

# Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018

*A Report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology\**

**P**RACTICE 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, these practice guidelines 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 document replaces the “Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: An Updated Report by the American Society of Anesthesiologists (ASA) Task Force on Sedation and Analgesia by Non-Anesthesiologists,” adopted in 2001 and published in 2002.<sup>1</sup>

## Methodology

### Definition of Procedural Moderate Sedation and Analgesia

These guidelines apply to moderate sedation and analgesia before, during, and after procedures. Sedation and analgesia comprises a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia, as defined by the American Society of Anesthesiologists and accepted by the Joint Commission (table 1).<sup>2,3</sup> Level of sedation is entirely independent of the route of administration. Moderate and deep sedation or general anesthesia may be achieved *via* any route of administration.

### Update Highlights

In October 2014, the American Society of Anesthesiologists Committee on Standards and Practice Parameters recommended that new practice guidelines addressing moderate procedural sedation and analgesia be developed.

These new guidelines:

- Replace the “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,” published in 2002.<sup>1</sup>
- Specifically address moderate sedation. They do not address mild or deep sedation and do not address the educational, training, or certification requirements for providers of moderate procedural sedation. (Separate Practice Guidelines are under development that will address deep procedural sedation.)
- Differ from previous guidelines in that they were developed by a multidisciplinary task force of physicians from several medical and dental specialty organizations with the intent of specifically addressing moderate procedural sedation provided by any medical specialty in any location.

New recommendations include:

- Patient evaluation and preparation.
- Continual monitoring of ventilatory function with capnography to supplement standard monitoring by observation and pulse oximetry.
- The presence of an individual in the procedure room with the knowledge and skills to recognize and treat airway complications.
- Sedatives and analgesics not intended for general anesthesia (e.g., benzodiazepines and dexmedetomidine).
- Sedatives and analgesics intended for general anesthesia (e.g., propofol, ketamine, and etomidate).
- Recovery care.
- Creation and implementation of quality improvement processes.

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These guidelines specifically apply to the level of sedation corresponding to moderate sedation/analgesia (previously called conscious sedation), which is defined as 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 when spontaneous ventilation is adequate.‡ Cardiovascular function is usually maintained. For these guidelines, analgesia refers to the management of patient pain or discomfort during and after procedures requiring moderate sedation.

### Purposes of the Guidelines

The purposes of these guidelines are to allow clinicians to optimize the benefits of moderate procedural sedation regardless of site of service; to guide practitioners in appropriate patient selection; to decrease the risk of adverse patient outcomes (e.g., apnea, airway obstruction, respiratory arrest, cardiac arrest, death); to encourage sedation education, training, and research; and to offer evidence-based data to promote cross-specialty consistency for moderate sedation practice.

Moderate sedation/analgesia provides patient tolerance of unpleasant or prolonged procedures through relief of anxiety, discomfort, and/or pain. If the patient response results in deeper sedation than intended, these sedation practices can be associated with cardiac or respiratory depression that must be rapidly recognized and appropriately managed to avoid the risk of hypoxic brain damage, cardiac arrest, or death. Conversely, inadequate sedation or analgesia can result in undue patient discomfort or patient injury, lack of cooperation, or adverse physiological or psychological responses to stress.

The appropriate choice of agents and techniques for moderate sedation/analgesia is dependent upon the experience, training, and preference of the individual practitioner, requirements or constraints imposed by associated medical issues of the patient or type of procedure, and the risk of producing a deeper level of sedation than anticipated. In some cases, the choice of agents or techniques

are limited by federal, state, or municipal regulations or statutes. 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, and support cardiovascular function in patients who become hypotensive, hypertensive, bradycardic, or tachycardic.

### Focus

These guidelines focus specifically on the administration of moderate sedation and analgesia for adults and children. The guidelines exclude patients who are not undergoing a diagnostic or therapeutic procedure (e.g., postoperative analgesia). Because minimal sedation (anxiolysis) may entail minimal risk, the guidelines specifically exclude it. Examples of minimal sedation are (1) less than 50% nitrous oxide in oxygen with no other sedative or analgesic medications by any route and (2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of anxiety or pain. The guidelines do not apply to patients receiving deep sedation, general anesthesia, or major conduction (*i.e.*, neuraxial) anesthesia. Additional interventions excluded from these guidelines include but are not limited to patient-controlled sedation/analgesia, sedatives administered before or during regional and central neuraxis anesthesia, premedication for general anesthesia, interventions without sedatives (e.g., hypnosis, acupuncture), new or rarely administered sedative/analgesics, new or rarely used monitoring or delivery devices, and automated sedative delivery systems. These guidelines do not address education, training, or certification requirements for practitioners who provide moderate procedural sedation.

### Application

These guidelines are intended for use by all providers who perform moderate procedural sedation and analgesia in any inpatient or outpatient setting including but not limited to hospitals, ambulatory procedural centers, hospital-connected or freestanding office practices (e.g., dental, urology, or ophthalmology offices), endoscopy suites, plastic surgery suites, radiology suites (magnetic resonance imaging, computed tomography), oral and maxillofacial surgery suites, cardiac catheterization laboratories, oncology clinics, electrophysiology laboratories, interventional radiology laboratories, neurointerventional laboratories, echocardiography laboratories, and evoked auditory testing laboratories. They are intended to serve as a resource for other physicians and patient care personnel who are involved in the care of these patients, including those involved in local policy development.

This article is featured in "This Month in Anesthesiology," page 1A. Supplemental Digital Content is available for this article. Direct URL citations appear in the printed text and are available in both the HTML and PDF versions of this article. Links to the digital files are provided in the HTML text of this article on the Journal's Web site ([www.anesthesiology.org](http://www.anesthesiology.org)). A complete bibliography used to develop these guidelines, arranged alphabetically by author, is available as Supplemental Digital Content 1, <http://links.lww.com/ALN/B594>.

†Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

‡However, as stated in the American Academy of Pediatrics–American Academy of Pediatric Dentistry guidelines on the monitoring and management of pediatric patients during sedation (2016), "in the case of procedures that may themselves cause airway obstruction (e.g., dental or endoscopic), the practitioner must recognize an obstruction and assist the patient in opening the airway."<sup>4</sup>

### Task Force Members and Consultants

These guidelines were developed by an ASA–appointed task force of 13 members, consisting of physician anesthesiologists in both private and academic practices from various geographic areas of the United States, a cardiologist, a dentist anesthesiologist, an oral/maxillofacial surgeon, a radiologist, an ASA staff methodologist, and two consulting methodologists for the ASA Committee on Standards and Practice Parameters. Conflict of interest documentation regarding current or potential financial and other interests pertinent to the practice guideline were disclosed by all task force members and managed.

The task force developed these guidelines by means of a seven-step process. First, criteria for evidence associated with moderate sedation and analgesia techniques were established. Second, original published research studies relevant to the guidelines were reviewed and analyzed; only articles relevant to the administration of moderate sedation were evaluated. Third, a panel of expert consultants was asked to (1) participate in opinion surveys on the effectiveness and safety of various methods and interventions that might be used during sedation/analgesia and (2) review and comment on a draft of the guidelines developed by the task force. Fourth, survey opinions about the guideline recommendations were solicited from a random sample of active members of the ASA and participating medical specialty societies. Fifth, the task force held open forums at major national meetings to solicit input on its draft recommendations. § National organizations representing specialties whose members typically provide moderate sedation were invited to participate in the open forums. Sixth, the consultants were surveyed to assess their opinions on the feasibility of implementing the guidelines. Seventh, all available information was used to build consensus within the task force to finalize the guidelines.

### Availability and Strength of Evidence

Preparation of these updated guidelines followed a rigorous methodological process. Evidence was obtained from two principal sources: scientific evidence and opinion-based evidence

**Scientific Evidence.** Scientific evidence used in the development of these guidelines is based on cumulative findings from literature published in peer-reviewed journals. Literature citations are obtained from healthcare databases, direct internet searches, task force members, liaisons with other

organizations, and manual searches of references located in reviewed articles.

Findings from the aggregated literature are reported in the text of these guidelines by evidence category, level, and direction. Evidence categories refer specifically to the strength and quality of the *research design* of the studies. Category A evidence represents results obtained from randomized controlled trials (RCTs), and category B evidence represents observational results obtained from nonrandomized study designs or RCTs without pertinent comparison groups. When available, category A evidence is given precedence over category B evidence for any particular outcome. These evidence categories are further divided into evidence levels. Evidence levels refer specifically to the strength and quality of the summarized study *findings* (i.e., statistical findings, type of data, and the number of studies reporting/replicating the findings). In this document, only the highest level of evidence is included in the summary report for each intervention–outcome pair, including a directional designation of benefit, harm, or equivocality.

**Category A.** RCTs report comparative findings between clinical interventions for specified outcomes. Statistically significant ( $P < 0.01$ ) outcomes are designated as either beneficial (B) or harmful (H) for the patient; statistically nonsignificant findings are designated as equivocal (E).

- Level 1: The literature contains a sufficient number of RCTs to conduct meta-analysis, and meta-analytic findings from these aggregated studies are reported as evidence.
- Level 2: The literature contains multiple RCTs, but the number of RCTs is not sufficient to conduct a viable meta-analysis for the purpose of these Guidelines. Findings from these RCTs are reported separately as evidence.
- Level 3: The literature contains a single RCT, and findings from this study are reported as evidence.

**Category B.** Observational studies or RCTs without pertinent comparison groups may permit *inference* of beneficial or harmful relationships among clinical interventions and clinical outcomes. Inferred findings are given a directional designation of beneficial (B), harmful (H), or equivocal (E). For studies that report statistical findings, the threshold for significance is  $P < 0.01$ .

- Level 1: The literature contains nonrandomized comparisons (e.g., quasiexperimental, cohort [prospective or retrospective], or case-control research designs) with comparative statistics between clinical interventions for a specified clinical outcome.

§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. A minimum of five independent RCTs are required for meta-analysis.

§American Dental Association Council on Dental Education and Licensure: Anesthesia Committee Meeting, April 20, 2017; 2017 Combined Annual Meeting of the Southwest Society of Oral and Maxillofacial Surgeons, the Texas Society of Oral and Maxillofacial Surgeons, the Midwestern Chapter of Oral and Maxillofacial Surgeons, and the Oklahoma Society of Oral and Maxillofacial Surgeons, April 21, 2017, Scottsdale, Arizona; the Society for Ambulatory Anesthesia 32nd Annual Meeting, May 5, 2017, Scottsdale, Arizona; International Anesthesia Research Society 2017 Annual Meeting; and the International Science Symposium, Washington, D.C., May 8, 2017.

- Level 2: The literature contains noncomparative observational studies with associative statistics (e.g., relative risk, correlation, sensitivity, and specificity).
- Level 3: The literature contains noncomparative observational studies with descriptive statistics (e.g., frequencies, percentages).
- Level 4: The literature contains case reports.

**Insufficient Literature.** The *lack* of sufficient scientific evidence in the literature may occur when the evidence is either unavailable (i.e., no pertinent studies found) or inadequate. Inadequate literature cannot be used to assess relationships among clinical interventions and outcomes because a clear interpretation of findings is not obtained due to methodological concerns (e.g., confounding of study design or implementation) or the study does not meet the criteria for content as defined in the “Focus” of the guidelines.

**Opinion-based Evidence.** All opinion-based evidence (e.g., survey data, open forum testimony, internet-based comments, letters, and editorials) relevant to each topic was considered in the development of these guidelines. However, only the findings obtained from formal surveys are reported in the document.

Opinion surveys were developed by the task force to address each clinical intervention identified in the document. Identical surveys were distributed to expert consultants and a random sample of members of the participating organizations.

**Expert and Participating Membership Opinion Surveys.** Survey findings from task force–appointed expert consultants, a random sample of the ASA membership, and membership samples from the American Association of Oral and Maxillofacial Surgeons (AAOMS) and the American Society of Dentist Anesthesiologists (ASDA) are fully reported in this document. Survey responses were recorded using a 5-point scale and summarized based on median values.

- Strongly Agree: Median score of 5 (at least 50% of the responses are 5)
- Agree: Median score of 4 (at least 50% of the responses are 4 or 4 and 5)
- Equivocal: Median score of 3 (at least 50% of the responses are 3, or no other response category or combination of similar categories contain at least 50% of the 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)

**Informal Opinion.** Open forum testimony obtained during development of these guidelines, internet-based comments, letters, and editorials are all informally evaluated and discussed during the formulation of guideline recommendations. When warranted, the task force may add educational information or cautionary notes based on this information.

## Guidelines

### Patient Evaluation

Preprocedure *patient evaluation* consists of the following strategies for reducing sedation-related adverse outcomes: (1) reviewing previous medical records for underlying medical problems (e.g., abnormalities of major organ systems, obesity, obstructive sleep apnea, anatomical airway problems, congenital syndromes with associated medical/surgical issues, respiratory disease, allergies, intestinal inflammation); sedation, anesthesia, and surgery history; history of or current problems pertaining to cooperation, pain tolerance, or sensitivity to anesthesia or sedation; current medications; extremes of age; psychotropic drug use; use of nonpharmaceuticals (e.g., nutraceuticals); and family history; (2) a focused physical examination; and (3) preprocedure laboratory testing (where indicated).

**Literature Findings.** Although it is well accepted clinical practice to review medical records, conduct a physical examination, and review laboratory test results, comparative studies are insufficient to evaluate the periprocedural impact of these activities. Observational studies indicate that some adverse outcomes (e.g., unintended deep sedation, hypoxemia,<sup>##</sup> or hypotension) may occur in patients with preexisting medical conditions when moderate sedation/analgesia is administered. These conditions include: (1) extremes of age, ASA status III or higher, and respiratory conditions (category B2-H evidence)<sup>5-7</sup>; and (2) obstructive sleep apnea, respiratory distress syndrome, obesity, allergies, psychotropic drug use, history of gastric bypass surgery, pediatric patients who are preoperative or who have behavior or attention disorders, cardiovascular disorders, history of gastric bypass, and history of long-term benzodiazepine use (category B3-H evidence).<sup>8-22</sup> Case reports indicate similar adverse outcomes for newborns, a patient with mitochondrial disease, a patient with grand mal epilepsy, and a patient with a history of benzodiazepine use (category B4-H evidence).<sup>23-26</sup>

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendations to (1) review previous medical records and interview the patient or family, (2) conduct a focused physical examination of the patient, and (3) review available laboratory test results. The consultants and ASA members agree with the recommendation to, if possible, perform the preprocedure evaluation well enough in advance (e.g., several days to weeks) to allow for optimal patient preparation; the AAOMS members and ASDA members strongly agree with this recommendation. Finally, consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendation to reevaluate the patient immediately before the procedure.

<sup>#</sup>Unless otherwise noted in this document, hypoxemia is reported in the literature to be oxygen desaturation to at most 90%.

<sup>\*\*</sup>This may not be feasible for urgent or emergency procedures, interventional radiology, or other radiology settings.

### Recommendations for Patient Evaluation

- Review previous medical records and interview the patient or family to identify:
  - Abnormalities of the major organ systems (*e.g.*, cardiac, renal, pulmonary, neurologic, sleep apnea, metabolic, endocrine)
  - Adverse experience with sedation/analgesia, as well as regional and general anesthesia
  - History of a difficult airway
  - Current medications, potential drug interactions, drug allergies, and nutraceuticals
  - History of tobacco, alcohol or substance use or abuse
  - Frequent or repeated exposure to sedation/analgesic agents
- Conduct a focused physical examination of the patient (*e.g.*, vital signs, auscultation of the heart and lungs, evaluation of the airway,†† and, when appropriate to sedation, other organ systems where major abnormalities have been identified)
- Review available laboratory test results
  - Order additional laboratory tests guided by a patient's medical condition, physical examination, and the likelihood that the results will affect the management of moderate sedation/analgesia
  - Evaluate results of these tests before sedation is initiated
- If possible, perform the preprocedure evaluation well enough in advance (*e.g.*, several days to weeks) to allow for optimal patient preparation.\*\*
- Reevaluate the patient immediately before the procedure.

### Preprocedure Patient Preparation

Preprocedure *patient preparation* consists of (1) consultation with a medical specialist when needed; (2) patient preparation for the procedure (*e.g.*, informing patients of the benefits and risks of sedatives and analgesics, preprocedure instruction, medication usage, counseling); and (3) preprocedure fasting from solids and liquids.

**Literature Findings.** The literature is insufficient regarding the benefits of consultation with a medical specialist or providing the patient (or legal guardian, in the case of a child or impaired adult) with preprocedure information about sedation and analgesia. A nonrandomized comparative study reported equivocal outcomes (*e.g.*, emesis, apnea, oxygen levels) when preprocedure fasting (*i.e.*, liquids or solids) is compared to no fasting (category B1-E evidence).<sup>27</sup> Another nonrandomized comparison of fasting for less than 2 h *versus* fasting for greater than 2 h reported equivocal findings for emesis, oxygen saturation levels, and arrhythmia for infants (category B1-E evidence).<sup>28</sup> Finally, a third nonrandomized comparison reported

††See table 2 for additional information related to airway assessment.

equivocal findings for gastric volume and pH when fasting of liquids for 0.5 to 3 h is compared with fasting times of greater than 3 h (category B1-E evidence).<sup>29</sup>

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendations to (1) consult with a medical specialist, when appropriate, before administration of moderate procedural sedation to patients with significant underlying conditions; (2) when feasible before the procedure, inform patients or legal guardians of the benefits, risks, and limitations of moderate sedation/analgesia and possible alternatives, and elicit their preferences; (3) before the day of the procedure, inform patients or legal guardians that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying; and (4) on the day of the procedure, assess the time and nature of the last oral intake. All four groups of survey respondents agreed with the recommendation that in urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone.

### Recommendations for Preprocedure Patient Preparation

- Consult with a medical specialist (*e.g.*, physician anesthesiologist, cardiologist, endocrinologist, pulmonologist, nephrologist, pediatrician, obstetrician, or otolaryngologist), when appropriate before administration of moderate procedural sedation to patients with significant underlying conditions
  - If a specialist is needed, select a specialist based on the nature of the underlying condition and the urgency of the situation
  - For severely compromised or medically unstable patients (*e.g.*, ASA status IV, 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, consult with a physician anesthesiologist
- Before the procedure, inform patients or legal guardians of the benefits, risks, and limitations of moderate sedation/analgesia and possible alternatives and elicit their preferences‡‡
- Inform patients or legal guardians before the day of the procedure that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before the procedure§§

‡‡This may not be feasible for urgent or emergency procedures.

§§See table 3 and/or refer to: 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: An updated report. *ANESTHESIOLOGY* 2017; 126:376–93.

- On the day of the procedure, assess the time and nature of last oral intake
  - Evaluate the risk of pulmonary aspiration of gastric contents when determining (1) the target level of sedation and (2) whether the procedure should be delayed
- In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone

### Patient Monitoring

Many of the complications associated with moderate sedation and analgesia may 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 may be at increased risk of these complications. Patient monitoring includes strategies for the following: (1) monitoring patient level of consciousness assessed by the response of patients, including spoken responses to commands or other forms of bidirectional communication during procedures performed with moderate sedation/analgesia<sup>||</sup>; (2) monitoring patient ventilation and oxygenation, including ventilatory function, by observation of qualitative clinical signs, capnography, and pulse oximetry; (3) hemodynamic monitoring, including blood pressure, heart rate, and electrocardiography; (4) contemporaneous recording of monitored parameters; and (5) availability/presence of an individual responsible for patient monitoring.

**Literature Findings.** The literature is insufficient to determine whether monitoring patients' level of consciousness improves patient outcomes or decreases risks. Also, the literature is insufficient to evaluate whether observation of the patient, auscultation, chest excursion, or plethysmography are associated with reduced sedation-related risks.

Meta-analysis of RCTs indicate that the use of continuous end-tidal carbon dioxide monitoring (*i.e.*, capnography) is associated with a reduced frequency of hypoxemic events (*i.e.*, oxygen saturation less than 90%) when compared to monitoring without capnography (*e.g.*, practitioners were blinded to capnography results) during procedures with moderate sedation (category A1-B evidence).<sup>30–34</sup> Findings for this comparison were equivocal for RCTs reporting severe hypoxemic events (*i.e.*, oxygen saturation less than 85%)<sup>30,32,33</sup> and for oxygen saturation levels of 92, 93, and 95% (category A2-E evidence).<sup>31,34–36</sup> Observational studies indicate that pulse oximetry is effective in the detection of oxygen saturation levels in patients administered sedatives and analgesics (category B3-B evidence).<sup>37–63</sup>

<sup>||</sup> Patients whose only response is reflex withdrawal from painful stimuli are deeply sedated, approaching a state of general anesthesia, and should be treated accordingly.

Observational studies also indicate that electrocardiography monitoring is effective in the detection of arrhythmias, premature ventricular contractions, and bradycardia (category B3-B evidence).<sup>46,49,64</sup>

The literature is insufficient to determine the benefits of contemporaneous recording of patients' level of consciousness, respiratory function, or hemodynamics. In addition, the literature is insufficient to evaluate whether the presence of an individual dedicated to patient monitoring will reduce adverse outcomes related to moderate sedation/analgesia.

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members agree with the recommendations to (1) periodically monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately or during procedures where movement could be detrimental clinically; and (2) during procedures where a verbal response is not possible, check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation. The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendations to (1) continually monitor ventilatory function by observation of qualitative clinical signs; (2) continually monitor ventilatory function with capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment; (3) monitor all patients by pulse oximetry with appropriate alarms; (4) determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation; (5) once moderate sedation/analgesia is established, continually monitor blood pressure and heart rate during the procedure unless such monitoring interferes with the procedure; (6) use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated; (7) record patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables 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; (8) set device alarms to alert the care team to critical changes in patient; (9) assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure; and (10) the individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be authorized to seek additional help. The consultants, ASA members, and ASDA members agree that the designated 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; the AAOMS members strongly agree with this recommendation.

### Recommendations for Patient Monitoring Monitoring Patient Level of Consciousness

- Periodically (*e.g.*, at 5-min intervals) monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately (*e.g.*, patients whose age or development may impair bidirectional communication) or during procedures where movement could be detrimental
- During procedures where a verbal response is not possible (*e.g.*, oral surgery, restorative dentistry, upper endoscopy), check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation; this suggests that the patient will be able to control his airway and take deep breaths if necessary##

### Monitoring Patient Ventilation and Oxygenation

- Continually\*\*\* monitor ventilatory function by observation of qualitative clinical signs
- Continually monitor ventilatory function with capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment
  - For uncooperative patients, institute capnography after moderate sedation has been achieved
- Continuously monitor all patients by pulse oximetry with appropriate alarms

### Monitoring Hemodynamics

- Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation
- Once moderate sedation/analgesia is established, continually monitor blood pressure (*e.g.*, at 5-min intervals) and heart rate during the procedure unless such monitoring interferes with the procedure (*e.g.*, magnetic resonance imaging where stimulation from the blood pressure cuff could arouse an appropriately sedated patient)
- Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated

##A response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

\*\*\*The term *continual* is defined as "repeated regularly and frequently in steady rapid succession," whereas *continuous* means "prolonged without any interruption at any time" (see Standards for Basic Anesthetic Monitoring, American Society of Anesthesiologists. Approved by the ASA House of Delegates October 21, 1986, and last amended October 28, 2015. Available at: <http://www.asahq.org/quality-and-practice-management/practice-guidance-resource-documents/standards-for-basic-anesthetic-monitoring>. Accessed on August 21, 2017).

### Contemporaneous Recording of Monitored Parameters

- Record patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables 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 occur (1) before the administration of sedative/analgesic agents†††; (2) after administration of sedative/analgesic agents; (3) at regular intervals during the procedure; (4) during initial recovery; and (5) just before discharge
- Set device alarms to alert the care team to critical changes in patient status

### Availability of an Individual Responsible for Patient Monitoring

- Assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure
  - The individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be authorized to seek additional help
  - The designated individual should not be a member of the procedural team but 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

### Supplemental Oxygen

**Literature Findings.** Meta-analysis of RCTs indicate that the use of supplemental oxygen *versus* no supplemental oxygen is associated with a reduced frequency of hypoxemia‡‡‡ during procedures with moderate sedation (category A1-B evidence).<sup>65–71</sup> The literature is insufficient to examine which methods of supplemental oxygen administration (*e.g.*, nasal cannula, face mask, or specialized devices) are more effective in reducing hypoxemia.

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendation to use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure.

†††For rare uncooperative patients (*e.g.*, children with autism spectrum disorder or attention deficit disorder), recording oxygenation status or blood pressure may not be possible until after sedation.

‡‡‡Reported by authors as oxygen desaturation to at most 95% or oxygen desaturation more than 5 or 10% below baseline.

### Recommendations for Supplemental Oxygen

- Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure

### Emergency Support

Emergency support strategies include (1) the presence of pharmacologic antagonists; (2) the presence of age and weight appropriate emergency airway equipment (*e.g.*, different types of airway devices, supraglottic airway devices); (3) the presence of an individual capable of establishing a patent airway and providing positive pressure ventilation and resuscitation; (4) the presence of an individual to establish intravenous access; and (5) the availability of rescue support.

**Literature Findings.** Although it is established clinical practice to provide access to emergency support, the literature is insufficient to assess the benefits or harms of keeping pharmacologic antagonists or emergency airway equipment available during procedures with moderate sedation and analgesia. The literature is insufficient to assess whether the presence of an individual capable of establishing a patent airway, positive pressure ventilation, and resuscitation will improve outcomes. In addition, the literature is insufficient to determine the benefits of keeping an individual present to establish intravenous access during procedures with moderate sedation/analgesia. Finally, the literature is insufficient to determine the benefits of rescue support availability during moderate procedural sedation/analgesia.

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendation to assure that (1) pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure suite or procedure room; (2) an individual is present in the room who understands the pharmacology of the sedative/analgesics administered and potential interactions with other medications and nutraceuticals the patient may be taking; (3) appropriately sized equipment for establishing a patent airway is available; (4) at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room; (5) suction, advanced airway equipment, positive pressure ventilation, and supplemental oxygen are immediately available in the procedure room and in good working order; (6) a member of the procedural team is trained in the recognition and treatment of airway complications, opening the airway, suctioning secretions, and performing bag-valve-mask ventilation; (7) a member of the procedural team has the skills to establish intravascular access; (8) a member of the procedural team has the skills to provide chest compressions; (9) a functional defibrillator or automatic external defibrillator is immediately available in the procedure area; (10) an individual or service is immediately available with advanced life support skills; and (11) members of the procedural team are

able to recognize the need for additional support and know how to access emergency services from the procedure room.

### Recommendations for Emergency Support§§§

- Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure suite or procedure room|| ||
- Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered (*e.g.*, opioids and benzodiazepines) and potential interactions with other medications and nutraceuticals the patient may be taking
- Assure that appropriately sized equipment for establishing a patent airway is available
- Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room
- Assure that suction, advanced airway equipment, a positive pressure ventilation device, and supplemental oxygen are immediately available in the procedure room and in good working order
  - Assure that a member of the procedural team is trained in the recognition and treatment of airway complications (*e.g.*, apnea, laryngospasm, airway obstruction), opening the airway, suctioning secretions, and performing bag-valve-mask ventilation
- Assure that a member of the procedural team has the skills to establish intravascular access
- Assure that a member of the procedural team has the skills to provide chest compressions
- Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area
- Assure that an individual or service (*e.g.*, code blue team, paramedic-staffed ambulance service) with advanced life support skills (*e.g.*, tracheal intubation, defibrillation, resuscitation medications) is immediately available
- Assure that members of the procedural team are able to recognize the need for additional support and know how to access emergency services from the procedure room (*e.g.*, telephone, call button)

### Sedative/Analgesic Medications Not Intended for General Anesthesia

For these guidelines, sedatives not intended for general anesthesia include benzodiazepines (*e.g.*, midazolam, diazepam,

§§§Refer to table 4 for examples of emergency support equipment and pharmaceuticals.

|| || | "Immediately available in the procedure room" refers to easily accessible shelving, cabinetry, and other measures to assure that there is no delay in accessing medications and equipment during the procedure.



flunitrazepam, lorazepam, or temazepam) and dexmedetomidine. Analgesics administered with sedatives include opioids such as fentanyl, alfentanil, remifentanyl, meperidine, morphine, and nalbuphine. This section of the guidelines addresses the following topics: (1) benzodiazepines and dexmedetomidine, (2) sedative/opioid combinations, (3) intravenous *versus* nonintravenous sedatives/analgesics not intended for general anesthesia,### and (4) titration of sedatives/analgesics not intended for general anesthesia.

**Literature Findings.** Meta-analysis of RCTs comparing midazolam combined with opioids *versus* midazolam alone report equivocal findings for pain and discomfort,<sup>72-77</sup> hypoxemia,<sup>\*\*\*74,75,77-80</sup> and patient recall of the procedure.<sup>72-74,77,80-83</sup> (category A1-E evidence). When midazolam combined with opioids are compared with opioids alone, RCTs report equivocal findings for patient recall, pain during the procedure, frequency of hypoxemia,### hypercarbia and respiratory depression (category A2-E evidence).<sup>75,78,83-85</sup>

One RCT comparing dexmedetomidine with midazolam reports equivocal outcomes for recovery time, oxygen saturation levels, apnea, and bradycardia (category A3-E evidence).<sup>86</sup> Another RCT reports a longer recovery time for dexmedetomidine compared with midazolam (category A3-H evidence), with equivocal findings for analgesia scores, oxygen saturation levels, respiratory rate, blood pressure, and pulse rate (category A3-E evidence).<sup>87</sup> One RCT reports a lower frequency of hypoxemia when dexmedetomidine is combined with an opioid analgesic compared with midazolam combined with an opioid analgesic (category A3-B evidence).<sup>88</sup> One RCT reports deeper sedation (*i.e.*, higher sedation scores) and a lower frequency of hypoxemia when dexmedetomidine combined with midazolam and meperidine is compared with midazolam combined with meperidine (category A3-B evidence).<sup>89</sup>

One RCT comparing intravenous midazolam with intramuscular midazolam reports equivocal findings for oxygen saturation levels, respiratory rate, and heart rate (category A3-E evidence).<sup>90</sup> One RCT comparing intravenous midazolam with intranasal midazolam reports equivocal findings for sedation efficacy (category A3-E evidence), but discomfort from the nasal administration was reported for all intranasal patients with no nasal discomfort from the intravenous patients (category A3-B evidence).<sup>91</sup> One RCT comparing intravenous diazepam with rectal diazepam reports lower recall for the intravenous method (category A3-B evidence); findings were equivocal for sedative effect, anxiety, and crying (category A3-E evidence).<sup>92</sup> One RCT comparing intravenous with intranasal dexmedetomidine reported equivocal

findings for sedation time, duration of the procedure, and the frequency of rescue doses of midazolam administered (category A3-E evidence).<sup>93</sup>

One RCT comparing titration (*i.e.*, administration of small, incremental doses of intravenous midazolam combined with meperidine until the desired level of sedation and/or analgesia is achieved) of midazolam combined with an opioid compared with a single, rapid bolus reports higher total physician times, medication dosages, frequencies of hypoxemia, and somnolence scores for titration (category A3-H evidence).<sup>94</sup>

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendation that combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient. The consultants, ASA members, and ASDA members agree that dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis; the AAOMS members are equivocal regarding this recommendation. The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendation that in patients receiving intravenous medications for sedation/analgesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression. The consultants agree and the ASA members, AAOMS members, and ASDA members strongly agree that in patients who have received sedation/analgesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of reestablishing intravenous access on a case-by-case basis. Finally, the consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendation to administer intravenous sedative/analgesic drugs in small, incremental doses, or by infusion, titrating to the desired endpoints.

#### **Recommendations for Sedative or Analgesic Medications Not Intended for General Anesthesia**

- Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient††††
  - Administer each component individually to achieve the desired effect (*e.g.*, additional analgesic medication to relieve pain; additional sedative medication to decrease awareness or anxiety)
- Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis

††††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. Knowledge of each drug's time of onset, peak response, and duration of action is important. Titration of drug to effect is an important concept; one must know whether the previous dose has taken full effect before administering additional drug.

###All routes of administration were considered, including oral, nasal, intramuscular, rectal, transdermal, sublingual, iontophoresis, and nebulization.

\*\*\*Reported by authors as oxygen desaturation to less than 94, 93, or 90%.

- In patients receiving intravenous medications for sedation/analgesia, maintain vascular access 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, determine the advisability of reestablishing intravenous access on a case-by-case basis
- Administer intravenous sedative/analgesic drugs in small, incremental doses, or by infusion, titrating to the desired endpoints
  - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration
- When drugs are administered by nonintravenous routes (e.g., oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to occur before supplementation is considered

### Sedative/Analgesic Medications Intended for General Anesthesia

For these guidelines, sedatives intended for general anesthesia include propofol, ketamine and etomidate. Sedatives not intended for general anesthesia (e.g., benzodiazepines, nitrous oxide, chloral hydrate, barbiturates, and antihistamines) are included either as comparison groups or in combination with sedatives intended for general anesthesia. Analgesics (e.g., opioids, nonsteroidal antiinflammatory drugs, and local anesthetics) are included either in comparison groups or in combination with sedatives intended for general anesthesia. This section of the guidelines addresses the following topics: (1) propofol *versus* other sedative/analgesics, (2) ketamine *versus* other sedative/analgesics, (3) etomidate *versus* other sedative/analgesics, (4) combinations of sedatives intended for general anesthesia *versus* other sedatives/analgesics, alone or in combination, (5) intravenous *versus* nonintravenous sedatives/analgesics intended for general anesthesia, and (6) titration of intravenous sedatives/analgesics intended for general anesthesia.

**Literature Findings.** Literature comparing propofol with other sedative/analgesic medications, either alone or in combination, report the following findings: (1) Meta-analysis of RCTs report faster recovery times for propofol *versus* midazolam after procedures with moderate sedation (category A1-B evidence),<sup>95-99</sup> with equivocal findings for patient recall,<sup>95,100-103</sup> and frequency of hypoxemia (category A1-E evidence).<sup>96,100,102,103</sup> One RCT reports shorter sedation time, a lower frequency of recall and higher recovery scores for propofol *versus* diazepam (category A3-B evidence).<sup>104</sup> (2)

¶¶¶¶Note that these guidelines do not address education, training, or certification requirements for practitioners who provide moderate procedural sedation with these drugs.

RCTs comparing propofol *versus* benzodiazepines combined with opioid analgesics report shorter sedation and recovery times for propofol alone (category A2-B evidence),<sup>105,106</sup> with equivocal findings for pain, oxygen saturation levels, and blood pressure (category A2-E evidence).<sup>107-109</sup> (3) RCTs comparing propofol combined with benzodiazepines *versus* propofol alone report equivocal findings for recovery and procedure times, pain with injection, and restlessness (category A2-E evidence).<sup>110-112</sup> One RCT comparing propofol combined with midazolam *versus* propofol alone reports deeper sedation levels and more episodes of deep sedation for the combination group (category A3-H evidence).<sup>112</sup> RCTs comparing propofol combined with opioid analgesics *versus* propofol alone report lower pain scores for the combination group (category A2-B evidence),<sup>113,114</sup> with equivocal findings for sedation levels, oxygen saturation levels, and respiratory and heart rates (category A2-E evidence).<sup>113-116</sup> (4) One RCT comparing propofol combined with remifentanyl *versus* remifentanyl alone reports deeper sedation, less recall (category A3-B evidence), and more respiratory depression (category A3-H evidence) for the combination group.<sup>117</sup> (5) RCTs comparing propofol combined with sedatives/analgesics not intended for general anesthesia *versus* combinations of sedatives/analgesics not intended for general anesthesia report equivocal findings for outcomes including sedation time, patient recall, pain scores, recovery time, oxygen saturation levels, blood pressure, and heart rate (category A2-E evidence).<sup>118-136</sup> (6) RCTs comparing propofol with ketamine report equivocal findings for sedation scores, pain during the procedure, recovery, oxygen saturation levels, respiratory rate, blood pressure, and heart rate (category A2-E evidence).<sup>137,138</sup> (7) One RCT comparing propofol *versus* ketamine combined with midazolam reports equivocal findings for recovery agitation, oxygen saturation levels, respiratory rate, blood pressure, and heart rate (category A3-E evidence).<sup>139</sup> (8) One RCT comparing propofol *versus* ketamine combined with fentanyl reports shorter recovery times and less recall for propofol alone (category A3-E evidence).<sup>140</sup> (9) RCTs comparing propofol combined with ketamine *versus* propofol alone report deeper sedation for the combination group (category A3-B evidence),<sup>141</sup> with more respiratory depression and a greater frequency of hypoxemia (category A3-H evidence).<sup>142</sup>

Literature comparing ketamine with other sedative/analgesic medications, either alone or in combination, report the following findings: (1) RCTs comparing ketamine with midazolam report equivocal findings for sedation scores, recovery time, and oxygen saturation levels (category A2-E evidence).<sup>87,143,144</sup> (2) One RCT comparing ketamine *versus* nitrous oxide reports longer sedation times and higher levels of sedation (i.e., deeper sedation levels) for ketamine (category A3-H evidence).<sup>145</sup> (3) One RCT comparing ketamine with midazolam combined with fentanyl reports a lower

§§§§Reported by author as oxygen desaturation to less than 94%.

depth of sedation for ketamine (category A3-B evidence), with equivocal findings for recall, pain scores and frequency of hypoxemia (category A3-E evidence).<sup>146</sup> (4) RCTs comparing ketamine combined with midazolam *versus* ketamine alone or midazolam alone report equivocal findings for sedation scores, sedation time, recovery, and recovery agitation (category A2-E evidence).<sup>143,147,148</sup> (5) One RCT comparing ketamine combined with midazolam *versus* midazolam combined with alfentanil reports a lower frequency of hypoxemia (category A3-B evidence) and increased disruptive movements, longer recovery times, and longer times to discharge for ketamine combined with midazolam (category A3-H evidence).<sup>149</sup> (6) RCTs comparing ketamine with propofol report equivocal findings for sedation scores, pain during the procedure, oxygen saturation levels, and recovery scores (category A2-E evidence).<sup>137,138</sup> RCTs comparing ketamine with etomidate report less airway assistance required and lower frequencies of myoclonus with ketamine (category A2-B evidence).<sup>150,151</sup> (7) RCTs comparing ketamine combined with propofol *versus* propofol combined with fentanyl report equivocal findings for recovery times, oxygen saturation levels, respiratory rate, and heart rate (category A3-H evidence).<sup>152-154</sup>

Literature comparing etomidate with other sedative/analgesic medications, either alone or in combination, report the following findings: (1) One RCT comparing etomidate with midazolam reports shorter sedation times for etomidate (category A3-B evidence), with equivocal findings for recovery agitation, oxygen saturation levels, and apnea (category A3-E evidence).<sup>155</sup> (2) One RCT comparing etomidate with pentobarbital reports shorter sedation times for etomidate (category A3-B evidence), with equivocal findings for recovery agitation and hypotension (category A3-B evidence).<sup>156</sup> (3) One RCT comparing etomidate combined with fentanyl *versus* midazolam combined with fentanyl reports deeper sedation (*i.e.*, higher sedation scores) for the combination group (category A3-B evidence), with equivocal findings for sedation times, recovery times, frequency of oversedation, and oxygen saturation levels (category A3-E evidence), and a higher frequency of myoclonus (category A3-H evidence).<sup>157</sup> (4) One RCT comparing etomidate combined with morphine and fentanyl *versus* midazolam combined with morphine and fentanyl reports shorter sedation times for the etomidate combination (category A3-B evidence), with equivocal findings for oxygen saturation levels, apnea, hypotension, and recovery agitation (category A3-E evidence), and a higher frequency of patient recall and myoclonus (category A3-H evidence).<sup>158</sup>

One RCT reports shorter sedation onset times, shorter recovery times, and fewer rescue doses administered for intravenous ketamine when compared with intramuscular ketamine (category A3-B evidence), with equivocal findings for sedation efficacy, respiratory depression, and time to discharge (category A3-E evidence).<sup>159</sup> One RCT comparing intravenous *versus* intramuscular ketamine with or without

midazolam reports equivocal findings for sedation time, recovery agitation, and duration of the procedure (category A3-E evidence).<sup>148</sup>

Observational studies reporting titrated administration of sedatives intended for general anesthesia report the frequency of hypoxemia ranging from 1.7 to 4.7% of patients,<sup>14,160-163</sup> with oversedation occurring in 0.13%-0.2% of patients.<sup>14,161</sup>

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendations to (1) provide care consistent with that required for general anesthesia when moderate procedural sedation with sedative or analgesic medications intended for general anesthesia by any route is intended; (2) assure that practitioners administering these drugs are able to reliably rescue patients from unintended deep sedation or general anesthesia; (3) maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression for patients receiving intravenous sedatives intended for general anesthesia; (4) determine the advisability of reestablishing intravenous access on a case-by-case basis in patients who have received sedatives intended for general anesthesia by nonintravenous routes or whose intravenous line has become dislodged or blocked; and (5) administer intravenous sedative/analgesic drugs intended for general anesthesia in small, incremental doses, or by infusion, titrating to the desired endpoints.

#### Recommendations for Sedative/Analgesic Medications Intended for General Anesthesia

- When moderate procedural sedation with sedative/analgesic medications intended for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia
- Assure that practitioners administering sedative/analgesic medications intended for general anesthesia are able to reliably identify and rescue patients from unintended deep sedation or general anesthesia
- For patients receiving intravenous sedative/analgesic medications intended for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression
- In patients who have received sedative/analgesic medications intended for general anesthesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of reestablishing intravenous access on a case-by-case basis
- Administer intravenous sedative/analgesic medications intended for general anesthesia in small, incremental doses or by infusion, titrating to the desired endpoints
  - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration

- When drugs intended for general anesthesia are administered by nonintravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to occur before supplementation is considered

### Reversal Agents: Naloxone and Flumazenil

**Literature Findings.** One placebo-controlled RCT reports that naloxone effectively reverses the effects of meperidine as measured by increasing alertness scores and respiratory rate (category A3-B evidence).<sup>164</sup> Reversal of respiratory depression, apnea, and oxygen desaturation after naloxone administration in other practice settings is also reported by observational studies (category B3-B evidence)<sup>165,166</sup> and case reports (category B4-B evidence).<sup>167–170</sup>

Meta-analysis of double-blind placebo-controlled RCTs indicates that flumazenil effectively antagonizes the effects of sedation within 15 min for patients who have been administered benzodiazepines (category A1-B evidence).<sup>171–178</sup> Placebo-controlled RCTs also indicate that flumazenil administration is associated with shorter recovery times for benzodiazepine sedation (category A2-B evidence).<sup>176,179–181</sup> Meta-analysis of placebo-controlled RCTs indicate that flumazenil effectively antagonizes the effects of benzodiazepines when combined with opioids (category A1-B evidence).<sup>182–186</sup>

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendations to (1) assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia, regardless of route of administration; (2) encourage or physically stimulate patients to breathe deeply if patients become hypoxemic or apneic during sedation/analgesia; (3) administer supplemental oxygen if patients become hypoxemic or apneic during sedation/analgesia; (4) provide positive pressure ventilation if spontaneous ventilation is inadequate when patients become hypoxemic or apneic during sedation/analgesia; (5) use reversal agents in cases where airway control, spontaneous ventilation, or positive pressure ventilation is inadequate; (6) administer naloxone to reverse opioid-induced sedation and respiratory depression; (7) administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression; (8) after pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates; and (9) not use sedation regimens that include routine reversal of sedative or analgesic agents.

### Recommendations for Reversal Agents

- Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia, regardless of route of administration

- If patients develop hypoxemia, significant hypoventilation or apnea during sedation/analgesia: (1) encourage or physically stimulate patients to breathe deeply, (2) administer supplemental oxygen, and (3) provide positive pressure ventilation if spontaneous ventilation is inadequate
- Use reversal agents in cases where airway control, spontaneous ventilation or positive pressure ventilation are inadequate
  - Administer naloxone to reverse opioid-induced sedation and respiratory depression || || || ||
  - Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression
- After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates
- Do not use sedation regimens that are intended to include routine reversal of sedative or analgesic agents

### Recovery Care

Patients receiving moderate procedural sedation may continue to be at risk for developing complications after their procedure is completed. Decreased stimulation from the proceduralist delayed drug absorption after nonintravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period. When sedation/analgesia is administered to outpatients, medical supervision may not be available once the patient leaves the medical facility. This section of the guidelines addresses the following recovery care topics: (1) continued observation and monitoring until discharge and (2) predetermined discharge criteria.

**Literature Findings.** Although it is well accepted clinical practice to continue patient observation until discharge, the literature is insufficient to evaluate the impact of postprocedural observation and monitoring. The literature is also insufficient to evaluate the effects of using predetermined discharge criteria on patient outcomes.

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendations to (1) observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression, (2) monitor oxygenation continuously until patients are no longer at risk for hypoxemia, (3) monitor ventilation and circulation at regular intervals until patients are suitable for discharge, and (4) design discharge criteria to minimize the risk of central

|| || || || Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema.

nervous system or cardiorespiratory depression after discharge from observation by trained personnel.

### Recommendations for Recovery Care

- After sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression
- Monitor oxygenation continuously until patients are no longer at risk for hypoxemia
- Monitor ventilation and circulation at regular intervals (*e.g.*, every 5 to 15 min) until patients are suitable for discharge
- Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel####

### Creation and Implementation of Patient Safety Processes

Patient safety processes include quality improvement and preparation for rare events.

**Literature Findings.** Regarding quality improvement, one observational study reported that use of a pre-sedation checklist compared to no checklist use may improve safety documentation in emergency department sedations (category B1-B evidence).<sup>187</sup>

**Survey Findings.** The consultants, ASA members, AAOMS members, and ASDA members strongly agree with the recommendations to (1) create and implement a quality improvement process based upon established national, regional, or institutional reporting protocols; (2) strengthen patient safety culture through collaborative practices; and (3) create an emergency response plan.

### Recommendations

- Create and implement a quality improvement process based upon established national, regional, or institutional reporting protocols, (*e.g.*, adverse events, unsatisfactory sedation)
  - Periodically update the quality improvement process to keep up with new technology, equipment or other advances in moderate procedural sedation/analgesia
- Strengthen patient safety culture through collaborative practices (*e.g.*, team training, simulation drills, development and implementation of checklists)
- Create an emergency response plan (*e.g.*, activating “code blue” team or activating the emergency medical response system: 911 or equivalent)

####Discharge criteria examples are noted in table 5.

## Appendix I: Summary of Recommendations

### Patient Evaluation

- Review previous medical records and interview the patient or family to identify:
  - Abnormalities of the major organ systems (*e.g.*, cardiac, renal, pulmonary, neurologic, sleep apnea, metabolic, endocrine)
  - Adverse experience with sedation/analgesia, as well as regional and general anesthesia
  - History of a difficult airway
  - Current medications, potential drug interactions, drug allergies, and nutraceuticals
  - History of tobacco, alcohol or substance use or abuse
  - Frequent or repeated exposure to sedation/analgesic agents
- Conduct a focused physical examination of the patient (*e.g.*, vital signs, auscultation of the heart and lungs, evaluation of the airway,\* and when appropriate to sedation, other organ systems where major abnormalities have been identified)
- Review available laboratory test results
  - Order additional laboratory tests guided by a patient’s medical condition, physical examination, and the likelihood that the results will affect the management of moderate sedation/analgesia
  - Evaluate results of these tests before sedation is initiated
- If possible, perform the preprocedure evaluation well enough in advance (*e.g.*, several days to weeks) to allow for optimal patient preparation†
- Reevaluate the patient immediately before the procedure.

### Preprocedure Patient Preparation

- Consult with a medical specialist (*e.g.*, physician anesthesiologist, cardiologist, endocrinologist, pulmonologist, nephrologist, pediatrician, obstetrician, or otolaryngologist), when appropriate before administration of moderate procedural sedation to patients with significant underlying conditions
  - If a specialist is needed, select a specialist based on the nature of the underlying condition and the urgency of the situation
  - For severely compromised or medically unstable patients (*e.g.*, ASA status IV, 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, consult with a physician anesthesiologist

\*See table 2 for additional information related to airway assessment.

†This may not be feasible for urgent or emergency procedures, interventional radiology or other radiology settings.

- Before the procedure, inform patients or legal guardians of the benefits, risks, and limitations of moderate sedation/analgesia and possible alternatives, and elicit their preferences‡
- Inform patients or legal guardians before the day of the procedure that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before the procedure§
- On the day of the procedure, assess the time and nature of last oral intake
  - Evaluate the risk of pulmonary aspiration of gastric contents when determining (1) the target level of sedation and (2) whether the procedure should be delayed
- In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone

## Patient Monitoring

### Monitoring Patient Level of Consciousness

- Periodically (*e.g.*, at 5-min intervals) monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately (*e.g.*, patients where age or development may impair bidirectional communication) or during procedures where movement could be detrimental
- During procedures where a verbal response is not possible (*e.g.*, oral surgery, restorative dentistry, upper endoscopy), check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation; this suggests that the patient will be able to control his airway and take deep breaths if necessary||

### Monitoring Patient Ventilation and Oxygenation

- Continually# monitor ventilatory function by observation of qualitative clinical signs

‡This may not be feasible for urgent or emergency procedures.

§See table 3 and/or refer to: 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: An updated report. *ANESTHESIOLOGY* 2017; 126:376–93

||A response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

#The term "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time" (see Standards for Basic Anesthetic Monitoring, American Society of Anesthesiologists. Approved by the ASA House of Delegates October 21, 1986, and last amended October 28, 2015. Retrieved May 9, 2017, from <http://www.asahq.org/quality-and-practice-management/standards-and-guidelines/search?q=basic+anesthesia+monitoring>).

- Continually monitor ventilatory function with capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment
  - For uncooperative patients, institute capnography after moderate sedation has been achieved
- Continuously monitor all patients by pulse oximetry with appropriate alarms

### Monitoring Hemodynamics

- Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation
- Once moderate sedation/analgesia is established, continually monitor blood pressure (*e.g.*, at 5-min intervals) and heart rate during the procedure unless such monitoring interferes with the procedure (*e.g.*, magnetic resonance imaging where stimulation from the blood pressure cuff could arouse an appropriately sedated patient)
- Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated

### Contemporaneous Recording of Monitored Parameters

- Record patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables 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 occur: (1) before the administration of sedative/analgesic agents,\*\* (2) after administration of sedative/analgesic agents, (3) at regular intervals during the procedure, (4) during initial recovery, and (5) just before discharge
- Set device alarms to alert the care team to critical changes in patient status

### Availability of an Individual Responsible for Patient Monitoring

- Assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure
  - The individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be authorized to seek additional help

\*\*For rare uncooperative patients (*e.g.*, children with autism spectrum disorder or attention deficit disorder) recording oxygenation status or blood pressure may not be possible until after sedation.

- The designated 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

### Supplemental Oxygen

- Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure

### Emergency Support

- Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure suite or procedure room††
- Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered (*e.g.*, opioids and benzodiazepines) and potential interactions with other medications and nutraceuticals the patient may be taking
- Assure that appropriately sized equipment for establishing a patent airway is available
- Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room
- Assure that suction, advanced airway equipment, a positive pressure ventilation device, and supplemental oxygen are immediately available in the procedure room and in good working order
  - Assure that a member of the procedural team is trained in the recognition and treatment of airway complications (*e.g.*, apnea, laryngospasm, airway obstruction), opening the airway, suctioning secretions, and performing bag-valve-mask ventilation
- Assure that a member of the procedural team has the skills to establish intravascular access
- Assure that a member of the procedural team has the skills to provide chest compressions
- Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area
- Assure that an individual or service (*e.g.*, code blue team, paramedic-staffed ambulance service) with advanced life support skills (*e.g.*, tracheal intubation, defibrillation, resuscitation medications) is immediately available
- Assure that members of the procedural team are able to recognize the need for additional support and know how to access emergency services from the procedure room (*e.g.*, telephone, call button)

††“Immediately available in the procedure room” refers to accessible shelving, unlocked cabinetry, and other measures to assure that there is no delay in accessing medications and equipment during the procedure.

### Sedative or Analgesic Medications Not Intended for General Anesthesia

- Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient‡‡
  - Administer each component individually to achieve the desired effect (*e.g.*, additional analgesic medication to relieve pain; additional sedative medication to decrease awareness or anxiety)
- Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis
- In patients receiving intravenous medications for sedation/analgesia, maintain vascular access 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, determine the advisability of reestablishing intravenous access on a case-by-case basis
- Administer intravenous sedative/analgesic drugs in small, incremental doses, or by infusion, titrating to the desired endpoints
  - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration
- When drugs are administered by nonintravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to occur before supplementation is considered

### Sedative/Analgesic Medications Intended for General Anesthesia

- When moderate procedural sedation with sedative/analgesic medications intended for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia
- Assure that practitioners administering sedative/analgesic medications intended for general anesthesia are able to reliably identify and rescue patients from unintended deep sedation or general anesthesia
- For patients receiving intravenous sedative/analgesics intended for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression

‡‡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. Knowledge of each drug's time of onset, peak response, and duration of action is important. Titration of drug to effect is an important concept; one must know whether the previous dose has taken full effect before administering additional drug.

- In patients who have received sedative/analgesic medications intended for general anesthesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of reestablishing intravenous access on a case-by-case basis
- Administer intravenous sedative/analgesic medications intended for general anesthesia in small, incremental doses, or by infusion, titrating to the desired endpoints
  - Allow sufficient time to elapse between doses so the peak effect of each dose can be assessed before subsequent drug administration
- When drugs intended for general anesthesia are administered by nonintravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allow sufficient time for absorption and peak effect of the previous dose to occur before supplementation is considered

### Reversal Agents

- Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia, regardless of route of administration
- If patients develop hypoxemia, significant hypoventilation or apnea during sedation/analgesia: (1) encourage or physically stimulate patients to breathe deeply, (2) administer supplemental oxygen, and (3) provide positive pressure ventilation if spontaneous ventilation is inadequate
- Use reversal agents in cases where airway control, spontaneous ventilation, or positive pressure ventilation is inadequate
  - Administer naloxone to reverse opioid-induced sedation and respiratory depression<sup>§§</sup>
  - Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression
- After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates
- Do not use sedation regimens that are intended to include routine reversal of sedative or analgesic agents

### Recovery Care

- After sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression
- Monitor oxygenation continuously until patients are no longer at risk for hypoxemia

<sup>§§</sup>Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema.

- Monitor ventilation and circulation at regular intervals (*e.g.*, every 5 to 15 min) until patients are suitable for discharge
- Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel<sup>|||</sup>

### Creation and Implementation of Patient Safety Processes

- Create and implement a quality improvement process based upon established national, regional, or institutional reporting protocols (*e.g.*, adverse events, unsatisfactory sedation)
  - Periodically update the quality improvement process to keep up with new technology, equipment or other advances in moderate procedural sedation/analgesia
- Strengthen patient safety culture through collaborative practices (*e.g.*, team training, simulation drills, development and implementation of checklists)
- Create an emergency response plan (*e.g.*, activating “code blue” team or activating the emergency medical response system: 911 or equivalent)

### Appendix 2: Methods and Analyses

For these guidelines, a systematic search and review of peer-reviewed published literature was conducted, with scientific findings summarized and reported below and in the document. Assessment of conceptual issues, practicality and feasibility of the guideline recommendations was also evaluated, with opinion data collected from surveys and other sources. Both the systematic literature review and the opinion data are based on *evidence linkages*, or statements regarding potential relationships between interventions and outcomes associated with moderate procedural sedation. The evidence model below guided the search, providing inclusion and exclusion information regarding patients, procedures, practice settings, providers, clinical interventions, and outcomes. After review of all evidentiary information, the task force placed each recommendation into one of three categories: (1) provide this intervention or treatment, (2) this intervention or treatment may be provided to the patient based on circumstances of the case and the practitioner’s clinical judgment, or (3) do not provide this intervention or treatment. The policy of the ASA Committee on Standards and Practice Parameters is to update practice guidelines every 5 yr. The ASA Committee on Standards and Practice Parameters reviews all practice guidelines at the ASA annual meeting and determines update and revision timelines.

#### Evidence Model

##### Patients

- Inclusion criteria:
  - Any patient having a diagnostic or therapeutic procedure for which moderate sedation is planned
- Exclusion criteria:
  - Patients in whom the level of sedation cannot reliably be established

<sup>|||</sup>Discharge criteria examples are noted in table 5.



- Patients who do not respond purposefully to verbal or tactile stimulation (*e.g.*, stroke victims, neonates)
- Patients in whom determining the level of sedation interferes with the procedure

### Procedures

- Inclusion criteria:
  - Elective and urgent/emergent procedures
  - Diagnostic and therapeutic procedures
    - Principal procedures (*e.g.*, upper endoscopy, colonoscopy, radiology, ophthalmology, cardiology, dentistry, plastics, orthopedic, urology, podiatry)
    - Diagnostic imaging (radiological scans, endoscopy)
    - Minor surgical procedures in all care areas (*e.g.*, cardioversion)
    - Pediatric procedures (*e.g.*, suture of laceration, setting of simple fracture, lumbar puncture, bone marrow with local, magnetic resonance imaging or computed tomography scan, routine dental procedures)
    - Pediatric cardiac catheterization (*e.g.*, cardiac biopsy after transplantation)
    - Obstetric procedures (*e.g.*, labor and delivery)
- Exclusion criteria:
  - Procedures using minimal sedation (*e.g.*, anxiolysis for insertion of peripheral nerve blocks, local or topical anesthesia)
  - Procedures where deep sedation is intended
  - Procedures where general anesthesia is intended
  - Procedures using major conduction anesthesia (*i.e.*, neuraxial anesthesia)
  - Procedures using sedatives in combination with regional anesthesia
  - Nondiagnostic or nontherapeutic procedures (*e.g.*, postoperative analgesia, pain management/chronic pain, critical care, palliative care)

### Practice Settings

- Inclusion criteria:
  - Settings where procedural moderate sedation may be administered
    - Hospitals
    - Ambulatory procedural centers
    - Office practices
      - Hospital connected
      - Free-standing
      - Dental office
      - Urology office
      - Ophthalmology office
    - Emergency settings
    - Endoscopy suite
    - Plastic surgery suite
    - Radiology suite (magnetic resonance imaging, computed tomography, invasive)

- Oral and maxillofacial surgery suite
- Cardiac catheterization laboratory
- Oncology clinics
- Electrophysiology laboratory
- Interventional radiology laboratory
- Neurointerventional laboratory
- Echocardiology laboratory
- Evoked auditory testing laboratory

- Exclusion criteria: (none indicated)

### Providers

- Inclusion criteria:
  - All providers who deliver moderate procedural sedation in any practice setting
    - Physician anesthesiologists and anesthesiologists
    - Cardiologists
    - Dentists
    - Dentist anesthesiologists
    - Emergency physicians
    - Gastroenterologists
    - Hospitalists
    - Nurse anesthetists
    - Nursing personnel who perform monitoring tasks
    - Oncologists
    - Oral/maxillofacial surgeons
    - Pulmonologists
    - Radiologists
    - Sedation nurses
    - Supervised physicians and dentists in training
    - Surgeons
- Exclusion criteria: (none indicated)

### Interventions

- Inclusion criteria:
  - Preprocedure patient evaluation and preparation
    - Medical records review (patient history/condition)
      - Underlying medical problems
        - Abnormalities of major organ systems
        - Obstructive sleep apnea
        - Respiratory distress syndrome
        - Allergies
        - Intestinal inflammation
        - Obesity
      - Sedation history
      - Anesthesia history
      - Surgical history
      - Problems pertaining to cooperation
      - Current medications
      - Extremes of age
      - Psychotropic drug use
      - Nonpharmaceutical (*e.g.*, nutraceutical) use
      - Family history

- Focused physical examination (*e.g.*, heart, lungs, airway)
- Consultation with a medical specialist (*e.g.*, physician anesthesiologist, cardiologist, endocrinologist, pulmonologist, nephrologist, obstetrician)
- Preparation of the patient (*e.g.*, preprocedure instruction, medication usage, counseling, fasting)
- Patient monitoring
  - Level of consciousness (*e.g.*, responsiveness)
  - Breathing/ventilation
    - Observation (color when the procedure allows)
    - Auscultation, chest excursion
    - Continual end tidal carbon dioxide monitoring (*e.g.*, capnography, capnometry) *versus* observation or auscultation
    - Plethysmography
      - Plethysmography *versus* observation or auscultation
      - Plethysmography *versus* capnography
  - Oxygenation
    - Pulse oximetry
  - Hemodynamic monitoring
    - Blood pressure
    - Heart rate
    - Electrocardiography
  - Contemporaneous recording of monitored parameters
  - Presence of an individual dedicated to patient monitoring
  - Creation and implementation of quality improvement processes
- Supplemental oxygen
  - Supplemental oxygen *versus* room air or no supplemental oxygen
    - Method of oxygen administration (*e.g.*, nasal cannula, face masks, specialized devices (*e.g.*, high-flow cannula))
- Emergency support
  - Presence of individual(s) capable of establishing a patent airway, positive pressure ventilation and resuscitation (*i.e.*, advanced life-support skills)
  - Presence of emergency and airway equipment
    - Types of airway devices (*e.g.*, nasal cannula, face masks, specialized devices (*e.g.*, high-flow cannula))
    - Supraglottic airway (*e.g.*, laryngeal mask airway)
  - Presence of an individual to establish intravenous access
  - Intravenous access *versus* no intravenous access
- Sedative or analgesic medications not intended for general anesthesia
  - Sedatives (all routes of administration)
    - Benzodiazepines
    - Dexmedetomidine *versus* other sedatives or analgesics
  - Sedative/opioid combinations (all routes of administration)
    - Benzodiazepines combined with opioids *versus* benzodiazepines
    - Benzodiazepines combined with opioids *versus* opioids
    - Dexmedetomidine combined with other sedatives or analgesics *versus* dexmedetomidine
    - Dexmedetomidine combined with other sedatives or analgesics *versus* other sedatives or analgesics (alone or in combination)
  - Intravenous *versus* nonintravenous sedative/analgesics not intended for general anesthesia (all non-IV routes of administration, including oral, nasal, intramuscular, rectal, transdermal, sublingual, iontophoresis, nebulized)
    - Titration *versus* single dose, repeat bolus, continuous infusion
- Sedative/analgesic medications intended for general anesthesia
  - Propofol
    - Propofol alone *versus* non-general anesthesia sedative/analgesics alone
    - Propofol alone *versus* non-general anesthesia sedative/analgesic combinations
    - Propofol combined with non-general anesthesia sedative/analgesics *versus* propofol alone
    - Propofol combined with non-general anesthesia sedative/analgesics *versus* non-general anesthesia sedative/analgesics (alone or in combination)
    - Propofol alone *versus* other general anesthesia sedatives (alone or in combination)
    - Propofol combined with sedatives intended for general anesthesia *versus* other sedatives intended for general anesthesia (alone or in combination)
    - Propofol combined with other sedatives intended for general anesthesia *versus* propofol (alone or in combination)
  - Ketamine
    - Ketamine alone *versus* non-general anesthesia sedative/analgesics alone
    - Ketamine alone *versus* non-general anesthesia sedative/analgesic combinations
    - Ketamine combined with non-general anesthesia sedative/analgesics *versus* ketamine alone

- Ketamine combined with non-general anesthesia sedative/analgesics *versus* non-general anesthesia sedative/analgesics (alone or in combination)
- Ketamine alone *versus* other general anesthesia sedatives (alone or in combination)
- Ketamine combined with sedatives intended for general anesthesia *versus* other sedatives intended for general anesthesia (alone or in combination)
- Ketamine combined with other sedatives intended for general anesthesia *versus* ketamine (alone or in combination)
- Etomidate
  - Etomidate alone *versus* non-general anesthesia sedative/analgesics alone
  - Etomidate alone *versus* non-general anesthesia sedative/analgesic combinations
  - Etomidate combined with non-general anesthesia sedative/analgesics *versus* etomidate alone
  - Etomidate combined with non-general anesthesia sedative/analgesics *versus* non-general anesthesia sedative/analgesics (alone or in combination)
  - Etomidate alone *versus* other general anesthesia sedatives (alone or in combination)
  - Etomidate combined with sedatives intended for general anesthesia *versus* other sedatives intended for general anesthesia (alone or in combination)
  - Etomidate combined with other sedatives intended for general anesthesia *versus* etomidate (alone or in combination)
- Intravenous *versus* nonintravenous sedatives intended for general anesthesia
- Titration of sedatives intended for general anesthesia
- Reversal agents
  - Naloxone for reversal of opioids with or without benzodiazepines
    - Naloxone *versus* placebo
    - Intravenous *versus* nonintravenous naloxone
  - Flumazenil for reversal of benzodiazepines with or without opioids
    - Flumazenil *versus* placebo
    - Intravenous *versus* nonintravenous flumazenil
- Recovery care
  - Continued observation and monitoring until discharge
  - Predetermined discharge criteria
- Exclusion criteria:
  - Minimal sedation
  - Deep sedation

- General anesthesia
- Patient-controlled sedation/analgesia
- Major conduction anesthetics (*i.e.*, neuraxial anesthesia)
- Sedatives combined with regional anesthesia
- Premedication administered before general anesthesia
- Interventions without sedatives (*e.g.*, hypnosis, acupuncture)
- New or rarely administered sedative/analgesics (*e.g.*, fospropofol)
- Automated sedative delivery systems
- New or rarely used monitoring or delivery devices
- Bispectral index monitoring

### Outcomes

- Expected benefits:
  - Sedation efficacy
    - Induction time
    - Duration of sedation
    - Successful procedure
    - Patient/family satisfaction
    - Proceduralist satisfaction
  - Improved pain management (*i.e.*, pain during a procedure)
  - Speed of recovery
    - Time to recovery
    - Time to discharge-ready
  - Reduced frequency/severity of sedation-related complications
    - Unintended deep sedation or general anesthesia
    - Conversion to deep sedation or general anesthesia
    - Undersedation
    - Unplanned hospitalization and/or intensive care unit admission
    - Unplanned emergency department visits
    - Unplanned use of rescue agents (naloxone, flumazenil)
    - Resedation after discharge criteria met
    - Postprocedure neurologic function
    - Need to change planned procedure or technique
    - Respiratory depression
    - Hypoxemia
    - Oxygen desaturation
    - Upper airway obstruction
    - Airway support required
    - Intubation required
    - Airway adjunct required
    - Pulmonary aspiration
    - Hypotension
    - Arrhythmias
    - Cardiac arrest
    - Bradycardia

- Hemodynamic support or rescue required
- Assistance request
- Neurologic injury
- Death

### Evidence Collection

- Literature inclusion criteria:
  - Randomized controlled trials
  - Prospective nonrandomized comparative studies (e.g., quasiexperimental, cohort)
  - Retrospective comparative studies (e.g., case-control)
  - Observational studies (e.g., correlational or descriptive statistics)
  - Case reports, case series
- Literature exclusion criteria (except to obtain new citations):
  - Editorials
  - Literature reviews
  - Meta-analyses
  - Abstracts greater than 5 yr old
  - Unpublished studies
  - Studies in non-peer-reviewed journals
  - Newspaper articles
- Survey evidence:
  - Expert consultant survey
  - ASA membership survey
  - Other participating organization surveys
  - Reliability survey
  - Feasibility survey

**State of the Literature.** For the systematic review, potentially relevant clinical studies were identified *via* electronic and manual searches. Healthcare database searches included PubMed, EMBASE, Web of Science, Google Books, and the Cochrane Central Register of Controlled Trials. The searches covered a 15.6-yr period from January 1, 2002, through July 31, 2017. Accepted studies from the previous guidelines were also rereviewed, covering the period of August 1, 1976, through December 31, 2002.<sup>1</sup> Only studies containing original findings from peer-reviewed journals were acceptable. Editorials, letters, and other articles without data were excluded. A literature search strategy and PRISMA\* flow diagram are available as Supplemental Digital Content 2, <http://links.lww.com/ALN/B597>.

In total, 4,349 new citations were identified, with 1,428 articles assessed for eligibility. After review, 1,140 were excluded, with 288 new studies meeting the above stated criteria. These studies were combined with 209 pre-2002 articles used in the previous guidelines, resulting in a total of 497 articles accepted as evidence for these guidelines. In this document, 187 are referenced, with a complete bibliography of articles used to develop these guidelines, organized by section, available as Supplemental Digital Content 3, <http://links.lww.com/ALN/B595>.

\*Preferred reporting items of systematic reviews and meta-analyses.

Results for each pertinent outcome were summarized, and when sufficient numbers of RCTs were found, study grading and meta-analyses were conducted. The literature relating to six evidence linkages contained enough studies with well defined experimental designs and statistical information to conduct formal meta-analyses. These seven evidence linkages are: (1) capnography *versus* blinded capnography, (2) supplemental oxygen *versus* no supplemental oxygen, (3) midazolam combined with opioids *versus* midazolam alone, (4) propofol *versus* midazolam, (5) flumazenil *versus* placebo for benzodiazepine reversal, and (6) flumazenil *versus* placebo for reversal of benzodiazepines combined with opioids (table 6). Fixed and random-effects odds ratios are reported for dichotomous outcomes, and raw and standardized mean differences are reported for findings with continuous data. An acceptable significance level was set at  $P < 0.01$ . No search for unpublished studies was conducted, and no reliability tests for locating research results were done.

Interobserver agreement among task force members and two methodologists was obtained by interrater reliability testing of 36 randomly selected studies. Agreement levels using a  $\kappa$  statistic for two-rater agreement pairs were as follows: (1) research design,  $\kappa = 0.57$  to  $0.92$ ; (2) type of analysis,  $\kappa = 0.60$  to  $0.75$ ; (3) evidence linkage assignment,  $\kappa = 0.76$  to  $0.85$ ; and (4) literature inclusion for database,  $\kappa = 0.28$  to  $1.00$ . Three-rater  $\kappa$  values were: (1) research design,  $\kappa = 0.70$ ; (2) type of analysis,  $\kappa = 0.68$ ; (3) linkage assignment,  $\kappa = 0.79$ ; and (4) literature database inclusion,  $\kappa = 0.43$ . 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 moderate procedural sedation and analgesia; (2) survey opinions from a randomly selected sample of active members of the ASA, AAOMS, and ASDA‡; (3) testimony from attendees of publicly held open forums at national anesthesia meetings§; (4) internet commentary; and (5) task force opinion and interpretation. The survey rate of return was 81% ( $n = 129$  of  $159$ ) for consultants. For membership respondents, survey data were collected from 69 ASA members, 104 AAOMS members, and 104 ASDA members. The results of the surveys are reported in tables 7–10 and are summarized in the text of the guidelines.

†Consultants were drawn from the following specialties where moderate procedural sedation/analgesia are commonly administered: anesthesiology, cardiology, dentistry, emergency medicine, gastroenterology, oral and maxillofacial surgery, pediatrics, radiology, and surgery.

‡All participating organizations were invited to participate in this survey.

§American Dental Association Council on Dental Education and Licensure: Anesthesia Committee Meeting, April 20, 2017; 2017 Combined Annual Meeting of the Southwest Society of Oral and Maxillofacial Surgeons, the Texas Society of Oral and Maxillofacial Surgeons, the Midwestern Chapter of Oral and Maxillofacial Surgeons, and the Oklahoma Society of Oral and Maxillofacial Surgeons, April 21, 2017, Scottsdale, Arizona; the Society for Ambulatory Anesthesia 32nd Annual Meeting, May 5, 2017, Scottsdale, Arizona; International Anesthesia Research Society 2017 Annual Meeting; and the International Science Symposium, Washington, D.C., May 8, 2017.

Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the guidelines were instituted. The rate of return was 34.6% (n = 55 of 159). The percent of responding consultants expecting *no change* associated with each linkage were as follows (preprocedure patient evaluation – %): preprocedure patient preparation – 93.75%; patient preparation – 87.5%; patient monitoring – 68.75%; supplemental oxygen – 93.75%; emergency support – 87.5%; sedative or analgesic medications not intended for general anesthesia – 87.5%; sedative or analgesic medications intended for general anesthesia – 75.00%; availability/use of reversal agents – 87.5%; recovery care – 75%; and creation and implementation of patient safety processes – 56.25%. Forty-four respondents (84.62%) indicated that the guidelines would have *no effect* on the amount of time spent on a typical case with the implementation of these guidelines. Seven respondents (13.46%) indicated that there would be an increase in the amount of time, with four of these respondents estimating an increase ranging from 5 to 15 min. One respondent (1.92%) estimated a decrease in the amount of time they would spend on a typical case.

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Support was provided solely from institutional and/or departmental sources in the American Society of Anesthesiologists.

### Competing Interests

The authors declare no competing interests.

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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) indicates 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) indicates 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 is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully\* after 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 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.

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, whereas those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia. (Developed by the American Society of Anesthesiologists: Approved by ASA House of Delegates on October 13, 1999 and last amended on October 15, 2014. Available at: <http://www.asahq.org/quality-and-practice-management/practice-guidance-resource-documents/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia>. Accessed on August 21, 2017.)

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

**Table 2.** 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. Also, 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 listed below.

#### 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

**Table 3.** Summary of American Society of Anesthesiologists Recommendations for Preoperative Fasting and Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures

	Recommendation
Ingested material	
Clear liquids†	2-h minimum fasting period*
Breast milk	4-h minimum fasting period*
Infant formula	6-h minimum fasting period*
Nonhuman milk‡	6-h minimum fasting period*
Light meal§	6-h minimum fasting period*
Fried foods, fatty foods, or meat	Additional fasting time (e.g., 8 h or more) may be needed
Pharmacologic recommendations (medication type and common examples)	
Gastrointestinal stimulants	
Metoclopramide	May be used/no routine use
Gastric acid secretion blockers	
Cimetidine	May be used/no routine use
Famotidine	May be used/no routine use
Ranitidine	May be used/no routine use
Omeprazole	May be used/no routine use
Lansoprazole	May be used/no routine use
Antacids	
Sodium citrate	May be used/no routine use
Sodium bicarbonate	May be used/no routine use
Magnesium trisilicate	May be used/no routine use
Antiemetics	
Ondansetron	May be used/no routine use
Anticholinergics	
Atropine	No use
Scopolamine	No use
Glycopyrrolate	No use
Combinations of the medications above	No routine use

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

**Table 4.** Emergency Equipment for Sedation and Analgesia

Intravenous equipment (age- and size-appropriate)
<ul style="list-style-type: none"> <li>• Gloves</li> <li>• Tourniquets</li> <li>• Alcohol wipes</li> <li>• Sterile gauze pads</li> <li>• Intravenous catheters</li> <li>• Intravenous tubing</li> <li>• Intravenous fluid</li> <li>• Assorted needles for drug aspiration, intramuscular injection</li> <li>• Intraosseous access kit</li> <li>• Appropriately sized syringes</li> <li>• Tape</li> </ul>
Basic airway management equipment (age- and size-appropriate)
<ul style="list-style-type: none"> <li>• Source of compressed O<sub>2</sub> (tank with regulator or pipeline supply with flowmeter)</li> <li>• Source of suction</li> <li>• Suction catheters</li> <li>• Yankauer-type suction</li> <li>• Face masks</li> <li>• Self-inflating breathing bag-valve set</li> <li>• Oral and nasal airways</li> <li>• Lubricant</li> </ul>
Advanced airway management equipment (age- and size-appropriate)
<ul style="list-style-type: none"> <li>• Supraglottic airway devices</li> <li>• Laryngoscope handles (tested)</li> <li>• Laryngoscope blades</li> <li>• Endotracheal tubes</li> <li>• Stylet</li> </ul>
Pharmacologic antagonists
<ul style="list-style-type: none"> <li>• Naloxone</li> <li>• Flumazenil</li> </ul>
Emergency medications
<ul style="list-style-type: none"> <li>• Epinephrine</li> <li>• Ephedrine</li> <li>• Vasopressin</li> <li>• Atropine</li> <li>• Nitroglycerin (tablets or spray)</li> <li>• Amiodarone</li> <li>• Lidocaine</li> <li>• Glucose (IV or oral)</li> <li>• Diphenhydramine</li> <li>• Hydrocortisone, methylprednisolone, or dexamethasone</li> <li>• Benzodiazepines</li> <li>• β blocker</li> <li>• Adenosine</li> </ul>

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. This table should be used as a guide, which should be modified depending upon the individual practice circumstances.

IV = intravenous.

**Table 5.** Recovery and Discharge Criteria after Sedation and Analgesia

## General principles

- Medical supervision of recovery and discharge after moderate sedation is the responsibility of the operating practitioner or a licensed physician.
- The recovery area should be equipped with or have direct access to age and size appropriate monitoring and resuscitation equipment.
- Patients receiving moderate sedation should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending upon 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.
- Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals.
- A nurse or other individual trained to monitor patients and recognize complications should be in attendance until discharge criteria are fulfilled.
- An individual capable of managing complications (e.g., establishing a patent airway, administering a reversal medication when appropriate, and providing positive pressure ventilation) should be immediately available until discharge criteria are fulfilled.

## Guidelines for discharge

- Patients should be alert and oriented; infants and patients whose mental or physical status was initially abnormal should have returned to their baseline status.
- Patients should be advised to avoid making life-changing decisions and activities that may impact their safety (e.g., operate a vehicle or heavy equipment) until the effects of the sedatives have worn off.
- Cardiovascular function, airway patency, and protective airway reflexes are satisfactory.
- 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 child safety seat.\*
- Vital signs should be stable and within acceptable limits.
- Use of scoring systems may assist in documentation of fitness for discharge.
- 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.
- Outpatients should be discharged in the presence of a responsible adult who will accompany them home or to a care facility and be able to report any postprocedure complications.
- 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.

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 in the table.

\*Drugs with long durations of action (e.g., chloral hydrate, intramuscular pentobarbital, phenothiazines) will require longer periods of observation even after the child achieves currently used recovery and discharge criteria. This concept is particularly important for infants and toddlers transported in car safety seats who are at risk of resedation after discharge because of residual prolonged drug effects with the potential for airway obstruction.

**Table 6.** Meta-analysis Summary

Evidence Linkages*	N†	Odds Ratio (CI)‡	Z Value	P Value	Odds Ratio (CI)§	Z Value	P Value	Heterogeneity
Patient monitoring (capnography versus blinded capnography)								
Hypoxemia ( $O_2 < 90\%$ ) <sup>30-34</sup>	6	0.68 (0.51-0.90)	-3.53	< 0.001	0.70 (0.47-1.02)	-2.44	0.015	0.110
Supplemental oxygen (supplemental oxygen vs. placebo)								
Hypoxemia ( $O_2 < 95\%$ ) <sup>65-71</sup>	7	0.15 (0.09-0.24)	-10.49	< 0.001	0.24 (0.07-0.81)	-3.01	< 0.001	< 0.001
Sedative/analgesics <i>not</i> intended for general anesthesia (midazolam combined with opioids vs. midazolam)								
Pain/discomfort during procedure <sup>72-77</sup>	6	0.57 (0.33-1.00)	-2.57	0.010	0.48 (0.16-1.43)	-1.73	0.084	0.061
Hypoxemia ( $O_2 < 95\%$ ) <sup>74,75,77-80</sup>	6	1.97 (1.00-3.90)	2.57	0.010	2.21 (0.80-6.12)	2.01	0.044	0.111
Recall (no recall during procedure) <sup>72-74,77,80-83</sup>	8	1.07 (0.62-1.84)	0.31	0.759	1.09 (0.58-2.06)	0.35	0.726	0.268
Sedative/analgesics intended for general anesthesia (propofol vs. midazolam)								
Recall <sup>95,99-102</sup>	5	0.49 (0.25-0.97)	-2.67	0.008	0.40 (0.07-2.21)	-1.38	0.168	0.002
Hypoxemia ( $O_2 < 95\%$ ) <sup>95,96,98-100</sup>	7	0.90 (0.47-1.70)	-0.431	0.666	0.92 (0.48-1.78)	-0.32	0.752	0.638
Sedation recovery (awakening time) <sup>95-99</sup>	5		-11.87	< 0.001		-4.55	< 0.001	< 0.001
Raw mean difference = -10.01 (CI = -11.63 to -8.39)								
Standard mean difference (fixed effects) = -1.23 (CI = -1.49 to -0.96)								
Standard mean difference (random effects) = -1.57 (CI = -2.46 to -0.68)								
Reversal agents (flumazenil vs. placebo [reversal of benzodiazepines])								
Recovery within 15 min <sup>171-178</sup>	8#	11.67 (6.47-21.05)	10.72	< 0.001	14.07 (5.59-35.45)	7.37	< 0.001	0.064
Reversal agents (flumazenil vs. placebo [reversal of benzodiazepines combined with opioids])								
Recovery within 30 min <sup>182-186</sup>	5	7.13 (4.49-11.32)	10.94	< 0.001	7.13 (4.49-11.32)	10.94	< 0.001	0.538

Statistics for individual studies and forest plots are available as supplemental digital content 4, <http://links.lww.com/ALN/B596>.

\*Evidence linkage with references for included studies.

†Number of studies included in the meta-analysis.

‡Mantel-Haenszel or Peto fixed-effects analysis (99% CI); using Comprehensive Meta-analysis software, version 3.3.070, November 20, 2014. Licensed to Richard T. Connis, Ph.D., March 20, 2017.

§DerSimonian-Laird random-effects analysis (99% CI), using Comprehensive Meta-analysis software version 3.3.070, November 20, 2014. Licensed to Richard T. Connis, Ph.D., March 20, 2017.

||Statistical significance values for homogeneity/heterogeneity of effect size; a *P* value of < 0.01 indicates that the studies are significantly heterogeneous.

#Double-blind studies only.

Table 7. Consultant Survey Responses

	N*	Percent Responding to Each Item				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Patient evaluation						
1. Review previous medical records and interview the patient or family	129	87.6*	10.1	2.3	0.0	0.0
2. Conduct a focused physical examination of the patient	129	86.0*	13.2	0.8	0.0	0.0
3. Review available laboratory test results and order additional laboratory tests when needed	129	71.3*	21.7	6.2	0.8	0.0
4. <i>If possible</i> , perform the preprocedure evaluation well enough in advance (e.g., several days to weeks) to allow for proper patient preparation	129	35.7	35.7*	19.4	4.7	4.7
5. Reevaluate the patient immediately before the procedure	127	80.3*	18.1	0.8	0.0	0.8
Preprocedure patient preparation						
6. Consult with a medical specialist, when appropriate, before administration of moderate procedural sedation to patients with significant underlying conditions	127	51.2*	22.8	15.7	5.5	4.7
7. When feasible before the procedure, inform patients or legal guardians of the benefits, risks, and limitations of moderate sedation/analgesia and possible alternatives and elicit their preferences	129	75.2*	20.2	1.6	2.3	0.8
8. Before the day of the procedure, inform patients or legal guardians that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying	128	71.9*	14.1	4.7	4.7	4.7
9. On the day of the procedure, assess the time and nature of last oral intake	128	82.0*	13.3	2.3	1.6	0.8
10. In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone	128	38.3	25.0*	17.2	10.2	9.4
Monitoring patient level of consciousness						
11. Periodically monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately or during procedures where movement could be detrimental clinically	129	46.5	37.2*	9.3	4.7	2.3
12. During procedures where a verbal response is not possible, check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile stimulation	128	39.1	38.3*	16.4	4.7	1.6
Monitoring patient ventilation and oxygenation						
13. Continually monitor ventilatory function by observation of qualitative clinical signs	126	76.2*	19.8	2.4	1.6	0.0
14. Continually monitor ventilatory function by capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment	127	67.7*	14.2	10.2	4.7	3.1
15. Monitor all patients by pulse oximetry with appropriate alarms	127	85.8*	14.2	0.0	0.0	0.0
Monitoring hemodynamics						
16. Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation	127	74.8*	22.0	0.0	2.4	0.8
17. Once moderate sedation/analgesia is established, continually monitor blood pressure and heart rate during the procedure unless such monitoring interferes with the procedure	127	69.3*	23.6	1.6	2.4	3.1
18. Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated	127	76.4*	15.7	3.1	0.8	3.9
Contemporaneous recording of monitored parameters						
19. Record level of consciousness, ventilatory and oxygenation status, and hemodynamic variables 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	126	60.3*	24.6	4.8	7.9	2.4
20. Set device alarms to alert the care team to critical changes in patient	126	75.4*	21.4	3.2	0.0	0.0
Availability of an individual responsible for patient monitoring						
21. Assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure	126	78.6*	18.3	0.8	0.8	1.6

(Continued)

Table 7. (Continued).

	N*	Percent Responding to Each Item				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
22. The individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be empowered to seek additional help	127	87.4*	11.8	0.0	0.8	0.0
23. The designated 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	127	47.2	30.7*	10.2	9.4	2.4
Supplemental oxygen						
24. Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure	126	54.0*	29.4	11.1	4.0	1.6
Emergency support						
25. Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure room	127	68.5*	20.5	6.3	3.1	1.6
26. Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered and potential interactions with other medications and nutraceuticals the patient may be taking	127	78.0*	16.5	3.9	1.6	0.0
27. Assure that appropriately sized equipment for establishing a patient airway is available	124	88.7*	10.5	0.8	0.0	0.0
28. Assure that at least one individual capable of establishing a patient airway and providing positive pressure ventilation is present in the procedure room	126	84.9*	12.7	1.6	0.8	0.0
29. Assure that suction, advanced airway equipment, positive pressure ventilation, and supplemental oxygen are immediately available in the procedure room and in good working order	126	84.1*	11.9	3.2	0.8	0.0
30. Assure that a member of the procedural team is trained in the recognition and treatment of airway complications, opening the airway, suctioning secretions, and performing bag-valve-mask ventilation	127	87.4*	10.2	0.8	0.8	0.8
31. Assure that a member of the procedural team has the skills to establish intravenous access	127	80.3*	14.2	0.8	3.9	0.8
32. Assure that a member of the procedural team has the skills to provide chest compressions	127	84.3*	13.4	0.8	0.8	0.8
33. Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area	127	77.2*	17.3	3.9	0.8	0.8
34. Assure that an individual or service is immediately available with advanced life support skills	127	77.2*	13.4	7.1	2.4	0.0
35. Assure that members of the procedural team are able to recognize the need for additional support and know how to access emergency services from the procedure room	127	89.0*	11.0	0.0	0.0	0.0
Sedative or analgesic medications not intended for general anesthesia						
36. Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient	124	65.3*	32.3	0.8	1.6	0.0
37. Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis	124	30.6	37.9*	21.0	9.7	0.8
38. In patients receiving intravenous medications for sedation/analgesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	124	83.1*	12.9	3.2	0.8	0.0
39. In patients who have received sedation/analgesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	124	48.4	40.3*	1.6	6.5	3.2
40. Administer intravenous sedative/analgesic drugs in small, incremental doses or by infusion, titrating to the desired endpoints	124	71.0*	26.6	1.6	0.0	0.0
Sedative or analgesic medications intended for general anesthesia						
41. When moderate procedural sedation with sedative or analgesic medications intended for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia	122	65.6*	18.9	4.9	4.9	5.7

(Continued)



Table 7. (Continued)

	N*	Percent Responding to Each Item				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
42. Assure that practitioners administering these drugs are able to reliably rescue patients from unintended deep sedation or general anesthesia	122	87.7*	9.8	0.8	0.8	0.8
43. For patients receiving intravenous sedatives intended for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	123	85.4*	9.8	1.6	1.6	1.6
44. In patients who have received sedatives intended for general anesthesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	121	51.2*	24.8	4.1	13.2	6.6
45. Administer intravenous sedative/analgesic drugs intended for general anesthesia in small, incremental doses, or by infusion, titrating to the desired endpoints	122	73.0*	21.3	2.5	1.6	1.6
Reversal agents						
46. Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia regardless of administration route	123	74.0*	17.1	5.7	1.6	1.6
47. If patients become hypoxemic or apneic during sedation/analgesia, encourage or physically stimulate patients to breathe deeply	120	82.5*	16.7	0.0	0.8	0.0
48. If patients become hypoxemic or apneic during sedation/analgesia, administer supplemental oxygen	124	84.7*	10.5	3.2	1.6	0.0
49. If patients become hypoxemic or apneic during sedation/analgesia, provide positive pressure ventilation if spontaneous ventilation is inadequate	122	82.8*	13.1	1.6	1.6	0.8
50. Use reversal agents in cases where airway control, spontaneous ventilation, or positive pressure ventilation is inadequate	124	69.4*	19.4	7.3	4.0	0.0
51. Administer naloxone to reverse opioid-induced sedation and respiratory depression	118	61.9*	25.4	8.5	3.4	0.8
52. Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression	123	58.5*	23.6	12.2	4.1	1.6
53. After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates	120	87.5*	10.8	0.0	1.7	0.0
54. Do not use sedation regimens that include routine reversal of sedative/analgesic agents	123	78.9*	13.0	3.3	3.3	1.6
Recovery care						
55. After sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression	123	85.4*	14.6	0.0	0.0	0.0
56. Monitor oxygenation continuously until patients are no longer at risk for hypoxemia	123	87.8*	10.6	0.0	0.8	0.8
57. Monitor ventilation and circulation at regular intervals until patients are suitable for discharge	122	83.6*	13.9	2.5	0.0	0.0
58. Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel	123	83.7*	16.3	0.0	0.0	0.0
Creation and implementation of patient safety processes						
59. Create and implement a quality improvement process based upon national, regional, or institutional reporting protocols	123	70.7*	26.0	2.4	0.8	0.0
60. Strengthen patient safety culture through collaborative practices (e.g., team training, simulation drills, development and implementation of checklists)	122	73.8*	22.1	3.3	0.8	0.0
61. Create an emergency response plan (e.g., activating "code blue" team or activating the emergency medical response system: 911 or equivalent)	121	77.7*	19.0	2.5	0.8	0.0

\*N = the number of consultants who responded to each item. An asterisk beside a percentage score in the columns to the right indicates the median.

Table 8. ASA Membership Survey Responses

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Patient evaluation						
1. Review previous medical records and interview the patient or family	444	91.0*	7.0	1.4	0.5	0.2
2. Conduct a focused physical examination of the patient	445	85.2*	13.5	0.9	0.2	0.2
3. Review available laboratory test results and order additional laboratory tests when needed	441	77.6*	19.0	2.7	0.2	0.5
4. <i>If possible</i> , perform the preprocedure evaluation well enough in advance (e.g., several days to weeks) to allow for proper patient preparation	441	37.6	34.7*	18.4	7.0	2.3
5. Reevaluate the patient immediately before the procedure	444	83.8*	14.0	1.6	0.2	0.5
Preprocedure patient preparation						
6. Consult with a medical specialist, when appropriate, before administration of moderate procedural sedation to patients with significant underlying conditions	445	61.3*	29.7	7.4	1.3	0.2
7. When feasible before the procedure, inform patients or legal guardians of the benefits, risks, and limitations of moderate sedation/analgesia and possible alternatives and elicit their preferences	443	74.9*	19.9	4.1	0.7	0.5
8. Before the day of the procedure, inform patients or legal guardians that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying	443	89.2*	9.0	1.4	0.0	0.5
9. On the day of the procedure, assess the time and nature of last oral intake	442	91.6*	7.2	0.7	0.2	0.2
10. In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone	440	27.5	27.5*	11.8	18.6	14.5
Monitoring patient level of consciousness						
11. Periodically monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately or during procedures where movement could be detrimental clinically	443	48.3	30.5*	13.8	5.4	2.0
12. During procedures where a verbal response is not possible, check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile stimulation	444	43.5	35.1*	14.9	4.7	1.8
Monitoring patient ventilation and oxygenation						
13. Continually monitor ventilatory function by observation of qualitative clinical signs	418	80.6*	15.3	1.9	1.9	0.2
14. Continually monitor ventilatory function by capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment	419	75.4*	17.7	4.1	1.9	1.0
15. Monitor all patients by pulse oximetry with appropriate alarms	415	95.7*	4.1	0.2	0.0	0.0
Monitoring hemodynamics						
16. Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation	415	84.3*	12.8	0.5	1.2	1.2
17. Once moderate sedation/analgesia is established, continually monitor blood pressure and heart rate during the procedure unless such monitoring interferes with the procedure	414	82.1*	12.6	1.2	2.4	1.7
18. Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated	415	82.2*	13.0	1.0	2.7	1.2
Contemporaneous recording of monitored parameters						
19. Record level of consciousness, ventilator and oxygenation status and hemodynamic variables 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	414	64.7*	26.1	2.7	4.1	2.4
20. Set device alarms to alert the care team to critical changes in patient	418	76.3*	18.7	3.6	1.2	0.2
Availability of an individual responsible for patient monitoring						
21. Assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure	418	90.4*	7.9	1.0	0.2	0.5

(Continued)

Table 8. (Continued)

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
22. The individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be empowered to seek additional help	416	93.8*	5.0	0.2	0.0	1.0
23. The designated 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	418	32.5	28.0*	12.0	17.0	10.5
Supplemental oxygen						
24. Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure	417	67.9*	21.1	8.6	1.7	0.7
Emergency support						
25. Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure room	417	73.6*	19.4	5.5	1.2	0.2
26. Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered and potential interactions with other medications and nutraceuticals the patient may be taking	415	83.1*	14.0	2.7	0.0	0.2
27. Assure that appropriately sized equipment for establishing a patent airway is available	416	91.6*	7.7	0.2	0.2	0.2
28. Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room	415	84.8*	12.8	2.4	0.0	0.0
29. Assure that suction, advanced airway equipment, positive pressure ventilation, and supplemental oxygen are immediately available in the procedure room and in good working order	415	90.4*	8.7	0.5	0.2	0.2
30. Assure that a member of the procedural team is trained in the recognition and treatment of airway complications, opening the airway, suctioning secretions, and performing bag-valve-mask ventilation	415	89.6*	9.4	0.7	0.2	0.0
31. Assure that a member of the procedural team has the skills to establish intravenous access	416	87.0*	11.1	1.7	0.0	0.2
32. Assure that a member of the procedural team has the skills to provide chest compressions	414	88.9*	10.1	1.0	0.0	0.0
33. Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area	412	83.5*	13.6	2.2	0.7	0.0
34. Assure that an individual or service is immediately available with advanced life support skills	414	74.6*	17.1	5.6	2.2	0.5
35. Assure that members of the procedural team are able to recognize the need for additional support and know how to access emergency services from the procedure room	415	88.4*	11.6	0.0	0.0	0.0
Sedative or analgesic medications not intended for general anesthesia						
36. Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient	403	57.8*	37.7	3.2	0.5	0.7
37. Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis	403	30.5	40.9*	17.4	8.4	2.7
38. In patients receiving intravenous medications for sedation/analgesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	400	89.8*	9.5	0.3	0.3	0.3
39. In patients who have received sedation/analgesia by non-intravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	402	51.2*	33.3*	3.7	6.2	5.5
40. Administer intravenous sedative/analgesic drugs in small, incremental doses or by infusion, titrating to the desired endpoints	402	82.1*	16.2	0.5	0.7	0.5
Sedative or analgesic medications intended for general anesthesia						
41. When moderate procedural sedation with sedative or analgesic medications intended for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia	401	83.5*	11.7	2.2	1.5	1.0

(Continued)

Table 8. (Continued)

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
42. Assure that practitioners administering these drugs are able to reliably rescue patients from unintended deep sedation/general anesthesia	404	94.1*	4.5	0.5	0.0	1.0
43. For patients receiving intravenous sedatives intended for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	399	93.7*	5.8	0.0	0.0	0.5
44. In patients who have received sedatives intended for general anesthesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	401	57.4*	20.2	2.7	9.5	10.2
45. Administer intravenous sedative/analgesic drugs intended for general anesthesia in small, incremental doses or by infusion, titrating to the desired endpoints	403	83.1*	12.7	2.0	1.0	1.2
Reversal agents						
46. Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia, regardless of administration route	402	78.4*	16.2	3.7	1.0	0.7
47. If patients become hypoxemic or apneic during sedation/analgesia, encourage or physically stimulate patients to breathe deeply	404	84.9*	13.4	1.2	0.2	0.2
48. If patients become hypoxemic or apneic during sedation/analgesia, administer supplemental oxygen	402	89.1*	8.0	0.7	1.5	0.7
49. If patients become hypoxemic or apneic during sedation/analgesia, provide positive pressure ventilation if spontaneous ventilation is inadequate	397	89.4*	9.8	0.8	0.0	0.0
50. Use reversal agents in cases where airway control, spontaneous ventilation, or positive pressure ventilation is inadequate	400	72.5*	22.5	3.8	0.8	0.5
51. Administer naloxone to reverse opioid-induced sedation and respiratory depression	399	61.2*	29.1	6.5	2.3	1.0
52. Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression	396	59.6*	29.0	8.1	2.0	1.3
53. After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates	401	87.8*	11.5	0.2	0.0	0.5
54. Do not use sedation regimens that include routine reversal of sedative/analgesic agents	401	80.3*	14.5	3.5	1.2	0.5
Recovery care						
55. After sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression	403	87.3*	12.7	0.0	0.0	0.0
56. Monitor oxygenation continuously until patients are no longer at risk for hypoxemia	402	89.1*	10.7	0.2	0.0	0.0
57. Monitor ventilation and circulation at regular intervals until patients are suitable for discharge	400	85.8*	12.5	1.3	0.3	0.3
58. Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel	399	85.7*	14.3	0.0	0.0	0.0
Creation and implementation of patient safety processes						
59. Create and implement a quality improvement process based upon national, regional, or institutional reporting protocols	403	73.7*	21.8	4.0	0.2	0.2
60. Strengthen patient safety culture through collaborative practices (e.g., team training, simulation drills, development and implementation of checklists)	401	72.1*	24.2	3.5	0.0	0.2
61. Create an emergency response plan (e.g., activating "code blue" team or activating the emergency medical response system: 911 or equivalent)	401	82.3*	16.0	1.7	0.0	0.0

\*N = the number of consultants who responded to each item. An asterisk beside a percentage score in the columns to the right indicates the median.

**Table 9.** American Association of Oral and Maxillofacial Surgeons Member Survey Responses

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Patient evaluation						
1. Review previous medical records and interview the patient or family	68	82.4*	16.2	1.5	0.0	0.0
2. Conduct a focused physical examination of the patient	68	80.9*	17.6	1.5	0.0	0.0
3. Review available laboratory test results and order additional laboratory tests when needed	68	76.5*	17.6	5.9	0.0	0.0
4. <i>If possible</i> , perform the preprocedure evaluation well enough in advance (e.g., several days to weeks) to allow for proper patient preparation	67	53.7*	28.4	9.0	9.0	0.0
5. Reevaluate the patient immediately before the procedure	69	78.3*	17.4	0.0	4.3	0.0
Preprocedure patient preparation						
6. Consult with a medical specialist, when appropriate, before administration of moderate procedural sedation to patients with significant underlying conditions	69	68.1*	24.6	5.8	1.4	0.0
7. When feasible before the procedure, inform patients or legal guardians of the benefits, risks, and limitations of moderate sedation/analgesia and possible alternatives and elicit their preferences	69	73.9*	23.2	2.9	0.0	0.0
8. Before the day of the procedure, inform patients or legal guardians that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying	68	86.8*	10.3	1.5	1.5	0.0
9. On the day of the procedure, assess the time and nature of last oral intake	68	89.7*	10.3	0.0	0.0	0.0
10. In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone	62	25.8	30.6*	21.0	22.6	0.0
Monitoring patient level of consciousness						
11. Periodically monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately or during procedures where movement could be detrimental clinically	67	40.3	29.9*	22.4	7.5	0.0
12. During procedures where a verbal response is not possible, check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile stimulation	69	30.4	36.2*	26.1	7.2	0.0
Monitoring patient ventilation and oxygenation						
13. Continually monitor ventilatory function by observation of qualitative clinical signs	66	84.8*	13.6	1.5	0.0	0.0
14. Continually monitor ventilatory function by capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment	61	65.6*	21.3	11.5	1.6	0.0
15. Monitor all patients by pulse oximetry with appropriate alarms	66	87.9*	12.1	0.0	0.0	0.0
Monitoring hemodynamics						
16. Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation	63	84.1*	14.3	0.0	1.6	0.0
17. Once moderate sedation/analgesia is established, continually monitor blood pressure and heart rate during the procedure unless such monitoring interferes with the procedure	64	79.7*	18.8	0.0	1.6	0.0
18. Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated	65	76.9*	12.3	7.7	3.1	0.0
Contemporaneous recording of monitored parameters						
19. Record level of consciousness, ventilator and oxygenation status, and hemodynamic variables 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	66	54.5*	24.2	16.7	4.5	0.0
20. Set device alarms to alert the care team to critical changes in patient	66	72.7*	22.7	4.5	0.0	0.0

(Continued)

Table 9. (Continued)

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Availability of an individual responsible for patient monitoring						
21. Assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure	65	53.8*	26.2	10.8	9.2	0.0
22. The individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be empowered to seek additional help	65	63.1*	30.8	3.1	3.1	0.0
23. The designated 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	64	50.0*	40.6	1.6	7.8	0.0
Supplemental oxygen						
24. Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure	64	78.1*	14.1	4.7	3.1	0.0
Emergency support						
25. Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure room	62	74.2*	14.5	9.7	1.6	0.0
26. Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered and potential interactions with other medications and nutraceuticals the patient may be taking	64	71.9*	17.2	6.3	4.7	0.0
27. Assure that appropriately sized equipment for establishing a patent airway is available	64	87.5*	12.5	0.0	0.0	0.0
28. Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room	64	82.8*	15.6	1.6	0.0	0.0
29. Assure that suction, advanced airway equipment, positive pressure ventilation, and supplemental oxygen are immediately available in the procedure room and in good working order	64	81.3*	12.5	3.1	3.1	0.0
30. Assure that a member of the procedural team is trained in the recognition and treatment of airway complications, opening the airway, suctioning secretions, and performing bag-valve-mask ventilation	64	87.5*	10.9	1.6	0.0	0.0
31. Assure that a member of the procedural team has the skills to establish intravenous access	64	76.6*	17.2	4.7	1.6	0.0
32. Assure that a member of the procedural team has the skills to provide chest compressions	62	87.1*	12.9	0.0	0.0	0.0
33. Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area	64	78.1*	18.8	1.6	1.6	0.0
34. Assure that an individual or service is immediately available with advanced life support skills	63	73.0*	19.0	6.3	1.6	0.0
35. Assure that members of the procedural team are able to recognize the need for additional support and know how to access emergency services from the procedure room	64	85.9*	10.9	1.6	1.6	0.0
Sedative or analgesic medications not intended for general anesthesia						
36. Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient	64	81.3*	18.8	0.0	0.0	0.0
37. Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis	63	14.3	17.5	63.5*	4.8	0.0

(Continued)

Table 9. (Continued)

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
38. In patients receiving intravenous medications for sedation/analgesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	64	85.9*	14.1	0.0	0.0	0.0
39. In patients who have received sedation/analgesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	63	66.7*	31.7	1.6	0.0	0.0
40. Administer intravenous sedative/analgesic drugs in small, incremental doses or by infusion, titrating to the desired endpoints	64	81.3*	15.6	0.0	3.1	0.0
Sedative or analgesic medications intended for general anesthesia						
41. When moderate procedural sedation with sedative or analgesic medications intended for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia	61	82.0*	16.4	1.6	0.0	0.0
42. Assure that practitioners administering these drugs are able to reliably rescue patients from unintended deep sedation or general anesthesia	64	90.6	7.8	1.6	0.0	0.0
43. For patients receiving intravenous sedatives intended for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	64	87.5*	12.5	0.0	0.0	0.0
44. In patients who have received sedatives intended for general anesthesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	61	73.8*	21.3	0.0	4.9	0.0
45. Administer intravenous sedative/analgesic drugs intended for general anesthesia in small, incremental doses, or by infusion, titrating to the desired endpoints	64	81.3*	15.6	0.0	3.1	0.0
Reversal agents						
46. Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia regardless of administration route	63	77.8*	17.5	4.8	0.0	0.0
47. If patients become hypoxemic or apneic during sedation/analgesia, encourage or physically stimulate patients to breathe deeply	64	81.3*	15.6	3.1	0.0	0.0
48. If patients become hypoxemic or apneic during sedation/analgesia, administer supplemental oxygen	61	82.0*	16.4	1.6	0.0	0.0
49. If patients become hypoxemic or apneic during sedation/analgesia, provide positive pressure ventilation if spontaneous ventilation is inadequate	64	85.9*	14.1	0.0	0.0	0.0
50. Use reversal agents in cases where airway control, spontaneous ventilation or positive pressure ventilation is inadequate	63	71.4*	22.2	4.8	1.6	0.0
51. Administer naloxone to reverse opioid-induced sedation and respiratory depression	63	55.6*	36.5	3.2	4.8	0.0
52. Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression	63	57.1*	33.3	6.3	3.2	0.0
53. After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates	64	79.7*	18.8	1.6	0.0	0.0
54. Do not use sedation regimens that include routine reversal of sedative/analgesic agents	62	67.7*	22.6	6.5	3.2	0.0

(Continued)

Table 9. (Continued)

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Recovery care						
55. After sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression	63	84.1*	15.9	0.0	0.0	0.0
56. Monitor oxygenation continuously until patients are no longer at risk for hypoxemia	63	85.7*	14.3	0.0	0.0	0.0
57. Monitor ventilation and circulation at regular intervals until patients are suitable for discharge	64	73.4*	21.9	4.7	0.0	0.0
58. Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel	64	78.1*	17.2	3.1	1.6	0.0
Creation and implementation of patient safety processes						
59. Create and implement a quality improvement process based upon national, regional, or institutional reporting protocols	61	54.1*	27.9	16.4	1.6	0.0
60. Strengthen patient safety culture through collaborative practices (e.g., team training, simulation drills, development and implementation of checklists)	63	71.4*	25.4	3.2	0.0	0.0
61. Create an emergency response plan (e.g., activating "code blue" team or activating the emergency medical response system: 911 or equivalent)	64	75.0*	23.4	1.6	0.0	0.0

\*N = the number of consultants who responded to each item. An asterisk beside a percentage score in the columns to the right indicates the median.

Table 10. American Society of Dentist Anesthesiologists Member Survey Responses

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Patient evaluation						
1. Review previous medical records and interview the patient or family	104	89.4*	10.6	0.0	0.0	0.0
2. Conduct a focused physical examination of the patient	104	87.5*	12.5	0.0	0.0	0.0
3. Review available laboratory test results and order additional laboratory tests when needed	104	72.1*	24.0	3.8	0.0	0.0
4. If possible, perform the preprocedure evaluation well enough in advance (e.g., several days to weeks) to allow for proper patient preparation	104	55.8*	30.8	9.6	2.9	1.0
5. Re-evaluate the patient immediately before the procedure	104	83.7*	16.3	0.0	0.0	0.0
Preprocedure patient preparation						
6. Consult with a medical specialist, when appropriate, before administration of moderate procedural sedation to patients with significant underlying conditions	104	81.7*	13.5	4.8	0.0	0.0
7. When feasible before the procedure, inform patients or legal guardians of the benefits, risks, and limitations of moderate sedation/analgesia and possible alternatives, and elicit their preferences	104	85.6*	12.5	1.9	0.0	0.0
8. Before the day of the procedure, inform patients or legal guardians that they should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying	104	94.2*	5.8	0.0	0.0	0.0
9. On the day of the procedure, assess the time and nature of last oral intake	104	93.3*	6.7	0.0	0.0	0.0
10. In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone	103	16.5	35.0*	21.4	13.6	13.6

(Continued)



Table 10. (Continued)

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
Monitoring patient level of consciousness						
11. Periodically monitor a patient's response to verbal commands during moderate sedation, except in patients who are unable to respond appropriately or during procedures where movement could be detrimental clinically	104	39.4	38.5*	12.5	8.7	1.0
12. During procedures where a verbal response is not possible, check the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile stimulation	104	46.2	38.5*	8.7	4.8	1.9
Monitoring patient ventilation and oxygenation						
13. Continually monitor ventilatory function by observation of qualitative clinical signs	95	84.2*	13.7	1.1	0.0	1.1
14. Continually monitor ventilatory function by capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment	95	54.7*	26.3	11.6	7.4	0.0
15. Monitor all patients by pulse oximetry with appropriate alarms	95	93.7*	6.3	0.0	0.0	0.0
Monitoring hemodynamics						
16. Determine blood pressure before sedation/analgesia is initiated unless precluded by lack of patient cooperation	95	85.3*	10.5	1.1	1.1	2.1
17. Once moderate sedation/analgesia is established, continually monitor blood pressure and heart rate during the procedure unless such monitoring interferes with the procedure	95	84.2*	9.5	1.1	3.2	2.1
18. Use electrocardiographic monitoring during moderate sedation in patients with clinically significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated	94	81.9*	13.8	1.1	2.1	1.1
Contemporaneous recording of monitored parameters						
19. Record level of consciousness, ventilator and oxygenation status, and hemodynamic variables 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	95	63.2*	18.9	8.4	3.2	6.3
20. Set device alarms to alert the care team to critical changes in patient	95	74.7*	21.1	3.2	1.1	0.0
Availability of an individual responsible for patient monitoring						
21. Assure that a designated individual other than the practitioner performing the procedure is present to monitor the patient throughout the procedure	95	77.9*	13.7	6.3	0.0	2.1
22. The individual responsible for monitoring the patient should be trained in the recognition of apnea and airway obstruction and be empowered to seek additional help	94	88.3*	6.4	3.2	0.0	2.1
23. The designated 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	95	44.2	28.4*	8.4	9.5	9.5
Supplemental oxygen						
24. Use supplemental oxygen during moderate procedural sedation/analgesia unless specifically contraindicated for a particular patient or procedure	95	63.2*	20.0	13.7	3.2	0.0
Emergency support						
25. Assure that pharmacologic antagonists for benzodiazepines and opioids are immediately available in the procedure room	94	79.8*	16.0	2.1	2.1	0.6
26. Assure that an individual is present in the room who understands the pharmacology of the sedative/analgesics administered and potential interactions with other medications and nutraceuticals the patient may be taking	93	91.4*	7.5	1.1	0.0	0.0

(Continued)

Table 10. (Continued)

	Percent Responding to Each Item					
	N*	Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
27. Assure that appropriately sized equipment for establishing a patent airway is available	94	92.6*	7.4	0.0	0.0	0.0
28. Assure that at least one individual capable of establishing a patent airway and providing positive pressure ventilation is present in the procedure room	93	95.7*	3.2	0.0	0.0	1.1
29. Assure that suction, advanced airway equipment, positive pressure ventilation, and supplemental oxygen are immediately available in the procedure room and in good working order	94	94.7*	4.3	1.1	0.0	0.0
30. Assure that a member of the procedural team is trained in the recognition and treatment of airway complications, opening the airway, suctioning secretions, and performing bag-valve-mask ventilation	93	91.4*	5.4	2.2	0.0	1.1
31. Assure that a member of the procedural team has the skills to establish intravenous access	93	81.7*	5.4	11.8	0.0	1.1
32. Assure that a member of the procedural team has the skills to provide chest compressions	94	95.7*	4.3	0.0	0.0	0.0
33. Assure that a functional defibrillator or automatic external defibrillator is immediately available in the procedure area	94	92.6*	5.3	1.1	1.1	0.0
34. Assure that an individual or service is immediately available with advanced life support skills	94	70.2*	16.0	7.4	4.3	2.1
35. Assure that members of the procedural team are able to recognize the need for additional support and know how to access emergency services from the procedure room	93	89.2*	9.7	1.1	0.0	0.0
Sedative or analgesic medications not intended for general anesthesia						
36. Combinations of sedative and analgesic agents may be administered as appropriate for the procedure and the condition of the patient	89	62.9*	30.3	6.7	0.0	0.0
37. Dexmedetomidine may be administered as an alternative to benzodiazepine sedatives on a case-by-case basis	90	33.3	22.2*	26.7	8.9	8.9
38. In patients receiving intravenous medications for sedation/analgesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	90	84.4*	15.6	0.0	0.0	0.0
39. In patients who have received sedation/analgesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	90	56.7*	30.0	6.7	4.4	2.2
40. Administer intravenous sedative/analgesic drugs in small, incremental doses or by infusion, titrating to the desired endpoints	89	74.2*	21.3	0.0	1.1	3.4
Sedative or analgesic medications intended for general anesthesia						
41. When moderate procedural sedation with sedative or analgesic medications intended for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia	88	81.8*	13.6	3.4	1.1	0.0
42. Assure that practitioners administering these drugs are able to reliably rescue patients from unintended deep sedation or general anesthesia	90	96.7*	2.2	0.0	1.1	0.0
43. For patients receiving intravenous sedatives intended for general anesthesia, maintain vascular access throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression	90	91.1*	7.8	0.0	0.0	1.1
44. In patients who have received sedatives intended for general anesthesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis	90	62.2*	12.2	4.4	12.2	8.9

(Continued)

Table 10. (Continued)

	N*	Percent Responding to Each Item				
		Strongly Agree	Agree	Equivocal	Disagree	Strongly Disagree
45. Administer intravenous sedative/analgesic drugs intended for general anesthesia in small, incremental doses, or by infusion, titrating to the desired endpoints	90	65.6*	12.2	5.6	5.6	11.1
Reversal agents						
46. Assure that specific antagonists are immediately available in the procedure room whenever opioid analgesics or benzodiazepines are administered for moderate procedural sedation/analgesia regardless of administration route	90	82.2*	14.4	1.1	2.2	0.0
47. If patients become hypoxemic or apneic during sedation/analgesia, encourage or physically stimulate patients to breathe deeply	90	88.9*	6.7	1.1	2.2	1.1
48. If patients become hypoxemic or apneic during sedation/analgesia, administer supplemental oxygen	90	92.2*	6.7	0.0	1.1	0.0
49. If patients become hypoxemic or apneic during sedation/analgesia, provide positive pressure ventilation if spontaneous ventilation is inadequate	90	92.2*	6.7	0.0	1.1	0.0
50. Use reversal agents in cases where airway control, spontaneous ventilation or positive pressure ventilation is inadequate	89	73.0*	16.9	3.4	3.4	3.4
51. Administer naloxone to reverse opioid-induced sedation and respiratory depression	90	62.2*	25.6	7.8	2.2	2.2
52. Administer flumazenil to reverse benzodiazepine-induced sedation and respiratory depression	90	61.1*	25.6	7.8	2.2	3.3
53. After pharmacologic reversal, observe and monitor patients for a sufficient time to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates	90	91.1*	8.9	0.0	0.0	0.0
54. Do not use sedation regimens that include routine reversal of sedative/analgesic agents	90	84.4*	10.0	2.2	2.2	1.1
Recovery care						
55. After sedation/analgesia, observe and monitor patients in an appropriately staffed and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression	88	86.4*	10.2	2.3	0.0	1.1
56. Monitor oxygenation continuously until patients are no longer at risk for hypoxemia	88	86.4*	13.6	0.0	0.0	0.0
57. Monitor ventilation and circulation at regular intervals until patients are suitable for discharge	88	77.3*	18.3	3.4	1.1	0.0
58. Design discharge criteria to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel	88	84.1*	14.8	1.1	0.0	0.0
Creation and implementation of patient safety processes						
59. Create and implement a quality improvement process based upon national, regional, or institutional reporting protocols	88	58.0*	31.8	9.1	1.1	0.0
60. Strengthen patient safety culture through collaborative practices (e.g., team training, simulation drills, development and implementation of checklists)	88	72.7*	22.7	4.5	0.0	0.0
61. Create an emergency response plan (e.g., activating "code blue" team or activating the emergency medical response system: 911 or equivalent)	88	79.5*	18.2	2.3	0.0	0.0

\*N = the number of consultants who responded to each item. An asterisk beside a percentage score in the columns to the right indicates the median.