Physician-Patient Alliance for Health & Safety Improving Health & Safety Through Innovation and Awareness

Survey on ASA Standards and APSF Recommendations

Mike Wong

Physician-Patient Alliance for Health & Safety

url: http://ppahs.wordpress.com/ email: <u>mike.ppahs@gmail.com</u>

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The Physician-Patient Alliance for Health & Safety ("PPAHS") is an advocacy group devoted to improving patient health and safety.¹

With the purpose of growing awareness and furthering discussion of patient health and safety issues, PPAHS conducted a survey on the American Society of Anesthesiologists ("ASA") Standards of Basic Anesthetic Monitoring ("ASA Standards") and the Anesthesia Patient Safety Foundation ("APSF") conclusions and recommendations ("APSF Recommendations"):

- The ASA Standards were in October 2010 updated to read: "During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring of the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment." The ASA Standards were implemented July 1, 2011.
- The Anesthesia Patient Safety Foundation (APSF) recently issued recommendations and conclusions on electronic monitoring strategies to detect drug-induced postoperative respiratory depression. Among other things, the APSF Recommendations provide, "Continuous electronic monitoring of oxygenation and ventilation should be available and considered for all patients and would reduce the likelihood of unrecognized clinically significant opioid-induced depression of ventilation in the postoperative period."2

This report is divided into the following three discussion parts

- A. Survey Recommendations
- B. Detailed Survey Analysis
- C. Respondent Analysis

Appendix A contains a summary of the survey results from Survey Monkey.

¹ PPAHS is inspired by Howard Snitzer, who survived 96 minutes without a heart beat. Howard's resuscitation by volunteer paramedics and Dr Roger White at the Mayo Clinic is a truly remarkable story. For more on Howard Snitzer's resuscitation, please see http://wp.me/p1JikT-c

² For more on these recommendations, please see http://wp.me/p1JikT-2L

Survey Recommendations

From the results of the survey, two immediate action steps are apparent and recommended:

Encourage Monitoring of All Post-Surgical Patients

Almost all respondents (90%) believe continuous electronic monitoring of oxygenation and ventilation should be available and considered for all patients. Such monitoring would reduce the likelihood of unrecognized clinically significant opioid-induced depression of ventilation in the postoperative period.

As explained by Dr. Daniel Sessler, who is Professor and Chair of the Department of Outcomes Research at the Cleveland Clinic, and Director of the Outcomes Research Consortium which is anesthesia's largest academic research organization:

Continuous respiratory monitoring, including the use of both capnography and pulse oximetry, is essential for the safe administration of patient-controlled analgesics. A patient experiencing respiratory depression, if undetected, can easily progress to respiratory arrest and consequent brain damage or death.

Develop and Distribute a Safety Checklist

Almost all the respondents (85%) favor the development and use of safety checklists. An example of a checklist is the surgical checklist that was created and is being promoted by the WHO³ and through the efforts of Dr Atul Gawande⁴. As their experience illustrates, focusing on common process failures is where a safety checklist would have great benefit in improving patient health and safety.

To support the call for the monitoring of all patients post-surgically, a safety checklist should focus on a common failure with patients after surgery. One such area is patient-controlled analgesia. According to the study by Dr Thomas McCarter and his colleagues published in America Health & Drug Benefits:⁵

Capnographic monitoring and automatic pausing of patient-controlled analgesia improved postoperative outcomes in situations that could have otherwise been fatal. Use of capnography improved clinician confidence that opioid dosing could be safely continued in postoperative patients for more effective pain management.

³ http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html

⁴ Dr Atul Gawande, The Checklist Manifesto (2009)

⁵ For more details, please see http://wp.me/P1JikT-T

Detailed Survey Analysis

The Survey was sent to doctors, nurses, hospital administrators, other healthcare providers, and advocates (for an analysis of respondents, please see the next section "Respondent Analysis"). Respondents answered the Survey over an approximate two week period beginning August 26, 2011.6

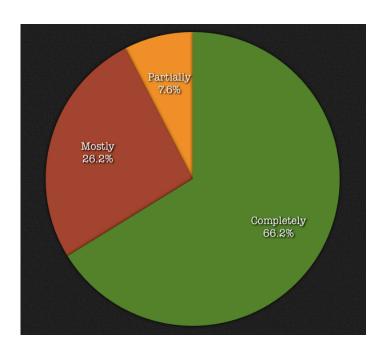
The Survey consisted of eight questions:

- Question 1 asked respondents to self-identify themselves. An analysis of Survey respondents is provided in the next section "Respondent Analysis".
- Six substantive questions (i.e. Questions 2 to 7), which are discussed in detail below.
- Question 8 asked whether the respondent wanted to receive a copy of this report, as well whether they wanted to be entered into a draw to win a randomly drawn iPad offered by a PPAHS supporter.

Question 2

As of July 1, 2011, I would describe the medical practices, of which I am aware, to be in accord with ASA Standards as

- Completely
- Mostly
- Partially



⁶ Although the survey did remain open for responding to after midnight of September 9, 2011, for the purposes of this Report the cut off date was midnight CT of September 9, 2011.

66.2% of respondents indicated that that the medical practices of which they are aware are completely in accord with ASA Standards. However, 33.8% answered "mostly" or "partially", which would seem to indicate a non-compliance issue.

There are two conclusions to be drawn from these results.

First, there is need for improvement. Even though this is a subjective question and is reliant upon the personal knowledge and information of the respondent, anything short of 100% responding "completely" indicates that there is room for improvement in how healthcare facilities adhere to ASA Basic Monitoring Standards.

As noted by Dr Richard Dutton (executive director of the Anesthesia Quality Institute):

"The safety of patients under anesthesia is extremely good, and the majority who believe that ASA Standards have been completely implemented is an indication of this. However, a significant minority clearly see room and areas for improvement, and I would concur with their observations. Quality of anesthesia provision can affect patient safety, quality outcomes, and finances facility. With the goal that no patient shall be harmed from anesthesia, healthcare facilities need to continually locate and deal with those areas."

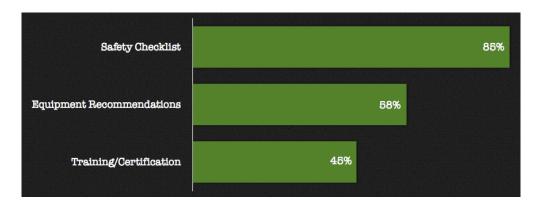
Second, some respondents may have been thinking of the application of ASA Standards outside of the operating room. For example, while there may be complete compliance inside operating rooms, there may not be compliance outside of the operating room. This would seem to be supported by some comments that were received regarding how to improve compliance with ASA Standards that referred to remote locations and the need for more capnography equipment:

"some remote non OR locations do not allow all ASA monitors (e.g. temp in mri)"

"need to get enough capnometry monitoring to supply our "off-site" locations where we do MAC cases"

To improve compliance with ASA Standards, I believe that it would help to have (check all that apply)

- Safety checklists that include ASA Standards.
- Recommendations on the equipment to be used to meet ASA Standards.
- Training or certification on ASA Standards.



This three part question first underscores the need for safety checklists. Almost all the respondents (85%) believe that safety checklists would improve compliance with ASA Standards. A surgical safety checklist was created and is now being used thanks to the WHO⁷ and the efforts of Dr Atul Gawande⁸. So, it is unlikely that respondents were referring to the need for a checklist in the operating room, but one that would address common failure problems post-surgery.

As a result, PPAHS is putting together a working group to create a checklist focused on patient-controlled analgesia. From 1999 to 2007, the number of U.S. poisoning deaths involving any opioid analgesic (e.g., oxycodone, methadone, or hydrocodone) more than tripled, from 4,041 to 14,459, or 36% of the 40,059 total poisoning deaths in 2007. In 1999, opioid analgesics were involved in 20% of the 19,741 poisoning deaths. During 1999–2007, the number of poisoning deaths involving specified drugs other than opioid analgesics increased from 9,262 to 12,790, and the number involving non-specified drugs increased from 3,608 to 8,947.

According to the study by Dr Thomas McCarter and his colleagues published in America Health & Drug Benefits:9

Capnographic monitoring and automatic pausing of patient-controlled analgesia improved postoperative outcomes in situations that could have otherwise been fatal. Use of capnography improved clinician confidence that opioid dosing could be safely continued in postoperative patients for more effective pain management.

⁷ http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html

⁸ Dr Atul Gawande, The Checklist Manifesto (2009)

⁹ For more details, please see

Moreover, better monitoring of patients using PCA pumps has been shown to improve patient safety and produce a significant return on investment. According to the study "Intravenous Infusion Safety Technology: Return on Investment",¹⁰ St. Joseph's/Candler Health System¹¹ found out that the "costs" over a 5-year period of implementing a patient safety initiative was the prevention of at least 471 adverse events, a return on investment of \$1.87 million, an internal rate of return of 81%.

Second, respondents (58%) saw the need for "recommendations on the equipment to be used to meet ASA Standards". While it may seem to be an obvious point, clearly knowing what equipment should best be used to for patients to be 'evaluated by continual observation of qualitative clinical signs and monitoring of the presence of exhaled carbon dioxide" would be helpful. Perhaps what people are asking is whether it would have been so hard to say, for example, "use capnography to monitor for the presence of exhaled carbon dioxide"?

Third, 44% of respondents saw the need for "training or certification on ASA Standards". As Dr Philip Lumb (Chair of Anesthesiology, Keck School of Medicine) said, "Continuing education should be provided for all individuals taking care of patients who have received procedural anesthesia/sedation. Special emphasis should be given to 'non-traditional' areas outside the purview of normal operating room and perioperative procedures and surveillance. This is increasingly important for office-based practices, interventional suites (GI, Radiology, etc) and ambulatory surgery centers."

In summary, the sentiment of a patient advocate should be noted:

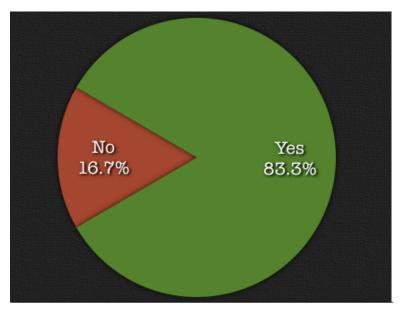
I believe you can't have too much training or too many checklists and equipment being checked should be a given

¹⁰ For more information, please see http://wp.me/p1JikT-24

¹¹ http://www.sjchs.org/default.cfm?id=1

Do you believe that 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?

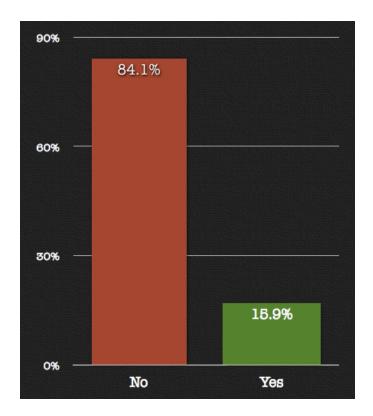


83.3% of respondents believe that clinically significant drug-induced respiratory depression (oxygenation and/or ventilation) in the postoperative period remains a serious patient safety risk that continues to be associated with significant morbidity and mortality.

Because a substantial majority believes that drug-induced respiratory depression continues to be a patient safety issue, this poses interesting questions for the 16.7% who answered "no":

- Have they figured it out? in the sense that in their healthcare facility, drug-induced respiratory depression is no longer an issue; or
- Are they not recognizing it? As one prominent neuroanesthesiologist emailed PPAHS on this question, "We should stop the found dead in bed syndrome." An argument for a non-recognition factor is supporter in the response to Question 7 (see below), where 61% believe that caregivers are failing to recognize the "true risk of drug-induced depression of ventilation".

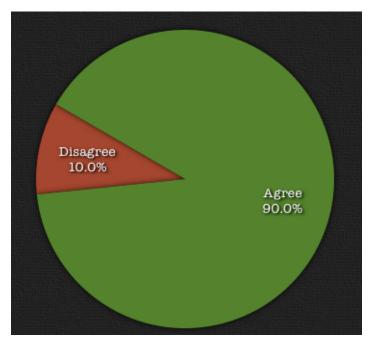
Do you believe that intermittent "spot checks" of oxygenation (pulse oximetry) and ventilation (nursing assessment) are adequate for reliably recognizing clinically significant evolving drug-induced respiratory depression in the postoperative period"



84.1% of respondents believe that intermittent spot checks are <u>not</u> adequate, which answer is consistent with the 83.3% who believe that drug-induced respiratory depression (oxygenation and/or ventilation) in the postoperative period remains a serious patient safety risk (see Question 4).

The answer to this question is interesting, not so much in the fact that 84.1% do not believe that intermittent spot checks are adequate, but that a sizable minority (15.9%) are in disagreement with their fellow practitioners and believe that these spot checks are adequate.

Do you agree or disagree with the following statement -- "Continuous electronic monitoring of oxygenation and ventilation should be available and considered for all patients and would reduce the likelihood of unrecognized clinically significant opioid-induced depression of ventilation in the postoperative period"



Almost all respondents (90%) believe continuous electronic monitoring of oxygenation and ventilation should be available and considered for all patients. Such monitoring would reduce the likelihood of unrecognized clinically significant opioid-induced depression of ventilation in the postoperative period.

What is interesting about this response is the 10% who believe that continuous electronic monitoring of oxygenation and ventilation should <u>not</u> be available and considered for all patients. As one medical director for a surgical intensive care unit of a prominent healthcare provider emailed, "I am quite shocked that the disagree group is that high!"

In practice, for example, some patients may not be continuously monitored electronically because they may not have been identified as having risks associated with obstructive sleep apnea, obesity, or chronic opioid therapy.

Perhaps, as one anesthesiologist emailed PPAHS, continuous monitoring is available and being considered, but not applied. However, in such cases, respondents should have more properly answered "agree" that monitoring is being considered, as the question was not whether monitoring was being applied to all patients. As a medical director for inpatient pain service at a prominent hospital emailed:

Of course these monitors "should be available and considered" but since clinically significant respiratory depression events, ie. hypoxemia or hypercapnia/acidosis requiring naloxone, are rare, I would only encourage routine or mandatory use of the "available" monitors on the highest risk patients. I don't think it's feasible or necessary for "all" patients.

However, more importantly, what 90% of respondents seem to be saying is that all patients should be continuously monitored. This was certainly the sentiment in direct Twitter messages and emails from healthcare providers and others on this question. As a physician at a well-known children's hospital emailed:

All post-operative patients should be monitored.

According to the HealthGrades study of patient safety in American hospitals,¹² "failure to rescue" and postoperative respiratory failure (also known as "Code Blue") are the first and third most common patient safety related adverse events affecting Medicare patients accounting for 113 events per 1,000 at-risk patient admissions.

"These adverse events which affect both Medicare and non-Medicare patients result in death or anoxic brain injury in the majority of cases," observes Dr. Daniel Sessler, who is Professor and Chair of the Department of Outcomes Research at the Cleveland Clinic, and Director of the Outcomes Research Consortium which is anesthesia's largest academic research organization. The Consortium conducts research in anesthesia, critical care, and comprehensive pain management.

"Continuous respiratory monitoring, including the use of both capnography and pulse oximetry, is essential for the safe administration of patient-controlled analgesics," explains Professor Sessler. "A patient experiencing respiratory depression, if undetected, can easily progress to respiratory arrest and consequent brain damage or death."

¹² http://www.healthgrades.com/business/img/ HealthGradesPatientSafetyInAmericanHospitalsStudy2011.pdf

Impediments to continuous electronic monitoring of oxygenation and ventilation (selected or all patients) in the postoperative period are (please check all that apply)

- Initial investment cost in instituting existing technology
- Failure of caregivers to recognize (inadequate education) the true risk of druginduced depression of ventilation
- Absence of evidence-based data to support value of electronic monitoring (55.6%)
- Existing technology is not practical
- Recommendations on the equipment to be used to meet APSF Recommendations
- Safety checklists that include APSF Recommendations

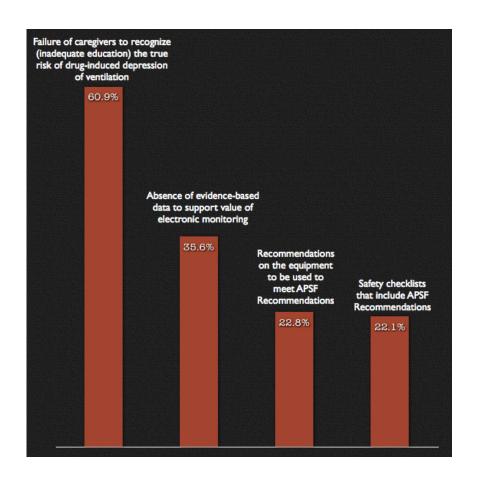
This question explores the impediments to continuous electronic monitoring of oxygenation and ventilation. Answers to this question reveal two main areas of interest or, if you will, concern.

The first is on the technology. The majority believe that the technology is practical (80.6%). In other words, from a use point of view, there does not seem to be a concern about existing technology (pulse oximetry or capnography).

However, a major impediment to adoption of continuous monitoring is cost (with 65.7% expressing this concern).

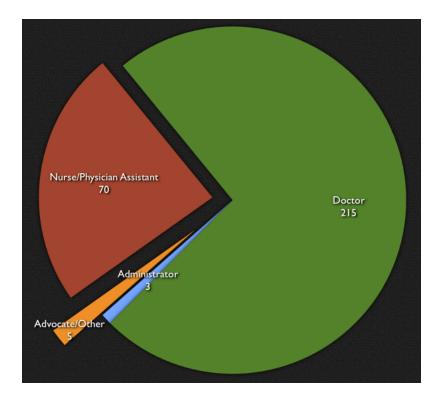
Initial investment cost in instituting existing technology	65.7%
Existing technology is not practical	19.4%

The second relates to awareness and the belief that caregivers are failing to recognize the "true risk of drug-induced depression of ventilation", with 61% expressing this concern (please see chart on next page). It is unlikely that the respondents are saying that caregivers do not know drug-induced respiratory depression when they see it, but they may not be recognizing the risk when it occurs. Continuous electronic monitoring of all patients (as suggested in response to Question 6) would eliminate this risk of non-identification.



Respondent Analysis

293 people responded to the survey. Almost all the respondents (285 or 97.2%) are healthcare providers, with about three-quarters of these being doctors and the rest nurses or physician assistants. The remainder were healthcare administrators, patient advocates, or in some way related to the healthcare system.

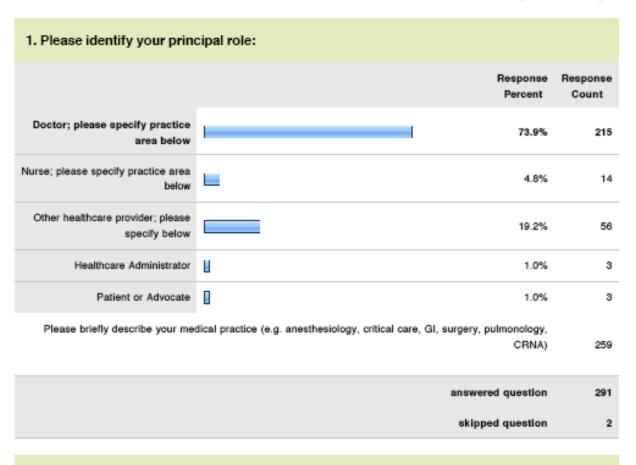


Moreover, most of the respondents (about 60%) indicated anesthesiology as their medical practice. Other practice areas represented were pediatric/neonatal (22%) and critical care (8%). In addition, other specialities represented constituted about 8% of the respondents indicating such areas as radiology, pulmonology, surgery, and neurology.

Appendix A

ASA Standards & APSF Recommendations Survey SurveyMonkey





2. As of July 1, 2011, I would describe the medical practices, of which I am aware, to be in accord with ASA Standards as:

	Response Percent	Response Count
Completely	66.2%	192
Mostly	26.2%	76
Partially	7.6%	22
	answered question	290
	skipped question	3

3. To improve compliance with ASA Standards, I believe that it would help to have (check all that apply):

	Response Percent	Response Count
Safety checklists that include ASA Standards.	85.3%	237
Recommendations on the equipment to be used to meet ASA Standards.	57.9%	161
Training or certification on ASA Standards.	45.3%	126
	Other (please specify)	12
	answered question	278
	skipped question	15

4. Do you believe that 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?

	Response Percent	Response Count
Yes	83.3%	240
No	16.7%	48
	answered question	288
	skipped question	5

5. Do you believe that intermittent "spot checks" of oxygenation (pulse oximetry) and ventilation (nursing assessment) are adequate for reliably recognizing clinically significant evolving drug-induced respiratory depression in the postoperative period.

	Response Percent	Response Count
Yes	15.9%	46
No	84.1%	243
	answered question	289
	skipped question	4

6. Do you agree or disagree with the following statement -- Continuous electronic monitoring of oxygenation and ventilation should be available and considered for all patients and would reduce the likelihood of unrecognized clinically significant opioidinduced depression of ventilation in the postoperative period:

	Response Percent	Response Count
Agree	90.0%	260
Disagree	10.0%	29
	answered question	289
	skipped question	4

7. Impediments to continuous electronic monitoring of oxygenation and ventilation (selected or all patients) in the postoperative period are (please check all that apply):

	Response Percent	Response Count
Initial investment cost in instituting existing technology	65.7%	190
Existing technology is not practical	19.4%	56
Absence of evidence-based data to support value of electronic monitoring	35.6%	103
Failure of caregivers to recognize (inadequate education) the true risk of drug-induced depression of ventilation	60.9%	176
Safety checklists that include APSF Recommendations.	22.1%	64
Recommendations on the equipment to be used to meet APSF Recommendations.	22.8%	66
	answered question	289
	skipped question	4

8. (optional) If you'd like to be entered into a lottery draw for an iPad 2 or would like to receive a copy of a report on this survey, please complete the following:

