

**PHYSICIAN-PATIENT ALLIANCE
FOR HEALTH & SAFETY**

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January 28, 2013

Re: CMS Proposed Quality Measure #3040

I am the founder and executive director of the Physician-Patient Alliance for Health & Safety (PPAHS), and am writing to you on behalf of PPAHS regarding CMS' proposed quality measure #3040 (the "Proposed Measure").

PPAHS is a non-profit advocacy group devoted to improving patient health and safety. PPAHS supporters and commentators include respected physicians, nurses, respiratory therapists, healthcare organizations, and patient safety advocates.

PPAHS has been particularly active in the area of opioid-induced respiratory depression. I invite you to review our website www.ppahs.org, as well as our supporters and those who provide us with expert opinion: <http://ppahs.org/our-health-experts/>

Our comments are divided into the following parts:

- Patient Deaths Caused by Inadequate Monitoring
- Expert Opinion on Proposed Quality Measure #3040
- Problem: Proposed Quality Measure #3040 Inadequately Protects Patients
- Solution: How PCA Safety Checklist May Help CMS Monitoring

Patient Deaths Caused by Inadequate Monitoring

The Proposed Measure seeks to address a critical patient safety issue.

I would like to draw your attention to the four patient deaths whose stories have been published on the PPAHS website and which are briefly excerpted below:

Amanda Abbiehl



8-year old Amanda Abbiehl tragically died July 17, 2010.

Amanda's parents talk about the fears all parents have for their children: "As parents of a teenage daughter, our worst fears were that our daughter would become pregnant, take drugs, or drink and drive. Never did we imagine that our daughter would go into a hospital with an infection, be hooked to a patient-controlled analgesia (PCA) pump to manage her pain, and never come out alive; but this is exactly what happened."

As Amanda's father asks: **"It isn't standard practice to monitor patients with Capnography. However, if Amanda's CO2 level had been monitored, wouldn't this have alerted her caregivers so her life could have been saved?"**

For Amanda's story, please see: http://promisetoamanda.org/?page_id=32

Louise's daughter, Laura Batz Townsend, tells what happened to her mother: "My Mom, Louise Batz, died from a preventable medical error after recovering knee surgery. Mom went into the hospital for knee replacement surgery ... This was not emergency surgery. She had planned the surgery so she would have enough time to heal and be ready to welcome the arrival of her fourth grandchild ...

"Like a lot of patients after surgery, my Mom was on patient-controlled analgesia (PCA) to manage her pain. **Sadly for my Mom, she was not monitored continuously by pulse oximetry for oxygenation or capnography for ventilation** once she arrive on the general floor." [emphasis added]

For the complete article on Louise, please see:

<http://ppahs.org/2012/01/13/guest-post-monitoring-can-prevent-errors-with-patient-controlled-analgesia/>

Louise Batz



Leah Katherine Coufal



Lenore Alexander (active member of [Mothers Against Medical Errors](#)) recalls the incidents leading to her daughter's death: "When I brought Leah to Cedars-Sinai hospital in Los Angeles that Friday morning, she was a healthy 11-year-old girl. She was scheduled to have elective surgery to repair a condition called pectus carinatum, which required the opening of her chest. The epidural anesthesia used during the operation had been left in place to manage her postoperative pain **"Would real-time monitoring have saved Leah? That is one of the many questions that I have asked myself every day since I found my daughter, Leah, dead in her hospital bed. The answer is yes, it would have."** [emphasis added]

For Lenore's article on her daughter, please see:

<http://ppahs.org/2012/02/01/guest-post-yes-real-time-monitoring-would-have-saved-leah-2/>

Justin's mother, Dale Ann Micalizzi, describes the impact his death had on her family: "My son was on a stretcher in the hall being wheeled away by the trauma team to the ambulance, after his cardiac arrest in the operating room. They would not let us ride along. I had broken my promise not to leave him already. My husband's promise that he would be fine was also broken. Our pain and guilt over these broken promises have eased only minimally over the ensuing years ... The pain of seeing my child in this condition was unfathomable. I left his room as the team attempted to revive him over and over again. I could not watch. I rocked back and forth while kneeling down outside his room. I remember a group of residents being briefed on the case, and one of them wanting to comfort me, but sadly turning away. I remember his dark hair and eyes looking down at me. Many years later, tears stream down my face, as if this happened yesterday."

For the complete article on Justin, please see:

<http://onlinelibrary.wiley.com/doi/10.1111/j.1460-9592.2010.03513.x/full>

Justin Micalizzi



On behalf of these and many other patients and their families, PPAHS encourages CMS to ensure that all patients using PCA are continuously electronically monitored with pulse oximetry and capnography, and not in the way that is currently proposed.

Expert Opinion on Proposed Quality Measure #3040

PPAHS asked health experts to provide their opinion on the Proposed Measure, and this is what they told us:

Frank Federico (member of the Patient Safety Advisory Group at The Joint Commission, and executive director at the Institute for Healthcare Improvement):

As currently written, the CMS proposed quality measure runs the risk of looking like it is protecting patients, while in reality not going far enough. Although nurse spot checks on patients are advisable, pulse oximetry and capnography are essential risk prevention tools in any pain management plan. The proposed CMS quality measure should include continuous electronic monitoring."

Matthew Grissinger (director, error reporting programs at ISMP):

The CMS proposed quality measure regarding patient-controlled analgesia deals with a critical patient safety issue that hospitals need to urgently address. Errors with PCA occur and, unfortunately, sometimes with tragic consequences. However, for patients to be safe, we would strongly recommend that the proposed measure to monitor patients using PCA include continuously electronically monitoring them with oximetry for oxygenation and capnography for adequacy of ventilation. In addition, [standardization of PCA procedures](#) would greatly reduce PCA errors and adverse events."

Robert Stoelting, MD (president of the Anesthesia Patient Safety Foundation):

"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."

Problem: Proposed Quality Measure #3040 Inadequately Protects Patients

Why does the Proposed Measure fall short of providing adequate patient safety?

CMS's proposed quality measure applies to "All patient admissions with initiation of an opioid via an IV PCA device that is active for more than 2.5 continuous hours."

Once PCA has been initiated, the proposed quality measure has two aspects:

- When monitoring needs to occur.
- What needs to be monitored.

When Monitoring Needs to Occur

However, [recommendations](#) by the Anesthesia Patient Safety Foundation provide that these "spot checks" are not sufficient:

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.

Matthew Grissinger (director, error reporting programs at ISMP) [explains](#) why "spot checks" and relying on pulse oximetry as a measure of a patient's oxygenation are not effective enough:

One reason why it is not effective is that a 'periodic check' and pulse oximetry would only catch an error, not prevent the error.

Additionally, the duration of the proposed CMS quality measure is "the first 24 hours after initiation of the first IV PCA opioid administration." Surely, it would be more appropriate to monitor patients for the entire period that they are connected to the PCA, rather than to stop monitoring after a predetermined period of time.

What Needs to Be Monitored

The CMS proposed quality measure provides that patients using PCA be monitored for three physiological factors: "respiratory rate, sedation score and pulse oximetry". Each factor is discussed below, with associated recommendations by key healthcare organizations and health experts:

Respiratory Rate: Measuring for respiratory rate is not enough. The [Pennsylvania Patient Safety Authority](#) recommends monitoring of patients include "frequent

assessment of the quality of respirations (not just a respiratory rate) ... ” [emphasis added].

Sedation Score: Sedation scores measure how the patient reacts to stimuli and the patient’s reaction are scaled, for example, from “no response to stimulus” to “anxious or restless”. However, Mr. Grissinger explains that a patient’s sedation score may not be an accurate measure, “ ... current standard methods for assessing a patient’s level of consciousness do not take into consideration that overly sedated patients can be aroused and respond to questions. Even though these patients can be aroused for a brief period of time and may in fact be able to speak, they immediately fall back into a state of oversedation. Accordingly, ISMP recommends observing the patient unobtrusively and noting both respiratory rate and depth of respiration in the absence of any stimulus.”

Pulse Oximetry: Monitoring a patient’s oxygenation by pulse oximetry is important. The Pennsylvania Patient Safety Authority recently [stated](#), “However, while useful, pulse oximetry does not measure ventilation. Since oxygen saturation is a lagging indicator of respiration, pulse oximetry may not indicate a problem early enough for effective intervention. Pulse oximetry is even more problematic for patients who are receiving supplemental oxygen, since they may be adequately oxygenated even with dangerously depressed ventilation. Capnography, or end-tidal carbon dioxide monitoring, allows clinicians to track several indicators, but for purposes of PCA it is primarily used as a reliable monitor for respiratory rate, including apneic episodes. The Anesthesia Patient Safety Foundation (APSF) advocates monitoring both oxygenation and ventilation in all patients receiving PCA.”

Dr. Frank Overdyk (executive director for research, North American Partners in Anesthesiology, and professor of anesthesiology at Hofstra North Shore-LIJ School of Medicine) explains the importance of PCA in managing pain, but also the [need for continuous electronic monitoring of patients](#):

Spot checks of SpO₂, as are commonly taken on med/surg floors, need to be eliminated from patient monitoring practice because these single measurements may mislead a provider into thinking the patient is fine when in fact they may be close to the precipice of unrecoverable respiratory depression.

Entering a patient room and placing a pulse oximeter on their finger stimulates their consciousness and respiration sufficiently to falsely elevate their reading, particularly when they are receive supplemental oxygen. Once the provider leaves the room, this stimulus fades and the patient may lapse back into a dangerous level of respiratory narcosis.

Although the Proposed Measure touches on a critical patient safety issue, the CMS measure only pays lip service to patient safety, as it goes against the recommenda-

tions of The Joint Commission, the Anesthesia Patient Safety Foundation, ISMP, and the Pennsylvania Patient Safety Authority.

Solution: How PCA Safety Checklist May Help CMS Monitoring

PPAHS recently released a concise checklist that reminds caregivers of the essential steps needed to be taken to initiate PCA with a patient and to continue to assess that patient's use of PCA. The PCA Safety Checklist can be viewed and downloaded free at www.ppahs.org

The checklist was developed in conjunction with renowned medical experts, including intensive care specialist and a leader in medical checklist development Peter J. Pronovost, MD, PhD, FCCM, Professor, Departments of Anesthesiology/Critical Care Medicine and Surgery, The Johns Hopkins University School of Medicine and Medical Director, Center for Innovation in Quality Patient Care, and Atul Gawande, MD, Professor in the Department of Health Policy and Management at Harvard School of Public Health, who is a surgeon at Brigham and Women's Hospital, Professor of Surgery at Harvard Medical School, and author of *The Checklist Manifesto*.

Regarding continued assessment of patients on PCA, the PCA Safety Checklist provides the following recommended steps:

- Patient satisfactorily assessed for:**
 - level of pain**
 - alertness**
 - adequacy of ventilation**

- PCA pump settings verified**

- Electronic monitoring verified:**
 - pulse oximetry and**
 - capnography**

- Patient assessment/condition has been added to flow sheet/
chart documenting PCA dosing and monitoring**

The Physician-Patient Alliance for Health & Safety encourages CMS to adopt as a quality measure the continuous electronic monitoring of all patients using PCA with pulse oximetry for oxygenation and with capnography for the adequacy of ventilation.

In addition, PPAHS offers its help and that of the undersigned, who has achieved sustained national and international recognition as a leading patient health and safety expert, and who is a founding member of the American Board of Patient Safety, s recently created board to certify and recertify physicians in patient safety through the American Board of Physician Specialties, one of the United States's main recognized physician multi-specialty certifying bodies.

Best regards,

A handwritten signature in black ink, appearing to read "Michael N. Wong".

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