When 18-year-old Amanda Abbiehl came down with strep throat shortly after her high school graduation party, no one would have predicted that her treatment would end her life.

Amanda was a healthy young woman in July 2010, with plans to attend Indiana University South Bend that coming fall. “She was a spitfire,” says her mother, Cindy Abbiehl. “We always say that she brought the sunshine into the room. She didn’t judge people by the color of their skin or the scars on their body. She definitely was this big, huge, loving, caring person.”
But once Amanda finished a course of antibiotics, the strep throat roared back, with swollen tonsils, glands, and uvula so painful she struggled to eat and drink. She lost 10 pounds in a week. On top of that, she came down with a sinus infection.

Given the options of continuing treatment at home or in the hospital, Cindy Abbiehl asked her daughter’s primary care physician the question that every parent asks: “If it was your kid, what would you do?” Her parents took his advice, hospitalizing Amanda for the first time in her life so she could be treated for dehydration and viral and bacterial infections. Amanda’s parents expected her to be home in a couple of days.

It was not to be. Admitted to a local hospital in Mishawaka, IN, on a Thursday, Amanda had a rocky night and another day of pain on Friday, despite intravenous (IV) infusions of morphine. On Friday evening, Amanda was hooked up to a patient-controlled analgesia (PCA) pump that delivered hydromorphone, another opioid analgesic.

This painkiller kicked in for Amanda, who told her mother she was ready to go home. The next morning, however, Amanda was found dead in her hospital bed.

‘Dead-in-Bed’ Syndrome

Devastated by the loss of their only daughter, Cindy and Brian Abbiehl spent months trying to understand what had gone so terribly wrong. “People kept saying, ‘This doesn’t make any sense, this doesn’t make any sense,’” Cindy Abbiehl says, echoing the family’s own bewilderment.

Autopsy reports done locally and by pathologists with Johns Hopkins Medicine in Baltimore, MD, were incomprehensible to Amanda’s parents. For help deciphering the reports, they turned to medical experts, who told them, according to Brian Abbiehl, “That’s exactly how you write an autopsy report when you have no idea what happened.” Amanda’s father wondered, “If the virus caused the problem, why can’t anybody detect it?”

Only when the Abbiehls retained legal counsel did they learn about the well-documented risk of respiratory depression that can culminate in respiratory arrest for PCA patients—a risk known to insiders as “dead-in-bed” syndrome. In medical terms, respiratory depression means that a person’s respiration has a rate below 12 breaths per minute or fails to provide full ventilation to the lungs. Slow, shallow, or labored breathing are signs of respiratory depression.

“We are never going to be able to say with 110% certainty what really caused her death,” Brian Abbiehl says. “But at this point in time we believe that the most likely cause of her death was respiratory depression.

“We’re not trying to place blame,” he adds. Instead, through the Promise to Amanda Foundation (www.promisetoamanda.org) they launched in 2012 on the second anniversary of their daughter’s death, the Abbiehls are trying to raise awareness about the risk of respiratory depression with PCA pumps. And they are joining a chorus of influential voices in advocating for the use of continuous electronic monitoring every time a patient is placed on a PCA pump or is treated with powerful opioids—a change they hope will avert deaths like Amanda’s.

Frank Overdyk, MD, executive director for research and quality with North American Partners in Anesthesia (NAPA), cautions that it would be a mistake to focus on PCA pumps in and of themselves. “This danger is related to opioid use and overuse, the latter of which can be mitigated by alternative pain treatment strategies,” he says. “Opioids will remain indispensable to treat moderate to severe pain, but we must use them appropriately and safely.”

Only when the Abbiehls retained legal counsel did they learn about the well-documented risk of respiratory depression that can culminate in respiratory arrest for PCA patients—a risk known to insiders as “dead-in-bed” syndrome.
Early in the use of PCA pumps, he says, there were two major risks, incorrect programming of the pump and “PCA by proxy,” where someone other than the patient hit the button. Through warnings and greater awareness, Overdyk says, those risks have decreased substantially. “We must be careful we don’t throw out the baby with the bathwater,” he adds, emphasizing that PCA pumps remain an effective tool.

The key, he says, is careful monitoring, adopting technologies that go far beyond spot checks of patients. Overdyk will chair a gathering of experts on this issue at a major meeting being planned by the AAMI Foundation’s Healthcare Technology Safety Institute. That meeting is tentatively scheduled for the fall of 2014 (see sidebar).

“A well-intentioned goal of giving patients more control so they can get better pain management is actually appropriate. But I don’t think we have been mindful enough of the unintended consequences.”

— Peter Pronovost, MD, Johns Hopkins Medicine

A Longstanding Danger

For most patients, PCA pumps safely and quickly ease pain—a benefit that is widely acknowledged. At least as far back as the 1990s, however, the risk of respiratory depression has been associated with PCA pumps.

“A well-intentioned goal of giving patients more control so they can get better pain management is actually appropriate,” says Peter Pronovost, an anesthesiologist and director of the Armstrong Institute for Patient Safety and Quality and senior vice president for patient safety and quality at Johns Hopkins Medicine. “But I don’t think we have been mindful enough of the unintended consequences.”

Pronovost recalls meeting Lenore Alexander, the mother of another girl who died from respiratory depression following successful surgery. More than a decade ago, Leah Coufal, who was 11 at the time, died following successful surgery at a Los Angeles hospital. The girl was on opioids after her surgery. In fact, an epidural anesthesia used during the operation was left in place to help manage her postoperative pain, but Leah was not electronically monitored. Alexander is pushing for what she calls Leah’s Law: that all

What Is Patient-Controlled Analgesia?

The following information comes from the online Encyclopedia of Surgery at www.surgeryencyclopedia.com/La-Pa/Patient-Controlled-Analgesia.html#ixzz2fjUBYJ4

Patient-controlled analgesia (PCA) is a means for a patient to self-administer pain medications intravenously by using a computerized pump, which introduces specific doses into an intravenous line. The purpose of PCA is improved pain control. The patient receives immediate delivery of pain medication without the need for a nurse to administer it. The patient controls when the medication is delivered. More importantly, PCA uses more frequent but smaller doses of medication, and thus provides more even levels of medication within the patient’s body, than syringe-injected pain medication by a nurse.

PCA uses a computerized pump, which is controlled by the patient through a hand-held button that is connected to the machine. The pump usually delivers medications in small regular doses, and it can be programmed to issue a large initial dose and then a steady, even flow.

When the patient feels the need for medication, the patient presses a button similar to a nurse call button. When this button is pressed, some sound (usually a beep) is heard, indicating that the pump is working properly and that the button was pressed correctly. The pump delivers the medication through an intravenous line, a plastic tube connected to a needle inserted into a vein.
patients receiving opioids must be continuously electronically monitored. “I urge you to make this a priority,” she writes in an online account about her daughter’s death. [http://ppahs.org/2012/02/01/guest-post-yes-real-time-monitoring-would-have-saved-leah-2/]

Researchers have identified risk factors that increase the hazard of respiratory depression, including obesity, low body weight, sleep apnea, chronic obstructive pulmonary disease (COPD), asthma, advanced age, and the use of other medications that produce sedative effects.

For PCA patients with no known risk factors, clinicians typically monitor them using protocols calling for spot checks every two to four hours. High-risk PCA patients might be bedded in intensive care units (ICUs) rather than general medical–surgical units, with continuous electronic monitoring or more frequent spot checks.

Amanda’s story illustrates the shortcomings of these approaches. She had no known risk factors, although her parents now believe her symptoms—difficulty breathing with the sinus infection and a compromised airway from swollen tonsils and glands, plus the initial doses of morphine still in her system—placed her at high risk of respiratory depression on PCA. “She was on a general care floor, and at the time she was in the hospital, nobody considered her a high risk,” says Brian Abbiehl. And spot checks did not detect that Amanda was in trouble.

Pronovost says considerable time is spent trying to predict who is at risk.

“The problem is that none of those risk-prediction models work very well,” Pronovost says. “And many people, including the Anesthesia Patient Safety Foundation, endorse and support the notion that we can’t predict very well and it’s a fool’s errand to try. We ought to monitor everybody on PCA.”

Tim Vanderveen, vice president of the Center for Safety and Clinical Excellence at CareFusion and a member of the AAMI Board of Directors, agrees. “Slowly the risk factors have increased as well,” he says. “There are so many more patients with sleep apnea—and undiagnosed sleep apnea—and patients who are overweight.”

Another criticism of standard clinical practice pertains to the spot checks of PCA patients. “Spot checks that occur on a periodic basis—say, once every two or four hours—are insufficient because they presume that the patient will show signs of deterioration at the precise moment the nurse or caregiver is in the patient’s room,” says Michael Wong, founder and executive director of the Physician-Patient Alliance for Health & Safety and a champion of continuous electronic monitoring.

Plus, spot checks often arouse patients, and temporarily spur their breathing and make them more alert. Patients with respiratory depression can fall right back into a dangerous state when the clinician leaves the room.

Moreover, spot checks can only detect respiratory depression once it’s in progress. It takes electronic monitors to detect subtle changes in respiration—and provide clinicians with actionable information to prevent it. “We viewed a lot of arrests at our hospital,” Pronovost says. “Though they always appear as if it is all of a sudden, a nurse walks in and finds someone not breathing, in almost every one of these cases we found there was a progressive decline in respiratory rate that was missed. Almost every one.”

Adds Wong, “What is needed is an electronic safety net under each patient, and this can only be done with continuous electronic monitoring.”

Evidence is mounting that monitoring both oxygen and carbon dioxide levels yields the best patient outcomes.

Experts say that healthcare technology management professionals have a key role to play in finding a system-wide solution to this challenge.

“Clinical engineers obviously have to bring the technical piece. But they also bring that appreciation of the clinical environment, and the tools of the environment. It’s a conscious understanding of the system of systems.”

— Carol Davis-Smith, Kaiser Permanente
New Impetus for Action

Many organizations, researchers, healthcare professionals, and patient safety advocates, including families who have lost loved ones, are making the same impassioned case for continuous electronic monitoring. In addition to the Anesthesia Patient Safety Foundation (ASPF) and the Physician-Patient Alliance for Health & Safety, the Institute for Healthcare Improvement, Institute for Safe Medication Practices, and Veterans Health Administration are among the organizations that have come out with recommendations or guidelines for continuous electronic monitoring.

For them, implementation of this recommendation is long overdue—especially since monitoring technology has been available for some time and continues to improve. Two technologies are at the forefront of the recommendations:

- **Pulse oximetry** is the measurement of oxygen saturation in the blood with a noninvasive sensor, usually a finger probe.
- **Capnography** is the measurement of respiratory rate and the concentration of exhaled carbon dioxide (end-tidal CO2) to monitor adequacy of ventilation, usually with a sensor connected to a nasal cannula.

Evidence is mounting that monitoring both oxygen and carbon dioxide levels yields the best patient outcomes; pulse oximetry alone is insufficient, according to many experts. When these technologies, which also track heart and respiratory rates, are integrated with PCA pumps, the system can stop delivery of opioids if respiratory depression is detected.

“We have far to go to reach the ideal scenario of zero preventable patient deaths,” says Joe Kiani, founder and CEO of Masimo, which develops noninvasive patient monitoring technologies. “Data suggest that while nearly all hospitals utilize PCA pumps, only a small fraction continuously monitor all of their patients while on PCA pumps. The ideal scenario is for all patients to have oxygenation and respiratory rate monitored for the duration of PCA therapy, and for the monitoring device to directly notify a nurse of an alarm condition.”

Two recent official statements are shining more light on the dangers of PCA pumps. In August 2012, The Joint Commission (TJC),...
the nation’s largest hospital accreditation organization, issued a Sentinel Event Alert about the risk of respiratory depression, which can be caused by “inadequate monitoring of patients on opioids,” and noted that pulse oximetry and capnography “can be used” for monitoring. In December 2012, the Centers for Medicare & Medicaid Services (CMS) announced that it is considering a proposed quality measure calling for “appropriate monitoring” of patients receiving an opioid via an IV PCA device.

Reactions to these two statements from advocates of continuous electronic monitoring have been mixed. Vanderveen and others applaud TJC for an earlier Sentinel Event Alert pushing hospitals to improve pain management for patients, and the latest citing pulse oximetry and capnography as effective tools. Still, as Vanderveen notes, “The Joint Commission is not prescriptive. They make recommendations, but it’s up to the hospitals how they want to interpret them.”

Pronovost believes the commission’s statement and regulatory policy should be stronger. “The Joint Commission should have to explain why it doesn’t think the evidence is good enough or what evidence is missing to make such a policy,” he says. “Let them say that so researchers can go get the evidence. But I can say the ASPF and many others believe the evidence is quite strong and that the recommendation should be much more specific.”

The CMS-proposed quality measure drew more criticism. “Unfortunately, the CMS proposal fell drastically short of what is needed to improve patient safety and reduce adverse events by relying on spot checks of patients on PCA,” Wong says.

Still, vendors are seeing increased interest in continuous electronic monitoring since TJC’s Sentinel Event Alert was announced. “Adoption is happening,” says Greg Spratt, director of clinical marketing at Covidien. “We’re coming out of the innovator/early adopter stage, where you see dramatic increases in usage. Certainly looking at our sales around capnography, not only our direct sales, but from our OEM partners, we’re
A Role for AAMI

The AAMI Foundation’s Health-care Technology Safety Institute hopes to convene a multidisciplinary gathering of experts and organizations in the fall of 2014 to address PCA safety.

“It is important for patients and providers to understand that the danger comes from the treatment of opioids for moderate to severe pain, and is not inherent in PCA, which is a very effective and desirable way to administer opioids,” said Frank Overdyk, MD, who will chair the meeting for HTSI.

AAMI President Mary Logan noted that many organizations have identified PCA safety as an important issue, but there’s been little progress in assembling a “united front” of different stakeholders to address the issue and find solutions collectively. “AAMI can help facilitate that,” Logan said.

Separately, an AAMI working group is developing an interoperability standard to specify the characteristics of an integrated PCA system. Such an integrated system would monitor the patient’s vital signs and interact with an infusion pump when it notices signs of overmedication.

Without exception, the experts interviewed for this article say they would want continuous electronic monitoring themselves, or for their family members, if they were receiving opioids via a PCA pump.

What’s the Holdup?

Without exception, the experts interviewed for this article say they would want continuous electronic monitoring themselves, or for their family members, if they were receiving opioids via a PCA pump. Some, in fact, recommend that patients find out if their hospitals offer continuous electronic monitoring with PCA before they schedule medical procedures.

What’s holding up broader adoption of this practice? Here’s what the experts say—and their responses to reluctant adopters:

Cost. Cost is the most commonly cited impediment to adopting continuous monitoring technology. Wong calls that “perceived cost” because hospitals aren’t factoring in in the long-term patient safety and financial benefits.

He points to a pioneer in continuous electronic monitoring, St. Joseph’s/Candler Health System in Savannah, GA, where the two main hospitals have been using pulse oximetry and capnography for patients on PCA pumps since 2004. These two hospitals have been event-free for more than eight years—and they’ve shown that the technology “makes great financial sense.” This system’s financial return includes:

• Almost $4 million in estimated potential expenses averted for managing serious, medication-related events (not including potential litigation costs) (Maddox & Williams, 2012)
• $2.5 million return on investment over five years (Danell, Maddox, & Schaack, 2009)

Wong also cites an American Hospital Association (AHA) report, Adopting Technological Innovation in Hospitals: Who Pays and Who Benefits, which notes: “Implementing new technology is costly to hospitals while the benefits—both financial and non-financial—accrue somewhat to hospitals, but primarily to payers and patients.

“Contrast this to other industries where most technology directly improves productivity, generates savings and thus builds profitability for the entity that invested in the new technology” (AHA, 2006).

Wong, however, points to another paper “Is Technological Change in Medicine Worth It” (Cutler and McClellan, 2001) that concluded that that “even though new technologies typically cost more than the technologies that they are replacing, ‘medical spending as a whole is worth the increased cost of care because on balance these new technologies produce health improvements that are more valuable than the costs.”

Pronovost counters the cost argument from a different vantage point. Right now, as a safety measure, TJC recommends double-checks by clinicians any time a PCA order is changed. Pronovost and his team at Johns Hopkins conducted a time-motion study to ascertain what that really means for a typical, 20-bed hospital unit. On average, pain medication for patients on PCA is changed four times a day. Every change takes 10 minutes for each nurse, times two nurses—the time it takes for one nurse to track down another and perform the check-double-check protocol.

“You do the math,” Pronovost says. “Four times 20 minutes times 20 beds—that’s two nursing FTEs [full-time equivalents] on every unit double-checking something manually—let alone the hazards that disruption introduces to whatever the other nurse is doing, because we know that there is great data that distractions and interrupting people introduce risks. We also know that that double-check is completely error ridden, because each nurse thinks the other one is really checking.”

Instead, if PCA (or infusion) pumps were integrated with continuous monitoring...
technology and electronic medical records (EMRs), Pronovost says, the technology would perform this double-checking more accurately—in addition to monitoring for respiratory depression. “Too often, our policies from regulators are based on pre-electronic medicine, and they haven’t been updated to reflect technology,” he says.

**Alarm Burden.** Alarm fatigue, alarm overload, and alarm management are perennial challenges in healthcare. TJC, in fact, this past summer issued a 2014 National Patient Safety Goal on alarm management, as part of an effort to improve clinical alarm safety for hospitals and critical access hospitals.

Some clinicians resist more medical equipment, such as PCA pumps, that adds to the alarm burden. “Some pushback has been raised around alarms,” Covidien’s Spratt says. “We’ve tried to be innovative and work through alarm management solutions to reduce the number of nonactionable or ‘nuisance’ alarms, which can disrupt clinicians’ workflow. We recognize that they’re not in the room all the time. We’ve made tools available that allow clinicians to be alerted to alarms remotely, via smartphones and pagers. And most recently, we’ve even come out with a solution that allows them to view detailed monitor information remotely through a smart device like an iPad. They can see the parameters that are on the screen of a monitor or an iPad, whether they’re in the respiratory therapy department, at the nurse’s station, or even at their own home.”

For a pilot of continuous electronic monitoring underway in Kaiser Permanente’s Northern California region, “monitoring occurs on the rounding carts, so nurses can get a status display wherever they are,” says Jacob Johnson, integrated systems manager and clinical systems engineer. “It’s a little friendlier to the workflow and the nursing ratio. Med-Surg doesn’t necessarily have to have someone sitting at the nurse’s station looking at the screen.” And Kaiser Permanente has worked with clinicians to adjust alarm parameters for specific patient populations, thus easing the alarm burden. (For more on the Kaiser Permanente pilot, see the next page.)

Vanderveen cautions, however, that “nuisance alarms” could be true alarm signals that indicate early stages of respiratory depression, which might not be picked up by spot checks on patients.

Related to this concern is that continuous monitoring equipment does not necessarily integrate readily with central monitoring systems or EMRs. This technical challenge is lessening, however, as vendors and healthcare delivery organizations themselves are developing solutions for this integration.

**Technical—and Clinical—Complexity.** Clinicians in operating rooms and ICUs tend to be more familiar with pulse oximetry and capnography than clinicians on general medical–surgical units.

“We’re talking about a whole new level of monitoring” for clinicians, says Kaiser Permanente’s Davis-Smith. Clinicians need to understand the principles of continuous electronic monitoring and the rationale for using it—and there’s a learning curve for interpreting the waveforms that the technologies produce.

Covidien has heard that feedback from clinicians. “We’re focusing on designing a monitoring system that’s easy to use and integrating it into the workflow of the post-operative, general care floor,” Spratt says. “We’ve designed tools for clinicians who are dealing with multiple patients, sometimes six to eight patients at a time, and clinicians who are less familiar with monitoring. One example is called the integrated pulmonary index, which combines the four parameters that you get from capnography and pulse oximetry—CO₂, respiratory rate, SPO₂ [oxygen saturation], and pulse rate. We take those four parameters and combine them into a single 1-to-10 index—1 is bad, 10 is good. This provides an immediate indication of how a patient is doing by looking at one number rather than looking at four, and the waveforms and all the other data.”

Still, it’s not just the technical complexity of continuous electronic monitoring that can confound clinicians. In some cases, PCA incidents can be traced back to poor assessments of patients who are candidates for some clinicians resist more medical equipment, such as PCA pumps, that adds to the alarm burden.
Kaiser Permanente and the Role of Clinical Engineering

‘You Can’t Just Drop This Technology in There’

Mindful of the risks of PCA pumps, Kaiser Permanente is in the midst of a continuous electronic respiratory monitoring pilot in its Northern California region, with a longer-term interest in implementing the initiative nationally.

Kaiser Permanente began its effort in 2011 by bringing together a multidisciplinary team driven at first by clinical engineers, nurses, physicians, and respiratory therapists. As the work progressed, business, IT, and quality experts joined this team. In addition to preventing adverse events among patients on PCA, Kaiser Permanente’s goals for the pilot include:

- Understanding the workflow
- Determining the best monitoring products, the best configuration, the best connectivity, and the best system
- Developing processes and criteria for ordering continuous monitoring, charting and managing data in electronic medical records (EMRs), and measuring the impact
- Managing alarm signals and alerts
- Decreasing the census of patients on telemetry units
- Making the business case and recommendations for adoption

Phase One

It took more than a year of preparation to start a small-scale pilot of continuous monitoring at the Kaiser Permanente Santa Clara Medical Center in October 2012. That year was spent evaluating pulse oximetry and capnography products from different vendors, securing funding, selecting pilot sites, determining criteria for monitoring, setting up the technology, and educating clinicians, among other preparations.

A former telemetry unit at Santa Clara was reconfigured for continuous monitoring at every bed. Monitoring alerts and alarm signals were sent to the central nursing station.

On the “go-live” day, every bed on a 12-bed medical-surgical unit had bedside equipment for pulse oximetry and capnography monitoring for high-acuity, post-surgical orthopedic patients.

Despite vendor and in-house training, the pilot started with a whimper more than a bang. “We had two or three patients on monitoring, and we expected to have all of the beds on monitoring,” Johnson says. “What we found was that a lot of the surgeons weren’t ordering the monitors. It was so new it was hard for folks to grasp.”

So the Kaiser Permanente team—led on the clinical side by Eugene Cheng, MD, an anesthesiologist—doubled down on communicating the reasons for using the technology, championing its use, and holding weekly “stop and learn” meetings with clinicians to tweak the system. Through that iterative process, continuous monitoring caught on.

Indeed, while the Kaiser Permanente team had not yet completed its data analysis from this six-month pilot, anecdotal evidence indicates it was highly successful. “Santa Clara thought that continuous monitoring was such a benefit to patient safety that they won’t let us take it out,” Johnson says.

Building on Success

Now, Kaiser Permanente is piloting continuous monitoring in two, 12-bed units with low-acuity patients at two more facilities, its Santa Rosa and San Jose medical centers. The team is using the lessons learned from the Santa Clara pilot to strengthen the rollout model. That includes decentralizing the monitor displays so nurses can check patients’ status from wherever they are, and trying wireless technology.

Throughout this initiative, the clinical engineering role has been crucial. Clinical engineers understand technical requirements; develop specifications; evaluate different products; help integrate, install, and upgrade the equipment; and support data collection and evaluation. Johnson also spends time communicating, championing, and driving the implementation. And he’s building the business case for expansion.

“Today’s economic environment requires the clinical engineer to be aware of the business considerations,” Carol Davis-Smith, vice president of clinical technology with Kaiser Permanente, says. “We need to be clinically responsible and responsive. But how do we do it in the most efficient manner? I do not mean to imply that we buy the least expensive technology. We have to be smart enough as engineers to look at the whole value proposition, the cost of training, the cost of implementation, the cost of ongoing support. It really is part of our job to be able to blend the technical, the clinical, and the business. We’re masters of the technical—and are becoming masters of the other two.”
this therapy—and failure to rule out PCA even for patients with known risk factors. Physicians might be relying too much on standardized order sets that do not truly address the specific needs of individual patients.

**Education and Training.** The challenges of alarm burden and technical complexity feed into another barrier to adoption of continuous electronic monitoring—the need to train, and sometimes retrain, clinicians to use the technology. Training must be a continual effort, as staff turnover and, sometimes, clinicians’ reluctance to embrace and understand technology can have significant consequences.

“That’s probably one of the big roadblocks—making sure that your nursing staff is appropriately trained and credentialed to care for these patients,” Davis-Smith says. “That’s been a challenge for the 23 years I’ve been in the business. Every time we come up with a new technology that’s one of the early roadblocks or at least speed bumps. If you throw the technology in there without the nurses or the physicians being prepared, it is a cataclysmic disaster in most cases.”

Education about continuous electronic monitoring is unusual as well because it must extend to patients and their families. While most patients are comfortable wearing finger probes for pulse oximetry, some patients resist the nasal cannula for capnography. But Spratt says explaining the need for the monitor to patients goes a long way.

“Once they understand that they are receiving a medication that is good because it’s alleviating their pain, but at the same time they run the risk of suppressed breathing, patients are more than happy to wear the monitor—you may have trouble getting them to take the monitor off,” Spratt says.

Family members need this information as well to support compliance. And they need to be cautioned against another hazard, known as “PCA by proxy,” which means that someone other than the patient pushes the PCA button to deliver opioids to the patient. Well-meaning family members have been known to do this, with adverse outcomes. Only patients should push that button.

**Leadership.** Perhaps the biggest impediment to broad adoption of continuous monitoring is C-Suite and organizational leadership, experts say. “Hospital leaders and healthcare professionals need to take a leadership role and adopt the best practices that other facilities, like Veterans Affairs and St Joseph’s/Candler Hospitals, already are using,” Wong says. “These practices have shown that they save lives and reduce healthcare costs. Saving lives and saving money—it sounds exactly like what our healthcare system is looking for!”

Pronovost says the engineering as it relates to integration and system issues is “trivial, truly trivial. The leadership is what is hard. That is what we really need.”

**Starting Small, Thinking Big**
The perceived challenges of implementing continuous electronic monitoring for patients on PCA therapy shouldn’t stop healthcare delivery organizations from doing...
something now to improve patient safety, experts say. Three ways to start:

1. **Track the incidence of respiratory depression and respiratory arrest.** “We have to do a better job of getting at the magnitude of the problem,” Pronovost says. The Veterans Health Administration, for example, investigated a decade’s worth of data and found that more than 60% of 69 adverse events related to PCA pumps could have been prevented with an integrated end-tidal CO2 monitor (capnography) that would have shut down the pumps when respiratory depression was detected (AAMI, 2010).

2. **Collaborate, pool expertise, and identify best practices.** The San Diego Patient Safety Council, a group of more than a dozen hospitals and health systems, puts aside competitive practices when it comes to patient safety challenges. Now, the group is focusing on continuous monitoring outside the ICU—not just patients on PCA or on opioids, but all patients who might need continuous monitoring. “The group believes that—despite the fact that technology in the future could be better—all patients, especially those on opioids, need to be monitored. And, ideally, they should be monitored for respiratory rate and CO2 excretion,” Vanderveen says. The goal of this work is to create a best practice toolkit for San Diego-area and other healthcare delivery organizations to use.

3. **Use the Patient-Controlled Analgesia (PCA) Safety Checklist.** This checklist, released in 2013, was developed by the Physician-Patient Alliance for Health & Safety with contributions from Pronovost and other experts. (*A copy of the checklist can be downloaded for free at http://ppahs.org.*)

   Checklists are useful for improving patient safety—but they are a stopgap measure, not the ultimate solution. “There has to be a better way of preventing this harm than another paper-based checklist,” Pronovost says.

   With funding from the Gordon and Betty Moore Foundation, his JHU Armstrong Institute for Patient Safety and Quality is looking comprehensively at respiratory depression and other major safety issues that put patients at risk. “As you can imagine, there are about a dozen, and every one of those harms has a checklist of interventions for how to prevent them,” Pronovost says. “When we added it up, an average patient in a hospital would need 200 things done every day to defend against all those harms, because some things need to be done three or four times a day.” That calls for every clinician to be a “hero”—a great expectation that is unrealistic, and decidedly not how other high-risk industries operate.

   Instead, Pronovost argues that only well-engineered, integrated systems—with built-in checks, double-checks, and closed-loop controls—can make healthcare a safer enterprise. For PCA, that requires interoperable technology—with pumps, continuous electronic monitoring, and EMRs all connected, communicating seamlessly, and providing decision support to clinicians. A 2012 Institute of Medicine (IOM) report, *Health IT and Patient Safety,* emphasizes the need for human factors engineering in the design, implementation, and use of medical administration technologies, such as PCA pumps.

   No other high-risk industry would tolerate the safety gaps that the healthcare community accepts routinely, Pronovost says. To support a shift in direction, Pronovost is developing a “pledge” for healthcare providers and organizations to convey to vendors, stating that they are committed to putting patient safety and productivity first—and that they will not purchase technology that does not share data and open interfaces with other systems.

   “As healthcare providers or organizations, we haven’t exerted the kind of leadership that we need to,” Pronovost says. “Can you imagine if United Airlines or Boeing would ever buy a plane if the landing gear company said, ‘I’m sorry, I’m not going to send my signal to you so that you can see if the landing gear is not right?’ It wouldn’t even be discussed. It’s almost unconscionable.”

   Pronovost references Avedis Donabedian, a medical doctor who died in 2000 and who is widely recognized as the father of quality improvement in healthcare. In talking about systems, Donabedian said, “The secret of quality is love … If you have love, you can then work backward to monitor and improve the system.”

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**A Resource for You**

The AAMI Foundation’s Healthcare Technology Safety Institute (HTSI) has published a paper that examines the promising experience of one hospital with surveillance monitoring, *Safeguarding Patients with Surveillance Monitoring: The Dartmouth-Hitchcock Medical Center Experience* is one of HTSI’s Safety Innovations papers. The paper and others in the series are available for free download at: www.aami.org/htsi/safety_innovation.html
Said Pronovost: “How right we was. No one stakeholder can solve this problem. Yet together we can move mountains. We need clinicians, technology experts, private industry, patients, policy makers, and payers to work together to eliminate preventable harm ... Let’s start today.”

References