Development of the ASA Critical Incidents Reporting System

I. Introduction

In 2008, the American Society of Anesthesiologists established the Anesthesia Quality Institute, a non-profit corporation focused on improving the processes and outcomes of perioperative care. As a part of this initiative, the ASA's Committee on Performance and Outcomes Measurement (CPOM) has been tasked with development of a set of measures to be included in a planned registry of perioperative events that may be used to assess patterns of quality in anesthetic care.

Between August, 2008 and February, 2009, a subcommittee of CPOM was convened via three conference calls to develop and revise the proposed list. The subcomittee members were:

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III. Methodology

Prior to the initial subcommittee meeting, CPOM was presented with a list of perioperative events solicited from anesthesia subspecialty societies (SAMBA, SPA, ASRA&PM, SOAP, SCA), as well as the ABG and the National Surgical Quality Improvement Program. This list is included as Appendix 1.

The CPOM subcommittee first defined a list of 26 variables through a three stage process. First, similar outcome measures proposed by different groups were merged to eliminate duplicates. Second, subcommittee members ranked all variables for appropriateness for inclusion. Third, all variables identified by any subcommittee member as appropriate for inclusion were discussed by the subcommittee members; final decisions for inclusion were reached by consensus.

To develop definitions for the measures selected, the subcommittee engaged in staged process. First, all practice parameters, advisories, and guidelines developed by the ASA were screened for pertinent definitions. Where available, we employed the ASA's definition of a specific event or complication. If a definition was unavailable from ASA documents, we then searched the websites of the Joint Commission and the Agency for Healthcare Research and Quality for previously published definitions of adverse outcomes. Where these definitions were unavailable or not applicable to the clinical scenarios described in the selected measures, definitions were developed through a consensus process among subcommittee members. Efforts have been made to support definitions reached through committee consensus by incorporating definitions put forth by medical societies and patient advocacy groups.

IV. List of Measurements: (For definitions, see below)

1. Death
2. Cardiac arrest
3. Perioperative myocardial infarction
4. Anaphylaxis
5. Malignant hyperthermia
6. Transfusion reaction
7. Stroke, cerebral vascular accident, or coma following anesthesia
8. Visual loss
9. Operation on incorrect site
10. Operation on incorrect patient
11. Medication error
12. Unplanned ICU admission
13. Intraoperative awareness
14. Unrecognized difficult airway
15. Reintubation
16. Dental trauma
17. Perioperative aspiration

18. Vascular access complication, including vascular injury or pneumothorax
19. Pneumothorax following attempted vascular access or regional anesthesia

20. Infection following epidural or spinal anesthesia
21. Epidural hematoma following spinal or epidural anesthesia
22. High spinal
23. Postdural puncture headache
24. Major systemic local anesthetic toxicity
25. Peripheral neurologic deficit following regional anesthesia
26. Infection following peripheral nerve block

V. Proposed Variables and Their Definitions

1. Death: Death within 48 hours after induction of anesthesia/ in-hospital death

No standard exists for the time frame defining perianesthetic mortality. The consensus of the subcommittee was that deaths within 48 hours of induction of anesthesia should be tracked in the proposed database. Additionally, it was proposed that in-hospital mortality be recorded as a secondary endpoint.

Induction of anesthesia was chosen as the beginning of the interval of observation because committee members agreed that it would allow precise measurement of the beginning of the interval of observation; 48 hours was chosen as the end of the interval of observation because committee members agreed that it would allow for measurement of mortality following surgical procedures of varying length.

2. Cardiac arrest: Cardiac arrest is broadly defined as the cessation of cardiac mechanical activity as confirmed by the absence of signs of circulation[1].
For the present registry, subcommittee members agreed that the definition should include the following criteria: (1) use of cardiac compressions and/or defibrillation and (2) during the first 48 hours after induction of anesthesia.

Subcommittee members discussed incorporation of features in the registry (i.e. computerized drop-down menus) allowing reporting of the etiology of cardiac arrest, possibly including:

a. Ventricular fibrillation
b. Rapid ventricular tachycardia with hemodynamic instability
c. Asystole
d. Extreme bradycardia with hemodynamic instability

3. Perioperative myocardial infarction: Perioperative myocardial infarction was defined in accordance with the Universal Definition of Myocardial Infarction by the Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction as published by the Journal of the American College of Cardiology in 2007 with the addition of diagnosis by cardiologist:

Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit together with evidence of myocardial ischemia with at least one of the following:

a. Symptoms of ischemia
b. ECG changes indicative of new ischemia (new ST-T changes or new left bundle branch block)
c. Development of pathological Q waves in the ECG
d. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.[2]

4. Anaphylaxis: Anaphylaxis is broadly defined as a severe, systemic allergic reaction characterized by multisystem involvement including the skin, airway, vascular system, and gastrointestinal tract, potentially resulting in obstruction of the airway, cardiovascular collapse, and death[3].

Subcommittee members agreed on the following definition of anaphylaxis for the present registry:

Clinical diagnosis of a severe, life-threatening allergic response, characterized by a sudden drop in blood pressure, especially if epinephrine is administered, and/or respiratory insufficiency.

Subcommittee members discussed incorporation of features in the registry allowing reporting of the suspected trigger.

5. Malignant hyperthermia: The subcommittee agreed on the following definition:

(1) Clinical diagnosis of suspected MH during or after exposure to anesthetic gases or to succinylcholine or (2) treatment with dantrolene

The subcommittee members agreed that the registry should include features to allow reporters to report known signs and symptoms of MH (Malignant Hyperthermia Association of the United States; http://www.mhaus.org): increasing end-tidal CO_2, trunk or total body rigidity, masseter spasm or trismus, tachycardia, tachypnea, mixed respiratory and metabolic acidosis, increased temperature, and myoglobinuria

6. Transfusion reaction: Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities is identified as a sentinel event by the Joint Commission (http://www.jointcommission.org/AboutUs/Fact Sheets/ sep facts.htm).

Subcommittee members agreed on the following definition of transfusion reaction for the present registry:

Clinical diagnosis of definite or suspected transfusion reaction during or following transfusion of blood products confirmed by blood bank results to be possibly incompatible with patient blood.

The subcommittee members agreed that the registry should include features to allow reporters to differentiate between suspected and laboratory-confirmed cases, as well as description of signs and symptoms indicating a transfusion reaction, possibly including new onset of: fever, chills, rash, flank pain or back pain, bloody urine, fainting or dizziness, kidney failure, delayed anemia, lung dysfunction, or shock

7. Stroke, cerebral vascular accident, or coma following anesthesia: The subcommittee agreed on reporting the following major neurologic events:

(1) Stroke, defined as an embolic, thrombotic, or hemorrhagic vascular accident with motor, sensory, or cognitive dysfunction (e.g., hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) that persists for 72 or more hours, confirmed by imaging

(2) Clinical diagnosis of a new postoperative coma that persists for at least 24 hours secondary to anoxic/ischemic and/or metabolic encephalopathy, thromboembolic event or cerebral bleed.

8. Visual loss: Permanent impairment or total loss of sight associated with a spine procedure during which general anesthesia is administered, as defined by the ASA Task Force of Perioperative Blindness[4]

9. Operation on incorrect site: Surgery or anesthesia (including regional nerve block) on the wrong body part or wrong side of patient. Wrong site surgery is defined as a sentinel event defined by the Joint Commission, (http://www.jointcommission.org/AboutUs/Fact Sheets/ sep facts.htm)

10. Operation on incorrect patient: Surgery or procedure on the wrong patient. Wrong-patient surgery is a sentinel event defined by the Joint Commission (http://www.jointcommission.org/AboutUs/Fact Sheets/ sep facts.htm)

11. Medication error: The members of the subcommittee agreed on reporting of administration of wrong medication or wrong dosing[5].

12. Unplanned ICU admission: The members of the subcommittee agreed on reporting of unplanned admission to the intensive care unit within 48 hours of induction

of anesthesia or start of monitored anesthesia care. The construct validity of unplanned admission to an intensive care unit as an indicator of perioperative patient safety was recently confirmed in an Australian study[6].

The members of the subcommittee agreed that the reason for ICU admission should be reported, and that the registry should include features to allow reporters to report such reasons, including: need for postoperative ventilation, need for ongoing vasopressor support, unanticipated unstable airway, unanticipated potential for apnea, unplanned prolonged anesthetic action or neuromuscular blockade

13. Intraoperative awareness: The subcommittee agreed on a definition of awareness during anesthesia as a scenario in which a patient becomes conscious during a procedure performed under general anesthesia and subsequently has recall of these events.

In accordance with the ASA Task Force on Intraoperative Awareness, the subcommittee recommends that reports of awareness be limited to explicit memory and should not include the time before general anesthesia is fully induced or the time of emergence from general anesthesia, when arousal and return of consciousness are intended[7].

14. Unrecognized difficult airway: For reporting of unrecognized difficult airway, we refer to the ASA's Practice Guidelines for Management of the Difficult Airway:

The clinical situation in which a conventionally trained anesthesiologist experiences difficulty with face mask ventilation of the upper airway, difficulty with tracheal intubation, or both[8].

15. Reintubation: The relevance of reintubations as a potential indicator for patient safety has been demonstrated in both the ASA Closed Claims Project[9] and a large-scale quality assurance database study[10]. It is known that the consequences of reintubation are significant, including increased duration of total ventilatory support, prolonged PACU stay, unexpected intensive care unit admission, and increased adverse cardiac events[11, 12].
In an effort to distinguish anesthesia-related causes from other conditions requiring reintubation, the subcommittee developed the following definition:

Patient requires placement of tracheal tube or other airway devices and mechanical or assisted ventilation within 6 hours after extubation because of severe respiratory distress, hypoxia, hypercapnia, or respiratory acidosis.

16. Dental trauma: The committee agreed that unanticipated loss of a tooth should be reported to the registry.

17. Perioperative aspiration: The subcommittee reached the conclusion that clinical diagnosis of aspiration consistent with radiologic findings should be reported to the registry.

18. Vascular access complication, including vascular injury or pneumothorax: Complications of central venous cannulation are well known[13]. The reviewers conducting the ASA Closed Claims Project stated that most of the complications appear to be the result of operator errors and thus potentially avoidable[14].
In an attempt to identify injuries of severity sufficient to require additional interventional therapy, the subcommittee agreed on the following definition:

Accidental intraarterial dilation or placement of central venous catheter, pneumothorax, thoracic duct injury, or other injuries requiring either surgical or interventional radiologic management

19. Pneumothorax following attempted vascular access or regional anesthesia: The subcommittee agreed that traumatic open or tension pneumothorax, diagnosed on clinical presentation or by imaging study (e.g. X-ray, CT, ultrasound), should be reported to the registry.

20. Infection following epidural or spinal anesthesia: Infectious complications associated with neuraxial anesthesia and analgesia are of great concern because of their potentially devastating sequelae – including meningitis, paralysis, and death[15]. The subcommittee agreed on the following definitions which were adapted from the ones proposed by the ASRA&PM for this registry.

Superficial soft tissue infection along the course of an epidural/spinal catheter or needle placement track – Swelling, local erythema and tenderness in combination with any of the following:

a. Fever (>38.0 degrees centigrade)
b. Drainage
c. Positive culture from the area
d. Leukocytosis >12/nl or CRP>20 mg/L

Epidural abscess – Radiological evidence of a mass in the epidural space consistent with an epidural abscess within 30 days following epidural/spinal needle/catheter placement/catheter removal or attempted epidural/spinal placement in combination with any of the following:

a. Fever (>38.0 degrees centigrade)
b. Drainage

c. Positive culture from surgical exploration or puncture
d. Leukocytosis >12/nl or CRP>20 mg/L
e. Local erythema
f. Local tenderness
g. Focal back pain
h. Neurologic deficit

Meningitis associated with central neuraxial block – Spinal or epidural block (catheter insertion/removal) in the last 72 hours in combination with

a. New onset of central neurologic symptoms
b. Headache
c. Stiff neck
d. Fever >38.0 degrees centigrade
e. Positive CSF culture
f. Meningitis specific antibiotic therapy started

Epidural infection with sepsis – Diagnostic criteria of Superficial soft tissue infection or Epidural abscess or Meningitis in combination with positive blood culture with the same organism isolated from puncture site or abscess or
clinical diagnosis of sepsis

21. Epidural hematoma following spinal or epidural anesthesia: The risk of neuraxial hematoma is rare[16] but remains of great concern due to its potentially devastating sequelae.

The subcommittee agreed that an epidural hematoma following neuraxial anesthesia, confirmed by imaging (MRI), should be reported to the registry.

22. High spinal: The subcommittee agreed on reporting of unintentional high spinal as indicated by paralysis higher than T4, hypotension, bradycardia, respiratory insufficiency, possibly necessitating intubation.

23. Postdural puncture headache: The subcommittee agreed on reporting of PDPH, diagnosed on the basis of a clinical history of a new onset of headache, worsening in the sitting or upright position, within 72 hours of intended or unintended dural puncture.

The committee agreed that PDPH occurring following blocks in close proximity to the neuraxis, such as paravertebral or interscalene blocks, should be reported and the causative nerve block specified.

24. Major systemic local anesthetic toxicity: Local anesthetic toxicity is broadly defined by the ASRA recommendations on systemic toxicity of local anesthetics

(http://www.aaos.org/news/aaosnow/aug08/clinical2.asp)

The members of the subcommittee agreed that major systemic effects observed following injection of local anesthetics should be reported, and that the registry should include features to allow reporters to report observed effects, including: seizures, somnolence, loss of consciousness, respiratory depression/apnea, bradycardia/asystole, or ventricular tachycardia/fibrillation.

25. Peripheral neurologic deficit following regional anesthesia: The subcommittee agreed on a reporting of peripheral neurologic deficits after regional anesthesia based on the original definition proposed by the ASRA & PM for the development of this registry:

Clinical diagnosis of residual sensory and/or motor and/or autonomic block 72 hours after last injection of local anesthetic without other identifiable etiology when no regional anesthetic/analgesia related infection is present.

The subcommittee agreed that such diagnoses could be confirmed, where appropriate by:

a. Electrophysiological evidence of new nerve damage (MEP, SEP, nerve conduction study, electromyography)
b. New loss of deep tendon reflexes
c. New loss of vibration sensation
d. Paresthesia in affected nerve distribution area
e. Sensory and/or motor and /or autonomic deficit consistent with dermatomes or nerve distribution affected by the regional anesthetic technique.

Additionally, the subcommittee agreed that data could be included in the registry describing events in the delivery of regional anesthesia that may be associated with subsequent neurologic deficits, including the following:

a. Multiple attempts at needle placement
b. Paresthesia during needle placement/injection
c. Pain on injection of local anesthetic
d. Regional blocks placed in adult patients under anesthesia

26. Infection following peripheral nerve block: The subcommittee agreed on the following definitions, which were adapted from the ones proposed by the ASRA&PM for this registry.

Peripheral nerve block associated superficial soft tissue infection - Swelling, local erythema, and tenderness along the catheter or needle placement track in combination with any of the following:

a. Fever (> 38.0 degrees centigrade)
b. Drainage
c. Positive culture from the area
d. Leukocytosis >12/nl or CRP>20mg/L

Peripheral nerve block associated abscess or deep tissue infection – Evidence of an abscess or fluid collection consistent with an infectious process by imaging or surgical exploration within 30 days following peripheral nerve block needle placement/catheter removal or attempted placement, especially if in combination with any of the following:

a. Fever (>38.0 degrees centigrade)
b. Neurologic deficit
c. Drainage
d. Positive culture from surgical exploration or puncture
e. Leukocytosis >12/nl or CRP>20 mg/L

Peripheral nerve block associated infection with sepsis – Diagnostic criteria of superficial soft tissue infection or abscess or deep tissue infection in combination with positive blood culture with the same organism isolated from puncture site or abscess or clinical diagnosis of sepsis.

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