

Considerations for Policy Development Number 4.3 Unintended Intraoperative Awareness



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Preamble

Anesthesia awareness is also referred to as unintended intraoperative awareness and occurs infrequently under general anesthesia when a patient becomes cognizant of some or all events during a procedure and has direct recall of those events. This may be distressing to some patients and may progress to Post-traumatic Stress Syndrome in a subset of these patients. Over the years, AANA has made efforts to inform members and the public about this important issue and fully supports measures to minimize the incidence and sequelae of awareness events. Working with the American Society of Anesthesiologists (ASA) and the Joint Commission on Healthcare Organizations (JCAHO), AANA leadership proactively represented the views of CRNAs as JCAHO developed and published Sentinel Event Alert (SEA) No. 32, which addressed this issue, on October 6, 2004 (See Appendix A).

In keeping with existing AANA Standards and Guidelines, as well as recommendations contained in the JCAHO document, the attached model policy on unintended intraoperative awareness during general anesthesia is offered as a tool for CRNAs and their health care facilities. While the AANA believes that the model policy addresses all relevant areas recommended in SEA 32, the Association does not warrant that adopting policies based on this example will guarantee compliance by JCAHO surveyors nor the prevention of any episode of intraoperative awareness or that its use will deter or affect the outcome of any litigation. We encourage CRNAs to customize this policy for use in their own institutions.

Approved by the Board of Directors February 2005.

POLICY TITLE: Prevention and Management of Unintended Awareness
Under General Anesthesia

POLICY #: _____

DATE EFFECTIVE: Month/Year

I. STATEMENT OF POLICY:

- a. General anesthesia administered to inpatients or outpatients at any anesthetizing location within the Hospital shall be carried out in such a manner as to minimize the occurrence of unintended intraoperative awareness. Existing policies and procedures during anesthesia care intended to safeguard the patient's well being and to provide for the best clinical conditions to perform the surgical, therapeutic, or diagnostic procedure will continue to be followed.
- b. Pre-operative anesthesia assessment will seek to identify patients at increased risk for unintended awareness. Such patients will receive additional preoperative discussion regarding the possibility of unintended awareness.
- c. Post-anesthesia follow-up of all patients receiving general anesthesia will include an assessment to determine if patients have experienced unintended awareness. Patients who have experienced unintended awareness will receive specific care and appropriate referrals for optimal patient outcome following this event.
- d. Relevant clinical staff will be educated about unintended intraoperative awareness, including the management of patients who have experienced an awareness event.

II. APPLIES TO:

- a. Anesthesia Personnel (Anesthesiologists, Certified Registered Nurse Anesthetists, Anesthesiology Residents, Student Nurse Anesthetists)
- b. Perioperative Team Members (Pre-Surgical Evaluation Clinic, Pre-operative Holding Area, Operating Room, Day Surgery Unit, Post-Anesthesia Care Unit, Intensive Care Unit, Medical/Surgical Units)
- c. Medical Staff (Physicians who perform surgical, diagnostic or therapeutic procedures under general anesthesia in any location within the Hospital).

III. PURPOSE:

- a. To establish appropriate policy and procedures within the Hospital to minimize the occurrence and consequences of unintended intraoperative awareness in patients receiving general anesthesia. It is recognized that there may be some instances where awareness is unavoidable or planned.

IV. RATIONALE:

- a. Unintended intraoperative awareness occurs during general anesthesia when a patient regains consciousness and becomes cognizant of some or all of the events

occurring during surgery or a procedure. Recent studies have found that this adverse event occurs in 1 in 500 to 1000 general anesthetics.¹ Some patient types are at increased risk (e.g., trauma patients, cardiac surgery patients, emergency obstetrical surgery) as well as some clinical situations (profound muscle relaxation, intravenous anesthesia). A patient who experiences unintended awareness is at increased risk for serious emotional and psychological injury, including the development of post-traumatic stress disorder. Prompt identification and management of patients who experience unintended awareness is indicated to minimize these complications.

V. IMPLEMENTATION:

a. Definition

The policy for prevention and management of unintended awareness applies when patients receive, in any setting, for any purpose, anesthesia care intended to produce loss of consciousness, i.e., general anesthesia.

b. Preoperative Identification of High-Risk Patients

Certain patient types are at increased risk for the occurrence of unintended awareness. Patients meeting the following criteria will be considered at increased risk.^{2,1}

- i. Cardiac surgery, including off-pump
- ii. Acute trauma with hypovolemia
- iii. Caesarean section under general anesthesia
- iv. ASA Physical Status 3, 4 and 5 Patients
- v. Impaired cardiovascular status
- vi. Expected intraoperative hypotension requiring treatment
- vii. Bronchoscopy, laryngoscopy or both
- viii. Anticipated difficult intubation
- ix. History of awareness
- x. Severe end-stage lung disease
- xi. Heavy alcohol intake
- xii. Chronic use of benzodiazepine, opioids or both

c. Patients at increased risk will be provided additional discussion of the possibility and clinical reasons that result in the increased risk of unintended awareness. In addition to utilizing clinically feasible strategies that minimize the risk of awareness (See Section V.d), the anesthesia team will instruct the patient to volunteer any descriptions or experiences of intraoperative awareness following the general anesthetic. Any occurrence of unintended awareness will be managed as described below (See Section V.f).

d. Reducing the risk of unintended intraoperative awareness³

- i. Periodic maintenance of the anesthesia machine and its vaporizers will be performed according to established policy.
- ii. Anesthesia providers will perform daily and pre-case checkout including inspection of anesthesia machine, monitors, vaporizers, and infusion pumps used to administer anesthetic agents and/or monitor the delivery and effect of anesthetic agents.
- iii. The anesthesia provider will consider the premedication of each patient with an amnestic agent (e.g. a benzodiazepine or scopolamine) – particularly if the clinical situation suggests that light anesthesia will be required.
- iv. Unless there is a clinical contraindication, an adequate dosage of hypnotic agent(s) will be used for induction of anesthesia, allowing sufficient time for onset prior to airway instrumentation and/or other stimulating interventions. If intubation of the trachea is found to be difficult, consideration will be given to administering additional dosages of induction agent(s).
- v. During the maintenance of general anesthesia, if a volatile anesthetic agent is administered, the end-tidal concentration will be measured and documented on the chart at 15 minute intervals.
- vi. Anesthesia practitioners should realize that certain medications (e.g. beta-blockers, calcium channel blockers, alpha-2 agonists) may mask the hemodynamic and physiologic responses to inadequate anesthesia.
- vii. Anesthesia practitioners should appreciate that administration of neuromuscular blocking agents will prevent a patient from moving in response to inadequate anesthesia. Neuromuscular blocking agents will be administered according to clinical requirements, and the level of relaxation will be assessed by objective peripheral nerve stimulation monitoring. During periods of profound or total neuromuscular block, anesthesia practitioners will closely monitor all other parameters for evidence of inadequate anesthesia.

[Note: The following section is intended only for institutions that have adopted consciousness monitoring. As a class, “consciousness monitors” comprise a variety of technologies, typically based on EEG signal processing. These devices are designed to measure the hypnotic component of the anesthetic state rather than provide a comprehensive assessment of anesthetic depth. As such, they should be considered adjuncts to other patient monitoring modalities. ***Not all devices being sold for this purpose have been studied for their effectiveness in reducing the incidence of anesthesia awareness.^{2,4} Therefore, it is incumbent upon individual anesthesia departments to determine that the products they select for this purpose are efficacious based on evidence-based merits.***]

- viii. Anesthesia practitioners will consider utilizing a consciousness monitor, particularly in all clinical situations that place a patient at increased risk for intraoperative awareness (See Section V.b), mask the patient's ability to show physiologic (blood pressure, heart rate) or somatic (movement) responses to inadequate anesthesia, (See Sections V.d.vi and V.d.vii), or utilize a primary intravenous anesthetic technique.
1. The Department of Anesthesiology will provide and document training of individual anesthesia providers on the consciousness monitoring system prior to clinical use.
 2. Except in extenuating clinical situations, consciousness monitoring will be used throughout the period of general anesthesia from immediately before induction until the patient emerges from anesthesia and regains consciousness.
 3. Sound clinical judgment should always be used when interpreting the consciousness monitor in conjunction with other available clinical signs.

e. Post-operative Follow-Up After General Anesthesia

- i. All patients, including children, will be assessed for the occurrence of unintended awareness following general anesthesia.
- ii. A specific, structured, non-leading interview will be used as the primary screening tool, utilizing the following, scientifically-validated questions:^{1,4,5}
 - *What is the last thing you remember before going to sleep?*
 - *What is the first thing you remember waking up?*
 - *Do you remember anything between going to sleep and waking up?*
 - *Did you dream during your procedure?*
 - *What was the worst thing about your operation?*

In pediatric patients, additional screening methods including parental interviews and behavioral observation may be used.

- iii. The first interview will be performed in the Post-Anesthesia Care Unit or Day Surgery Unit prior to discharge or transfer from that Unit. In patients transferred from the Operating Room to the Intensive Care Unit, the interview may occur in that Unit upon satisfactory recovery from

anesthesia and/or critical illness.

- iv. A second interview should occur within 1 – 7 days following the general anesthetic. This interview may be performed by an anesthesia provider or designated nursing staff, either in person or via the telephone, during routine follow-up.
- v. In addition, the Medical and Nursing staffs caring for patients should be attentive to a patient who spontaneously reports or complains about an experience of intraoperative awareness. Such reports may be quite delayed from the general anesthetic.
- vi. A positive response on any post-operative interview, and any spontaneous patient complaint, will be presumed to be indicative of a suspected awareness incident during general anesthesia. The patient should be assured of the credible nature of their account, and the entire medical and nursing staff should be alerted to sympathize with the patient's experience.
- vii. Any positive responses occurring on the interview or patient complaints will be reported promptly to the Department of Anesthesiology and to Hospital Risk Management for additional follow-up.

f. Management of an Occurrence of Intraoperative Anesthesia Awareness

- i. The anesthesia provider(s) of record will be responsible for the assessment and management of a suspected intraoperative awareness incident.
- ii. Following the notification of a suspected awareness episode, an anesthesia provider will interview the patient as soon as possible and take a detailed account of the episode to determine if the account is consistent with intraoperative awareness (confirmed awareness), or classified as possible awareness or intraoperative dreaming. The account should be documented in the patient's medical record.
- iii. If unintended awareness has occurred, an apology and sympathy will be offered to the patient, and the credibility of the patient's account will be assured. In addition, the patient's surgeon, nurse, and other key personnel should be informed of the adverse event.
- iv. If possible, the patient should be offered an explanation of the etiology of the awareness episode – e.g., the clinical situation that developed that prevented the administration of adequate anesthesia.
- v. In addition to these initial steps, referral to additional health team experts should be considered. Depending upon the scenario, the physicians and nurses caring for the patients as well as the Hospital will seek to involve mental health experts (e.g., social workers, psychologists and/or

psychiatrists) to assess the patient and determine the best course of action to mitigate any long-term consequences.

- vi. Any patient who suffers an experience of unintended awareness will be assured of continued access to Hospital resources in the event of delayed sequelae from the awareness episode. Appropriate contact information will be provided to the patient, and in addition, the patient will be contacted for additional follow-up at 60 and 120 days following the procedure.

VI. *Clinical Staff Education*

- a. The Chief of the Department of Anesthesiology and The Chief Nursing Officer will insure that appropriate staff participating in the care of a patient receiving general anesthesia (See Section II) will be alerted to this Policy. In addition, a core education module consisting of the JCAHO Sentinel Event Alert #32 (Appendix A) and **[insert facility-specific training initiative]** will be implemented into staff education, training, and review procedures.
- b. All surgeons and physicians who perform procedures under general anesthesia shall be made aware of this policy and included in relevant staff training initiatives. The core education module will be distributed to these members of the Medical Staff.

VII. *Process and Outcome Measurement and Quality Improvement*

- a. The Department of Anesthesia will identify an individual responsible for unintended awareness reporting and follow-up.
- b. The Department of Anesthesia will determine a system for assuring compliance with the documentation and practice requirements as outlined in this policy.
- c. Quarterly summary reports will be made to the Hospital Office of Quality Management. Among these specific events to be reported include:
 - i. Total Number of General Anesthesia surgeries/procedures.
 - ii. Percentage of General Anesthesia patients with documented Post-operative Awareness interview.
 - iii. Total Number of Suspected Awareness incidents and resulting evaluation of Suspected Awareness Incidents into: Confirmed Awareness, Possible Awareness, Dreaming.
 - iv. Percentage of Confirmed Awareness cases in “High-risk” patients.
 - v. Potential Process Improvement Markers:

1. “High-risk” patients not identified through preoperative evaluation process.
 2. Percentage application of intraoperative consciousness monitoring in appropriate patients. (If monitors are used.)
- d. These quarterly reports will be reviewed by the Office of Quality Management and the Department’s Quality Officer. In addition, the report will be reviewed at a Department of Anesthesia Quality Assurance/Quality Improvement meeting.

References

1. Sebel PS, Bowdle TA, et al. The incidence of awareness during anesthesia: a multicenter United States study. *Anesthesia and Analgesia*. 2004; 99:833-839.
2. Myles PS, Leslie K, et al. Bispectral index monitoring to prevent awareness during anaesthesia: The B-Aware randomized controlled trial. *Lancet*. 2004; 363:1757-1763.
3. Ghoneim MM. Awareness during anesthesia. *Anesthesiology*. 2000; 92:597-602
4. Ekman A, Lindholm ML, et al. Reduction in the incidence of awareness using BIS monitoring. *Acta Anaesthesiologica Scandinavica*. 2004;48:20-26.
5. Sandin RH, Enlund G, Samuelsson P, Lennmarken C. Awareness during anaesthesia: a prospective case study. *Lancet*. 2000; 355:707-711.

Appendix A

JCAHO Sentinel Event Alert 32 located at

http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_32.htm