamemomsonline.org/

Source: empoweredpatientcoalition.org/

15. National Comprehensive Cancer Network Adult Cancer Pain Guidelines (2010)

Source: www.nccn.org/professionals/physician_gls/f_guidelines.asp

16. Oridion Learning Center

The learning center is committed to the development of educational programs to train clinicians in the use of Microstream® EtCO₂ monitoring (capnography) technology. These tools are designed to meet the needs of a broad range of clinicians.

Source: www.oridion.com/eng/learning-center/learning-center.asp

17. The Patient Safety Movement Foundation

The Patient Safety Movement is connecting people, ideas, and technology to confront the large scale problem of over 200,000 preventable patient deaths in US hospitals each year by providing actionable ideas and innovations that can transform the process of care, dramatically improve patient safety, and help eliminate patient preventable deaths. We are doing this one solution, one commitment, one hospital, one act of kindness and love, and one patient at a time. The movement is breaking down silos between hospitals, medical technology companies, patient advocates, patients, the government, and all the stakeholders affected in healthcare—all of us. Together we are pushing toward ZERO preventable deaths by 2020.

Specific resources about post-operative respiratory depression and other patient safety solutions can be found here:

Source: patientsafetymovement.org/challenges-and-solutions/

Source: www.patientsafetymovement.org

18. Pennsylvania Patient Safety Authority

“Making Patient-Controlled Analgesia Safer for Patients”
Vol. 8, No. 3 (September 2011)

Source: patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/sep8%283%29/documents/94.pdf

19. The Physician-Patient Alliance for Health & Safety

To improve patient safety and save patients' lives, we recommend adopting continuous respiratory monitoring of all patients receiving opioids with pulse oximetry for oxygenation and with capnography for adequacy of ventilation to improve timely recognition of respiratory depression, decompensation or clinical deterioration.

Source: www.ppahs.org

20. Promise to Amanda

The mission of the Foundation is to raise awareness of respiratory depression so it becomes mandatory to continuously electronically monitor all patients using capnography and pulse oximetry:

- Every time a patient is placed on a PCA pump
- Every time a patient is sedated.
- Every patient that requires a stay in the PACU following general anesthetic.
- Every patient that requires a stay in the PACU following sedation.

Source: www.promisetoamanda.org/

21. San Diego Patient Safety Council

The San Diego Patient Safety Council published “Respiratory Monitoring of Patients Outside the ICU: Guidelines of Care Tool Kit” in June 2014. The toolkit provides evidence-based recommendations on safe and effective assessment, monitoring, and interventions for patients at risk for unrecognized respiratory depression.

Source: www.carefusion.com/safety-clinical-excellence/medication-safety/patient-safety-council.aspx

22. Society for Hospital Medicine (SHM)

SHM does not have an explicit position or policy on monitoring patients on opioids. Its mission statement reads as follows:

The Society of Hospital Medicine (SHM) promotes exceptional care for hospitalized patients.

SHM Objectives include the following:

- Promoting high quality and high value health for every hospitalized patient
- Advancing the state of the art in hospital medicine through education and research
- Improving hospitals and the healthcare community through innovation, collaboration, and patient centered care
- Supporting and nurturing a vibrant, diverse, and multi-disciplinary membership to ensure the long term health of hospital medicine

Consistent with this mission statement, SHM's leadership recognizes that opioids are a top source of inpatient adverse drug events, and that a systems approach to opioid prescribing, monitoring programs, and early intervention systems should be undertaken by every hospital. While more research is needed to define the optimal approach to these issues, medical centers should act now on the best available evidence with a solution informed by their local data and circumstances.

Source: www.hospitalmedicine.org

23. St. Joseph's/Candler Health System, Inc.

St. Joseph's/Candler Health System has established a PCA policy, flowsheet, and monitoring guidelines for hydromorphone. The policy requires the use of capnography for all patients receiving intravenous PCA; epidural pain control, except for the OB population; and high dose hydromorphone. The facility also uses capnography for moderate sedation procedures performed by anyone other than anesthesia personnel.

Source: www.sjchs.org/

24. Wesley Medical Center (Wichita, Kansas)

Prior to implementing capnography monitoring in 2010, 12.5% of moderate-to-severe patients at the medical center progressed to Code Blue. After implementing end-tidal CO₂ monitoring, that rate fell to 4.3% and then 0% in 2011. This retrospective study showed the number of blood gas measurements declined from 13,171 to 8,070, resulting in a total cost savings of almost \$1 million over a 6-month period. Dr. Mark Wencel and Debra Fox, RN at Wesley Medical Center concluded: "End-tidal CO₂ monitoring is an effective method for early detection of respiratory depression in patients receiving PCA and intermittent intravenous opioid pain management."

Source: ppahs.org/2012/03/29/reducing-healthcare-costs-how-one-hospital-minimized-blood-draws-and-laboratory-tests-while-increasing-patient-safety/

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