APPENDIX C

SHADY GROVE ADVENTIST HOSPITAL
MEDICAL STAFF POLICY MANUAL

SEDATION/ANALGESIA

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Approved:	**7/25/07; 2/22/12**		

PURPOSE

To optimize patient safety by establishing uniform hospital-wide processes for the management of patients receiving procedural sedation by non-anesthesiologists. In general, non-anesthesiologists will administer sedative medications in doses intended to produce moderate levels of sedation.*

POLICY

Moderate sedation is intended to reduce a patient's pain and awareness during diagnostic or therapeutic procedures. The sedative medication dosages are not intended to result in loss of protective airway reflexes, significantly depress ventilation, or cause cardiovascular compromise. However, because sedation is a continuum and because there is wide variation in patient response to sedative agents, it is not always possible to predict how an individual patient will respond. Occasionally a patient who receives sedation medication in doses that typically produce moderate sedation will slip into a deeper level of sedation. The deeper level of sedation may be associated with potentially catastrophic airway obstruction, hypoventilation, or cardiovascular instability. At Shady Grove Adventist Hospital medical staff and nurses who participate in moderate sedation will have the skills and equipment necessary to recognize the different levels of sedation and then "rescue" patients who slip into deeper-than-intended levels of sedation. Pre-sedation evaluation will be designed to identify appropriate candidates for sedation by non-anesthesiologists and then optimize these patients prior to sedation. Intra-procedure monitoring and post-sedation care will insure that adverse physiologic changes are rapidly recognized and corrected. The processes included in this policy are based upon standards and guidelines developed by the American Society of Anesthesiologists, the American Academy of Pediatrics, and the Joint Commission on Accreditation of Healthcare Organizations.
This policy applies to patients who receive sedation/analgesia in all locations within Shady Grove Adventist Hospital and Germantown Emergency Center (GEC). Moderate sedation may be performed in the following locations: Cardiac Cath Lab, Emergency Department, Intensive Care Unit, Radiology, Surgical Services, Endoscopy and any other area under emergent conditions at the discretion of the physician when appropriate staff and equipment are available. This policy does not apply to patients receiving analgesia on nursing units for control of pain. Also excluded are critical care patients who receive sedation for tolerance of mechanical ventilation and patients undergoing emergent intubation. Ketamine is not included in the moderate sedation protocol and guidelines for its administration by non-anesthesiologists may be found in the Ketamine Sedation Policy.

*Only specially-credentialed emergency medicine physicians and pediatric intensivists may administer sedation in doses intended to produce deep sedation. Please see Shady Grove Hospital policies on the use of propofol and ketamine by non-anesthesiologists for specific requirements.

Exceptions. The moderate sedation policy applies only when sedation is given under the direction of a non-anesthesiologist for patients undergoing diagnostic or therapeutic procedures. The policy specifically excludes the following:

1. Sedation/Analgesia for the control of pain, anxiety, seizures or insomnia.
2. Sedation of patients on ventilators.
3. Sedation/Analgesia used in obstetrical labor.
4. Patients requiring urgent intubation.
5. Sedation/Analgesia given by an anesthesiologist's order in the pre-operative or PACU areas.

Locations. This policy applies to moderate sedation in all locations within Shady Grove Adventist Hospital and the Germantown Emergency Center. This includes the Cardiovascular/Interventional Radiology Labs, Emergency Department, Critical Care areas, Surgical Services, GI endoscopy, and any other area at the discretion of the supervising physician where appropriate staff and equipment are available.

Staff. A physician and registered nurse must be involved in the care of each patient undergoing moderate sedation during the entire procedure:

1. A qualified physician who performs the diagnostic or therapeutic procedure supervises the administration of sedation. The physician must remain with the patient from the time of the first dose of sedation until the patient is accepted by a recovery room nurse.
2. A Registered Nurse with special training is responsible for administering sedation and monitoring the patient at the direction of the physician. The nurse should remain at the head of the bed whenever possible to facilitate direct observation of the airway.
3. If assistance is required with the procedure, then additional personnel (>2) must be utilized. The nurse monitoring the patient may not assist with the procedure.

Essential Equipment. The following equipment and supplies must be available wherever sedation is to be used:

1. Minimal monitoring equipment includes non-invasive blood pressure, continuous EKG, pulse oximeter, and end-tidal CO2 monitor. Whenever possible the monitor alarms will be set to indicate oxygen saturation less than 90% and apnea e 30 seconds. In addition, when available, the pulse oximeter will be set to have a variable-pitch tone that is audible to the supervising physician. When audible alarms are not available the sedation nurse will remain at the head of bed in continuous visual contact with both the patient and display of vital signs.
2. Resuscitation equipment for management of the airway (including ambu-bag and intubation tray) along with a fully assembled and functioning suction apparatus must be immediately available. Airway equipment must be of appropriate size for the patient.
3. A defibrillator and cardiac resuscitation drugs in accordance with ACLS standards must be readily available.
4. Reversal agents must be immediately available.
5. Wall oxygen source must be present and at least one full oxygen E-cylinder with regulator as back-up must be readily available.
6. Appropriate equipment to administer intravenous fluids and drugs must be immediately available.

DEFINITIONS

Definitions of four levels of sedation and anesthesia include the following:

1. Minimal sedation (anxiolysis)
   A drug- induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

2. Moderate sedation/analgesia (formerly conscious sedation)
   A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Note: reflex withdrawal from a painful stimulus is not considered a purposeful response). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

3. Deep Sedation
   A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Deep sedation is restricted for use by anesthesiologists and specially-credentialed emergency medicine and pediatric critical care physicians.

4. Anesthesia
   Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. Anesthesia is restricted to use by anesthesiologists.

5. Aldrete Score
Physiologic assessment scoring system used to evaluate patients' recovery from sedation or anesthesia (Appendix 1).

6. ASA Score
American Society of Anesthesiologists physical status classification system (Appendix 2).

7. Mallampati Classification
Airway evaluation technique that predicts difficult intubation using direct laryngoscopy (Appendix 3).

8. Motor Activity Assessment Scale
Scale used to assess level of sedation (Appendix 4)

9. Fasting Protocol
Nationally recognized guidelines that establish the safe length of time from intake of food or liquid until administration of sedation. It represents the time necessary to ensure gastric emptying and is intended to reduce the risk of catastrophic aspiration of gastric contents (Appendix 5)

10. Recommended Doses of Sedative Medications
Institution specific guidelines for drug dosages intended to produce a moderate level of sedation (Appendix 6)

11. Immediately available
Located at the bedside and obtainable within seconds.

12. Readily available
Located within the same suite and obtainable within one to two minutes.

CREDENTIALING REQUIREMENTS

Only physicians are qualified by specialized training will be permitted to supervise the administration of moderate sedation. Physicians must demonstrate competency in: (1) the safe administration of sedative and analgesic drugs used to establish a moderate level of sedation, (2) rescue of patients who exhibit adverse physiologic consequences of a deeper-than-intended level of sedation, and (3) awareness of the patient care processes outlined in this policy. The Chairman of the Department of Anesthesia is responsible for reviewing each application for privileges in moderate sedation and making a recommendation to the Credentials Committee regarding competency. Only specially credentialed pediatric physicians may supervise the administration of sedation to pediatric patients. Credentialing requirements are as follows:

Physician Adult Sedation Privileges. Physicians with adult sedation privileges may provide sedation care to patients twenty-one (21) years of age and older regardless of weight AND patients fifteen (15) years of age and older whose weight equal or exceeds thirty-six (36) kilograms.

1. Initial Competency Requirements.
   a. Current ACLS certificate OR medical staff privileges in Emergency Medicine.

   b. Completion of a residency/fellowship training program within the last two (2) years that includes a formalized education component on the safe administration of sedative drugs. (letter from the residency director required).

   OR

   Review of the Shady Grove self-education module on moderate sedation including:

   a) ASA Guidelines on Preoperative Fasting
   b) ASA Guidelines for Administration of Moderate Sedation
   c) ASA Video on Sedation and Analgesia by Non-Anesthesiologists

   c. Review of the Shady Grove Adventist Hospital Policy on Moderate Sedation.

   d. Score of e 80% on the Shady Grove Adventist Hospital Moderate Sedation Competency Test.

2. Ongoing Competency Requirements. Recredentialing of sedation privileges will be evaluated on the same two year cycle as staff appointments.

a. Current ACLS certificate OR medical staff privileges in Emergency Medicine.

b. Review of the most recent revision of the Shady Grove Adventist Hospital Policy on Moderate Sedation.

c. A minimum of eight (8) sedations during the previous two years with satisfactory outcomes as documented in the physician's OPPE.

OR

Completion of the above Initial Competency Requirements in Moderate Sedation.

Pediatric Sedation Privileges. Emergency Medicine and Pediatric Critical Care Physicians who have fulfilled requirements for adult moderate sedation privileges may request pediatric moderate sedation privileges. Only physicians with pediatric moderate sedation privileges may provide sedation to patients less than fifteen (15) years of age and patients less than twenty-one (21) years of age who weigh less than thirty-six (36) kilograms.

1. Initial Competency Requirements
   a. Successful completion of the medical staff credentialing requirements for adult moderate sedation privileges.

   b. Medical staff privileges in Emergency Medicine or Pediatric Critical Care.

   c. Documentation confirming completion of a training program in Pediatric Critical Care or Emergency Medicine within the last two (2) years.

   OR

   A letter from the Chairman of a previous department confirming that the physician has supervised a minimum of eight (8) pediatric sedations within the previous two (2) years with satisfactory outcomes.

   d. Physicians must attest that they have reviewed the Shady Grove Moderate Sedation Policy.

2. Ongoing Competency Requirements. Recredentialing of pediatric sedation privileges will be evaluated on the same two year cycle as staff appointments.

   1. A minimum of eight (8) pediatric sedations during the previous two years with satisfactory outcomes as documented in the physician's OPPE.
   2. Attestation of review of the most recent revision of the Shady Grove Moderate Sedation Policy

Competency Requirements for Nurses.

1. Only Registered Nurses who have completed the Shady Grove sedation competency module may assist in the administration of sedation.
2. Current ACLS certification or PALS certification (for those nurses who assist in the administration of sedation to patients less than fifteen years of age).

Special Considerations for Pediatric Sedation

Sedation of pediatric patients has serious associated risks such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment. Because pediatric patients have less physiologic reserve than adult patients, a more rapid deterioration in vital signs usually follows an adverse respiratory event. Therefore the presence of appropriate resuscitation equipment as well as a physician with advanced pediatric airway skills are essential. Younger children (less than six years of age) and those with developmental delays frequently require deep levels of sedation in order to cooperate with even relatively minor procedures (see the ketamine and propofol sedation Policies for details).

Patient Care Process

Pre-procedure Care.

1. RN Responsibilities. Nursing is responsible for collecting pertinent data and preparing the patient for the physician pre-sedation assessment. The nurse performs this task by completing The standard Pre-procedure Checklist which includes:

    a. Confirmation that a valid history and physical exam is part of the medical record (the H&P must be performed within 30 days with updated heart and lung assessment within 7 days). The history and physical must be signed or co-signed by a credentialed member of the Shady Grove medical staff.
    b. Most recent laboratory values.
    c. Pregnancy tests should be considered for females greater than 12 years of age.
    d. Point of care blood glucose measurement is performed for diabetic patients.
    e. Consent signed by the performing physician and patient. The consent must include The name of the procedure, the side (for procedures that involve laterality), and designate that moderate sedation will be used.
    f. Completed nursing assessment.
    g. DNR status documented, if applicable
    h. Up-to-date medication administration record.
    i. Pre-procedure vital signs.
    j. NPO status. The physician should be notified whenever a patient does not Meet the criteria set forth in the fasting protocol.
    k. Confirmation that the anatomical site is marked by the physician.

2. Physician Responsibilities
    a. Informed Consent. The physician performing the procedure and supervising the sedation must inform the patient/guardian about the risks, possible complications benefits and alternatives to sedation as a component of the planned procedure.Patients or their authorized representatives should agree to the administration of moderate sedation before the procedure begins.
    b. The physician orders and reviews the results of pertinent laboratory testing. Pre-sedation testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation.
    c. The physician conducts and documents a pre-sedation assessment within 24 hours of the start of the procedure. The assessment may be documented on the standard "Pre-sedation Assessment Form" (appendix 6) and must include the following:

        i. Physical Status Classification.
        ii. Focused history documenting any interim changes in health or previous adverse reaction to sedation/anesthesia.
        iii. Airway Examination.
        iv. NPO status*.
        v. Review of pertinent lab values (patients with end-stage renal disease must have a basic metabolic panel within 24 hours of sedation).
        vi. Plan for sedation.
        vii. Re-evaluation of the patient (including vital signs and mental status) just prior to sedation.

d. The physician conducts a "Time-Out" according to the Shady Grove Policy# 25098 just prior to starting the procedure.
e. For outpatients, the physician will confirm that appropriate arrangements have been made for a responsible adult to drive the patient home.
f. The physician will consider consultation with an anesthesiologist for high-risk patients. The criteria listed in Appendix 7 may be used as guide to help determine when consultation is indicated.

*The NPO protocol should be observed whenever a delay will not jeopardize the well being of the patient. Emergent and urgent clinical situations are expected to arise that preclude strict adherence to these guidelines. In these cases the amount of sedation should be minimized and carefully titrated in order to prevent the loss of protective airway reflexes. The risk of aspiration pneumonitis may be further reduced by the use of a non-particulate antacid (bicitra), H2-blockers and/or metoclopramide prior to sedation.

Intra-Procedure Care.

1. RN responsibilities. The nurse is responsible for administering sedation at the order of the physician while continuously assessing the patient's physiologic status.

   a. Documentation of the physiologic status of the patient.
      i. Vital signs including blood pressure, heart rate, respiratory rate, oxygen saturation, and level of consciousness will be assessed and recorded prior to initiation of the procedure and on arrival to the recovery area.
      ii. Blood pressure and heart rate will be assessed and documented every five minutes during the procedure. Cardiac rhythm, respiratory rate, level of consciousness, presence of EtCO2 and oxygen saturation will be continuously monitored and recorded at least every fifteen minutes.
      iii. Medication administration, including dose, route, and times.
      iv. IV fluid replacement.

   b. The nurse will be positioned at the head of the bed and assess the patient continuously for changes in condition or appearance. The nurse will report any of these changes to the responsible physician immediately and initiate the appropriate intervention.

   c. Administer oxygen as needed. Typically oxygen via nasal cannula will be administered in order to maintain oxygen saturation above 92% with the following considerations:

      i. The application of oxygen reduces the incidence and severity of hypoxemia during moderate sedation. However, it must be remembered that the use of S
      supplemental oxygen will delay the detection of apnea by the pulse oximeter.
      This emphasizes the importance of monitoring respiratory function by
      observation of chest excursion and EtCO2 detection.
      ii. Fire Safey: If electrocautery is to be used near the airway, then oxygen flow
      should be minimized to the lowest amount necessary to maintain acceptable hemoglobin saturation. Sedation providers must minimize the build-up of oxygen beneath drapes and in oropharynx and position drapes so that gases will not collect. If possible, supplemental oxygen should be stopped at least one minute before and during the activation of the electrosurgical unit.

2. Physician Responsibilities. The physician orders sedative medication, determines dosage, and responds to adverse physiologic effects.

   a. The responsible physician selects and orders all sedative medication.
   b. The physician is responsible for airway interventions, if necessary.
   c. The physician orders the administration of reversal agents when indicated.

   Note: Because reversal agents may have serious side-effects their use should be minimized and their dose titrated to effect (see recommended drug doses). Naloxone is relatively contraindicated in patients with a history of narcotic tolerance. Flumazenil is relatively contraindicated in patients with a history of alcohol abuse or long-standing benzodiazepine use.

Post-Procedure Care

1. RN Responsibilities. Nursing is responsible for monitoring the patient until their physiologic status has returned to a level at or close to their baseline. The following standards for monitoring and discharge criteria will be used:

   a. Oxygen saturation and EKG will be continuously monitored. Vital signs including blood pressure, heart rate, oxygen saturation, level of consciousness and respiratory rate will be documented on arrival to the recovery area and every fifteen (15) minutes thereafter.
   b. Significant changes in the patient's condition are reported to the physician immediately. These include:

      i. Symptomatic changes in blood pressure.
      ii. Oxygen saturation less than 90% with supplemental oxygen.
      iii. Heart rate <45 or >110.
      iv. Dyspnea, apnea, diaphoresis.
      v. Inability to arouse.
      vi. Need for mechanical airway support.
      vii. Any other unexpected patient response

   c. Pain level will be assessed every fifteen (15) minutes using a visual analog scale. Pain score greater than five (5) not easily controlled with ordered post-procedure analgesics will be reported to the responsible physician.
   d. The nurse will assess the Aldrete score every fifteen minutes and discharge the patient according to the below criteria as approved by the Medical Staff.

2. Physician Responsibilities.
   a. The procedural physician is responsible for all orders in the recovery phase including but not limited to: analgesics, oxygen therapy, hemodynamic medications and reversal agents.
   b. The procedural physician signs the discharge order.
   c. The procedural physician documents a post-procedure/sedation progress note immediately following the procedure.

3. Discharge Criteria.
   a. Inpatients will be discharged from the recovery area to other inpatient areas when they have met the following criteria and after SBAR report is given to the receiving nurse. Inpatients will be transported via stretcher or wheelchair accompanied by a staff member. Patients will be instructed regarding post-procedure status and activities.

      i. Aldrete score of ten (10). Patients with an Aldrete score less than ten may be discharged only by physician order.
      ii. A minimum of thirty minutes from the last dose of sedation is required unless reversal agents are used. If reversal agents are used then the patient must be observed for two hours after the last dose of an antagonist to insure that respiratory depression does not recur.
      ii. Stable vital signs over a period of at least fifteen minutes.
      iv. Adequate ventilation and oxygenation as evidenced by a stable respiratory rate and oxygen saturation appropriate for the patient. (Patients with room air oxygen saturation of less than 90 percent will be transported with supplemental oxygen).
      v. Ability to maintain/protect airway with level of alertness and orientation appropriate to pre-procedure status.

   b. Outpatients will be discharged to home from the recovery area when they have met the following criteria:

      i. All discharge criteria listed above for inpatients have been met.
      ii. Patients who have received sedation are discharged in the company of a responsible adult. The patient will have arrangements for transportation home. Patients who have received sedation will not be allowed to drive themselves home.
      iii. The patient has received written discharge instructions that have been reviewed with the patient and/or escort.

PERFORMANCE IMPROVEMENT

Data Collection.

1. Sedation P.I. Officer. Each procedural area (CVIR, ED, Endoscopy) will identify an individual who will be responsible for collecting data on adverse sedation-related events. The sedation P.I. Officer will also be responsible for tracking the total number of sedation cases for each physician.

2. Performance Improvement Indicators. The following adverse sedation-related events will be reported through the hospital's incident reporting system. Minor events will be forwarded to the Sedation P.I. Officer. Major events will be forwarded to Office of Medical Staff, the Sedation P.I. Officer, and the Chair of Anesthesia. Major events will be reviewed and scored by the respective department's Quality Assurance/Review Committee. Data on the total number of sedations, number of minor events, and category 3 and 4 major events will be reported on each physician's OPPE.

   a. Minor events:
      i. Use of a reversal agent.
      ii. Respiratory depression or obstruction requiring ventilation via ambu-bag.
      iii. Sustained SpO2< 88% (>3 minutes) with supplemental oxygen.
      iv. Drug reaction (rash, SOB, agitation).
      v. Prolonged unresponsiveness (>30 minutes).

   b. Major Events:
      i. Sedation related death.
      ii. Sedation related cardiac/respiratory arrest.
      iii. Aspiration pneumonia.
      iv. Sedation related rapid response or "Anesthesia stat" call.

Appendix 1.

Aldrete Scoring System

Activity	Score
Able to move four extremities voluntarily or on command	2
Able to move two extremities voluntarily or on command	1
Unable to move extremities voluntarily or on command	0
Respiration	
Able to breathe freely and cough deeply	2
Dyspnea or limited breathing	1
Apneic	0
Circulation	
BP within 20% of pre-sedation level	2
BP within 21 to 49% of pre-sedation level	1
BP more than 50% different from pre-sedation level	0
Consciousness	
Fully awake	2
Arousable on calling	1
No response	0
Oxygen saturation	
Able to maintain O2 saturation greater than 92% on room air	2
Needs O2 inhalation to maintain O2 saturation greater than 90%	1
O2 saturation 90% or less even with O2 supplementation	0

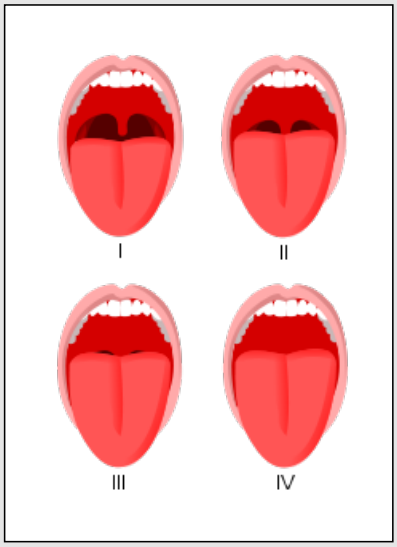
Appendix 2.

ASA Physical Status Classification

Status I	Normal healthy patient
Status II	Mild systemic disease
Status III	Severe systemic disease with definite functional impairment
Status IV	Severe systemic disease that is a constant threat to life
Status V	Moribund patient, not expected to survive

Appendix 3.

Mallampati Classification



The Mallampati classification is a tool used to predict the ease or difficulty of intubation. It is determined by looking at the anatomy of the oral cavity. A high classification score (class 3 or 4) is predictive of difficult intubation and sleep apnea.

Technique:

The patient sits upright with head tipped back, mouth opened and tongue protruded. Classifications are described below.

Class I: Can visualize soft palate, all of uvula, tonsillar pillars
Class II: Can visualize soft palate, tip of uvula is obscured
Class III: Can visualize soft palate
Class IV: Can visualize hard palate only

Appendix 4.

Motor Activity Assessment Scale

The MAAS is a standardized method for describing level of sedation. Target MAAS scores for patients under moderate sedation are 2 to 3.

Clinical Score	MAAS – Level of Sedation Achieved
0	Unresponsive - Does not move with noxious stimuli
1	Responsive only to noxious stimuli - Opens eyes, OR raises eyebrows, OR turns head toward stimulus, OR moves limbs with noxious stimuli
2	Responsive only to touch - Opens eyes, OR raises eyebrows, OR turns head toward stimulus, OR moves limbs when touched, OR when name loudly spoken
3	Calm & cooperative - No external stimulus required to elicit movement AND patient adjusts sheets or clothes purposefully and follows Commands
4	Restless &cooperative - No external stimulus required to elicit Movement AND patient picks at sheets or tubes uncovering self AND follows command
5	Agitated - No external stimulus required to elicit movement AND patient attempts to sit up or move limbs out of bed AND does not consistently follow commands
6	Dangerously agitated - No external stimulus required to elicit movement AND patient pulls at tubes or catheters, OR thrashes side to side, OR strikes at staff, OR tries to climb out of bed and does not calm down when asked

Appendix 5.

Fasting Protocol

The following is a summary of American Society of Anesthesiologists Pre-procedure Fasting Guidelines:

Ingested Material	Minimum Fasting Period
Clear liquids	2 hours
Breast milk	4 hours
Infant formula	6 hours
Non-human milk	6 hours
Light meal	6 hours
Full meal	8 hours

Please note:

1. These recommendations apply to healthy patients who are undergoing elective procedures. Following these guidelines does not guarantee that complete gastric emptying has occurred.
2. In emergency situations, when following the guidelines might result in patient harm, the physician providing sedation may proceed with the procedure while using precautions to minimize the risk of pulmonary aspiration.
3. Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.
4. A light meal typically consists of toast and clear liquids.
5. Full meals include fried, fatty foods, or meats.

SHADY GROVE ADVENTIST HOSPITAL MODERATE SEDATION ADULT DOSING SCHEDULE

Generic Name (Trade Name)	Use	Dosing Guidelines	Onset, Peak, Duration of Action	Adverse Effects	Reversal
BENZODIAZEPINES					
Midazolam (Versed)	Sedation Amnesia Anxiolysis	Adults <60 years old: IV: 0.5mg to 2.5mg over 2 to 3 minutes. Wait 2 minutes to evaluate effect before giving additional doses. IM: 0.07 to 0.08mg/kg as one time dose Total Dose- 7.5 mg IV Adults≥60 years old: IV: 0.5 to 1.5mg IV over 2 to 3 minutes. Titrate as above. IM: 0.02 to 0.05mg/kg Total Dose- 5mg IV	Onset: IV: 1-5 min IM: 15 min Peak: IV: 20-60 min IM: 30-60 min Duration: IV: 1-2 hours IM: 6 hours	Respiratory depression Paradoxical agitation Hypotension (especially With opioid) Arrhythmias Nausea/emesis/ headache Hallucinations Hiccoughs	Flumazenil (Watch for rebound sedation)
Lorazepam (Ativan)	Sedation Amnesia	IV: 2-3 mg over 2-5 min IM: 0.025 to 0.05mg/kg PO: 2 to 4mg Total Dose- 4mg	Onset: IV: 1-5 min IM: 15 min PO: 30-60 minutes Peak: IV: 15-20 min IM: 2-3 hours PO: 2 hours Duration: 4-8 hours	See Midazolam	Flumazenil
Diazepam (Valium)	Sedation Amnesia	IV: 2-5 mg Administer at a rate less than 1.5mg/min to avoid phlebitis IM: 5-10 mg Total Dose: 10mg	Onset: IV: 1-5 min IM: 30 min Peak: IV: 10-30 min IM: 2-3 hours Duration: 2-6 hours	Venous thrombosis and phlebitis at injection site SeeMidazolam	Flumazenil

Comment [MC1]:

SHADY GROVE ADVENTIST HOSPITAL MODERATE SEDATION
PEDIATRIC DOSING SCHEDULE

Generic Name	Use	Dosing Guidelines	Onset and Duration of Action	Adverse Effects	Reversals	Comments
Chloral Hydrate	Pediatric Sedative/ Hypnotic NO Analgesia	25-100 mg/kg PO or PR Total Dose: 1 gram or 2 grams/ 24 hours	Onset: 45-60 min Duration: 4-9 hours	CNS Depression Resp Depression Arrhythmias Paradoxical Agitation Urticaria	None	Wide safety margin Not a good choice if attempt to titrate dose to effect

BENZODIAZEPINES

Generic Name	Use	Dosing Guidelines	Onset and Duration of Action	Adverse Effects	Reversals	Comments
Midazolam (Versed) Versed syrup (10 mg/2 cc)	Sedation Amnesia Anxiolytic	IV: 0.05-0.1 mg/kg/dose IV Total IV Dose: 0.2 mg/kg PO 0.5-0.75 mg/kg Total dose: 15 mg PO IM 0.1-0.2 mg/kg/dose IN: 0.3-0.4 mg/kg	Onset : IV: 1-5 min IN: 10-15 min PO: 15 min Duration: 20-60 min PO: up to 2 hours	Resp Depression Paradoxical agitation Hypotension (esp w opioid) Arrhythmias Nausea/ vomiting Headache Hallucinations Hiccoughs	Flumazenil:	Reduce dose by 25-50% when giving with narcotic (e.g Fentanyl) and wait 10 min for desired effect
Lorazepam (Ativan)	Sedation Amnesia	IV: 0.05-0.1 mg/kg PO: 0.05-0.2 mg/kg Max: 4 mg total	Onset: IV: 1-5 min Duration: 4-6 hours	See Midazolam	Flumazenil	Midazolam a better choice unless desire a long duration of action

SHADY GROVE ADVENTIST HOSPITAL MODERATE SEDATION
PEDIATRIC DOSING SCHEDULE (con't)

OPIOIDS

- Avoid repeat IM dosing
- If titrating to response, IV route is recommended

Generic Name (Trade Name)	Use	Dosing Guidelines	Onset and Duration of Action	Adverse Effects	Reversals	Comments
Fentanyl (Sublimaze)	Sedation Analgesia	0.7-1.0 mcg/kg/dose May repeat in 2-3 min Total dose:5 mcg/kg Total 2.5 mcg/kg if admin with Benzo (Versed)	Onset: 1 min IV Duration 30-60 min IV	Respiratory depression Hypotension Bradycardia Chest wall rigidity w/ rapid admin. Facial pruritis	Naloxone	Do NOT exceed rate of admin of 1 mcg/kg/min IV
Morphine sulfate	Sedation Analgesia	0.05-0.15 mg/kg/dose IV 0.1 mg/kg IM or SC Total dose: 0.2 mg/kg	Onset: 5 min IV 15-30 min IM or SC Duration: 1-5 hr	Resp depression Hypotension Bradycardia Nausea Pruritis Urinary retention Epileptogenic	Naloxone	Reduce dose by 50% if given with Benzodiazepine
Meperidine (Demerol)	Sedation Analgesia	0.5-1 mg/kg/dose IV 1-2 mg/kg IM Max total: 3 mg/kg or 150 mg	Onset 5 min IV 15-30 min IM Duration: 2-4 hours	Resp depression Hypotension Bradycardia Tachycardia Nausea Pruritis Urinary retention Epileptogenic	Naloxone	Avoid rapid IV push Better choices exist (Fentanyl/ MSO4)

SHADY GROVE ADVENTIST HOSPITAL MODERATE SEDATION
PEDIATRIC DOSING SCHEDULE (con't)

BARBITURATES

Generic name (Trade name)	Use	Dosing guidelines	Onset and Duration of Action	Adverse Effects	Reversals	Comments
Pentobarbital (Nembutal)	Sedation Amnesia	IV: 1-2 mg/kg IM: 2-6 mg/kg PO: 2-6 mg/kg PR: 2-6 mg/kg Total: 6 mg/kg= 100mg	Onset: IV: 1-5 min IM: 10-15 min PO/PR: 30-60 min Duration: IV: 15 min PO/PR: 1-4 hours	Resp depression Hypertension Painful injection Hyperactive after awakening	None	
Methohexital (Brevital)	Sedation	PR: 20-30 mg/kg Use 100mg/ml solution	Onset: 5-10 min Duration: PR: 1-1.5 hours	See Pentobarbital Also: Hiccups, laryngospasm Seizures Muscle twitching, tremors	None	Rectal only

REVERSAL AGENTS

Generic name (Trade name)	Use	Dosing Guidelines	Onset and Duration of Action	Adverse Effects	Comments
Naloxone (Narcan)	Reverses opioid induced analgesia & sedation May reverse chest wall rigidity	Apnea or arrest: 0.01-0.1 mg/kg; redose at 2 min intervals to effect Resp depression: 0.001 mg/kg/dose OR Narcan drip: 1-30 ug/kg/hour	IV: 1-2 min IM/ETT: 2-5 min Duration: < 45 min The duration of the opioid may be longer than the duration of the antagonist	Severe pain Excitement Hypertension Tachycardia Ventricular arrhythmia Pulmonary edema Myocardial Ischemia	Watch for return of respiratory depression
Flumazenil (Romazicon)	Complete or partial reversal of benzodiazepine Sedation	0.01mg/kg IV q 1 min Total dose: 0.2 mg	Onset 1-3 min IV Duration: 45-60 min	May precipitate seizures	Use with extreme caution Watch for return of sedation/ respiratory depression

Guidelines for Determining Need for Anesthesia Consultation

This document is intended to serve as a guide for physicians when deciding on the need for consultation with an anesthesiologist prior to sedation. These recommendations have been developed by consensus opinion of the Department of Anesthesia and are based on the best available medical evidence. The incidence of adverse outcomes related to sedation is increased in the presence of multiple risk factors and is especially high when risk factors from multiple categories (medical, behavioral, procedure- related) are present. In general, consultation is usually only necessary for the highest risk patients.

Patient related medical risk factors:

- ASA status e 3 (especially due to end-stage renal/liver disease, severe pulmonary disease, obstructive sleep apnea, morbid obesity, ejection fraction < 25%)
- History of drug reaction to sedative agent
- History of drug or alcohol abuse/dependence
- Orthopnea
- Pregnancy
- Difficult airway by history or exam (Mallampati score e3, rigid c-spine, mouth opening <3cm, prominent incisors)

Patient behavioral risk factors:

- Dementia
- Highly anxious
- Uncooperative/hostile
- Altered mental status/delirium
- Significant mental illness (schizophrenia, bipolar)
- Autism

Procedure related risk factors:

- Procedures with the potential for causing significant pain
- Prolonged procedures (> 2 hours)
- Procedures requiring unusual positioning (prone)

Anesthesia consultation should be considered whenever one of the above risk factors is present. Consultation is recommended whenever risk factors from more than one category are present. For emergency procedures the physician should weigh the risk of proceeding immediately against the risk of delay associated with obtaining consultation.

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Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists

An Updated Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists

ANESTHESIOLOGISTS possess specific expertise in the pharmacology, physiology, and clinical management of patients receiving sedation and analgesia. For this reason, they are frequently called on to participate in the development of institutional policies and procedures for sedation and analgesia for diagnostic and therapeutic procedures. To assist in this process, the American Society of Anesthesiologists (ASA) has developed these "Guidelines for Sedation and Analgesia by Non-Anesthesiologists."

Practice guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. The guidelines provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data.

This revision includes data published since the "Guidelines for Sedation and Analgesia by Non-Anesthesiologists" were adopted by the ASA in 1995; it also includes data and recommendations for a wider range of sedation levels than was previously addressed.

Definitions

"Sedation and analgesia" comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia. Definitions of levels of sedation–analgesia, as developed and adopted by the ASA, are given in table 1. These Guidelines specifically apply to levels of sedation corresponding to moderate sedation (frequently called conscious sedation) and deep sedation, as defined in table 1.

Focus

These Guidelines are designed to be applicable to procedures performed in a variety of settings (*e.g.*, hospitals, freestanding clinics, physician, dental, and other offices) by practitioners who are not specialists in anesthesiology. Because minimal sedation (anxiolysis) entails minimal risk, the Guidelines specifically exclude it. Examples of minimal sedation include peripheral nerve blocks, local or topical anesthesia, and either (1) less than 50% nitrous oxide (N_2O) in oxygen with no other sedative or analgesic medications by any route, or (2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. The Guidelines also exclude patients who are not undergoing a diagnostic or therapeutic procedure (*e.g.*, postoperative analgesia, sedation for treatment of insomnia). Finally, the Guidelines do not apply to patients receiving general or major conduction anesthesia (*e.g.*, spinal or epidural/caudal block), whose care should be provided, medically directed, or supervised by an anesthesiologist, the operating practitioner, or another licensed physician with specific training in sedation, anesthesia, and rescue techniques appropriate to the type of sedation or anesthesia being provided.

Purpose

The purpose of these Guidelines is to allow clinicians to provide their patients with the benefits of sedation/analgesia while minimizing the associated risks. Se-

Additional material related to this article can be found on the ANESTHESIOLOGY Web site. Go to the following address, click on Enhancements Index, and then scroll down to find the appropriate article and link. http://www.anesthesiology.org

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The accompanying Web site enhancement is a bibliography.

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Table 1. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) = a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (Conscious Sedation) = a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep Sedation/Analgesia = a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia = a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering *Moderate Sedation/Analgesia (Conscious Sedation)* should be able to rescue patients who enter a state of *Deep Sedation/Analgesia*, while those administering *Deep Sedation/Analgesia* should be able to rescue patients who enter a state of general anesthesia.

* Reflex withdrawal from a painful stimulus is not considered a purposeful response.

Developed by the American Society of Anesthesiologists; approved by the ASA House of Delegates October 13, 1999.

dation/analgesia provides two general types of benefit: (1) sedation/analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain; and (2) in children and uncooperative adults, sedation–analgesia may expedite the conduct of procedures that are not particularly uncomfortable but that require that the patient not move. At times, these sedation practices may result in cardiac or respiratory depression, which must be rapidly recognized and appropriately managed to avoid the risk of hypoxic brain damage, cardiac arrest, or death. Conversely, inadequate sedation–analgesia may result in undue patient discomfort or patient injury because of lack of cooperation or adverse physiologic or psychological response to stress.

Application

These Guidelines are intended to be general in their application and broad in scope. The appropriate choice of agents and techniques for sedation/analgesia is dependent on the experience and preference of the individual practitioner, requirements or constraints imposed by the patient or procedure, and the likelihood of producing a deeper level of sedation than anticipated. Because it is not always possible to predict how a specific patient will respond to sedative and analgesic medications, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. For moderate sedation, this implies the ability to manage a compromised airway or hypoventilation in a patient who *responds purposefully* after repeated or painful stimulation, whereas for deep sedation, this implies the ability to manage respiratory or cardiovascular instability in a patient who *does not respond purposefully* to painful or repeated stimulation. Levels of sedation referred to in the recommendations relate to the level of sedation intended by the practitioner. Examples are provided to illustrate airway assessment, preoperative fasting, emergency equipment, and recovery procedures; however, clinicians and their institutions have ultimate responsibility for selecting patients, procedures, medications, and equipment.

Task Force Members and Consultants

The ASA appointed a Task Force of 10 members to (1) review the published evidence; (2) obtain the opinion of a panel of consultants, including non-anesthesiologist physicians and dentists who routinely administer sedation–analgesia, as well as of anesthesiologists with a special interest in sedation–analgesia (see Appendix I); and (3) build consensus within the community of practitioners likely to be affected by the Guidelines. The Task Force included anesthesiologists in both private and academic practices from various geographic areas of the United States, a gastroenterologist, and methodologists from the ASA Committee on Practice Parameters.

This Practice Guideline is an update and revision of the ASA "Guidelines for Sedation and Analgesia by Non-

Anesthesiologists."[1] The Task Force revised and updated the Guidelines by means of a five-step process. First, original published research studies relevant to the revision and update were reviewed and analyzed; only articles relevant to the administration of sedation by nonanesthesiologists were evaluated. Second, the panel of expert consultants was asked to (1) participate in a survey related to the effectiveness and safety of various methods and interventions that might be used during sedation–analgesia, and (2) review and comment on the initial draft report of the Task Force. Third, the Task Force held open forums at two major national meetings to solicit input on its draft recommendations. National organizations representing most of the specialties whose members typically administer sedation–analgesia were invited to send representatives. Fourth, the consultants were surveyed to assess their opinions on the feasibility and financial implications of implementing the revised and updated Guidelines. Finally, all of the available information was used by the Task Force to finalize the Guidelines.

Availability and Strength of Evidence

Evidence-based Guidelines are developed by a rigorous analytic process. To assist the reader, the Guidelines make use of several descriptive terms that are easier to understand than the technical terms and data that are used in the actual analyses. These descriptive terms are defined below.

The following terms describe the strength of scientific data obtained from the scientific literature:

Supportive: There is sufficient quantitative information from adequately designed studies to describe a statistically significant relationship ($P < 0.01$) between a clinical intervention and a clinical outcome, using metaanalysis.

Suggestive: There is enough information from case reports and descriptive studies to provide a directional assessment of the relationship between a clinical intervention and a clinical outcome. This type of qualitative information does not permit a statistical assessment of significance.

Equivocal: Qualitative data have not provided a clear direction for clinical outcomes related to a clinical intervention, and (1) there is insufficient quantitative information or (2) aggregated comparative studies have found no quantitatively significant differences among groups or conditions.

The following terms describe the *lack* of available scientific evidence in the literature:

Inconclusive: Published studies are available, but they cannot be used to assess the relation between a clinical intervention and a clinical outcome because the studies either do not meet predefined criteria for content as defined in the "Focus" of these Guidelines, or do not provide a clear causal interpretation of findings because of research design or analytic concerns.

Insufficient: There are too few published studies to investigate a relationship between a clinical intervention and clinical outcome.

Silent: No studies that address a relationship of interest were found in the available published literature.

The following terms describe survey responses from the consultants for any specified issue. Responses were solicited on a five-point scale, ranging from 1 (strongly disagree) to 5 (strongly agree), with a score of 3 being neutral.

Strongly Agree: median score of 5
Agree: median score of 4
Equivocal: median score of 3
Disagree: median score of 2
Strongly Disagree: median score of 1

Guidelines

Patient Evaluation

There is insufficient published evidence to evaluate the relationship between sedation–analgesia outcomes and the performance of a preprocedure patient evaluation. There is suggestive evidence that some preexisting medical conditions may be related to adverse outcomes in patients receiving either moderate or deep sedation/analgesia. The consultants strongly agree that appropriate preprocedure evaluation (history, physical examination) increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes for both moderate and deep sedation.

Recommendations. Clinicians administering sedation/analgesia should be familiar with sedation-oriented aspects of the patient's medical history and how these might alter the patient's response to sedation/analgesia. These include: (1) abnormalities of the major organ systems; (2) previous adverse experience with sedation/analgesia as well as regional and general anesthesia; (3) drug allergies, current medications, and potential drug interactions; (4) time and nature of last oral intake; and (5) history of tobacco, alcohol, or substance use or abuse. Patients presenting for sedation/analgesia should undergo a focused physical examination, including vital signs, auscultation of the heart and lungs, and evaluation of the airway. (Example I). Preprocedure laboratory testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia. These evaluations should be confirmed immediately before sedation is initiated.

Example I. Airway Assessment Procedures for Sedation and Analgesia

Positive pressure ventilation, with or without tracheal intubation, may be necessary if respiratory compromise develops during sedation–analgesia. This may be more difficult in patients with atypical airway anatomy. In addition, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors that may be associated with difficulty in airway management are:

History
- Previous problems with anesthesia or sedation
- Stridor, snoring, or sleep apnea
- Advanced rheumatoid arthritis
- Chromosomal abnormality (*e.g.*, trisomy 21)

Physical Examination
- Habitus
  - Significant obesity (especially involving the neck and facial structures)
- Head and Neck
  - Short neck, limited neck extension, decreased hyoid–mental distance (< 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, dysmorphic facial features (*e.g.*, Pierre-Robin syndrome)
- Mouth
  - Small opening (< 3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula
- Jaw
  - Micrognathia, retrognathia, trismus, significant malocclusion

Preprocedure Preparation

The literature is insufficient regarding the benefits of providing the patient (or legal guardian, in the case of a child or impaired adult) with preprocedure information about sedation and analgesia. For moderate sedation the consultants agree, and for deep sedation the consultants strongly agree that appropriate preprocedure counseling of patients regarding risks, benefits, and alternatives to sedation and analgesia increases patient satisfaction.

Sedatives and analgesics tend to impair airway reflexes in proportion to the degree of sedation–analgesia achieved. This dependence on level of sedation is reflected in the consultants opinion: They agree that preprocedure fasting decreases risks during moderate sedation, while strongly agreeing that it decreases risks during deep sedation. In emergency situations, when preprocedure fasting is not practical, the consultants agree that the target level of sedation should be modified (*i.e.*, less sedation should be administered) for moderate sedation, while strongly agreeing that it should be modified for deep sedation. The literature does not provide sufficient evidence to test the hypothesis that preprocedure fasting results in a decreased incidence of adverse outcomes in patients undergoing either moderate or deep sedation.

Recommendations. Patients (or their legal guardians in the case of minors or legally incompetent adults) should be informed of and agree to the administration of sedation/analgesia, including its benefits, risks, and limitations associated with this therapy, as well as possible alternatives. Patients undergoing sedation/analgesia for elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before their procedure, as recommended by the ASA "Guidelines for Preoperative Fasting"[2] (Example II). In urgent, emergent, or other situations in which gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed, or (3) whether the trachea should be protected by intubation.

Monitoring

Level of Consciousness. The response of patients to commands during procedures performed with sedation/analgesia serves as a guide to their level of consciousness. Spoken responses also provide an indication that the patients are breathing. Patients whose only response is reflex withdrawal from painful stimuli are deeply sedated, approaching a state of general anesthesia, and should be treated accordingly. The literature is silent regarding whether monitoring patients' level of consciousness improves patient outcomes or decreases risks. The consultants strongly agree that monitoring level of consciousness reduces risks for both moderate and deep sedation. The members of the Task Force believe that many of the complications associated with sedation and analgesia can be avoided if adverse drug responses are detected and treated in a timely manner (*i.e.*, before the development of cardiovascular decompensation or cerebral hypoxia). Patients given sedatives or analgesics in unmonitored settings in anticipation of a subsequent procedure may be at increased risk of these complications.

Example II. Summary of American Society of Anesthesiologists Preprocedure Fasting Guidelines[2]*

Ingested Material	Minimum Fasting Period†
Clear liquids‡	2 h
Breast milk	4 h
Infant formula	6 h
Nonhuman milk§	6 h
Light meal‖	6 h

* These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the Guidelines does not guarantee a complete gastric emptying has occurred.

† The fasting periods apply to all ages.

‡ Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

§ Since nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

‖ A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

Pulmonary Ventilation. It is the opinion of the Task Force that the primary causes of morbidity associated with sedation/analgesia are drug-induced respiratory depression and airway obstruction. For both moderate and deep sedation, the literature is insufficient to evaluate the benefit of monitoring ventilatory function by observation or auscultation. However, the consultants strongly agree that monitoring of ventilatory function by observation or auscultation reduces the risk of adverse outcomes associated with sedation/analgesia. The consultants were equivocal regarding the ability of capnography to decrease risks during moderate sedation, while agreeing that it may decrease risks during deep sedation. In circumstances in which patients are physically separated from the caregiver, the Task Force believes that automated apnea monitoring (by detection of exhaled carbon dioxide or other means) may decrease risks during both moderate and deep sedation, while cautioning practitioners that impedance plethysmography may fail to detect airway obstruction. The Task Force emphasizes that because ventilation and oxygenation are separate though related physiologic processes, monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function.

Oxygenation. Published data suggest that oximetry effectively detects oxygen desaturation and hypoxemia in patients who are administered sedatives/analgesics. The consultants strongly agree that early detection of hypoxemia through the use of oximetry during sedation–analgesia decreases the likelihood of adverse outcomes such as cardiac arrest and death. The Task Force agrees that hypoxemia during sedation and analgesia is more likely to be detected by oximetry than by clinical assessment alone.

Hemodynamics. Although there are insufficient published data to reach a conclusion, it is the opinion of the Task Force that sedative and analgesic agents may blunt the appropriate autonomic compensation for hypovolemia and procedure-related stresses. On the other hand, if sedation and analgesia are inadequate, patients may develop potentially harmful autonomic stress responses (*e.g.*, hypertension, tachycardia). Early detection of changes in patients' heart rate and blood pressure may enable practitioners to detect problems and intervene in a timely fashion, reducing the risk of these complications. The consultants strongly agree that regular monitoring of vital signs reduces the likelihood of adverse outcomes during both moderate and deep sedation. For both moderate and deep sedation, a majority of the consultants indicated that vital signs should be monitored at 5-min intervals once a stable level of sedation is established. The consultants strongly agree that continuous electrocardiography reduces risks during deep sedation, while they were equivocal regarding its effect during moderate sedation. However, the Task Force believes that electrocardiographic monitoring of selected patients (*e.g.*, with significant cardiovascular disease or dysrhythmias) may decrease risks during moderate sedation.

Recommendations. Monitoring of patient response to verbal commands should be routine during moderate sedation, except in patients who are unable to respond appropriately (*e.g.*, young children, mentally impaired or uncooperative patients), or during procedures where movement could be detrimental. During deep sedation, patient responsiveness to a more profound stimulus should be sought, unless contraindicated, to ensure that the patient has not drifted into a state of general anesthesia. During procedures where a verbal response is not possible (*e.g.*, oral surgery, upper endoscopy), the ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation suggests that the patient will be able to control his airway and take deep breaths if necessary, corresponding to a state of moderate sedation. Note that a response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

All patients undergoing sedation/analgesia should be monitored by pulse oximetry with appropriate alarms. If available, the variable pitch "beep," which gives a continuous audible indication of the oxygen saturation reading, may be helpful. In addition, ventilatory function should be continually monitored by observation or auscultation. Monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and for patients whose ventilation cannot be directly observed during moderate sedation. When possible, blood pressure should be determined before sedation/analgesia is initiated. Once sedation–analgesia is established, blood pressure should be measured at 5-min intervals during the procedure, unless such monitoring interferes with the procedure (*e.g.*, pediatric magnetic resonance imaging, where stimulation from the blood pressure cuff could arouse an appropriately sedated patient). Electrocardiographic monitoring should be used in all patients undergoing deep sedation. It should also be used during moderate sedation in patients with significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated.

Recording of Monitored Parameters

The literature is silent regarding the benefits of contemporaneous recording of patients' level of consciousness, respiratory function, or hemodynamics. Consultant opinion agrees with the use of contemporaneous recording for moderate sedation and strongly agrees with its use for patients undergoing deep sedation. It is the consensus of the Task Force that, unless technically precluded (*e.g.*, uncooperative or combative patient), vital signs and respiratory variables should be recorded before initiating sedation/analgesia, after administration

of sedative-analgesic medications, at regular intervals during the procedure, on initiation of recovery, and immediately before discharge. It is the opinion of the Task Force that contemporaneous recording (either automatic or manual) of patient data may disclose trends that could prove critical in determining the development or cause of adverse events. In addition, manual recording ensures that an individual caring for the patient is aware of changes in patient status in a timely fashion.

Recommendations. For both moderate and deep sedation, patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables should be assessed and recorded at a frequency that depends on the type and amount of medication administered, the length of the procedure, and the general condition of the patient. At a minimum, this should be: (1) before the beginning of the procedure; (2) after administration of sedative-analgesic agents; (3) at regular intervals during the procedure, (4) during initial recovery; and (5) just before discharge. If recording is performed automatically, device alarms should be set to alert the care team to critical changes in patient status.

Availability of an Individual Responsible for Patient Monitoring

Although the literature is silent on this issue, the Task Force recognizes that it may not be possible for the individual performing a procedure to be fully cognizant of the patient's condition during sedation/analgesia. For moderate sedation, the consultants agree that the availability of an individual other than the person performing the procedure to monitor the patient's status improves patient comfort and satisfaction and that risks are reduced. For deep sedation, the consultants strongly agree with these contentions. During moderate sedation, the consultants strongly agree that the individual monitoring the patient may assist the practitioner with interruptible ancillary tasks of short duration; during deep sedation, the consultants agree that this individual should have no other responsibilities.

Recommendation. A designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation/analgesia. During deep sedation, this individual should have no other responsibilities. However, during moderate sedation, this individual may assist with minor, interruptible tasks once the patient's level of sedation-analgesia and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.

Training of Personnel

Although the literature is silent regarding the effectiveness of training on patient outcomes, the consultants strongly agree that education and training in the pharmacology of agents commonly used during sedation-analgesia improves the likelihood of satisfactory sedation and reduces the risk of adverse outcomes from either moderate or deep sedation. Specific concerns may include: (1) potentiation of sedative-induced respiratory depression by concomitantly administered opioids; (2) inadequate time intervals between doses of sedative or analgesic agents, resulting in a cumulative overdose; and (3) inadequate familiarity with the role of pharmacologic antagonists for sedative and analgesic agents.

Because the primary complications of sedation/analgesia are related to respiratory or cardiovascular depression, it is the consensus of the Task Force that the individual responsible for monitoring the patient should be trained in the recognition of complications associated with sedation/analgesia. Because sedation/analgesia constitutes a continuum, practitioners administering moderate sedation should be able to rescue patients who enter a state of deep sedation, whereas those intending to administer deep sedation should be able to rescue patients who enter a state of general anesthesia. Therefore, the consultants strongly agree that at least one qualified individual trained in basic life support skills (cardiopulmonary resuscitation, bag-valve-mask ventilation) should be present in the procedure room during both moderate and deep sedation. In addition, the consultants strongly agree with the immediate availability (1–5 min away) of an individual with advanced life support skills (*e.g.*, tracheal intubation, defibrillation, use of resuscitation medications) for moderate sedation and in the procedure room itself for deep sedation.

Recommendations. Individuals responsible for patients receiving sedation-analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines. Individuals monitoring patients receiving sedation/analgesia should be able to recognize the associated complications. At least one individual capable of establishing a patent airway and positive pressure ventilation, as well as a means for summoning additional assistance, should be present whenever sedation-analgesia is administered. It is recommended that an individual with advanced life support skills be immediately available (within 5 min) for moderate sedation and within the procedure room for deep sedation.

Availability of Emergency Equipment

Although the literature is silent, the consultants strongly agree that the ready availability of appropriately sized emergency equipment reduces risks associated with both moderate and deep sedation. The literature is also silent regarding the need for cardiac defibrillators during sedation/analgesia. During moderate sedation, the consultants agree that a defibrillator should be immediately available for patients with both mild (*e.g.*, hypertension) and severe (*e.g.*, ischemia, congestive failure) cardiovascular disease. During deep sedation, the

consultants agree that a defibrillator should be immediately available for all patients.

Recommendations. Pharmacologic antagonists as well as appropriately sized equipment for establishing a patent airway and providing positive pressure ventilation with supplemental oxygen should be present whenever sedation–analgesia is administered. Suction, advanced airway equipment, and resuscitation medications should be immediately available and in good working order (Example III). A functional defibrillator should be immediately available whenever deep sedation is administered and when moderate sedation is administered to patients with mild or severe cardiovascular disease.

Example III. Emergency Equipment for Sedation and Analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The lists below should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated.

Intravenous equipment
- Gloves
- Tourniquets
- Alcohol wipes
- Sterile gauze pads
- Intravenous catheters [24-22-gauge]
- Intravenous tubing [pediatric "microdrip" (60 drops/ml)]
- Intravenous fluid
- Assorted needles for drug aspiration, intramuscular injection [intraosseous bone marrow needle]
- Appropriately sized syringes [1-ml syringes]
- Tape

Basic airway management equipment
- Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)
- Source of suction
- Suction catheters [pediatric suction catheters]
- Yankauer-type suction
- Face masks [infant/child]
- Self-inflating breathing bag-valve set [pediatric]
- Oral and nasal airways [infant/child-sized]
- Lubricant

Advanced airway management equipment (for practitioners with intubation skills)
- Laryngeal mask airways [pediatric]
- Laryngoscope handles (tested)
- Laryngoscope blades [pediatric]
- Endotracheal tubes
  - Cuffed 6.0, 7.0, 8.0 mm ID
  - [Uncuffed 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm ID]
- Stylet (appropriately sized for endotracheal tubes)

Pharmacologic Antagonists
- Naloxone
- Flumazenil

Emergency medications
- Epinephrine
- Ephedrine
- Vasopressin
- Atropine
- Nitroglycerin (tablets or spray)
- Amiodarone
- Lidocaine
- Glucose, 50% [10 or 25%]
- Diphenhydramine
- Hydrocortisone, methylprednisolone, or dexamethasone
- Diazepam or midazolam

Use of Supplemental Oxygen

The literature supports the use of supplemental oxygen during moderate sedation and suggests that supplemental oxygen be used during deep sedation to reduce the frequency of hypoxemia. The consultants agree that supplemental oxygen decreases patient risk during moderate sedation, while strongly agreeing with this view for deep sedation.

Recommendations. Equipment to administer supplemental oxygen should be present when sedation/analgesia is administered. Supplemental oxygen should be considered for moderate sedation and should be administered during deep sedation unless specifically contraindicated for a particular patient or procedure. If hypoxemia is anticipated or develops during sedation/analgesia, supplemental oxygen should be administered.

Combinations of Sedative–Analgesic Agents

The literature suggests that combining a sedative with an opioid provides effective moderate sedation; it is equivocal regarding whether the combination of a sedative and an opioid may be more effective than a sedative or an opioid alone in providing adequate moderate sedation. For deep sedation, the literature is insufficient to compare the efficacy of sedative–opioid combinations with that of a sedative alone. The consultants agree that combinations of sedatives and opioids provide satisfactory moderate and deep sedation. However, the published data also suggest that combinations of sedatives and opioids may increase the likelihood of adverse outcomes, including ventilatory depression and hypoxemia; the consultants were equivocal on this issue for both moderate and deep sedation. It is the consensus of the Task Force that fixed combinations of sedative and analgesic agents may not allow the individual components of sedation/analgesia to be appropriately titrated to meet the individual requirements of the patient and procedure while reducing the associated risks.

Recommendations. Combinations of sedative and analgesic agents may be administered as appropriate for the procedure being performed and the condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (*e.g.*, additional analgesic medication to relieve pain; additional sedative medication to decrease awareness or anxiety). The propensity for combinations of sedative and analgesic agents to cause respiratory depression and airway obstruction emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function.

Titration of Intravenous Sedative-Analgesic Medications

The literature is insufficient to determine whether administration of small, incremental doses of intravenous sedative/analgesic drugs until the desired level of sedation or analgesia is achieved is preferable to a single dose based on patient size, weight, or age. The consultants strongly agree that incremental drug administration improves patient comfort and decreases risks for both moderate and deep sedation.

Recommendations. Intravenous sedative/analgesic drugs should be given in small, incremental doses that are titrated to the desired end points of analgesia and sedation. Sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allowance should be made for the time required for drug absorption before supplementation is considered. Because absorption may be unpredictable, administration of repeat doses of oral medications to supplement sedation/analgesia is not recommended.

Anesthetic Induction Agents Used for Sedation/Analgesia (Propofol, Methohexital, Ketamine)

The literature suggests that, when administered by non-anesthesiologists, propofol and ketamine can provide satisfactory moderate sedation, and suggests that methohexital can provide satisfactory deep sedation. The literature is insufficient to evaluate the efficacy of propofol or ketamine administered by non-anesthesiologists for deep sedation. There is insufficient literature to determine whether moderate or deep sedation with propofol is associated with a different incidence of adverse outcomes than similar levels of sedation with midazolam. The consultants are equivocal regarding whether use of these medications affects the likelihood of producing satisfactory moderate sedation, while agreeing that using them increases the likelihood of satisfactory deep sedation. However, the consultants agree that avoiding these medications decreases the likelihood of adverse outcomes during moderate sedation and are equivocal regarding their effect on adverse outcomes during deep sedation.

The Task Force cautions practitioners that methohexital and propofol can produce rapid, profound decreases in level of consciousness and cardiorespiratory function, potentially culminating in a state of general anesthesia. The Task Force notes that ketamine also produces dose-related decreases in level of consciousness, culminating in general anesthesia. Although it may be associated with less cardiorespiratory depression than other sedatives, airway obstruction, laryngospasm, and pulmonary aspiration may still occur with ketamine. Furthermore, because of its dissociative properties, some of the usual signs of depth of sedation may not apply (*e.g.*, the patient's eyes may be open while in a state of deep sedation or general anesthesia). The Task Force also notes that there are no specific pharmacologic antagonists for any of these medications.

Recommendations. Even if moderate sedation is intended, patients receiving propofol or methohexital by any route should receive care consistent with that required for deep sedation. Accordingly, practitioners administering these drugs should be qualified to rescue patients from any level of sedation, including general anesthesia. Patients receiving ketamine should be cared for in a manner consistent with the level of sedation that is achieved.

Intravenous Access

Published literature is equivocal regarding the relative efficacy of sedative-analgesic agents administered intravenously as compared with those administered by non-intravenous routes to achieve moderate sedation; the literature is insufficient on this issue for deep sedation. The literature is equivocal regarding the comparative safety of these routes of administration for moderate sedation and is insufficient for deep sedation. The consultants strongly agree that intravenous administration of sedative and analgesic medications increases the likelihood of satisfactory sedation for both moderate and deep sedation. They also agree that it decreases the likelihood of adverse outcomes. For both moderate and deep sedation, when sedative-analgesic medications are administered intravenously, the consultants strongly agree with maintaining intravenous access until patients are no longer at risk for cardiovascular or respiratory depression, because it increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes. In situations where sedation is initiated by nonintravenous routes (*e.g.*, oral, rectal, intramuscular), the need for intravenous access is not sufficiently addressed in the literature. However, initiation of intravenous access after the initial sedation takes effect allows additional sedative-analgesic and resuscitation drugs to be administered if necessary.

Recommendations. In patients receiving intravenous medications for sedation/analgesia, vascular access should be maintained throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression. In patients who have received sedation-analgesia by nonintravenous routes, or whose intravenous line has become dislodged or blocked, practitioners should determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis. In all instances, an individual with the skills to establish intravenous access should be immediately available.

Reversal Agents

Specific antagonist agents are available for the opioids (*e.g.*, naloxone) and benzodiazepines (*e.g.*, flumazenil). The literature supports the ability of naloxone to reverse opioid-induced sedation and respiratory depression. Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema. The literature supports the ability of flumazenil to antagonize benzodiazepine-induced sedation and ventilatory depression in patients who have received benzodiazepines alone or in combination with an opioid. The consultants strongly agree that the immediate availability of reversal agents during both moderate and deep sedation is associated with decreased risk of adverse outcomes. It is the consensus of the Task Force that respiratory depression should be initially treated with supplemental oxygen and, if necessary, positive pressure ventilation by mask. The consultants disagree that the use of sedation regimens that are likely to require routine reversal with flumazenil or naloxone improves the quality of sedation or reduces the risk of adverse outcomes.

Recommendations. Specific antagonists should be available whenever opioid analgesics or benzodiazepines are administered for sedation/analgesia. Naloxone or flumazenil may be administered to improve spontaneous ventilatory efforts in patients who have received opioids or benzodiazepines, respectively. This may be especially helpful in cases where airway control and positive pressure ventilation are difficult. Before or concomitantly with pharmacologic reversal, patients who become hypoxemic or apneic during sedation/analgesia should: (1) be encouraged or stimulated to breathe deeply; (2) receive supplemental oxygen; and (3) receive positive pressure ventilation if spontaneous ventilation is inadequate. After pharmacologic reversal, patients should be observed long enough to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates. The use of sedation regimens that include routine reversal of sedative or analgesic agents is discouraged.

Recovery Care

Patients may continue to be at significant risk for developing complications after their procedure is completed. Decreased procedural stimulation, delayed drug absorption following nonintravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period. Examples include intramuscular meperidine-promethazine-chlorpromazine mixtures and oral or rectal chloral hydrate. When sedation-analgesia is administered to outpatients, it is likely that there will be no medical supervision once the patient leaves the medical facility. Although there is not sufficient literature to examine the effects of postprocedure monitoring on patient outcomes, the consultants strongly agree that continued observation, monitoring, and predetermined discharge criteria decrease the likelihood of adverse outcomes for both moderate and deep sedation. It is the consensus of the Task Force that discharge criteria should be designed to minimize the risk for cardiorespiratory depression after patients are released from observation by trained personnel.

Recommendations. Following sedation/analgesia, patients should be observed in an appropriately staffed

Example IV. Recovery and Discharge Criteria after Sedation and Analgesia

Each patient-care facility in which sedation–analgesia is administered should develop recovery and discharge criteria that are suitable for its specific patients and procedures. Some of the basic principles that might be incorporated in these criteria are enumerated below.

General principles

1. Medical supervision of recovery and discharge after moderate or deep sedation is the responsibility of the operating practitioner or a licensed physician.
2. The recovery area should be equipped with, or have direct access to, appropriate monitoring and resuscitation equipment.
3. Patients receiving moderate or deep sedation should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending on the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.
4. Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals.
5. A nurse or other individual trained to monitor patients and recognize complications should be in attendance until discharge criteria are fulfilled.
6. An individual capable of managing complications (*e.g.*, establishing a patent airway and providing positive pressure ventilation) should be immediately available until discharge criteria are fulfilled.

Guidelines for discharge

1. Patients should be alert and oriented; infants and patients whose mental status was initially abnormal should have returned to their baseline status. Practitioners and parents must be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat.
2. Vital signs should be stable and within acceptable limits.
3. Use of scoring systems may assist in documentation of fitness for discharge.
4. Sufficient time (up to 2 h) should have elapsed after the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal effects have worn off.
5. Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any postprocedure complications.
6. Outpatients and their escorts should be provided with written instructions regarding postprocedure diet, medications, activities, and a phone number to be called in case of emergency.

and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression. Oxygenation should be monitored periodically until patients are no longer at risk for hypoxemia. Ventilation and circulation should be monitored at regular intervals until patients are suitable for discharge. Discharge criteria should be designed to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel (Example IV).

Special Situations

The literature suggests and the Task Force members concur that certain types of patients are at increased risk for developing complications related to sedation/analgesia unless special precautions are taken. In patients with significant underlying medical conditions (*e.g.*, extremes of age; severe cardiac, pulmonary, hepatic, or renal disease; pregnancy; drug or alcohol abuse) the consultants agree that preprocedure consultation with an appropriate medical specialist (*e.g.*, cardiologist, pulmonologist) decreases the risks associated with moderate sedation and strongly agree that it decreases the risks associated with deep sedation. In patients with significant sedation-related risk factors (*e.g.*, uncooperative patients, morbid obesity, potentially difficult airway, sleep apnea), the consultants are equivocal regarding whether preprocedure consultation with an anesthesiologist increases the likelihood of satisfactory moderate sedation, while agreeing that it decreases adverse outcomes. The consultants strongly agree that preprocedure consultation increases the likelihood of satisfactory outcomes while decreasing risks associated with deep sedation. The Task Force notes that in emergency situations, the benefits of awaiting preprocedure consultations must be weighed against the risk of delaying the procedure.

For moderate sedation, the consultants are equivocal regarding whether the immediate availability of an individual with postgraduate training in anesthesiology increases the likelihood of a satisfactory outcome or decreases the associated risks. For deep sedation, the consultants agree that the immediate availability of such an individual improves the likelihood of satisfactory sedation and that it will decrease the likelihood of adverse outcomes.

Recommendations. Whenever possible, appropriate medical specialists should be consulted before administration of sedation to patients with significant underlying conditions. The choice of specialists depends on the nature of the underlying condition and the urgency of the situation. For severely compromised or medically unstable patients (*e.g.*, anticipated difficult airway, severe obstructive pulmonary disease, coronary artery disease, or congestive heart failure), or if it is likely that sedation to the point of unresponsiveness will be necessary to obtain adequate conditions, practitioners who are not trained in the administration of general anesthesia should consult an anesthesiologist.

References

1. Practice Guidelines for sedation and analgesia by non-anesthesiologists: A report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. ANESTHESIOLOGY 1996; 84:459–71

2. Practice Guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: A report by the American Society of Anesthesiologist Task Force on Preoperative Fasting. ANESTHESIOLOGY 1999; 90:896–905

Appendix I: Methods and Analyses†

The scientific assessment of these Guidelines was based on the following statements or evidence linkages. These linkages represent directional statements about relationships between sedation/analgesia interventions by non-anesthesiologists and clinical outcomes.

1. A preprocedure patient evaluation, (i.e., history, physical examination, laboratory evaluation, consultation)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
2. Preprocedure preparation of the patient (*e.g.*, counseling, fasting)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
3. Patient monitoring (*i.e.*, level of consciousness, pulmonary ventilation [observation, auscultation], oxygenation [pulse oximetry], automated apnea monitoring [capnography], hemodynamics [electrocardiogram, blood pressure, heart rate])
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
4. Contemporaneous recording of monitored parameters (*e.g.*, level of consciousness, respiratory function, hemodynamics) at regular intervals in patients receiving sedation or analgesia
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
5. Availability of an individual who is dedicated solely to patient monitoring and safety
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

6a. Education and training of sedation and analgesia providers in the pharmacology of sedation-analgesia agents
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

6b. The presence of an individual(s) capable of establishing a patent airway, positive pressure ventilation, and resuscitation (*i.e.*, advanced life-support skills) during a procedure
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

7. Availability of appropriately sized emergency and airway equipment (*e.g.*, laryngeal mask airway, defibrillators)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)

†Readers with special interest in the statistical analysis used in establishing these Guidelines can receive further information by writing to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

b. Reduces adverse outcomes

8. The use of supplemental oxygen during procedures performed with sedation or analgesia
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
9. Use of sedative agents combined with analgesic agents (*e.g.*, sedative-analgesic cocktails, fixed combinations of sedatives and analgesics, titrated combinations of sedatives and analgesics)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
10. Titration of intravenous sedative-analgesic medications to achieve the desired effect
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
11. Intravenous sedation-analgesic medications specifically designed to be used for general anesthesia (*i.e.*, methohexital, propofol, and ketamine)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

12a. Administration of sedative-analgesic agents by the intravenous route
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

12b. Maintaining or establishing intravenous access during sedation or analgesia until the patient is no longer at risk for cardiorespiratory depression
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

13. Availability of reversal agents (naloxone and flumazenil only) for the sedative or analgesic agents being administered
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
14. Postprocedural recovery observation, monitoring, and predetermined discharge criteria reduce adverse outcomes
15. Special regimens (*e.g.*, preprocedure consultation, specialized monitoring, special sedatives-techniques) for patients with special problems (*e.g.*, uncooperative patients; extremes of age; severe cardiac, pulmonary, hepatic, renal, or central nervous system disease; morbid obesity; sleep apnea; pregnancy; drug or alcohol abuse; emergency-unprepared patients; metabolic and airway difficulties)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

Scientific evidence was derived from aggregated research literature and from surveys, open presentations, and other consensus-oriented activities. For purposes of literature aggregation, potentially relevant clinical studies were identified *via* electronic and manual searches of the literature. The electronic search covered a 36-yr period from 1966 through 2001. The manual search covered a 44-yr period from 1958 through 2001. More than 3,000 citations were initially identified, yielding a total of 1,876 nonoverlapping articles that addressed topics related to the 15 evidence linkages. After review of the articles, 1,519 studies did not provide direct evidence and were subsequently eliminated. A total of 357 articles contained direct linkage-related evidence.

A directional result for each study was initially determined by a literature count, classifying each outcome as either supporting a linkage, refuting a linkage, or neutral. The results were then summarized to obtain a directional assessment of support for each linkage. Literature pertaining to three evidence linkages contained enough studies with well-defined experimental designs and statistical information to conduct formal metaanalyses. These three linkages were: linkage 8 [supplemental oxygen], linkage 9 [benzodiazepines combined with opioids *vs.* benzodiazepines alone], and linkage 13 [naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine-opioid combinations].

Combined probability tests were applied to continuous data, and an odds-ratio procedure was applied to dichotomous study results. Two combined probability tests were employed as follows: (1) the Fisher combined test, producing chi-square values based on logarithmic transformations of the reported *P* values from the independent studies; and (2) the Stouffer combined test, providing weighted representation of the studies by weighting each of the standard normal deviates by the size of the sample. An odds-ratio procedure based on the Mantel-Haenszel method for combining study results using 2×2 tables was used with outcome frequency information. An acceptable significance level was set at $P < 0.01$ (one-tailed), and effect size estimates were calculated. Tests for heterogeneity of the independent studies were conducted to assure consistency among the study results. Der Simonian-Laird random-effects odds ratios were calculated when significant heterogeneity was found. To assess potential publishing bias, a "fail-safe N" value was calculated for each combined probability test. No search for unpublished studies was conducted, and no reliability tests for locating research results were performed.

Metaanalytic results are reported in table 2. The following outcomes were found to be significant for combined probability tests: (1) *oxygen saturation*, linkage 8 (supplemental oxygen); (2) *sedation recovery*, linkage 13 (naloxone for antagonism of opioids and flumazenil for antagonism of benzodiazepine-opioid combinations); (3) *psychomotor recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (4) *respiratory-ventilatory recovery*, linkage 13 (naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine-opioid combinations). To be considered acceptable findings of significance, both the Fisher and weighted Stouffer combined test results must agree. Weighted effect size values for these linkages ranged from $r = 0.19$ to 0.80, representing moderate to high effect size estimates.

Mantel-Haenszel odds ratios were significant for the following outcomes: (1) *hypoxemia*, linkage 8 (supplemental oxygen) and linkage 9 (benzodiazepine-opioid combinations *vs.* benzodiazepines alone); (2) *sedation recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (3) *recall of procedure*, linkage 9 (benzodiazepine-opioid combinations). To be considered acceptable findings of significance, Mantel-Haenszel odds ratios must agree with combined test results when both types of data are assessed.

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a Kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.25$–0.64; (2) type of analysis, $\kappa = 0.36$–0.83; (3) evidence linkage assignment, $\kappa = 0.78$–0.89; and (4) literature inclusion for database, $\kappa = 0.71$–1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.45, Var (Sav) = 0.012; (2) type of analysis, Sav = 0.51, Var (Sav) = 0.015; (3) linkage assignment, Sav = 0.81 Var (Sav) = 0.006; (4) literature database inclusion, Sav = 0.84 Var (Sav) = 0.046. These values represent moderate to high levels of agreement.

The findings of the literature analyses were supplemented by the opinions of Task Force members as well as by surveys of the opinions of a panel of consultants drawn from the following specialties where sedation and analgesia are commonly administered: Anesthesiology, 8; Cardiology, 2; Dental Anesthesiology, 3; Dermatology, 2; Emergency Medicine, 5; Gastroenterology, 9; Intensive Care, 1; Oral and Maxillofacial Surgery, 5; Pediatrics, 1; Pediatric Dentistry, 3; Pharmacology, 1; Pulmonary Medicine, 3; Radiology, 3; Surgery, 3; and Urology, 2. The rate of return for this Consultant survey was 78% (n = 51/65). Median agreement scores from the Consultants regarding each linkage are reported in table 3.

Table 2. Meta-analysis Summary

Linkages	No. Studies	Fisher Chi-square	P	Weighted Stouffer Zc	P	Effect Size	Mantel-Haenszel Chi-square	P	Odds Ratio	Heterogeneity Significance	Heterogeneity Effect Size
Supplemental oxygen											
Oxygen saturation*	5	71.40	<0.001	5.44	<0.001	0.40	—	—	—	>0.90 (NS)	>0.50 (NS)
Hypoxemia*	7	—	—	—	—	—	44.15	<0.001	0.20	—	>0.50 (NS)
Sedatives/Opioids combined:											
Benzodiazepines + opioids											
Sedation efficacy	7	—	—	—	—	—	3.79	>0.05 (NS)	1.87§	—	<0.01
Recall of procedure	6	—	—	—	—	—	18.47	<0.001	2.18§	—	<0.01
Hypoxemia	5	—	—	—	—	—	11.78	<0.001	2.37	—	>0.05 (NS)
Naloxone for opioids											
Sedation recovery at 5 min*,†,‡	5	38.36	<0.001	3.13	<0.001	0.23	—	—	—	>0.30 (NS)	>0.02 (NS)
Respiration/ventilation*,†,‡	5	38.72	<0.001	3.97	<0.001	0.33	—	—	—	>0.10 (NS)	<0.001
Flumazenil for benzodiazepines											
Sedation recovery at 5 min	6	—	—	—	—	—	104.76	<0.001	8.15	—	>0.10 (NS)
Psychomotor recovery											
at 15 min	5	41.80	<0.001	1.69	0.046 (NS)	0.20	—	—	—	>0.70 (NS)	>0.50 (NS)
at 30 min	5	43.02	<0.001	3.36	<0.001	0.19	—	—	—	>0.90 (NS)	>0.50 (NS)
Respiration/ventilation†,‡	6	53.25	<0.001	5.03	<0.001	0.80	—	—	—	<0.01	<0.001
Flumazenil for benzodiazepine-opioid combinations											
Sedation recovery at 5 min	5	72.12	<0.001	6.76	<0.001	0.37	—	—	—	<0.001	<0.001
Respiration/ventilation†,‡	6	55.06	<0.001	5.11	<0.001	0.25	—	—	—	>0.10 (NS)	<0.001
Nausea/vomiting	5	—	—	—	—	—	0.28	>0.80 (NS)	1.22	—	>0.70 (NS)

* Nonrandomized comparative studies are included; † Studies in which anesthesiologist administered benzodiazepines, opioids, or reversal agents are included; ‡ Studies in which subjects consist of intensive care unit patients, postoperative patients, or volunteers with no procedures are included.

§ Der Simonian-Laird random-effects odds ratio.

For moderate sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 3 (electrocardiogram monitoring and capnography), linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives for improving satisfactory sedation), linkage 13b (routine administration of naloxone), linkage 13c (routine administration of flumazenil), and linkage 15b (anesthesiologist consultation for patients with medical conditions to provide satisfactory moderate sedation). In addition, Consultants were equivocal regarding whether postgraduate training in anesthesiology improves moderate sedation or reduces adverse outcomes.

For deep sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives), linkage 13b (routine administration of naloxone), and linkage 13c (routine administration of flumazenil).

The Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the updated Guidelines were instituted. The rate of return was 57% (n = 37/65). The percent of responding Consultants expecting no change associated with each linkage were as follows: preprocedure patient evaluation, 94%; preprocedure patient preparation, 91%; patient monitoring, 80%; contemporaneous recording of monitored parameters, 91%; availability of individual dedicated solely to patient monitoring and safety, 91%; education and training of sedation-analgesia providers in pharmacology, 89%; presence of an individual(s) capable of establishing a patent airway, 91%; availability of appropriately sized emergency and airway equipment, 94%; use of supplemental oxygen during procedures, 100%; use of sedative agents combined with analgesic agents, 91%; titration of sedatives-analgesics, 97%; intravenous sedation-analgesia with agents designed for general anesthesia, 77%; administration of sedative-analgesic agents by the intravenous route, 94%; maintaining or establishing intravenous access, 97%; availability-use of flumazenil, 94%; availability-use of naloxone, 94%; observation and monitoring during recovery, 89%; special care for patients with underlying medical problems, 91%; and special care for uncooperative patients, 94%. Seventy-four percent of the respondents indicated that the Guidelines would have no effect on the amount of time spent on a typical case. Nine respondents (26%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of these Guidelines. The amount of increased time anticipated by these respondents ranged from 1 to 60 min.

Table 3. Consultant Survey Summary

Intervention or Linkage	Outcome	Moderate Sedation N	Moderate Sedation Median* or Percent	Deep Sedation N	Deep Sedation Median* or Percent
1. Preprocedure patient evaluation	Satisfactory sedation	51	5	51	5
	Adverse outcomes	51	5	51	5
2. Preprocedure fasting	Satisfactory sedation	51	4	51	5
	Adverse outcomes	51	4	51	5
3. Monitoring					
a. Level of consciousness	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
b. Breathing (observation/auscultation)	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
c. Pulse oximetry	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
d. Blood pressure/heart rate	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
e. Electrocardiogram	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	49	5
f. Capnography	Satisfactory sedation	50	3	48	4
	Adverse outcomes	50	3	49	4
4. Contemporaneous recording	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
5. Individual for patient monitoring	Satisfactory sedation	49	4	48	5
	Adverse outcomes	49	4	48	5
6a. Education and training	Satisfactory sedation	50	5	49	5
	Adverse outcomes	50	5	49	5
6b. Individual with basic life support skills present in room		50	5	49	5
6c. Availability of advanced life support skills					
In the procedure room		2	4.2%	39	79.6%
Immediate vicinity (1–5 min)		27	56.2%	8	16.3%
Same building (5–10 min)		14	29.2%	2	4.1%
Outside provider		5	10.4%	0	0.0%
7. Emergency intravenous and airway equipment	Adverse outcomes	51	5	49	5
8. Supplemental oxygen	Adverse outcomes	50	4	49	5
9. Sedatives combined with analgesics	Satisfactory sedation	50	4	49	4
	Adverse outcomes	50	3	49	3
10. Titration	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
11. Avoiding general anesthetic sedatives	Satisfactory sedation	50	3	49	2
	Adverse outcomes	50	4	49	3
12a. Intravenous sedatives	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	4	50	4
12b. Intravenous access	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
13a. Immediate availability of naloxone or flumazenil	Adverse outcomes	51	5	51	5
13b. Routine administration of naloxone	Satisfactory sedation	37	2	37	2
	Adverse outcomes	37	2	37	2
13c. Routine administration of flumazenil	Satisfactory sedation	37	1	37	2
	Adverse outcomes	37	2	37	2
14. Observation, monitoring, and discharge criteria	Adverse outcomes	50	5	49	5
15a. Medical specialist consultation, patients with underlying medical conditions	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	4	49	5
15b. Anesthesiologist consultation, patients with underlying medical conditions	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	4	50	5
15c. Anesthesiologist consultation, patients with significant sedation risk factors	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
16. Postgraduate training in anesthesiology	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	50	4
17. In emergency situations, sedate patients less deeply		51	4	51	5

* Strongly agree: Median score of 5; Agree: Median score of 4; Equivocal: Median score of 3; Disagree: Median score of 2; Strongly disagree: Median score of 1.

Appendix II: Summary of Guidelines‡

Except as noted, recommendations apply to both moderate and deep sedation.

1. Preprocedure evaluation
   - Relevant history (major organ systems, sedation–anesthesia history, medications, allergies, last oral intake)
   - Focused physical examination (to include heart, lungs, airway)
   - Laboratory testing guided by underlying conditions and possible effect on patient management
   - Findings confirmed immediately before sedation
2. Patient counseling
   - Risks, benefits, limitations, and alternatives
3. Preprocedure fasting
   - Elective procedures—sufficient time for gastric emptying
   - Urgent or emergent situations—potential for pulmonary aspiration considered in determining target level of sedation, delay of procedure, protection of trachea by intubation
   - See ASA Guidelines for Preoperative Fasting[2]
4. Monitoring

   (Data to be recorded at appropriate intervals before, during, and after procedure)
   - Pulse oximetry
   - Response to verbal commands when practical
   - Pulmonary ventilation (observation, auscultation)
   - Exhaled carbon dioxide monitoring considered when patients separated from caregiver
   - Blood pressure and heart rate at 5-min intervals unless contraindicated
   - Electrocardiograph for patients with significant cardiovascular disease

   For deep sedation:
   - Response to verbal commands or more profound stimuli unless contraindicated
   - Exhaled CO_2 monitoring considered for all patients
   - Electrocardiograph for all patients
5. Personnel
   - Designated individual, other than the practitioner performing the procedure, present to monitor the patient throughout the procedure
   - This individual may assist with minor interruptible tasks once patient is stable

   For deep sedation:
   - The monitoring individual may not assist with other tasks
6. Training
   - Pharmacology of sedative and analgesic agents
   - Pharmacology of available antagonists
   - Basic life support skills—present
   - Advanced life support skills—within 5 min

   For deep sedation:
   - Advanced life support skills in the procedure room
7. Emergency Equipment
   - Suction, appropriately sized airway equipment, means of positive-pressure ventilation
   - Intravenous equipment, pharmacologic antagonists, and basic resuscitative medications
   - Defibrillator immediately available for patients with cardiovascular disease

   For deep sedation:
   - Defibrillator immediately available for all patients
8. Supplemental Oxygen
   - Oxygen delivery equipment available
   - Oxygen administered if hypoxemia occurs

   For deep sedation:
   - Oxygen administered to all patients unless contraindicated
9. Choice of Agents
   - Sedatives to decrease anxiety, promote somnolence
   - Analgesics to relieve pain
10. Dose Titration
    - Medications given incrementally with sufficient time between doses to assess effects
    - Appropriate dose reduction if both sedatives and analgesics used
    - Repeat doses of oral medications not recommended
11. Use of anesthetic induction agents (methohexital, propofol)
    - Regardless of route of administration and intended level of sedation, patients should receive care consistent with deep sedation, including ability to rescue from unintended general anesthesia
12. Intravenous Access
    - Sedatives administered intravenously—maintain intravenous access
    - Sedatives administered by other routes—case-by-case decision
    - Individual with intravenous skills immediately available
13. Reversal Agents
    - Naloxone and flumazenil available whenever opioids or benzodiazepines administered
14. Recovery
    - Observation until patients no longer at risk for cardiorespiratory depression
    - Appropriate discharge criteria to minimize risk of respiratory or cardiovascular depression after discharge
15. Special Situations
    - Severe underlying medical problems—consult with appropriate specialist if possible
    - Risk of severe cardiovascular or respiratory compromise or need for complete unresponsiveness to obtain adequate operating conditions—consult anesthesiologist

‡This is a summary of the Guidelines. The body of the document should be consulted for complete details.

Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures

An Updated Report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters

PRACTICE Guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies. In addition, Practice Guidelines developed by the American Society of Anesthesiologists (ASA) are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice Guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert and practitioner opinion, open forum commentary, and clinical feasibility data.

This update includes data published since the Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration were adopted by the ASA in 1998 and published in 1999.*

Methodology

Definition of Preoperative Fasting and Pulmonary Aspiration

For these Guidelines, preoperative fasting is defined as a prescribed period of time before a procedure when patients are not allowed the oral intake of liquids or solids. Perioperative pulmonary aspiration is defined as aspiration of gastric contents occurring after induction of anesthesia, during a procedure, or in the immediate period after surgery.

Purposes of the Guidelines

The purposes of these Guidelines are to (1) enhance the quality and efficiency of anesthesia care, (2) stimulate evaluation of clinical practices, and (3) reduce the severity of complications related to perioperative pulmonary aspiration of gastric contents.

Enhancements in the quality and efficiency of anesthesia care include, but are not limited to, the cost-effective use of perioperative preventive medication, increased patient satisfaction, avoidance of delays and cancellations, decreased risk

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Updated by the American Society of Anesthesiologists (ASA) Committee on Standards and Practice Parameters, Jeffrey L. Apfelbaum, M.D. (Chair), Chicago, Illinois; Robert A. Caplan, M.D., Seattle, Washington; Richard T. Connis, Ph.D., Woodinville, Washington; Burton S. Epstein, M.D., Washington, D.C.; David G. Nickinovich, Ph.D., Bellevue, Washington; and Mark A. Warner, M.D., Rochester, Minnesota. Originally developed by the ASA Task Force on Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Mark A. Warner, M.D. (Chair), Rochester, Minnesota; Robert A. Caplan, M.D., Seattle, Washington; Burton S. Epstein, M.D., Washington, D.C.; Charles P. Gibbs, M.D., Denver, Colorado; Candace E. Keller, M.D., M.P.H., Hattiesburg, Mississippi; Jessie A. Leak, M.D., Fayetteville, North Carolina; Roger Maltby, M.B.B.S., Calgary, Alberta; David G. Nickinovich, Ph.D., Bellevue, Washington; Mark S. Schreiner, M.D., Philadelphia, Pennsylvania; and Chris M. Weinlander, M.D., Appleton, Wisconsin.

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Address correspondence to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573. These Practice Guidelines, as well as all published ASA Practice Parameters, may be obtained at no cost through the Journal Web site, www.anesthesiology.org.

* American Society of Anesthesiologists: Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: Application to healthy patients undergoing elective procedures–a report by the American Society of Anesthesiologists Task Force on Preoperative Fasting. ANESTHESIOLOGY 1999; 90:896–905

of dehydration or hypoglycemia from prolonged fasting, and the minimization of perioperative morbidity.

Clinical practices include, but are not limited to, withholding solids and liquids for specified time periods before surgery, and prescribing pharmacologic agents to reduce gastric volume and acidity.

Complications of aspiration include, but are not limited to, aspiration pneumonia, respiratory disabilities, and related morbidities.

Focus

These Guidelines focus on preoperative fasting recommendations, as well as recommendations regarding the administration of pharmacologic agents to modify the volume and acidity of gastric contents during procedures in which upper airway protective reflexes may be impaired. Prevention of perioperative pulmonary aspiration is part of the larger process of preoperative evaluation and preparation of the patient.

Airway management techniques that are intended to reduce the occurrence of pulmonary aspiration are not the focus of these Guidelines. For example, a rapid-sequence induction/tracheal intubation technique or an awake tracheal intubation technique may be useful to prevent this problem during the delivery of anesthesia care. In addition, these Guidelines do not address the selection of anesthetic technique.

The intended patient population for these Guidelines is limited to healthy patients of all ages undergoing elective procedures. These Guidelines do not apply to patients who undergo procedures with no anesthesia or only local anesthesia when upper airway protective reflexes are not impaired, and when no risk factors for pulmonary aspiration are apparent. These Guidelines are also not intended for women in labor.

These Guidelines may not apply to, or may need to be modified for (1) patients with coexisting diseases or conditions that can affect gastric emptying or fluid volume (*e.g.*, pregnancy, obesity, diabetes, hiatal hernia, gastroesophageal reflux disease, ileus or bowel obstruction, emergency care, enteral tube feeding) and (2) patients in whom airway management might be difficult. Anesthesiologists and other anesthesia providers should recognize that these conditions can increase the likelihood of regurgitation and pulmonary aspiration. Additional or alternative preventive strategies may be appropriate for such patients.

Application

These Guidelines are intended for use by anesthesiologists and other anesthesia providers. They also may serve as a resource for other health care professionals who advise or care for patients who receive anesthesia care during procedures. Anesthesia care during procedures refers to general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care). Throughout these Guidelines, preoperative should be considered synonymous with preprocedural, as the latter term is often used to describe procedures that are not considered operations.

Task Force Members and Consultants

The original Guidelines were developed by a Task Force of 10 members, including anesthesiologists in both private and academic practice from various geographic areas of North America, and a consulting methodologist from the ASA Committee on Standards and Practice Parameters.

The Task Force developed the original Guidelines by means of a six-step process. First, they reached consensus on the criteria for evidence. Second, original published research studies from peer-reviewed journals relevant to preoperative fasting were reviewed and evaluated. Third, expert consultants were asked (1) to participate in opinion surveys on the effectiveness of various preoperative fasting management recommendations and (2) to review and comment on a draft of the Guidelines. Fourth, the Task Force held open forums at a national meeting† to solicit input on the draft recommendations. Fifth, expert consultants were surveyed to assess their opinions on the feasibility of implementing the Guidelines. Sixth, all available information was used to build consensus within the Task Force to finalize the Guideline recommendations (appendix 1).

In 2009, the ASA Committee on Standards and Practice Parameters requested that scientific evidence for these Guidelines be updated. This update consists of an evaluation of literature that includes new studies obtained after publication of the original Guidelines, new surveys of expert consultants, and a survey of a randomly selected sample of active ASA members.

Availability and Strength of Evidence

Preparation of this update used the same methodologic process as was used in the original Guidelines to obtain new evidence from two principal sources: scientific evidence and opinion-based evidence (appendix 2). The protocol for reporting each source of evidence is described below.

Scientific Evidence

Study findings from published scientific literature were aggregated and are reported in summary form by evidence category, as described below. All literature (*e.g.*, randomized controlled trials, observational studies, case reports) relevant to each topic was considered when evaluating the findings. However, for reporting purposes in this document, only the highest level of evidence (*i.e.*, level 1, 2, or 3 within category A, B, or C) is included in the summary.

Category A: Supportive Literature

Randomized controlled trials report statistically significant ($P < 0.01$) differences between clinical interventions for a specified clinical outcome.

† 12th Annual Meeting of the Society for Ambulatory Anesthesia, Orlando, Florida, May 2, 1997.

Level 1. The literature contains multiple randomized controlled trials. Aggregated findings are supported by meta-analysis.‡

Level 2. The literature contains multiple randomized controlled trials, but there is an insufficient number of studies to conduct a viable meta-analysis for the purpose of these Guidelines.

Level 3. The literature contains a single randomized controlled trial.

Category B: Suggestive Literature

Information from observational studies permits inference of beneficial or harmful relationships among clinical interventions and clinical outcomes.

Level 1. The literature contains observational comparisons (*e.g.*, cohort, case-control research designs) of clinical interventions or conditions and indicates statistically significant differences between clinical interventions for a specified clinical outcome.

Level 2. The literature contains noncomparative observational studies with associative (*e.g.*, relative risk, correlation) or descriptive statistics.

Level 3. The literature contains case reports.

Category C: Equivocal Literature

The literature cannot determine whether there are beneficial or harmful relationships among clinical interventions and clinical outcomes.

Level 1. Meta-analysis did not find significant differences among groups or conditions.

Level 2. The number of studies is insufficient to conduct meta-analysis, and (1) randomized controlled trials have not found significant differences among groups or conditions, or (2) randomized controlled trials report inconsistent findings.

Level 3. Observational studies report inconsistent findings or do not permit inference of beneficial or harmful relationships.

Category D: Insufficient Evidence from Literature

The lack of scientific evidence in the literature is described using the terms defined below.

Silent. No identified studies address the specified relationships among interventions and outcomes.

Inadequate. The available literature cannot be used to assess relationships among clinical interventions and clinical outcomes. The literature either does not meet the criteria for content as defined in the "Focus" of the Guidelines or does not permit a clear interpretation of findings due to methodological concerns (*e.g.*, confounding in study design or implementation).

‡ All meta-analyses are conducted by the ASA methodology group. Meta-analyses from other sources are reviewed but not included as evidence in this document.

§ When an equal number of categorically distinct responses are obtained, the median value is determined by calculating the arithmetic mean of the two middle values. Ties are calculated by a predetermined formula.

Opinion-based Evidence

All opinion-based evidence relevant to each topic (*e.g.*, survey data, open-forum testimony, Internet-based comments, letters, editorials) was considered in the development of the original Guidelines. New opinion surveys were developed to address each clinical intervention identified in the document, and identical surveys were distributed to both expert consultants and a random sample of active ASA members.

Category A: Expert Opinion

Survey responses from Task Force–appointed expert consultants are reported in summary form in the text. A complete listing of consultant survey responses reported in a table in appendix 2.

Category B: Membership Opinion

Survey responses from active ASA members are reported in summary form in the text. A complete listing of ASA member survey responses reported in appendix 2.

Survey responses are recorded using a 5-point scale and summarized based on median values.§

Strongly Agree. Median score of 5 (at least 50% of responses are 5).

Agree. Median score of 4 (at least 50% of responses are 4 [or 4 and 5]).

Equivocal. Median score of 3 (at least 50% of responses are 3—or no other response category or combination of similar categories contain at least 50% of responses).

Disagree. Median score of 2 (at least 50% of responses are 2 [or 1 and 2]).

Strongly Disagree. Median score of 1 (at least 50% of responses are 1).

Category C: Informal Opinion

Open-forum testimony, Internet-based comments, letters, and editorials were all informally evaluated and discussed during the development of the original Guideline recommendations.

Guidelines

Preoperative Assessment

No controlled trials were found that address the impact of conducting a preoperative assessment (*e.g.*, history, physical examination, survey/interview) on the frequency or severity of pulmonary aspiration of gastric contents during the perioperative period (*Category D evidence*). Studies with observational findings suggest that certain predisposing conditions (*e.g.*, age, comorbid disease) may be associated with the risk of perioperative aspiration (*Category B2 evidence*).[1,2]

The consultants and ASA members strongly agree that a review of pertinent medical records, a physical examination, and patient survey or interview should be performed as part of preoperative evaluation. They also strongly agree that patients should be informed of fasting requirements, and the

reasons for them, sufficiently in advance of their procedures. In addition, both the consultants and ASA members strongly agree that verification of patient compliance with fasting requirements should be assessed at the time of the procedure.

Recommendations for Preoperative Assessment. A review of pertinent medical records, a physical examination, and patient survey or interview should be performed as part of preoperative evaluation. The history, examination, and interview should include pertinent assessment of gastroesophageal reflux disease, dysphagia symptoms, or other gastrointestinal motility disorders, potential for difficult airway management, and metabolic disorders (*e.g.*, diabetes mellitus) that may increase the risk of regurgitation and pulmonary aspiration. Patients should be informed of fasting requirements, and the reasons for them, sufficiently in advance of their procedures. Verification of patient compliance with fasting requirements should be assessed at the time of the procedures. When the fasting recommendations in these Guidelines are not followed, the practitioner should compare the risks and benefits of proceeding, with consideration given to the amount and type of liquids or solids ingested.

Preoperative Fasting Status: Clear Liquids

Meta-analysis of randomized controlled trials[3–10] comparing fasting times of 2–4 h *versus* more than 4 h report smaller gastric volumes and higher gastric pH values in adult patients given clear liquids 2–4 h before a procedure (*Category A1 evidence*); findings for gastric pH values more than 2.5 are equivocal (*Category C1 evidence*).[3–7,9] Meta-analysis of randomized controlled trials[11–19] report higher gastric pH values (*Category A1 evidence*) and equivocal findings regarding differences in gastric volume for children given clear liquids 2–4 h before a procedure *versus* fasting for more than 4 h before a procedure (*Category C1 evidence*).[11–19] Ingested volumes of clear liquids in the above studies range from 100 ml to unrestricted amounts for adults, and 2 ml/kg to unrestricted amounts for children. Published clinical evidence is insufficient to address the relationship between fasting times for clear liquids and the risk of emesis/reflux or pulmonary aspiration (*Category D evidence*).

Both the consultants and ASA members strongly agree that for otherwise healthy infants (younger than 2 yr), children (2–16 yr), and adults, fasting from the intake of clear liquids at least 2 h before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained.

Recommendations for Clear Liquids. It is appropriate to fast from intake of clear liquids at least 2 h before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care). Examples of clear liquids include, but are not limited to, water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee. These liquids should not include alcohol. The volume of liquid ingested is less important than the type of liquid ingested.

Preoperative Fasting Status: Breast Milk

Studies with observational findings are equivocal regarding the impact of ingesting breast milk 4 h before a procedure on the risk of higher volumes or lower pH levels of gastric contents during a procedure (*Category C3 evidence*).[20–22] The literature is insufficient to evaluate the effect of the timing of ingestion of breast milk and the perioperative incidence of emesis/reflux or pulmonary aspiration (*Category D evidence*).

The consultants agree and the ASA members strongly agree that for otherwise healthy neonates (younger than 44 gestational weeks) and infants, fasting from the intake of breast milk at least 4 h before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained.

Recommendations for Breast Milk. It is appropriate to fast from intake of breast milk at least 4 h before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care).

Preoperative Fasting Status: Infant Formula

A study with observational findings is equivocal regarding the impact of ingesting infant formula 4 h before a procedure on the risk of higher volumes or lower pH levels of gastric contents during a procedure (*Category C3 evidence*).[23] The literature is insufficient to evaluate the effect of the timing of ingestion of infant formula and the perioperative incidence of emesis/reflux or pulmonary aspiration (*Category D evidence*).

Both the consultants and ASA members agree that for neonates and infants, fasting from the intake of infant formula at least 6 h before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained. The consultants agree and the ASA members strongly agree that for children, fasting from the intake of infant formula at least 6 h before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained.

Recommendations for Infant Formula. It is appropriate to fast from intake of infant formula at least 6 h before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care).

Preoperative Fasting Status: Solids and Nonhuman Milk

A randomized controlled trial comparing a light breakfast consumed an average of less than 4 h before a procedure with overnight fasting reports equivocal findings regarding gastric volume and pH levels for adults (*Category C2 evidence*).[24] Studies with nonrandomized comparative findings for children given nonhuman milk 4 h or less before a procedure *versus* children who fasted for more than 4 h report higher gastric volumes (*Category B2 evidence*) and equivocal gastric pH (*Category C3 evi-*

dence).[21,25,26] A study with observational findings suggests that fasting for more than 8 h may be associated with hypoglycemia in children (*Category B2 evidence*).[26] The literature is insufficient to evaluate the effect of the timing of ingestion of solids and nonhuman milk and the perioperative incidence of emesis/reflux or pulmonary aspiration (*Category D evidence*).

The consultants agree and the ASA members strongly agree that fasting from the intake of a light meal (*e.g.*, toast and a clear liquid) 6 h or more before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained. Both the consultants and ASA members strongly agree that fasting from the intake of a meal that includes fried or fatty foods 8 h or more before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained.

Both the consultants and ASA members agree that for infants, fasting from the intake of nonhuman milk 6 h or more before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained. The consultants agree and the ASA members strongly agree that for children and adults, fasting from the intake of nonhuman milk 6 h or more before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained.

Recommendations for Solids and Nonhuman Milk. It is appropriate to fast from intake of a light meal or nonhuman milk 6 h or more before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care). The Task Force notes that intake of fried or fatty foods or meat may prolong gastric emptying time. Additional fasting time (*e.g.*, 8 h or more) may be needed in these cases. Both the amount and type of food ingested must be considered when determining an appropriate fasting period. Because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

Preoperative Gastrointestinal Stimulants

Meta-analysis of randomized placebo-controlled trials[8–32] supports the efficacy of metoclopramide to reduce gastric volume (*Category A1 evidence*)[2] and is equivocal regarding the effect of metoclopramide on gastric acidity (*Category C1 evidence*)[28–32] during the perioperative period. The literature is insufficient to evaluate the effect of administering gastrointestinal stimulants on the perioperative incidence of emesis/reflux or pulmonary aspiration (*Category D evidence*).

Both the consultants and ASA members disagree that gastrointestinal stimulants should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have no apparent increased risk for pulmonary aspiration.

Recommendations for Gastrointestinal Stimulants. The routine preoperative use of gastrointestinal stimulants to decrease the risk of pulmonary aspiration in patients who have no apparent increased risk for pulmonary aspiration is not recommended.

Preoperative Pharmacologic Blockade of Gastric Acid Secretion

Histamine-2 receptor antagonists: Meta-analysis of double-blind randomized placebo-controlled trials support the efficacy of cimetidine to reduce gastric volume[31–36] and acidity[31–37] during the perioperative period (*Category A1 evidence*). Meta-analysis of double-blind randomized placebo-controlled trials[35,38–43] also supports the efficacy of ranitidine to reduce gastric volume and acidity during the perioperative period (*Category A1 evidence*). Randomized placebo-controlled trials indicate that famotidine is effective in reducing gastric volume and acidity (*Category A2 evidence*).[39,44,45]

Proton pump inhibitors: Randomized controlled trials support the efficacy of omeprazole in reducing gastric volume and acidity (*Category A2 evidence*),[41,46–48] with similar findings reported for lansoprazole (*Category A2 evidence*).[41,42,49,50]

The literature is insufficient to evaluate the effect of administering either histamine-2 receptor antagonists or proton pump inhibitors on the perioperative incidence of emesis/reflux or pulmonary aspiration (*Category D evidence*).

Both the consultants and ASA members disagree that histamine-2 receptor antagonists should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have no apparent increased risk for pulmonary aspiration. The ASA members disagree and the consultants strongly disagree that proton pump inhibitors should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have no apparent increased risk for pulmonary aspiration.

Recommendations for Preoperative Pharmacologic Blockade of Gastric Acid Secretion. The routine preoperative use of medications that block gastric acid secretion to decrease the risks of pulmonary aspiration in patients who have no apparent increased risk for pulmonary aspiration is not recommended.

Preoperative Antacids

Randomized controlled trials indicate that preoperative antacids (*e.g.*, sodium citrate, magnesium trisilicate) increase gastric pH during the perioperative period (*Category A2 evidence*),[29,51–54] with equivocal findings regarding gastric volume (*Category C2 evidence*). The literature does not sufficiently examine the relationship between reduced gastric acidity and the frequency of pulmonary aspiration or emesis in humans; nor does the literature sufficiently examine whether reduced gastric

acidity or volume is associated with decreased morbidity or mortality in patients given preoperative antacids who have aspirated gastric contents (*Category D evidence*).

The consultants and ASA members both disagree that preoperative antacids should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have no apparent increased risk for pulmonary aspiration. The consultants and ASA members both strongly agree that only nonparticulate antacids should be used when antacids are indicated for selected patients.

Recommendations for Preoperative Antacids. The routine preoperative use of antacids to decrease the risks of pulmonary aspiration in patients who have no apparent increased risk for pulmonary aspiration is not recommended. Only nonparticulate antacids should be used when antacids are indicated for selected patients for purposes other than reducing the risk of pulmonary aspiration.

Preoperative Antiemetics

Randomized controlled trials indicate that the preoperative administration of droperidol[55–57] and ondansetron[58–60] are effective in reducing nausea and vomiting during the period after surgery (*Category A2 evidence*). The literature does not sufficiently examine the relationship between the preoperative use of antiemetics and the frequency of pulmonary aspiration (*Category D evidence*).

The consultants and ASA members both disagree that preoperative antiemetics should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have no apparent increased risk for pulmonary aspiration.

Recommendations for Preoperative Antiemetics.‖ The routine preoperative use of antiemetics to reduce the risks of pulmonary aspiration in patients who have no apparent increased risk for pulmonary aspiration is not recommended.

Preoperative Anticholinergics

Randomized placebo-controlled trials are equivocal regarding the efficacy of atropine[61] and glycopyrrolate[62–65] to reduce gastric volume or acidity (*Category C2 evidence*).

The ASA members disagree and the consultants strongly disagree that preoperative anticholinergics should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) to decrease the risk of pulmonary aspiration.

Recommendations for Preoperative Anticholinergics. The use of anticholinergics to decrease the risks of pulmonary aspiration is not recommended.

Preoperative Multiple Agents

Randomized controlled trials indicate that, when histamine-2 receptor antagonists (*i.e.*, cimetidine, ranitidine) are combined with gastrointestinal stimulants (*i.e.*, metoclopramide), the combined influence of the two drugs is effective in reducing both gastric volume and acidity (*Category A2 evidence*).[28,30–32,66–68] Therefore, when histamine-2 receptor antagonists combined with gastrointestinal stimulants are compared to histamine-2 receptor antagonists alone, comparable reductions in gastric acidity are reported. Similarly, when the combined drugs are compared to gastrointestinal stimulants alone as the single-drug comparison, equivocal findings for gastric volume are reported.[28,30–32,66–68] Randomized controlled trials comparing other drug combinations *versus* single drugs alone report inconsistent findings regarding gastric volume and pH outcomes (*Category C2 evidence*).[29,57,65,69–71]

The ASA members disagree and the consultants strongly disagree that preoperative multiple agents should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have no apparent risk for pulmonary aspiration.

Recommendations for Preoperative Multiple Agents. The routine preoperative use of multiple agents in patients who have no apparent increased risk for pulmonary aspiration is not recommended.

Appendix 1: Summary of Fasting and Pharmacologic Recommendations

Summary of Fasting Recommendations

Ingested Material	Minimum Fasting Period
Clear liquids	2 h
Breast milk	4 h
Infant formula	6 h
Nonhuman milk	6 h
Light meal	6 h

These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the Guidelines does not guarantee complete gastric emptying. The fasting periods noted above apply to patients of all ages.

Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee. Because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Additional fasting time (*e.g.*, 8 h or more) may be needed in these cases. Both the amount and

‖ These Guidelines do not address the use of antiemetics during the extended period after surgery when the upper airway protective reflexes are no longer impaired.

type of food ingested must be considered when determining an appropriate fasting period.

Pharmacologic Recommendations

These recommendations are listed by medication type with common examples. In addition, combinations of the medications listed are not recommended for routine use.

Gastrointestinal Stimulants
- Metoclopramide: No routine use

Gastric Acid Secretion Blockers
- Cimetidine: No routine use
- Famotidine: No routine use
- Ranitidine: No routine use
- Omeprazole: No routine use
- Lansoprazole: No routine use

Antacids
- Sodium citrate: No routine use
- Sodium bicarbonate: No routine use
- Magnesium trisilicate: No routine use

Antiemetics
- Droperidol: No routine use
- Ondansetron: No routine use

Anticholinergics
- Atropine: No use
- Scopolamine: No use
- Glycopyrrolate: No use

Multiple Agents
- No routine use

Appendix 2: Methods and Analyses

State of the Literature

For these Guidelines, a literature review is used in combination with opinions obtained from expert consultants and other sources (*e.g.*, American Society of Anesthesiologists members, open forums, Internet postings). Both the literature review and opinion data are based on evidence linkages, or statements regarding potential relationships between clinical interventions and outcomes. The interventions listed below were examined to assess their impact on pulmonary aspiration and other outcomes. Outcomes for the listed interventions include, but are not limited to, pulmonary aspiration, volume and acidity of gastric contents, adverse effects (*e.g.*, thirst, hunger, nausea, vomiting), adverse outcomes (*e.g.*, pneumonitis, mortality), and other outcomes (*e.g.*, length of stay in hospital, costs).

Preoperative Assessment

1. Medical record review or patient condition
2. Physical examination
3. Patient survey/questionnaire

Preoperative Fasting Status

1. Adults: Clear liquids between 2 and 4 h *versus* more than 4 h
2. Children: Clear liquids between 2 and 4 h *versus* more than 4 h
3. Breast milk between 2 and 4 h *versus* more than 4 h
4. Infant formula between 2 and 4 h *versus* more than 4 h
5. Solids or nonhuman milk less than 4 h *versus* more than 4 h
6. Solids or nonhuman milk between 4 and 8 h *versus* more than 8 h

Preoperative Pharmacologic Interventions

1. Gastrointestinal stimulants (*e.g.*, metoclopramide, cisapride)
2. Blockage of gastric acid secretion
   a. Histamine-2 receptor antagonists (*e.g.*, cimetidine, ranitidine, famotidine)
   b. Proton pump inhibitors (*e.g.*, omeprazole, lansoprazole)
3. Antacids (e.g., sodium citrate, magnesium trisilicate)
4. Antiemetics (e.g., ondansetron, droperidol)
5. Anticholinergics (*e.g.*, atropine, glycopyrrolate)
6. Multiple agents/drugs *versus* single agents/drugs

For the literature review, potentially relevant clinical studies were identified *via* electronic and manual searches of the literature. For the original Guidelines, electronic and manual searches covered a 57-yr period from 1940 through 1996. The literature search for this update covered the 15-yr period from 1996 through 2010 and included review of 1,223 nonoverlapping articles that addressed topics related to the evidence linkages. After review of the articles, 1,065 studies did not provide direct evidence and were subsequently eliminated. A total of 158 articles contained findings directly related to at least one of the evidence linkages listed above. No evidence linkage contained sufficient literature with well-defined experimental designs and statistical information to conduct an analysis of aggregated studies (*i.e.*, meta-analysis). A complete bibliography used to develop these updated Guidelines, organized by section, is available as Supplemental Digital Content 2, http://links.lww.com/ALN/A661.

The literature is categorized according to the proximity or directness of the outcome to the intervention. To appropriately evaluate an outcome, a study should either evaluate a direct comparison or institute methodological controls (*e.g.*, control for intervening variables). For these Guidelines, the primary outcomes of interest are pulmonary aspiration and its adverse consequences. Therefore, these Guidelines focus on assessing the causal relationship between a preoperative intervention and the frequency of pulmonary aspiration, and assessing the causal relationship between a preoperative intervention and the frequency or severity of an adverse consequence associated with aspiration (*e.g.*, pneumonitis). However, the literature is insufficient to evaluate such relationships. The literature reveals four types of analytic relationships between preoperative interventions and out-

comes of interest. These types of relationships are referred to as first-, second-, third-, or fourth-order comparisons.

A first-order comparison represents a direct comparison either between an intervention (*e.g.*, antacid administration) and a clinical outcome, or between two outcomes (*e.g.*, gastric volume and emesis). In the studies reviewed with first-order comparisons, the relationship between one of the identified interventions in the Guidelines and the incidence of pulmonary aspiration was not assessed. Therefore, a cause-and-effect relationship between an intervention of interest and pulmonary aspiration cannot be shown. Although some outcomes (*e.g.*, gastric volume, pH) were considered by the authors to be representative of a predicted risk of pulmonary aspiration, results of such comparisons are not sufficient to provide methodologically acceptable evidence.

Levels 2 through 4 represent comparisons that must first control for an intermediate outcome. For example, to examine the effectiveness of a histamine-2 receptor antagonist on pulmonary aspiration, the effect of the histamine-2 receptor antagonist on gastric content as well as the occurrence of emesis must be methodologically controlled. Gastric content and emesis "outcomes" are intervening steps between the intervention and pulmonary aspiration. This example would be considered a third-order comparison.

Level 2 represents a comparison in which one step, or intermediate outcome, exists between the intervention and the outcome of interest. However, level 2 relationships do not examine the association between an intervention of interest and the occurrence of pulmonary aspiration.

Level 3 contains one relationship of interest to the Guidelines (*i.e.*, intervention/pulmonary aspiration). Level 4 contains the other relationship of interest to the Guidelines (*i.e.*, association between an intervention and clinical consequences from pulmonary aspiration).

Table 1 indicates that outcomes related to preoperative fasting and the administration of pharmacologic agents were insufficient to evaluate cause-and-effect relationships that link the interventions of interest in these Guidelines with the occurrence of pulmonary aspiration or the clinical consequences from pulmonary aspiration.

Although the literature was not sufficient for causal assessment related to pulmonary aspiration, findings for each intervention of interest regarding intermediate outcomes is reported. Initially, each pertinent outcome reported in a study is classified as supporting an evidence linkage, refuting a linkage, or equivocal. These results are then summarized to obtain a directional assessment for each evidence linkage before conducting a formal meta-analysis. The literature relating to five evidence linkages contained enough studies with well-defined experimental designs and statistical information to conduct formal meta-analyses. These five evidence linkages are: (1) preoperative fasting status of liquids between 2 and 4 h for adults, (2) preoperative fasting status of liquids between 2 and 4 h for children, (3) preoperative metoclopramide, (4) preoperative cimetidine, and (5) preoperative ranitidine. Meta-analysis was limited to gastric volume and acidity outcomes (table 2).

General variance-based effect-size estimates or combined probability tests are obtained for continuous outcome measures. Mantel-Haenszel odds ratios are obtained for dichotomous outcome measures. Two combined probability tests are used as follows: (1) the Fisher combined test, producing chi-square values based on logarithmic transformations of the reported P values from the independent studies, and (2) the Stouffer combined test, providing weighted representations of the studies by weighting each of the standard normal deviates by the size of the sample. An odds-ratio procedure based on the Mantel-Haenszel method for combining study results using 2×2 tables is used with outcome frequency information. An acceptable significance level is set at a P value of less than 0.01 (one-tailed). Tests for heterogeneity of the independent studies are conducted to ensure consistency among study results. DerSimonian-Laird random-effects odds ratios are obtained when significant heterogeneity is found ($P < 0.01$). To control for potential publishing bias, a "fail-safe n value" is calculated. No search for unpublished studies was conducted; no reliability tests for locating research results were done. To be accepted as significant findings, Mantel-Haenszel odds ratios must agree with combined test results whenever both types of data are assessed. In the absence of Mantel-Haenszel odds ratios, findings from the Fisher and weighted Stouffer combined tests must agree with each other to be considered statistically significant.

For the original Guidelines, interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a κ statistic for two-rater agreement pairs are as follows: (1) type of study design, $\kappa = 0.75–0.95$; (2) type of analysis, $\kappa = 0.54–0.85$; (3) evidence linkage assignment, $\kappa = 0.68–0.82$; and (4) literature inclusion for database, $\kappa = 0.64–0.78$. Three-rater chance-corrected agreement values are: (1) design, Sav = 0.81, Var (Sav) = 0.006; (2) analysis, Sav = 0.66, Var (Sav) = 0.014; (3) linkage identification, Sav = 0.75, Var (Sav) = 0.005; (4) literature database inclusion, Sav = 0.67, Var (Sav) = 0.050. These values represent moderate to high levels of agreement.

Consensus-based Evidence

Consensus was obtained from multiple sources, including: (1) survey opinion from consultants who were selected based on their knowledge or expertise in preoperative fasting and prevention of pulmonary aspiration, (2) survey opinions solicited from active members of the American Society of Anesthesiologists, (3) testimony from attendees of a publicly held open forum for the original Guidelines held at a national anesthesia meeting, (4) Internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was 59.7% (37 of 62) for the

consultants (table 3); 471 responses were received from active American Society of Anesthesiologists members (table 4).

For the original Guidelines, an additional survey was sent to the consultants asking them to indicate which, if any, of the evidence linkages would change their clinical practices if the Guidelines were instituted. The percent of consultants expecting no change associated with each linkage were as follows: preoperative assessment, 95%; preoperative fasting of solids, 75%; preoperative fasting of liquids, 67%; preoperative fasting of breast milk, 78%; gastrointestinal stimulants, 95%; pharmacologic blockage of gastric secretion, 91%; antacids, 100%; antiemetics, 98%, anticholinergics, 100%, and multiple agents, 98%. Ninety-six percent of respondents indicated that the Guidelines would have no effect on the amount of time spent on a typical case. For all respondents, the mean increase in the amount of time spent on a typical case was 2.4 min. Two respondents reported that the Guidelines would increase the amount of time spent per case. The anticipated time increase for these two respondents was 5 and 120 min, respectively.

Table 1. Summary of First-, Second-, Third-, and Fourth-order Comparisons of Outcomes Related to Fasting and Pharmaceutical Interventions

Fasting or Pharmaceutical Intervention	Studies, No.
First-order comparisons	
Intervention - gastric outcomes	132
Gastric volume or pH - emesis/reflux	1
Emesis/reflux - pulmonary aspiration	0
Pulmonary aspiration - adverse outcomes	3
Second-order comparisons	
Intervention - emesis/reflux	15
Gastric volume or pH - pulmonary aspiration	1
Emesis/reflux - adverse outcomes	0
Third-order comparisons	
Intervention - pulmonary aspiration	3
Gastric volume or pH - adverse outcomes	0
Fourth-order Comparisons	
Intervention - adverse outcomes	0

Table 2. Meta-analysis Summary

Evidence Linkages	No.	Fisher χ^2	*P* Value	Z Score	*P* Value	Effect Size	OR	CI	Significance	Effect Size
Preoperative fasting: clear liquids										
Adults, 2–4 *vs.* > 4 h										
Gastric volume	8	39.80	0.001	−2.44	0.007	−0.11	—	—	ns	ns
Gastric volume, < 25 ml	6	—	—	—	—	—	1.68	1.00–2.80	—	ns
Gastric pH	8	36.26	0.005	2.69	0.004	0.12	—	—	ns	ns
Gastric pH, > 2.5	6	—	—	—	—	—	1.83	0.91–3.69	—	ns
Low risk	6	—	—	—	—	—	1.86*	1.10–3.14	—	ns
Children, 2–4 *vs.* > 4 h										
Gastric volume	9	39.07	0.005	−1.37	0.085	−0.05	—	—	ns	ns
Gastric volume, < 0.04 ml/kg	7	—	—	—	—	—	1.30	0.81–2.10	—	ns
Gastric pH	9	35.88	0.006	2.89	0.002	0.10	—	—	ns	ns
Gastric pH, > 2.5	5	—	—	—	—	—	0.81	0.37–1.74	—	ns
Low risk	8	—	—	—	—	—	1.06	0.71–1.57	—	ns
Metoclopramide *vs.* placebo										
Gastric volume	6	49.61	0.001	−5.06	0.001	−0.34	—	—	ns	ns
Gastric pH	5	37.06	0.001	3.56	0.001	0.28	—	—	ns	ns

(*continued*)

Table 2. Continued

Evidence Linkages	No.	Fisher χ^2	*P* Value	Z Score	*P* Value	Effect Size	OR	CI	Significance	Effect Size
Cimetidine *vs.* placebo										
Gastric volume	6	54.24	0.001	−5.50	0.001	−0.39	—	—	ns	ns
Gastric volume, < 25 ml	8	—	—	—	—	—	4.38*	2.41–7.96	—	ns
Gastric pH	7	93.37	0.001	11.73	0.001	0.78	—	—	0.005	0.001
Gastric pH, > 2.5	11	—	—	—	—	—	12.60*	8.02–19.78	—	ns
Low risk	5	—	—	—	—	—	5.69	2.63–12.35	—	ns
Ranitidine *vs.* placebo										
Gastric volume	7	78.73	0.001	−9.46	0.001	−0.55	—	—	0.001	0.001
Gastric volume, < 25 ml	14	—	—	—	—	—	4.83*	3.21–7.27	—	ns
Gastric pH	7	106.41	0.001	14.05	0.001	0.85	—	—	ns	0.001
Gastric pH, > 2.5	6	—	—	—	—	—	16.61*	9.12–30.26	—	ns
Low risk	6	—	—	—	—	—	9.31*	5.97–14.51	—	ns

* Odds ratios from double-blind studies.

CI = confidence interval; low risk = patients with gastric volume <25 ml and pH >2.5; ns = nonsignificant ($P > 0.01$); OR = odds ratio; χ^2 = chi-square test.

Table 3. Consultant Responses per Survey Item (N = 37)

	Response, No.	Response, %				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Preoperative Assessment						
1. A review of pertinent records, a physical examination, and patient survey or interview should be performed as part of the preoperative evaluation	37	86.5*	13.5	0	0	0
2. Patients should be informed of fasting requirements and the reasons for them sufficiently in advance of their procedures	37	97.3*	2.7	0	0	0
3. Verification of patient compliance with the fasting requirements should be assessed immediately prior to the time of the procedure	36	94.4*	5.6	0	0	0
Preoperative NPO Status						
Clear liquids						
4a. For otherwise healthy *infants* (<2 yr of age), fasting from the intake of clear liquids for *2 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	59.5*	27.0	10.8	0	2.7
4b. For otherwise healthy *children* (2 to 16 yr of age), fasting from the intake of clear liquids for *2 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	54.1*	32.4	10.8	2.7	0
4c. For otherwise healthy *adults*, fasting from the intake of clear liquids for *2 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	56.8*	40.5	2.7	0	0

(*continued*)

Table 3. Continued

	Response, No.	Response, %				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Breast milk						
5a. For otherwise healthy *neonates* (<44 gestational weeks), fasting from the intake of breast milk for *4 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	37.8	35.1*	18.9	8.1	0
5b. For otherwise healthy *infants*, fasting from the intake of breast milk for *4 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	43.2	37.8*	18.9	0	0
Infant formula						
6a. For *neonates*, fasting from the intake of infant formula for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	27.0	32.4*	24.3	13.5	2.7
6b. For infants, fasting from the intake of infant formula for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	36	36.1	30.6*	16.7	13.9	2.8
6c. For children, fasting from the intake of infant formula for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	32.4	40.5*	21.6	5.4	0
Nonhuman milk						
7a. For infants, fasting from the intake of non-human milk for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	35	31.4	34.3*	22.9	11.4	0
7b. For children, fasting from the intake of non-human milk for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	29.7	46.0*	18.9	5.4	0
7c. For adults, fasting from the intake of non-human milk for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	37	43.2	46.0*	5.4	5.4	0
Solids						
8. Fasting from the intake of a *light meal* (*e.g.*, toast and a clear liquid) for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	36	41.7	44.4*	0	13.9	0
9. Fasting from the intake of a meal that includes *fried or fatty foods* for *8 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	36	63.9*	27.8	2.8	2.8	2.8

(*continued*)

Table 3. Continued

	Response, No.	Response, %				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Preoperative Gastrointestinal Stimulants						
10. Gastrointestinal stimulants should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	36	0	0	5.6	47.2*	47.2
Preoperative Pharmacologic Blockade of Gastric Acid Secretion						
11. Histamine-2 receptor antagonists should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	36	0	2.8	5.6	44.4*	47.2
12. Proton pump inhibitors should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	37	0	2.7	8.1	37.8	51.4*
Preoperative Antacids						
13a. Preoperative antacids should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	36	0	2.8	2.8	47.2*	47.2
13b. When antacids are indicated for selected patients, only non-particulate antacids should be used	36	55.6*	27.8	11.1	0	5.6
Preoperative Antiemetics						
14. Preoperative antiemetics should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	37	0	5.4	0	51.4*	43.2
Preoperative Anticholinergics						
15. Preoperative anticholinergics should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) to decrease the risk of pulmonary aspiration	37	0	2.7	2.7	40.5	54.1*
Preoperative Multiple Agents						
16. Preoperative multiple agents should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	37	0	2.7	0	43.2	54.1*

Survey rate of return was 59.7% (37 of 62) for consultants.

* Median response.

NPO = Nil Per Os (nothing by mouth).

Table 4. American Society of Anesthesiologists Members Responses per Survey Item (N = 471)

	Response, No.	Response, %				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Preoperative Assessment						
1. A review of pertinent records, a physical examination, and patient survey or interview should be performed as part of the preoperative evaluation	470	93.2*	6.0	0.4	0.2	0.2
2. Patients should be informed of fasting requirements and the reasons for them sufficiently in advance of their procedures	470	93.4*	6.4	0	0	0.2
3. Verification of patient compliance with the fasting requirements should be assessed immediately prior to the time of the procedure	468	88.5*	9.6	1.3	0.2	0.4
Preoperative NPO Status						
Clear liquids						
4a. For otherwise healthy *infants* (<2 yr of age), fasting from the intake of clear liquids for *2 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	471	66.9*	25.1	5.7	2.1	0.2
4b. For otherwise healthy *children* (2 to 16 yr of age), fasting from the intake of clear liquids for *2 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	467	67.0*	23.3	5.6	3.6	0.4
4c. For otherwise healthy *adults*, fasting from the intake of clear liquids for *2 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	465	64.5*	21.5	6.0	6.5	1.5
Breast milk						
5a. For otherwise healthy *neonates* (<44 gestational weeks), fasting from the intake of breast milk for *4 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	465	53.6*	29.5	13.1	3.0	0.9
5b. For otherwise healthy *infants*, fasting from the intake of breast milk for *4 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	466	55.6*	32.4	8.6	2.8	0.6
Infant formula						
6a. For *neonates*, fasting from the intake of infant formula for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	455	45.7	30.1*	16.9	5.9	1.3
6b. For infants, fasting from the intake of infant formula for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	459	47.9	33.8*	12.4	4.8	1.1

(*continued*)

Table 4. Continued

	Response, No.	Response, %				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
6c. For children, fasting from the intake of infant formula for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	456	52.6*	32.5	10.5	3.3	1.1
Nonhuman milk						
7a. For infants, fasting from the intake of non-human milk for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	458	47.6	33.4*	12.5	5.0	1.5
7b. For children, fasting from the intake of non-human milk for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	460	51.1*	34.4	8.4	4.8	1.3
7c. For adults, fasting from the intake of non-human milk for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	462	55.6*	33.3	5.0	4.8	1.3
Solids						
8. Fasting from the intake of a *light meal* (*e.g.*, toast and a clear liquid) for *6 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	468	59.0*	29.7	4.1	6.2	1.1
9. Fasting from the intake of a meal that includes *fried or fatty foods* for *8 or more hours* before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) should be maintained	470	68.5*	22.6	4.7	3.6	0.6
Preoperative Gastrointestinal Stimulants						
10. Gastrointestinal stimulants should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	468	1.9	4.5	8.3	48.8*	36.5
Preoperative Pharmacologic Blockade of Gastric Acid Secretion						
11. Histamine-2 receptor antagonists should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	470	4.0	7.9	9.2	44.7*	34.2
12. Proton pump inhibitors should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	470	1.3	3.6	11.9	46.8*	36.4

(*continued*)

Table 4. Continued

	Response, No.	Response, %				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Preoperative Antacids						
13a. Preoperative antacids should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	467	0.6	2.8	6.6	52.0*	37.9
13b. When antacids are indicated for selected patients, only non-particulate antacids should be used	466	65.2*	28.5	4.5	1.5	0.2
Preoperative Antiemetics						
14. Preoperative antiemetics should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	461	4.3	11.9	8.5	49.9*	25.4
Preoperative Anticholinergics						
15. Preoperative anticholinergics should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) to decrease the risk of pulmonary aspiration	466	1.3	1.7	7.6	53.4*	36.1
Preoperative Multiple Agents						
16. Preoperative multiple agents should be routinely administered before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (*i.e.*, monitored anesthesia care) in patients who have *no apparent* increased risk for pulmonary aspiration	470	2.3	4.7	7.9	44.3*	40.9

* Median response.

NPO = Nil Per Os (nothing by mouth).

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