

# First National Survey of Patient-Controlled Analgesia Practices

by

Michael Wong, JD

(Executive Director, Physician-Patient Alliance for Health & Safety)

Anuj Mabuyi, PhD

(Assistant Professor Department of Mathematics, Northeastern Illinois University)

Beverly Gonzalez, ScM

(Biostatistician, Johns Hopkins Bloomberg School of Public Health)



## **Executive Summary**

In early 2013, for the very first time, a national survey of hospitals was conducted to determine practices around patient-controlled analgesia (PCA) pumps. With responses from hospitals from 40 states, the survey provides a baseline of information about (1) the practices and standards currently followed by hospitals in PCA administration; (2) the way hospitals view the role of technology in administration and monitoring of opioids; and (3) the technology, training and information healthcare providers think are important for greater patient safety in the future.

On the negative side, there is a huge cause for concern for patient safety, as there is a great lack of consistency in safety procedures being followed by hospitals across the country. This most likely accounts for a large proportion of adverse events and deaths associated with PCA use.

On the positive side, survey findings also show that adverse events have been averted or costs and expenses reduced by hospitals that are continuously monitoring their patients with pulse oximetry and/or capnography. This demonstrates the critical importance of using continuous monitoring as a technological safety net for patients. As well, it also points to a way hospitals may reduce their costs and expenses.

Below are summarized some of the key findings of the survey:

### **Patient Risk Factors Considered:**

- Despite much discussion by key healthcare organizations like The Joint Commission and the Institute for Safe Medication Practice about assessing the risk factors of patients, there is a huge variation among hospitals about what risk factors are being considered before initiating PCA. About two out of every three hospitals are not considering the six major patient risk factors of these healthcare organizations.
- The Joint Commission [recommends](#)<sup>1</sup> taking “extra precautions with patients who are new to opioids or who are being restarted on opioids.” However, almost one out of five hospitals are not assessing patients for being opioid naive.
- Pharmacists were four times more likely to consider opioid naive as a risk factor versus other healthcare professions. However, physicians were approximately 70 percent less likely than other types of respondents to say that they consider opioid naive as a patient risk factor.
- Although many studies have shown the increased risk of using anesthesia with [obese patients](#),<sup>2</sup> three out of every 20 hospitals do not consider obesity as a patient risk factor.
- Even though The Joint Commission cautions against the use of opioids in older patients because of the heightened risk of over-sedation and respiratory depression,

---

<sup>1</sup> The Joint Commission, Sentinel Event Alert, Issue 49, August 8, 2012

<sup>2</sup> J. Ingrande and H. J. M. Lemmens, “Dose adjustment of anaesthetics in the morbidly obese” British of Journal of Anesthesia Volume 105, Issue suppl 1

about three out of every 20 hospitals do not consider advanced age as a patient risk factor.

### **Double-Checks to Verify Proper PCA Connection and Settings:**

- Although [approximately 70% of the PCA adverse events are due to errors](#) associated with PCA pump use (e.g., misprogrammed doses and concentrations, installation of the wrong drug or concentration),<sup>3</sup> one out of ten hospitals performed one or less double checks to ensure that the correct patient is receiving the correct dosage from a PCA pump that have been programmed and attached correctly.
- On-going training could prevent many adverse events. Those receiving on-going training were almost three times more likely to double-check the line attachment to patient and tubing insertion into pump than their counterparts who did not received on-going training.

### **Technological Safety Practices**

- More than three out of every 20 hospitals are not using “smart” pumps for any of their patients. “Smart” pumps contain safety software and medication "libraries" for improved patient safety.
- Despite recommendations by the Anesthesia Patient Safety Foundation, patients are not monitored with either pulse oximetry or capnography at over three out of every 20 hospitals (16.07 percent). However, of the hospitals that are not electronically monitoring any of their patients, almost nine out of 10 (86.7 percent) say they are considering the use of monitoring. This suggests that continuous electronic monitoring will likely become a standard procedure.
- Of those hospitals that monitor some or all of their patients with pulse oximetry or capnography, 65 percent have experienced positive results — either in terms of a reduction of overall adverse events or of costs and expenses. The other 35 percent of those that monitor say it is “too early to determine or have not determined.”
- Those using smart pumps with integrated end tidal monitoring were almost three times more likely to have had a reduction in adverse events or a return on investment when measured against costs and expenses (including litigation costs) that might have been incurred.

### **Role of Alarm Fatigue:**

- Concern about alarm fatigue was extremely high, with only less than one in 20 hospitals (4.9 percent) saying that they were “not concerned at all”.
- To help manage alarm fatigue, hospitals indicate that tools and training would be of assistance. Seven out of 10 hospitals (70.7 percent) would like “a single indicator that accurately incorporates key vital signs, such as pulse rate, SpO2, respiratory rate, and etCO2.”
- Those concerned that alarm fatigue is an unmanageable problem were twice as likely to want a single-indicator assessment tool and recommendations for ease of assessment for their nursing staff.

---

<sup>3</sup> Pennsylvania Patient Safety Authority, “Making Patient-Controlled Analgesia Safer for Patients” Vol. 8, No. 3 (September 2011).

**Education of Patients:**

- Patients are probably safer at hospitals that provide information about PCA.
- Those using only smart pumps and smart pumps with integrated end tidal monitoring were almost four times as likely to provide their patients with educational materials. Moreover, those hospitals that have been using smart pump technology for the last three to five years were almost six and a half times more likely to provide their patients with information on the purpose of monitoring.
- The likelihood that the patient will be monitored with either pulse oximetry and/or capnography goes up when the hospital is providing their patients with monitoring information. This is three times more likely for patients at hospitals monitoring with pulse oximetry, and is higher for all hospitals that monitor their patients electronically.

## **Background**

A national survey of United States hospitals regarding practices around patient-controlled analgesia (PCA) pumps administration has never been conducted.

Using PCA pumps to help manage patients' pain has become accepted medical practice and is generally considered safe and effective. In its Sentinel Event Alert, "[Safe Use of Opioids in Hospitals](#),"<sup>4</sup> The Joint Commission recommends the use of PCA to help avoid adverse events associated with the use of opioids.

However, in this very same Sentinel Event Alert, The Joint Commission also warns against the possibility of opioid-induced respiratory depression (OIRD):

*While opioid use is generally safe for most patients, opioid analgesics may be associated with adverse effects, the most serious effect being respiratory depression, which is generally preceded by sedation.*

According to [reports made to the Food and Drug Administration](#)<sup>5</sup> between 2005 and 2009, more than 56,000 adverse events and 700 patient deaths were linked to PCA pumps. One out of 378 post-surgical patients were harmed or died from errors related to the patient-controlled pumps that help relieve pain after surgical procedures, such as knee or abdominal surgery.

More recently, the Pennsylvania Patient Safety Authority released its [analysis of medication errors and adverse drug reactions involving intravenous fentaNYL](#)<sup>6</sup> that were reported to them. Researchers found 2,319 events between June 2004 to March 2012 — that's almost 25 events per month or about one every day. Although one error a day may seem high, their analysis is confined to reports made to the Pennsylvania Patient Safety Authority and only include fentaNYL, a potent, synthetic narcotic analgesic with a rapid onset and short duration of action.

This latest analysis complements earlier research conducted by the Pennsylvania Patient Safety Authority. As Tim Ritter, senior patient safety analyst at the Authority has [said](#):<sup>7</sup>

---

<sup>4</sup> The Joint Commission, Sentinel Event Alert, Issue 49, August 8, 2012

<sup>5</sup> Association for the Advancement of Medical Instrumentation, "Infusing Patients Safely: Priority Issues From AAMI/FDA Infusion Device Summit" (2010)

<sup>6</sup> Pennsylvania Patient Safety Authority, "Analysis of the Multiple Risks Involving the Use of IV FentaNYL" Pa Patient Saf Advis 2012 Dec; 9(4):122-9

<sup>7</sup> Michael Wong, "Hospitals Need to Address PCA Pump Patient Safety: Q&A with ISMP & Pennsylvania Patient Safety Authority" (Physician-Patient Alliance for Health & Safety, March 20, 2012)

*Over the six-year period from June 2004 to May 2010, data collected by Pennsylvania Patient Safety Authority revealed that there were approximately 4,500 reports associated with PCA pumps. Moreover, U.S. Food and Drug Administration’s Manufacturer and User Device Experience database demonstrates that PCA-related device events are three times as likely to result in injury or death as reports of device events involving general-purpose infusion pumps.*

While the above numbers may seem daunting, Richard Dutton, MD (Executive Director, Anesthesia Quality Institute) says, “PCA errors certainly occur, both in programming and in delivery, but any published estimate is likely to be only the [tip of the iceberg](#).”<sup>8</sup>

In his recent presentation at the [Patient, Safety Science & Technology Summit](#), Robert Stoelting, MD (President, Anesthesia Patient Safety Foundation) stated that more than 13 million patients each year receive PCA in the United States. Estimates of respiratory depression range from 0.16 percent to 5.2 percent. This means that, each year, between 20,800 to 676,000 PCA patients will experience opioid-induced respiratory depression.

Fifty percent of Code Blue events involve patients receiving opioid analgesia. Unrecognized postoperative respiratory failure that results in cardiopulmonary arrest is a daily occurrence at healthcare facilities across the United States. Since cardiopulmonary arrest often results in death or anoxic brain injury, these events have been termed “failure to rescue.” Failure to rescue is the first and third most common cause of adverse events related to patient safety, [accounting for 113 events per 1,000 at-risk patient admissions](#).<sup>9</sup>

As Dr. Stoelting [explains](#),<sup>10</sup> “Clinically significant drug-induced respiratory depression (oxygenation and/or ventilation) in the postoperative period remains a serious patient safety risk that continues to be associated with significant morbidity and mortality.”

## **Methodology**

During March and April 2013, this national survey of hospitals was conducted regarding practices related to PCA by [A Promise to Amanda Foundation](#) and the [Physician-Patient Alliance for Health & Safety](#). The survey questions were prepared with the assistance and input from the individuals listed on Appendix “A”.

---

<sup>8</sup> Michael Wong, “Errors with patient-controlled analgesia (PCA): just the tip of the iceberg” (Physician-Patient Alliance for Health & Safety, November 30, 2011)

<sup>9</sup> Overdyk FJ, et. al., “Continuous Oximetry/Capnometry Monitoring Reveals Frequent Desaturation and Bradypnea During Patient-Controlled Analgesia” *Anesth Analg* 2007; 105: 412–8

<sup>10</sup> Michael Wong, “Post-Surgical Patients Require Better Monitoring” (Physician-Patient Alliance for Health & Safety, August 9, 2011)

The survey was distributed through:

- The Institute for Healthcare Improvement hospital networks.
- Hospital members of the Premier Safety Institute.

As well, the survey was distributed to an email list of hospital-based pharmacists obtained and paid for by funding from contributions from corporate-sponsors. Hospital-based pharmacists were targeted to answer the survey, because all orders for PCA at any given institution must be processed by a pharmacist.

Hospitals from across 40 US states responded to the survey. Respondent hospitals were evenly split between non-teaching (45 percent) and teaching institutions (55 percent). Moreover, they came from a range of sizes, from a small of 14 beds to the largest having more than 1,500 beds, with the median hospital having 200 beds.

As the survey was distributed through an email list of hospital-based pharmacists, almost half (47 percent) of the 168 respondents identified themselves as pharmacists. The remaining respondents identified themselves as either physicians (18 percent) or a non-physician healthcare provider, such as a nurse or respiratory therapist (35 percent).

### **Survey Analysis**

Survey questions revolved around five critical issues:

- Patient Risk Factors Considered
- Double-Checks to Verify Proper PCA Connection and Settings
- Technological Safety Practices
- Role of Alarm Fatigue
- Education of Patients

Each of these issues and respondents' answers are discussed in detail below.

## **Patient Risk Factors Considered**

Many respected healthcare organizations have provided warnings that safe PCA use starts with selecting suitable patients. In discussing this issue of patient selection, the Pennsylvania Patient Safety Authority in its analysis of approximately 4,500 event reports it received from June 2004 through May 2010 provides the following [caution](#):<sup>11</sup>

*“... candidates for PCA should have the mental alertness and cognitive ability to manage their pain and communicate their pain level to their caregiver.”*

Moreover, The Joint Commission in its Sentinel Event Alert #49 [“Safe Use of Opioids in Hospitals”](#) provides the following chart showing characteristics of patients who are at higher risk for over-sedation and respiratory depression:<sup>12</sup>

### **Characteristics of patients who are at higher risk for oversedation and respiratory depression**

- Sleep apnea or sleep disorder diagnosis<sup>5,6,19</sup>
- Morbid obesity with high risk of sleep apnea<sup>5,6</sup>
- Snoring<sup>5,6</sup>
- Older age; risk is
  - 2.8 times higher for individuals aged 61-70
  - 5.4 times higher for age 71-80
  - 8.7 times higher for those over age 80<sup>5,12,20</sup>
- No recent opioid use<sup>6,21</sup>
- Post-surgery, particularly if upper abdominal or thoracic surgery<sup>5,22</sup>
- Increased opioid dose requirement<sup>6</sup> or opioid habituation
- Longer length of time receiving general anesthesia during surgery<sup>5,23</sup>
- Receiving other sedating drugs, such as benzodiazepines, antihistamines, diphenhydramine, sedatives, or other central nervous system depressants<sup>5,6,8,12</sup>
- Preexisting pulmonary or cardiac disease or dysfunction or major organ failure<sup>5,6</sup>
- Thoracic or other surgical incisions that may impair breathing<sup>5,6</sup>
- Smoker<sup>5,6</sup>

---

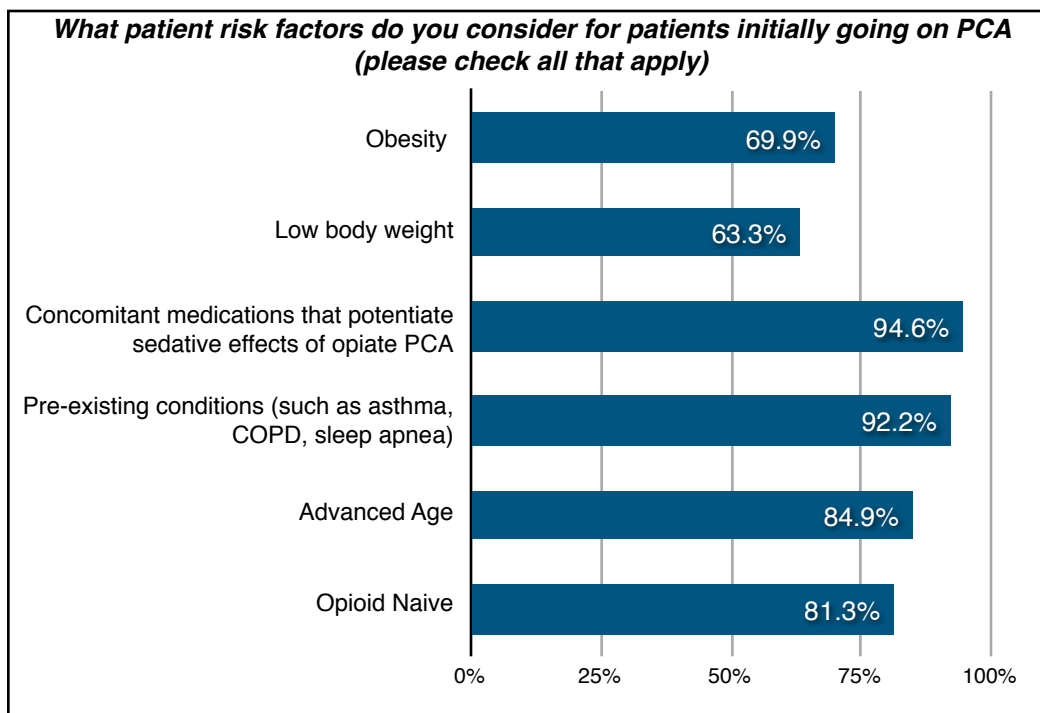
<sup>11</sup> Pennsylvania Patient Safety Authority, “Making Patient-Controlled Analgesia Safer for Patients” Vol. 8, No. 3—September 2011

<sup>12</sup> The Joint Commission, Sentinel Event Alert, Issue 49, August 8, 2012



To determine which patient risk factors are assessed by hospitals prior to the initiation of PCA, the survey provided a shortlist of factors listed in the PCA Safety Checklist recently developed with the assistance of a [group of renowned health experts](#) assembled by the Physician-Patient Alliance for Health & Safety.<sup>13</sup> The PCA Safety Checklist contains the six major patient risk factors listed by healthcare organizations like The Joint Commission and the Institute for Safe Medication Practice.

The survey found that, although patient risk factors are considered, this is not being done by every hospital, with every patient:



There is a tremendous variation between the treatment being received by patients across the country. More than 60 percent of respondents are considering five or less factors, with less than 40 percent indicating that they were considering all six patient risk factors.

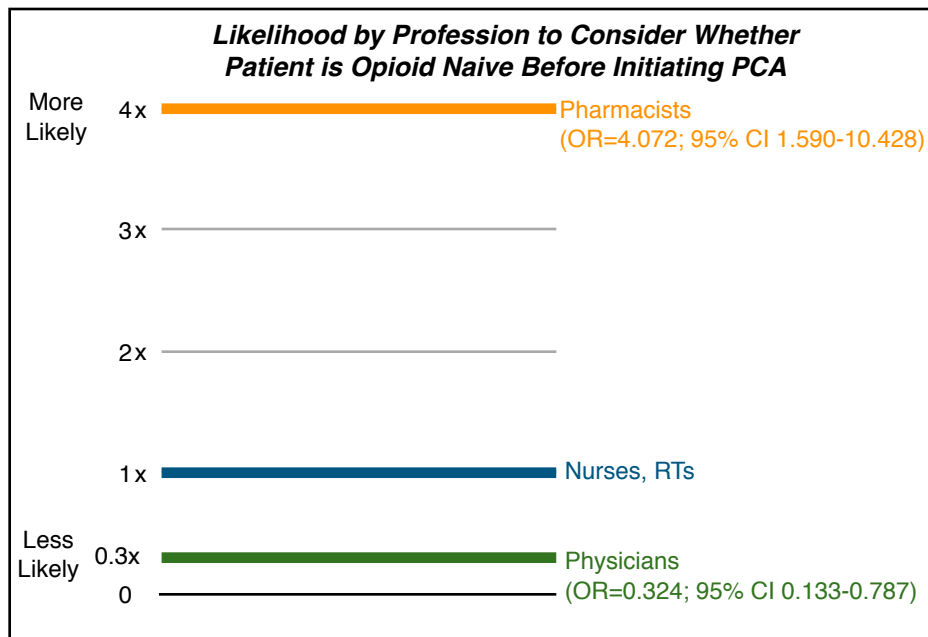
To ensure patient safety for each and every patient, all healthcare facilities should be considering all of these risk factors before commencing PCA on every patient. Nonetheless, below we have discussed areas of particular concern:

<sup>13</sup> Reuters, “Physician-Patient Alliance for Health & Safety Announces New Expert Checklist for Facilitating Safety of Hospital-Based Intravenous Patient-Controlled Analgesia Pumps” (July 12, 2012)

## Opioid naive patients

The National Comprehensive Cancer Network defines opioid naive patients as those “who are not chronically receiving opioid analgesic on a daily basis.”<sup>14</sup> Consequently, because opioid naive patients are at greater risk for over-sedation and respiratory depression, The Joint Commission recommends taking “extra precautions with patients who are new to opioids or who are being restarted on opioids.”<sup>15</sup> Yet, the survey indicates that almost one out of five hospitals are not assessing patients for being opioid naive.

Moreover, pharmacists were four times more likely to consider opioid naive as a risk factor versus other healthcare professions. However, physicians were approximately 70 percent less likely than other types of respondents to say that they consider opioid naive as a patient risk factor. This indicates the need for greater awareness among physicians to the heightened risk of the use of opioids with opioid naive patients.



The survey findings suggest that some opioid naive patients may be receiving PCA when perhaps they should not be.

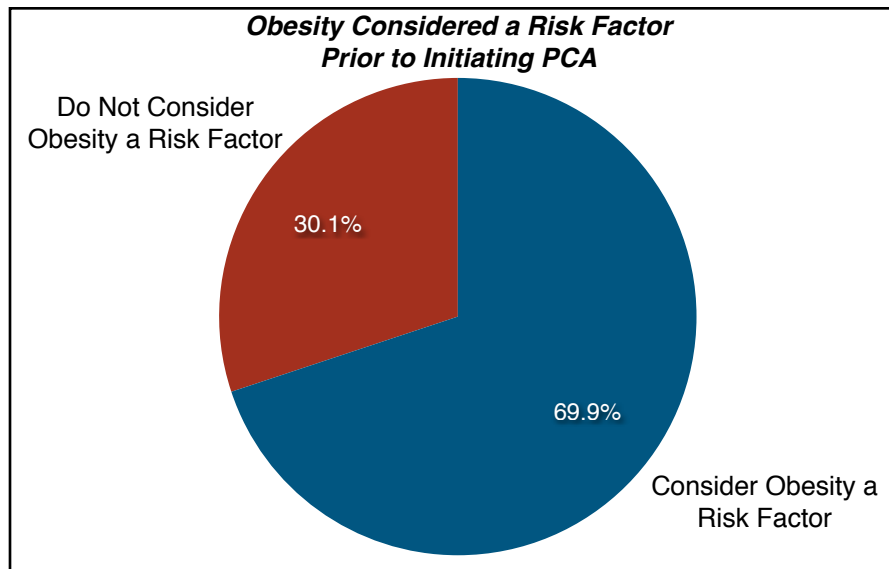
<sup>14</sup> National Comprehensive Cancer Network, Adult Cancer Pain guidelines (2010).

<sup>15</sup> The Joint Commission, Sentinel Event Alert, Issue 49, August 8, 2012

## Obesity

About three out of 10 hospitals do not consider obesity as a patient risk factor, despite the indications of many studies that have shown the [increased risk of using anesthesia with obese patients](#).<sup>16</sup> As researchers have [stated](#):<sup>17</sup>

*One of the many problems in providing anaesthesia for morbidly obese patients is the influence of obesity on pharmacokinetics and pharmacodynamics. Drug administration in obese patients is difficult because recommended doses are based on pharmacokinetic data obtained from individuals with normal weights; therefore, mistakes in the determination of the appropriate dose are often made. Because of comorbidity in these patients, the function of organs involved in drug elimination (e.g. kidney, liver) can be affected making pharmacokinetics more difficult and complex.*



The survey findings suggest that some obese patients may be receiving PCA when perhaps they should not be.

## Advanced Age

The risk of respiratory depression increases substantially for patients over 60 years of age. The Joint Commission cautions against the use of opioids in older patients because of the heightened risk of over-sedation and respiratory depression:

- 2.8 times higher for individuals aged 61-70
- 5.4 times higher for age 71-80

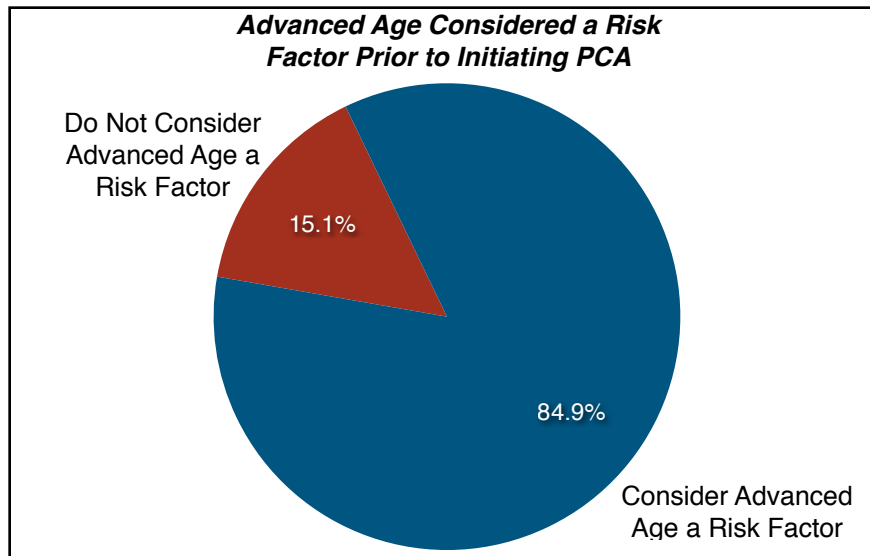
---

<sup>16</sup> J. Ingrande and H. J. M. Lemmens, "Dose adjustment of anaesthetics in the morbidly obese" British of Journal of Anesthesia Volume 105, Issue suppl 1

<sup>17</sup> Luc De Baerdemaeker et al, "Pharmacokinetics in obese patients" Contin Educ Anaesth Crit Care Pain (2004) 4 (5): 152-155

- 8.7 times higher for those over age 80

Yet, not all healthcare facilities consider advanced age as a risk factor — 84.9 percent do so — with about three out of every 20 hospitals not assessing their patients using PCA for advanced age.



However, at those hospitals that provide on-going training in PCA administration, advanced age was more likely to be considered a patient risk factor. This suggests the need for on-going training in the factors that place a patient at greater risk of over-sedation and respiratory depression.

#### Risk Factors Conclusion & Future Suggestion

Survey results for the three factors discussed above — opioid naive, obesity, and advanced age — would seem to point to the need for better selection of patients who are placed on PCA. Perhaps a scoring system for the inclusion or exclusion of patients using PCA might be of assistance.

For example, recent research has found that, in general, physicians do attempt to tailor their treatment plans to patients' needs, but this is difficult in the case of obstructive sleep apnea (OSA). A [recent study](#)<sup>18</sup> published in the British Journal of Anesthesia found that anaesthetists and surgeons failed to identify a significant number of patients with pre-existing OSA and symptomatic undiagnosed OSA, before operation. The [STOPBang questionnaire](#) looks to determine if a patient is at risk for OSA by assigning a scoring system for risk factors. This scoring system places patients in three different categories — high, intermediate, and low.

---

<sup>18</sup> M. Singh et al, "Proportion of surgical patients with undiagnosed sleep apnoea" British Journal of Anaesthesia (British Journal of Anaesthesia)

Combined with the survey result showing the desire by healthcare providers for recommendations on easily assessing patients in the discussion below on alarm fatigue, this suggests a similar approach could be useful in identifying suitable candidates for PCA.

## **Double-Checks to Verify Proper PCA Connection and Settings**

When initiating, refilling, or making programming changes, it is recommended that healthcare providers double-check to ensure that the PCA pump has been done so correctly. As the Institute for Safe Medication Practices (ISMP) [recommends](#):<sup>19</sup>

*Require two clinicians to independently double-check the patient's identification, drug and concentration, PCA pump settings, and the line attachment before use (and before pump refill or programming change). Bedside barcoding can be used to verify the patient and drug/concentration; however, pump settings may still require an independent double check.*

The survey asked respondents whether double-checks were made regarding the following factors that answer essential patient safety questions:

- Patient's identification — is the correct patient receiving the opioid?
- Patient allergies — is the patient allergic to the medication?
- Drug selection and concentration — is the patient receiving the prescribed medication and dosage?
- Dose adjustments — has any dose adjustment been completed?
- PCA pump settings — has the pump been programmed correctly?
- Line attachment — has the pump been attached correctly to the patient?

These double-checks ensure that correct patients receive correct dosages from pumps that have been programmed and attached correctly. As ISMP has stated:<sup>20</sup>

*Misprogramming of the PCA pump is, by far, the most frequently reported practice-related issue. Pump design issues that have led to programming errors are described in the section that follows. Other practice-related issues that have contributed to PCA errors include incorrect transcription of prescriptions into pharmacy computers or medication administration records (often related to look-alike product names), calculation errors when determining the patient's dose or rate of infusion, and IV admixture errors.*

The Pennsylvania Patient Safety Authority in its analysis of the six-month period (December 2009 through May 2010), found that “approximately 70% of the PCA therapy related reports to the Authority were attributable to errors associated with pump use (e.g., misprogrammed doses and concentrations, installation of the wrong drug or concentration).”<sup>21</sup>

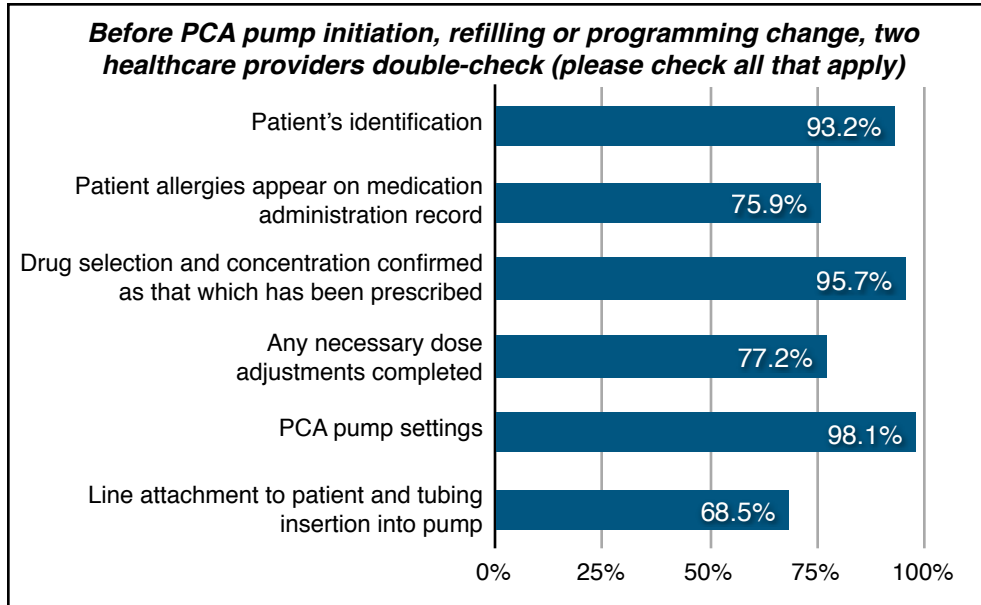
---

<sup>19</sup> Institute for Safe Medication Practices, “Part II - How to Prevent Errors - Safety Issues with Patient-Controlled Analgesia (July 24, 2003)

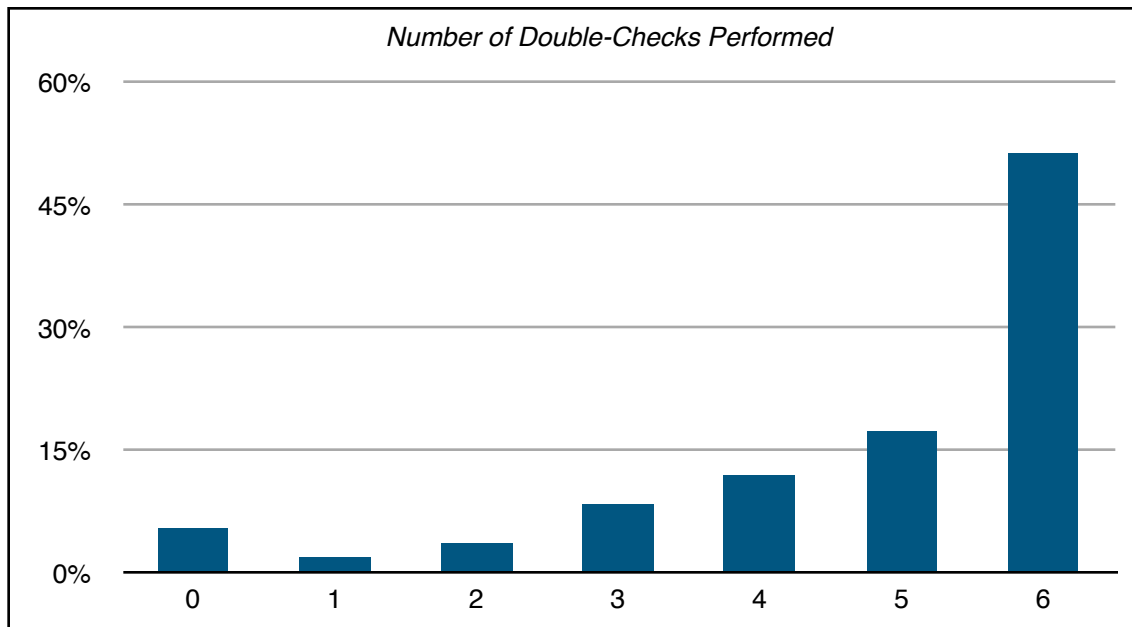
<sup>20</sup> Institute for Safe Medication Practices, “Safety issues with patient-controlled analgesia Part I - How errors occur” ISMP Med Saf Alert, 2003 Jul 10; 8(14):1.

<sup>21</sup> Pennsylvania Patient Safety Authority, “Making Patient-Controlled Analgesia Safer for Patients” Vol. 8, No. 3 (September 2011).

Based on the responses to the survey question on what double-checks are performed, there is great variation between what double-checks are made at hospitals across the country:



Although almost all confirmed the PCA pump settings (98.1 percent), only slightly more than 1 out of every 2 hospitals (51.19 percent) performed all six double-checks; and 1 out of ten performed just one or less double checks (10.71 percent):



However, the survey indicates that on-going training is essential to maintaining these patient safety standards. Those receiving on-going training were almost three times more likely to double-check the line attachment to patient and tubing insertion into pump than their counterparts who did not received on-going training (OR=2.618; 95% CI 1.091-6.282).

Moreover, based on those surveyed, compared to healthcare providers who did not receive on-going training, those who received on-going training were:

- More than twice as likely to double-check the patient's identification
- More than twice as likely to double-check that the patient's allergies appear on the medication administration record.
- Almost four times as likely to double-check the drug selection and concentration.
- Twice as likely to double-check any necessary dose change has been completed.

For greater patient safety and to ensure that correct patients receive correct dosages from pumps that have been programmed and attached correctly, the survey strongly suggests the role of on-going training for those involved with the administration of PCA.



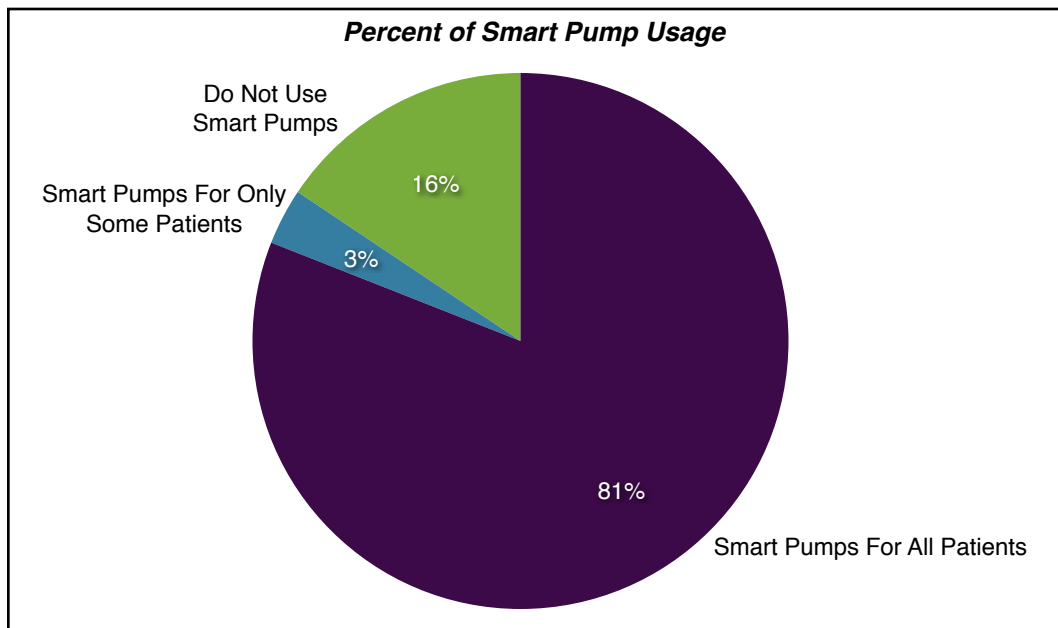
## Technological Safety Practices

### Use of Smart Pumps

The Institute of Medicine (IOM) Quality Chasm Series report “Preventing Medication Errors” recommends the use of “smart” PCA pumps to deliver safer patient care. A [PCA pump is considered “smart”](#) when it includes “software [that] allows an organization to create a library of medications that provides medication dosing guidelines, by establishing concentrations, dose limits, and clinical advisories.”<sup>22</sup>

As a recommended patient safety feature, the survey has confirmed that the use of “smart” pumps is increasingly being used. In 2005, American Society of Health-System Pharmacists in its survey, “[National Survey of Pharmacy Practice in Hospital Settings](#)” found that 32 percent of hospitals were using smart pump technology at that time.

In 2013, 80.1 percent of hospitals are using “smart” pumps for all of their patients. Although an improvement over the 2005 numbers, this still means that almost one out of every four hospitals do not use “smart” pumps that contain safety software and medication “libraries” for greater patient safety for all of their patients. Moreover, more than three out of every 20 hospitals are not using “smart” pumps for any of their patients.



<sup>22</sup> Institute for Safe Medication Practices, “Proceedings from the ISMP Summit on the Use of Smart Infusion Pumps”

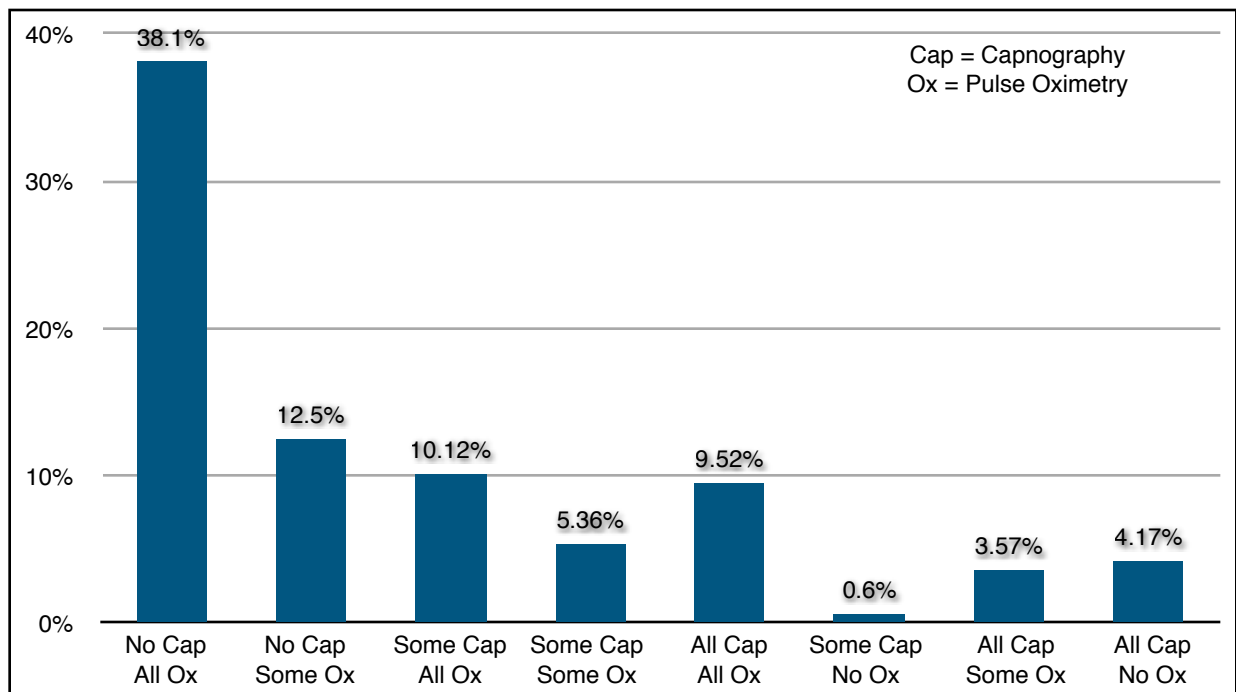
## Continuous Electronic Monitoring

Continuous electronic monitoring with pulse oximetry for oxygenation and capnography for adequacy of ventilation is recommended for greater patient safety. As Dr. Stoelting [states](#) in discussing patient safe measures to be used for patients using PCA:<sup>23</sup>

*“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.”*

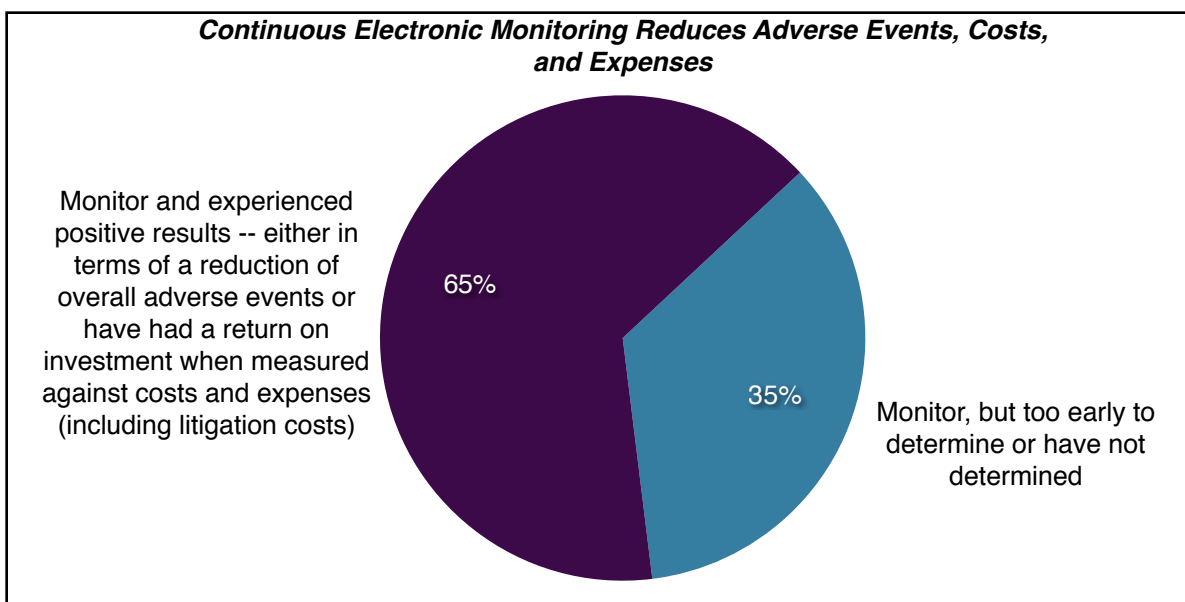
Despite these recommendations, patients are not monitored with either pulse oximetry or capnography at over three out of every 20 hospitals (16.07 percent). However, of the hospitals that are not electronically monitoring any of their patients, almost nine out of 10 (86.7 percent) say they are considering the use of monitoring. This suggests that continuous electronic monitoring will likely become a standard procedure.

There is a predominance of hospitals monitoring their patients using PCA with pulse oximetry with more than one out of every two using just oximetry (50.6 percent) to monitor all or some of their patients. This is likely due to oximetry being an older technology. Two of three hospitals (66.67 percent) are using a mix of pulse oximetry and capnography:



<sup>23</sup> Michael Wong, “Does CMS’ Proposed Quality Measure on Patient Monitoring Adequately Address Patient Safety?” Becker’s Clinical Quality & Infection Control (January 15, 2013) <http://>

Of great significance for patient safety and for those hospitals looking to reduced their costs and expenses is the experience of hospitals that are continuously electronically monitoring their patients with pulse oximetry and/or capnography. Of these hospitals that do monitor, 65 percent have experienced positive results -- either in terms of a reduction of overall adverse events or have had a return on investment when measured against costs and expenses (including litigation costs). The other 35 percent of those that monitor say it is “too early to determine or have not determined” whether they have seen a reduction in adverse events, costs, or expenses.



Those hospitals that do monitor and have experienced a positive result are split as to whether they use both monitoring devices or just one is used. Slightly less than half of these hospitals (44 percent) monitored with both pulse oximetry and capnography, while the others (56 percent) monitored with either one of pulse oximetry or capnography.

While the merits or demerits of using pulse oximetry or capnography has been much debated, the survey results indicate the value of patient surveillance monitoring, as has been suggested by research conducted by Andreas Taenzer, MD, and his colleagues at the Dartmouth-Hitchcock Medical Center.<sup>24</sup> Patient surveillance monitoring, where all patients are continuously electronically monitored, is distinct from condition monitoring where some patients are selected for monitoring,

---

<sup>24</sup> Taenzer et al, “A Review of Current and Emerging Approaches to Address Failure-to-Rescue” *Anesthesiology* 2011; 115:421–31

As Frank Overdyk, MD, [writes](#) in describing this work at Dartmouth:<sup>25</sup>

*In their review of the approaches to address fail failure-to-rescue (FTR), Dr. Andreas Taenzer and his colleagues found that [previous attempts](#) have largely focused, with limited success, on improving the response to an identified patient crisis. Such approaches have led to the development of rapid response teams (RRTs). However, the primary determinant for the success of RRTs has been found to be early recognition and this is where continuous electronic monitoring may provide a early-detection solution.*

As recent [APSF recommendations and conclusions](#) state:

*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.*

This positive experience reported by survey respondents in averting adverse events or reducing costs mirrors the experience of other hospitals that have instituted continuous monitoring of their patients, like St. Joseph/Candler Hospitals (“SJ/C”) in Savannah, Georgia.

As was recently described in the RT Magazine article “[8 years of Event-Free PCA Monitoring](#)”, Harold Oglesby, RRT, manager of respiratory care at SJ/C, describes how his hospital has had more than eight years of event-free use of PCA using “smart” PCA pumps with integrated capnography monitoring:

*A lot of the information comes from the research that we've done that has been focused on PCA patients monitored with capnography and the effectiveness gained in monitoring ventilation versus oxygenation. What we found is that we have an earlier recognition of any patient deterioration using capnography versus using oximetry alone. We also have looked at several case studies of patients, and we noted that by the use of capnography, we've recognized deteriorating patients early; so it gives us the leeway to take actions before those patients get into any trouble.*

Moreover, although a human life should never be measures in dollars and cents, St. Joseph's/Candler Hospitals calculated that their decision made [great financial sense](#):

- \$4 million — estimated potential expenses averted (not including potential litigation costs)
- \$2.5 million — 5-year return on investment

However, when we looked at the type of smart pump being used at the facilities reporting a decline in adverse events or a return on investment, there was a significant correlation with those using smart pumps with integrated end tidal monitoring. Those

---

<sup>25</sup> Overdyk, Frank, “Monitoring the High-Acuity Patient: Does Risk Stratification Increase or Decrease Patient Safety?” (PPAHS July 12, 2012)

using smart pumps with integrated end tidal monitoring were almost three times more likely to have had a reduction in adverse events or a return on investment when measured against costs and expenses (including litigation costs) that might have been incurred. (OR=2.789; 95% CI 1.112-6.996).

From an engineering perspective, this “closed” system of having the capnography monitor integrated with the PCA pump is the ideal patient safety guardrail. A PCA pump with integrated end tidal monitoring allows the pump to automatically shut off when the monitor senses that the patient is becoming oversedated. As Bryanne Patail, biomedical engineer at the U.S. Department of Veterans Affairs, National Center for Patient Safety, explains about what the Veterans Health Administration has done to [reduce errors related to PCA use and improve patient safety](#).<sup>26</sup>

*Use of PCA pumps is a process, and improving that process is an area that involves many stakeholders. In looking at fixes, they can be categorized as strong, intermediate or weak fixes. The strongest fix for PCA pumps is a forcing function, such as an integrated end tidal CO2 monitor that will pause the pump if a possible over infusion occurred. So, healthcare providers should first look at these strong fixes. There they will see the most impact on reducing errors and improving patient safety.*

The survey results strongly suggest that using PCA pumps with integrated end tidal monitors will greatly improve patient safety.

---

<sup>26</sup> Michael Wong, “Reducing Errors With Patient-Controlled Analgesia Pumps: Q&A With Bryanne Patail of the National Center for Patient Safety”, Becker’s ASC Review (February 9, 2012)

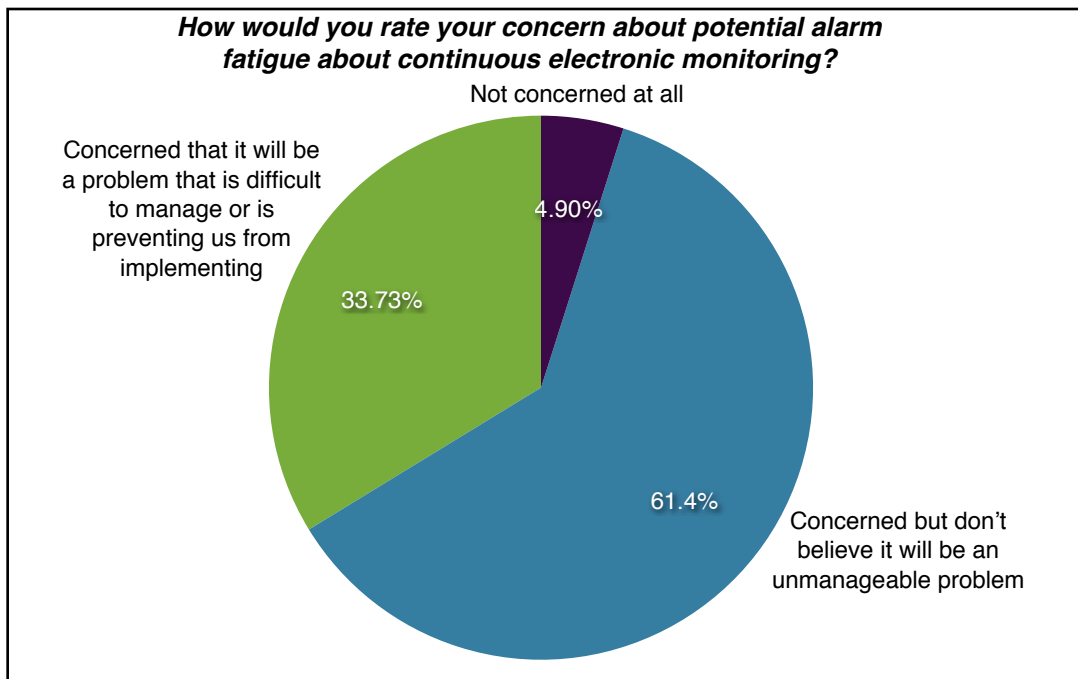
## Role of Alarm Fatigue<sup>27</sup>

According to The Joint Commission, [alarm fatigue occurs when clinicians become desensitized or immune to the sound of an alarm](#). Fatigued clinicians may:

- Turn down alarm volume
- Turn off alarm
- Adjust alarm settings.

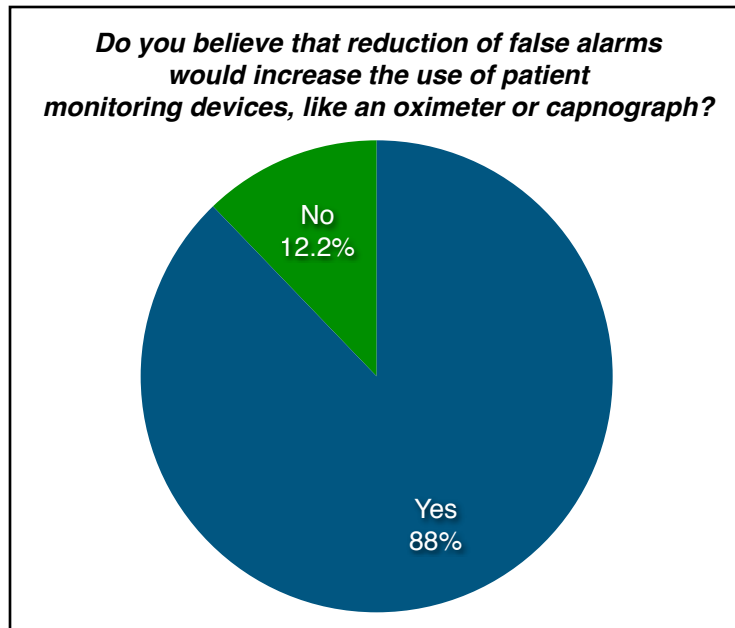
Concern about alarm fatigue was extremely high, with only less than one in 20 hospitals (4.9 percent) saying that they were “not concerned at all”. The vast majority (more than 95 percent) are concerned about the issue of alarm fatigue, with 61.3 percent reporting that they are concerned but don’t believe alarm fatigue is an “unmanageable problem”. With almost two out of three hospitals seeing alarm fatigue as “manageable”, this bodes well for the successful achievement of The Joint Commission’s [national patient safety goal to manage alarms](#).

About one out of three hospitals (33.7 percent) are either concerned that alarm fatigue will be a problem that is difficult to manage or the potential for alarm fatigue is preventing them from implementing continuous electronic monitoring. This indicates that for these hospitals, the issue of alarm fatigue is negatively impacting work processes and the safety of their patients.



<sup>27</sup> This survey was conducted prior to the announcement by The Joint Commission of national patient safety goals regarding alarm management, so answers are not biased because of The Joint Commission’s concerns.

Moreover, almost nine out of ten hospitals (87.8 percent) believe that a reduction of false alarms would increase the use of patient monitoring devices, like an oximeter or capnograph:



Alarm fatigue and the need to better manage alarms that sound is therefore preventing hospitals from implementing continuous electronic monitoring as a patient safety measure. As noted earlier, hospitals continuously monitoring have experienced a reduction in adverse events, costs and expenses.

In the following analysis, three levels of concern with alarm fatigue have been used:

- Not concerned about alarm fatigue (4.9 percent of hospitals)
- Concerned alarm fatigue is an unmanageable problem (33.73 percent of hospitals)
- Managing alarm fatigue (61.4 percent of hospitals)

Alarm management becomes of greater importance, the more monitors are attached to a patient, because of the increased possibility of a non-actionable alarm sounding. Consequently, it is understandable that all respondents expressed concern about the impact continuous monitoring may have on alarm fatigue (including those who said that they do not electronically monitor their patients). For example, those that monitor some but not all of their patients with capnography were almost three times more likely to be concerned alarm fatigue is an unmanageable problem.

This expressed concern regarding capnography would seem to indicate less familiarity with capnography than pulse oximetry. A statistically significant correlation was not found with those that monitor all of their patients with capnography and are concerned that alarm fatigue is an unmanageable problem. This suggests that those who monitor all of their patients using PCA with capnography may simply have more familiarity with capnography monitoring and hence less concern with unmanageable alarm fatigue.

Pulse oximetry has long been recognized as a leading contributor to alarm fatigue and this has been well documented. As Maria Cvach, DNP, RN, CCRN (Assistant Director of Nursing, Clinical Standards, The Johns Hopkins Hospital) and her colleague Kelly Creighton Graham, RN, BS, write in their much-referenced research on alarm fatigue:<sup>28</sup>

*Nurses in intensive care units stated that the primary problem with alarms is that they are continuously going off and that the largest contributor to the number of false alarms in intensive care units is the pulse oximetry alarm.*

To help manage alarm fatigue, hospitals indicate that tools and training would be of assistance. Seven out of 10 hospitals (70.7 percent) would like “a single indicator that accurately incorporates key vital signs, such as pulse rate, SpO<sub>2</sub>, respiratory rate, and etCO<sub>2</sub>.” Additionally, almost half of the respondents (44.6 percent) would like “recommendations on how best to easily make such assessments” of patients, and more than half (52.9 percent) would like to see more clinical training.

However, those concerned alarm fatigue is an unmanageable problem were more than twice as likely to want a single-indicator assessment tool (OR=2.278; 95% CI 1.073-4.838) and recommendations for ease of assessment for their nursing staff (OR=2.039; 95% CI 0.992-4.190). This indicates that nursing staff may be having difficulty interpreting the data. This does not suggest a lack of knowledge (as there was no statistically significant correlation with a desire for more clinical training for nurses), but that the amount of data needing to be interpreted may be becoming overwhelming.

The volume of data about a patient together with the sheer number of alarms is a critical patient safety issue. The survey indicates that providing tools to address patient assessment, with both a technological aid to gather multiple parameters into a single indicator, as well as a recommendations for easily assessing a patient, would assist with alarm management.

---

<sup>28</sup> Crrighton and Cvach, “Monitor Alarm Fatigue: Standardizing Use of Physiological Monitors and Decreasing Nuisance Alarms” American Association of Critical-Care Nurses, January 2010, Volume 19, No. 1



## **Patient Education**

[The Joint Commission](#) recommends that patients and their families be educated and provided written instructions about:<sup>29</sup>

- The various generic and brand names, formulations, and routes of administration of opioids in order to prevent confusion and reduce the accidental duplication of opioid prescriptions;
- The principal risks and side effects of opioids, including the likelihood of constipation, and the risk of falls, nausea and vomiting;
- The impact of opioid therapy on psychomotor and cognitive function (which may affect driving and work safety);
- The potential for serious interactions with alcohol and other central nervous system depressants;
- The potential risks of tolerance, addiction, physical dependency, and withdrawal symptoms associated with opioid therapy.
- The specific dangers as a result of the potentiating effects when opioids are used in combination, such as oral and transdermal (fentanyl patches).
- The safe and secure storage of opioid analgesics in the home.

A cursory look at the survey responses to whether information is given to patients about the proper use of PCA pumps and the purpose of monitoring indicates that most hospitals are providing such information:

- Almost all who responded to this question (98.1 percent) provide their patients with information about proper use of PCA pumps. In comments left by respondents, this included issues such as PCA by proxy, side effects, medication used, expected outcomes, and pain control.
- As well, more than seven out of 10 hospitals (71.9 percent) provide information to their patients about the purpose of monitoring.

However, when this answer was correlated with answers to the type of smart pump and whether continuous electronic monitoring was used, the survey suggests that patients are probably safer at hospitals that provide information about PCA.

Those hospitals that are more technologically advanced (that is, using “smart” pumps or “smart” pumps with integrated end tidal monitoring) are taking better care to provide information to their patients.

Although this survey did not evaluate the content of actual information provided by these hospitals, the provision of patient educational material is indicative of an added level of concern for patient safety. Those using only smart pumps and smart pumps with integrated end tidal monitoring were almost four times (OR=3.839, 95% CI 1.411-10.447 and OR=3.793, 95% CI 1.070-13.444 respectively) as likely to provide their patients with educational materials. Moreover, those hospitals that have been using smart pump

---

<sup>29</sup> The Joint Commission, Sentinel Event Alert, Issue 49, August 8, 2012

technology for the last three to five years were almost six and a half times more likely to provide their patients with information on the purpose of monitoring (OR=6.440, 95% CI 1.436-28.885).

Moreover, the likelihood that the patient will be monitored with either pulse oximetry and/or capnography goes up when the hospital is providing their patients with monitoring information. This is three times more likely for patients at hospitals monitoring with pulse oximetry (OR=3.327; 95% CI 1.241-8.921), and according to the survey, responses are higher for all hospitals that monitor their patients electronically.

The association between the provision of continuous monitoring and information about it seems obvious; after all, why provide information about monitoring when the facility is not planning to monitor its patients. However, this suggests that the development of patient education information about PCA pumps and monitoring could encourage hospitals to adopt better monitoring practices.

## **Conclusion**

Because of the high incidence of adverse events and deaths that have and continue to occur with the use of PCA pumps, we were not surprised to see a great deal of variation in procedures and the lack of risk factors and double-checks being performed at hospitals across the country.

Checklists and the implementation of standard procedures have been shown to prevent errors across different industries, including healthcare. Brigitte Hales, the manager of patient safety and performance improvement at Sunnybrook Health Sciences Centre in Toronto, Ontario, and her colleagues reviewed more than 1,000 abstracts on medical checklists in their paper, "[Development of Medical Checklists for Improved Quality of Patient Care](#)."<sup>30</sup>

"Checklists have been shown to play a fundamental role in error management," [explains](#) Ms. Hales, "High-intensity fields of work, such as the airline industry and the military, already employ checklists to decrease errors of omission, improper implementation of procedures and protocols, and to decrease human error under stressful conditions."<sup>31</sup>

For greater patient safety and to reduce the variation in procedures, we would encourage the adoption of standards, like the [PCA Safety Checklist](#). Moreover, the survey indicates that ongoing training of those involved with PCA administration at hospitals would help reinforce and ensure that standards are continually put into practice.

Additionally, the survey results indicate the value of continuous electronic monitoring in averting adverse events and in reducing expenditures. The reported experience of hospitals using monitoring as a technological safety net for patients receiving opioids is encouraging and indicative of the direction where all hospitals should go to improve patient safety.

Lastly, the survey points to areas in which greater work and effort needs to be placed. Tools must be placed in the hands of nursing staff responsible for PCA administration. In particular, of value would be a single-indicator assessment that accurately incorporates multiple key vital signs, such as pulse rate, SpO<sub>2</sub>, respiratory rate, and etCO<sub>2</sub>, as well as recommendations for making easy assessments of patient conditions.

This first national survey of PCA practices provides a baseline from which future practices and efforts can be measured. Further research on best practices such as the correlation between double-checks and adverse events averted and technologies like

---

<sup>30</sup> Hales et al, "Development of Medical Checklists for Improved Quality of Patient Care" International Journal for Quality in Health Care 2008; Volume 20, Number 1: pp. 22–30

<sup>31</sup> Michael Wong, "6 Steps to Improved Pain Pump Safety: New checklist can help prevent 14,000 adverse events annually" (PPAHS, March 7, 2013)

continuous electronic monitoring that reduce adverse events as well as costs would be of interest.

## **Appendix “A”**

### **Survey Question Development**

A Promise to Amanda Foundation and the Physician-Patient Alliance for Health & Safety would like to thank the following individuals for their time and input in developing the survey questions:

- Corey Angst, PhD, MBA (Assistant Professor, Department of Management, Mendoza College of Business, University of Notre Dame)
- Richard Dutton, MD, MBA (Executive Director, Anesthesia Quality Institute)
- Frank Federico, RPh (Executive Director, Institute for Healthcare Improvement; Patient Safety Advisory Group, The Joint Commission)
- Matthew Grissinger (Director, Error Reporting Programs, ISMP)
- Stephen Howell, MSN (Lead Nurse Practitioner, University of Alabama School of Medicine)
- Ken Kelley, PhD, MA (Viola D. Hank Associate Professor of Management, Department of Management, Mendoza College of Business, University of Notre Dame)
- Joe Kiani, MSEE (CEO, Masimo)
- Carter King, MBA (Vice-President, Business Operations, AcelRx)
- Mary Lynn McPherson (Professor, University of Maryland School of Pharmacy)
- John Tucker, MBA (Chief Commercial Officer, Incline Therapeutics)
- Rodney Tucker, MD, MMM (Associate Professor, University of Alabama)
- Greg Spratt, RRT, CPFT (Director of Clinical Marketing, Covidien)
- Tim Vanderveen, PharmD, MS (Vice President, Center for Safety and Clinical Excellence, CareFusion)
- Michael Wong, JD (Executive Director, Physician-Patient Alliance for Health & Safety)