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Developing a Moderate Sedation Policy: Essential Elements and Evidence-Based Considerations

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ABSTRACT

Developing an institutional policy for moderate sedation is a multidisciplinary effort that should involve close collaboration among clinicians, administrators, and risk managers. A variety of health care providers administer moderate sedation. Sedation policy should address essential elements, such as clinician training and credentialing, equipment, preprocedure evaluation, periprocedure patient monitoring, postprocedure observation and discharge, pharmaceutical agents, and outcomes assessment. Sedation policy should comply with local, state, and national guidelines and standards. Furthermore, sedation policy should be evidence based to incorporate the latest information about best practices and outcomes. Advances in pharmacology, monitoring, medication delivery systems, and simulation training can help improve quality of care and patient safety in the administration of moderate sedation. *AORN J* 99 (March 2014) 416-430. © AORN, Inc, 2014. <http://dx.doi.org/10.1016/j.aorn.2013.09.015>

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The practice of moderate sedation has evolved continuously during the past decade as a result of changing regulations, increased procedure complexity, and increased patient acuity. In the past, only anesthesia professionals could administer moderate sedation. Currently, nonanesthesia providers (eg, periprocedure RNs, advanced practice RNs) have become active participants in managing patients who are receiving moderate sedation. The Joint Commission,¹ Centers for Medicare & Medicaid Services,² state licensing and medical boards, and specialty-specific governing bodies³⁻⁵ have

established guidelines to address nonanesthesia provider education and qualification requirements and other patient care standards related to sedation.

The American Society of Anesthesiologists (ASA) defines *moderate sedation* as

a drug-induced depression of consciousness during which patients respond purposely 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.^{5(p1005)}

Health care facilities should have a policy in place for safe administration of medications, provider qualifications, and monitoring of patients undergoing moderate sedation.⁶ To create an evidence-based institutional policy requires a multidisciplinary effort from a diverse mix of stakeholders, including nurses, physicians, physician extenders, administrators, pharmacists, and risk managers as well as patient safety and quality assurance specialists. A policy should serve as a guideline to follow regardless of the type of procedure being performed or the location of the sedation services being provided. The periprocedure RN's integral roles during the care and management of the patient receiving moderate sedation should be outlined. Competency and education requirements also should be in the policy, because proper training of periprocedure personnel is critical to compliance. Required educational activities should encompass both clinical and administrative aspects of sedation. For a moderate sedation policy to help achieve optimal patient outcomes, and for it to be effective in putting patient safety first, the policy should be evidence based; if research-based outcomes are not readily available, then the policy should incorporate recommendations from existing national standards and guidelines.

Whether a sedation policy is already in place at a facility or is in the process of being developed, this article addresses essential policy elements as well as emerging research and literature topics related to sedation that administrators and health care providers can use to ensure that their sedation policy is evidence based. Also provided in this article are tools and resources for maintaining evidence-based policies as part of a robust sedation program.

ESSENTIAL POLICY ELEMENTS

Multidisciplinary team members who are developing a sedation policy should consider the following elements: administrative aspects (eg, purpose and scope statements, governance, necessary equipment), assignment of responsibilities, competency

and credentialing, preprocedure evaluation, medications, and documentation. Facilities typically will have a policy and procedure template to help standardize and guide policy decisions.

Administrative Aspects

A sedation policy should begin with the purpose and scope. The purpose and scope clarify patient populations, types of practitioners, and types of sedation (eg, moderate, deep) to which the policy pertains. Regarding sedation types, it is helpful to include a list of sedation levels as defined by the ASA,⁷ particularly because some health care providers may be new to moderate sedation. A section on governance should identify which administrative entities (eg, clinical departments, hospital committees) have oversight of the sedation program. In addition, the policy should delineate specific locations where sedation may be administered. Necessary equipment and other measures to ensure patient safety (eg, heart monitoring, pulse oximetry, supplemental oxygen delivery, resuscitative equipment) can guide selection of these locations. For example, procedures and sedation should not be performed in locations where an emergency code cart with resuscitation equipment is not available.

Assignment of Responsibilities

The policy should assign responsibilities to both the “operator” (ie, the practitioner, often a physician, who is performing the procedure, directing sedation, or performing the procedure and directing sedation) and the “monitor” (ie, the clinician, often a periprocedure RN, who is monitoring the patient during sedation and administering medications). Having role delineation in a policy addresses periprocedure patient monitoring and satisfies an important regulatory issue: the operator does not perform the procedure and simultaneously monitor the patient while administering sedation.⁸ For instance, the Institute for Safe Medication Practices states, “...only persons trained in the administration of general anesthesia, who are not simultaneously

involved in the procedures, should administer propofol to nonventilated patients.”⁹

Competency and Credentialing

A sedation policy should describe education and training requisites for nonanesthesia providers. For periprocedure RNs and independently licensed practitioners, regulations regarding medication administration and oversight vary by state, which the policy must reflect. In addition, the policy must have a provision for training oversight as well as training and credentialing requirements for each type of practitioner and clinician involved. For example, criteria may involve formal testing on topics related to sedation, such as basic life support (BLS) and advanced cardiovascular life support (ACLS) certification, as well as hands-on skills training and state-specific licensure requirements (eg, prohibitions on nurse-administered propofol).

Preprocedure Evaluation

The policy's preprocedure evaluation section must describe all essential elements of patient preparation, such as

- specifics regarding the length of time the patient should remain NPO,
- history and physical examination, and
- preprocedure vital signs.

Based on preprocedure evaluation by a licensed health care practitioner, some patients may not be deemed appropriate candidates for sedation. Therefore, the policy should include anesthesia consultation criteria. Each facility should develop its own policy criteria for consultation, which should identify the types of patients who either are considered high risk or who might otherwise benefit from being evaluated by an anesthesia professional.¹⁰

Medications

Pharmacology plays an important role in sedation; therefore, a sedation policy must contain a list of

permitted medications that can be administered to achieve the desired level of sedation. Medications most often used are benzodiazepines (eg, diazepam, midazolam), opioids (eg, fentanyl), and hypnotics (eg, propofol) as well as other adjunct medications (eg, diphenhydramine, scopolamine, nonsteroidal anti-inflammatory drugs). The list of permitted medications must be reviewed periodically by clinicians and pharmacists and amended as needed. Ideally, the policy should provide suggested dosing per single administration and the maximum allowed dose for a given time period to prevent oversedation and cardiopulmonary compromise.

Documentation

The policy should include documentation requirements for moderate sedation procedures, including the preprocedure encounter, the procedure itself, and the recovery period. Patient monitoring requirements (eg, how frequently to record vital signs, when to use the Richmond Agitation Sedation Scale or capnography) must be clearly stated. Capnography helps monitor the concentration of exhaled carbon dioxide (CO₂). A capnograph is a numeric readout and waveform tracing that directly reflects the adequacy of ventilation during anesthesia and provides information about elimination of CO₂ from both intubated and nonintubated patients. Capnography is gaining in popularity, and health care providers use the tool during procedures involving moderate and deep sedation in addition to those performed under general anesthesia. A discussion about capnography appears later in this article.

The importance of proper patient care during the recovery period cannot be overstated because of the possibility of adverse events related to both sedation and the procedure itself. Therefore, documenting this phase of care should be an important procedural step in the policy. The policy also must establish criteria for patient observation as well as for patient discharge or transfer after recovery is complete (eg, the Aldrete Scoring System,¹¹ White's Fast Tracking Scoring System,¹² Modified

Aldrete Scoring System,¹³ or Post Anesthetic Discharge Scoring System¹⁴).

Documentation guidelines help to establish a robust quality assessment and improvement structure. The policy must list all accountable parties and describe the administrative structure for continuous quality improvement and outcomes assessment as well as review and documentation of any complications.

CONSTRUCTING A MODERATE SEDATION POLICY

Table 1 provides a suggested framework for a moderate sedation policy that incorporates the essential policy elements discussed in the preceding text. In constructing a moderate sedation policy, several elements warrant a more in-depth discussion.

Establishing Roles and Core Competencies

All patients should receive the same level of care by qualified health care providers, regardless of the location where moderate sedation is being administered. According to The Joint Commission,

*In addition to the individual performing the procedure, a sufficient number of qualified staff [should be] present to evaluate the patient, to provide the sedation and/or anesthesia, to help with the procedure, and to monitor and recover the patient.*¹⁵

To meet these criteria, a moderate sedation policy should require a minimum of two qualified professionals attending the patient. The periprocedure RN has a number of important duties to accomplish before the procedure can proceed; however, the policy should make clear that the RN's primary responsibility during moderate sedation is exclusively to that patient. According to the American Association of Nurse Anesthetists, the RN who manages and monitors the patient receiving sedation should have no other responsibilities during the procedure that would compromise continuous patient monitoring.⁸ Rules governing the practice

TABLE 1. Suggested Structure for a Moderate Sedation Policy

Purpose
Scope
Definitions of sedation levels
Governance
Location requirements
Equipment requirements
Personnel roles and requirements
Competency and credentialing requirements
Preprocedure evaluation
Considerations for anesthesia consultation
Periprocedure monitoring requirements
Medication administration guidelines
Postprocedure observation and discharge
Outcomes assessment
Documentation guidelines

of certified RN anesthetists (CRNAs) vary by state. Some states allow CRNAs to practice independently without physician oversight, whereas other states require supervision by a physician.

The role of the “monitor” can be filled by a periprocedure RN, physician assistant, physician, or other appropriately trained and licensed health care provider. However, the periprocedure RN usually takes the role of the “monitor.” As a licensed and credentialed health care professional, an RN monitor can check physiological parameters as well as the patient's response to medications administered and to the procedure itself. A non-anesthesia provider, such as a physician or physician assistant, usually takes the role of the “operator.” The operator performs the procedure for which sedation is being administered.

According to the ASA, to administer moderate sedation, certain educational and training requirements must be met.¹⁶ Examples of requirements can be specific to a facility or state but typically include specific education and training, mandated licensure, a process to establish criteria for credentialing and to evaluate the practitioner's and clinician's performance, and continual performance assessment. Additional professional organizations

have established guidelines for clinicians who monitor moderate sedation. In general, the following items should be identified in the moderate sedation policy and included in a formal training program.⁶ The monitor must be able to

- perform a preprocedure patient assessment, including history and physical examination;
- understand the different sedation levels;
- demonstrate a strong foundation in pharmacology and safe administration of sedatives and analgesics used to establish a level of moderate sedation and antagonists for medications administered;
- demonstrate strong airway management skills and knowledge of the modes of oxygen delivery;
- monitor and document the patient's physiological parameters (eg, blood pressure, respiratory rate, oxygen saturation by pulse oximetry, electrocardiography monitoring, depth of sedation, capnography);
- demonstrate the proper recognition and use of audible alarms for all physiological parameters;
- recognize common complications (eg, onset of hypoxia) and the suitable intervention; and
- demonstrate strong communication and teamwork skills.

Clinicians who are the designated monitors also must be competent in cardiopulmonary resuscitation skills. In addition to this initial education, a formal recertification process must be in place for all monitors. Administrators must also ensure that evaluation and documentation of competency occurs on a regular basis, in accordance with each facility's established policy guidelines.⁶ These educational requirements must be part of a facility-wide process and should be consistent across the entire health care organization.

Managing Preprocedure Patient Preparation

The sedation team is responsible for ensuring that proper documentation is maintained throughout the procedure. For example, informed consent,

physical examination and medical history review, and a review of test results should be completed before the procedure. Patients with significant comorbidities or other conditions representing a higher risk of complications should be identified during this time.¹⁷

A member of the sedation team should

- review the patient's current medications;
- evaluate the patient's state of consciousness;
- check the patient's weight, particularly if there is a potential for weight-based medication dosing;
- review vital signs, oxygen saturation, and respiratory pattern and quality;
- perform an airway assessment, including an evaluation performed in anticipation of the possible need for positive pressure ventilation; and
- review pulmonary, cardiac, and neurological status.

Known allergies or sensitivities should be documented electronically and made evident to all involved parties. Determinations reached by the sedation team that the patient has no allergy, sensitivity, or contraindication to the planned prescribed pharmacological agents also should be shared. In keeping with ASA standards, the moderate sedation policy should include verification of NPO status,¹⁸ a procedural step that should occur before the start of sedation and analgesia.

In the case of ambulatory patients, the discharge plan must be established before the procedure. If there is not an accompanying adult, the clinician must plan for an alternate form of postdischarge observation and care that is sufficient. For instance, depending on the medications being administered, the patient may not be allowed to drive home and may require someone to remain with him or her for 24 hours after the procedure. If this level of postdischarge care is not possible for the patient, the procedure may need to be performed on an inpatient or 23-hour observation basis. In addition, the preprocedure nurse should be responsible for

- ensuring that the patient and family members understand what to expect from the procedure,
- verifying the patient's ability to tolerate positioning required for the procedure and the recovery phase,
- ensuring the patient's ability both to understand and to communicate with the monitoring clinician, and
- ensuring that the patient and his or her family members understand what the postprocedure course will entail.

This planning begins in the preprocedure period and is picked up by the postprocedure recovery room nurse when discharging the patient from the facility.

The preprocedure nurse should instruct the patient to report any problems associated with the procedure itself (eg, pain) or medications being administered (eg, difficulty breathing, nausea). The monitoring clinician should obtain and document baseline vital signs, level of consciousness, and sedation and pain level scores immediately before administration of medications.¹⁹ As a final point, a safety pause (ie, time out) must be completed before the start of the procedure, as required by the Universal Protocol™ and as a regulatory consideration.

Determining the Need for Anesthesia Consultation

During the preprocedure assessment of the patient, the clinician may determine that consultation with an anesthesia professional is necessary. Consultation with the anesthesia professional may result from the following clinician observations or reports from the patient:

- a patient who reports significant opioid use or other medications that might alter the effects of the sedative agents,
- a documented history of the patient not being able to tolerate moderate sedation in the past,
- the patient's inability to lie still for the duration of the procedure or to assume certain positions needed to safely complete the procedure,
- a concerning airway examination (eg, thick neck, inability to open the mouth widely, limited neck extension) or a known history of a difficult airway,
- allergies to commonly used sedative agents, or
- hemodynamic instability, or
- significant comorbidities (eg, obesity, heart disease, obstructive sleep apnea).

If the consulting anesthesia professional determines that the patient is not suitable for the planned level of sedation by a nonanesthesia provider, the sedation policy must account for arrangements to be made by members of the sedation team that are in accordance with the anesthesia professional's recommendations. In some instances, the addition of another clinician to the sedation team should be considered to assist with procedures that are particularly complex or with patients whose medical condition (eg, trauma) requires management beyond the capacity of assigned clinicians.¹⁹

Selecting the Medication Regimen

The moderate sedation policy should include a list of medications that are allowed for use, as well as dosages and limits. The goals of moderate sedation are analgesia, sedation, and amnesia. Altering the patient's level of consciousness usually is accomplished by administering a combination of opioids and benzodiazepines, and the most common combination of IV medications is midazolam and fentanyl. However, other medication classes, such as hypnotics, and combinations of medications, such as propofol, dexmedetomidine, and ketamine, have been used. Adjunct sedative and analgesic agents also have been used, including diphenhydramine, scopolamine, nonsteroidal anti-inflammatory drugs, acetaminophen, and clonidine.²⁰

Typically, moderate sedation is accomplished with IV medications, but oral doses may be suitable in some situations (eg, oral lorazepam). No single regimen is ideal for all situations, and patients may react differently.⁶ Each facility should determine which medications and medication combinations

are allowed, and this should be reflected in the moderate sedation policy. Determinations should be based on assessment of the patient population and the training level of facility personnel.

It is important to remember that medications used for moderate sedation should not be administered without full knowledge of that medication's pharmacology. The clinician must be aware of particular institutional and state board of nursing guidelines regarding the administration of sedation medications. For example, one controversial subject is propofol administration by nonanesthesia providers, such as nurses (nurse-administered propofol sedation), for which there are limited data on patient outcomes.²¹⁻²³ More studies are needed in this area to fully assess its effect on patient safety.

Managing Postprocedure Recovery: Observation and Discharge

The monitoring clinician must coordinate postprocedure recovery, including observation and arrangements for home discharge or transfer to a suitable level of monitored care. Most of the medications administered during the procedure are not immediately metabolized, thus requiring adequate monitoring in the postprocedure recovery setting. According to The Joint Commission, the patient must be assessed in a postsedation recovery area before discharge and be discharged by a qualified, licensed independent practitioner.¹⁵ Alternatively, patients can be discharged according to established institutional criteria. Many institutions choose to adopt discharge criteria based on the Aldrete scoring system,¹¹ which scores the patient using five parameters: activity, respiration, oxygenation, circulation, and consciousness. Each of the criteria receives anywhere from zero to two points, based on the absence or presence of the parameter. A total of eight points must be achieved for discharge. If a patient receives a score of seven or lower, a physician must reevaluate the patient before discharge can occur. For a patient transferred

back to the inpatient unit, an adequate hand-over communication must occur.


The discharge nurse must provide the patient being discharged to home with both oral and written discharge instructions, including specific limitations or requirements as a result of the procedure. The nurse should instruct the patient to contact the health care provider listed on the written instructions if he or she experiences problems or has questions. If the patient decides to travel home without a responsible adult to accompany him or her, despite the clinician's best efforts to prevent the patient from doing so, the nurse should ask the patient to sign an "against medical advice" or equivalent form.⁶

Assessing Outcomes

A facility must have a robust risk management structure with an outcomes assessment process to support the sedation program. Risk management should be guided by local, state, and national accrediting and governing bodies, such as the Centers for Medicare & Medicaid Services, The Joint Commission, the Department of Public Health, and state medical and nursing licensing boards. The individual designated as the medical director of moderate sedation is accountable for the outcomes assessment process and reporting to other hospital governance and oversight committees. The medical director should work closely with other multidisciplinary stakeholders, such as the nursing director, to focus on areas governed by the moderate sedation policy, including

- selection of appropriate patients and procedures;
- preparation of patients for procedures;
- procedure performance and patient monitoring;
- provision of postprocedure care, including patient education; and
- documentation standards.

In addition, a provision must be made in the policy for standard auditing and chart reviews. The medical

 **Ambulatory Takeaways****Resources for Moderate Sedation Policies and Procedures in the Ambulatory Setting**

Sedation policies and procedures should be in place in ambulatory surgery centers (ASCs), and all policy decisions should be approved by the facility's governing body. The term *moderate sedation*, as defined by the American Society of Anesthesiologists (ASA), is widely accepted and can be included in the policy. However, the medications administered and the health care provider who administers the medications vary according to state law, which should be reflected in the policy.

When considering personnel requirements for the policy, a perioperative RN often administers IV sedation under the supervision of a physician. The Centers for Medicare & Medicaid Services (CMS) does not define moderate sedation as anesthesia, as appears in the ASA guidelines¹; however, CMS recognizes that sedation occurs on a continuum. The continuum of sedation affects competency and role requirements of the RN who is engaged in the administration of moderate sedation. The RN who is monitoring the patient must have the critical thinking skills necessary to intervene if the patient progresses into deep sedation. Additionally, the physician-directed, designated RN who administers moderate sedation and monitors the patient should have no other competing responsibilities during the procedure.

For a sedation policy to address competencies for nonanesthesiologist administration of moderate sedation, a joint collaborative effort among the national gastroenterology societies, including the Society of Gastroenterology Nurses and Associates, created the "Multisociety sedation curriculum for gastrointestinal endoscopy."² This curriculum is robust (eg, didactic, Web-based learning, simulation) and should be considered as a resource in developing training and competencies for moderate sedation during gastrointestinal procedures.

In an ASC or office-based setting, a moderate sedation policy must have checks and balances in place, such as a plan of action in the event of emergencies or inadvertent progression to deep sedation and the necessary equipment to perform these actions. An additional RN circulator is strongly suggested for situations during which procedure complexity may change over time or whenever a child or patient who has cognitive challenges is receiving care.

As new technology for monitoring the patient and administering medication evolves, policy stakeholders must stay informed and be aware of how policy may be affected. For example, a colonoscopy is one of the most frequently performed procedures in ASCs. New monitoring tools allow for nonanesthesiologist administration of propofol for gastrointestinal endoscopy. There are many considerations, and AORN encourages nurses to take part in these discussions. Clear guidelines, specific training and competencies, contingency plans, and compliance with all applicable local, state, and federal regulations should be part of an ASC's policy and procedure on moderate sedation.

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1. 416.42(b) &(c). Administration of anesthesia. Interpretive guideline. Centers for Medicare & Medicaid Services. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_1_ambulatory.pdf. Accessed December 19, 2013.
2. Vargo JJ, DeLegge MH, Feld AD, et al; American Association for Study of Liver Diseases; American College of Gastroenterology; American Gastroenterological Association Institute; American Society for Gastrointestinal Endoscopy; Society for Gastroenterology Nurses and Associates. Multisociety sedation curriculum for gastrointestinal endoscopy. *Gastrointest Endosc*. 2012;76(1):e1-e25.

director must ensure that audit data and all mandatory adverse event summaries are analyzed and that any variances in the procedure or the process regarding care are acted on.

The University HealthSystem Consortium has established process and outcome measures to be used.²⁴ Recommended process measures include

- informed consent for procedures,
- a record of history and physical examination,
- proper credentialing of personnel,
- proper patient monitoring,
- patient NPO status, and
- identification of requirements for anesthesia consultation.

Recommended University HealthSystem Consortium outcomes measures that should require mandatory review of events include

- inability to complete the procedure as planned,
- adverse medication reactions,
- aspiration,
- use of reversal or nonapproved agents,
- unplanned admission or transfer to a higher level of care,
- cardiopulmonary arrest, and
- death.²⁴

EMERGING TOPICS TO INCORPORATE INTO THE POLICY

The practice of sedation is constantly evolving; therefore, it is important for health care providers to stay abreast of the latest developments affecting patient care. Examples of emerging topics to be considered for inclusion in a moderate sedation policy are new research, new regulations, advances in technology, and educational resources.

Outcomes Research

There is a growing body of literature demonstrating a knowledge of sedation-related outcomes of patients undergoing various procedures.²⁵⁻²⁷ Data that describe complications related to moderate sedation are available for both adult and pediatric

populations. Researchers studying 49,836 propofol sedation and anesthesia encounters in the pediatric population reported no deaths and a rare incidence of aspiration or need for cardiopulmonary resuscitation.²⁵ Results from another study showed that a more frequent rate of sedation-related incidents is linked to events such as desaturation less than 90% for more than 30 seconds, central apnea or airway obstruction, stridor, and laryngospasm.²⁶ The investigators suggested that pediatric sedation and anesthesia for procedures performed outside the OR are not likely to result in serious adverse outcomes in facilities with already high standards of care and well-organized sedation program.²⁶

Results from a study of the adult population that underwent sedation at a large tertiary care hospital showed a low death rate and identified the following outcomes as having the highest incidence rate: desaturation less than 90%; apnea or the use of a reversal agent; and pain, anxiety, or both.²⁷ These findings were based on more than 63,000 patients undergoing diagnostic or therapeutic procedures under sedation or anesthesia, with 41% of patients sedated by nonanesthesia providers. The investigator also suggested that capnography can improve early detection of apnea and that respiratory compromise related to sedation with propofol occurs less frequently than when it is related to sedation with opiates and benzodiazepines.

Following are additional examples of outcomes research that have emerged in the anesthesia literature and are relevant to moderate sedation policy.²⁸⁻³⁴ In one study, researchers compared closed claims cases involving monitored anesthesia care (MAC) with those involving general anesthesia.²⁸ All cases involved anesthesia professionals. The MAC claims had older and sicker patients compared with the general anesthesia claims. More than 40% of claims associated with MAC involved death or permanent brain damage, similar to general anesthesia claims. Respiratory depression was the most common specific damaging mechanism in MAC claims. The researchers suggested that nearly half of those claims were preventable with better

monitoring, such as capnography, improved vigilance, or audible alarms. Another finding from this study was that fires from the use of electro-surgery in the presence of supplemental oxygen during facial surgery resulted in burn injuries in 20 MAC claims.

The investigators of one study used data from the ASA Closed Claims database and suggested that anesthesia at remote locations poses a significant risk for the patient, particularly related to oversedation and inadequate oxygenation and ventilation during monitored anesthesia care.²⁹ This evidence calls for the use of the same monitoring standards and guidelines, regardless of the location, which should be reflected in a moderate sedation policy. The results of the study showed that, compared with OR claims, claims of respiratory damaging events were more common in remote locations, and death was increased in remote location claims. Inadequate oxygenation/ventilation was the most common specific event. The investigators suggested that many remote location claims were judged as being preventable with better monitoring. Two additional studies highlight the importance of capnography in detecting impending airway or respiratory adverse events,^{30,31} although more research needs to be performed to determine the incidence of complications associated with sedation and to compare practice outcomes among different practitioners and specialties.

Finally, preliminary data from one tertiary care academic institution indicate that patients with a higher ASA physical status classification are at risk for high-severity incidents while undergoing moderate sedation. Patients with a higher severity score were, on average, 10 years older than those with a lower severity score. In addition, a high severity score was associated with a higher ASA score.³² Results from several studies on sedation for endoscopic procedures also point to a higher incidence of complications in patients with an ASA score greater than or equal to three³³ and in those undergoing emergency examinations.³⁴

Although there is limited literature and research addressing outcomes related to sedation, it is an important consideration for creating an evidence-based moderate sedation policy. Staying informed about new literature and research findings helps to shed some light on patient outcomes related to patient selection, perioperative monitoring, and the type of anesthesia/sedation being administered.

Capnography

Effective July 2011, the ASA “Standards for basic anesthetic monitoring” recommend the use of capnography for all procedures involving moderate and deep sedation.³⁵ Capnography, however, is not uniformly endorsed by all professional entities at this time. As discussed in the preceding text, capnography measures CO₂ that the patient exhales and is a tool to measure adequate ventilation. If pulse oximetry is the best measure of oxygenation, capnography is a better measure of ventilation because, in the case of airway obstruction, oxygenation levels can remain normal for some time, resulting in a detection delay that can cause apnea or hypoventilation to go unrecognized. Evidence shows, however, that the use of capnography during sedation can help decrease the incidence of adverse respiratory events during sedation and that it is an effective method for clinicians to quickly recognize respiratory compromise.³⁶⁻³⁸

New Methods of Delivering Sedation

The US Food and Drug Administration recently granted premarket approval to SEDASYS® for a computer-assisted personalized sedation (CAPS) device that delivers propofol for minimal to moderate sedation. The device provides comprehensive patient monitoring and limits the depth of sedation by adjusting medication delivery accordingly. The device can detect signs associated with oversedation and can automatically modify or stop infusion.³⁹ Results from a study of the CAPS system demonstrated that healthy patients who were sedated by using the device had fewer occurrences of hypoxemia compared with similarly healthy

patients who were sedated by using a midazolam/opioid combination during elective colonoscopy and upper endoscopy procedures.⁴⁰ Results from another study showed that the CAPS system can facilitate administration of minimal to moderate propofol sedation for patients undergoing endoscopic procedures. However, more studies are needed to determine the types of patient populations for which the device can be used safely.⁴¹ If nonanesthesia providers use the CAPS device, they should be properly trained. The device's labeling instructions require an anesthesia professional to be immediately available for assistance or consultation, and they limit the types of medications that can be administered concurrently with propofol.

Patient-Controlled Sedation

Patient-controlled sedation (PCS) has been reported with the use of propofol, opioids, and benzodiazepines or in a combination of medications, such as propofol-remifentanyl and midazolam-fentanyl.⁴²⁻⁴⁵ The PCS system resembles the commonly used patient-controlled analgesia device, which allows patients to determine the suitable level of sedation/analgesia while undergoing a procedure. The device comprises an infusion pump and a handheld control panel. Patients can self-administer a bolus of medication and control the infusion rate within preset parameters. Results of studies have shown that patients can use PCS safely and that the use of PCS can lead to high patient satisfaction, decreased usage of medications, and faster recovery.^{31,45,46}

Educational Resources From Professional Societies

Many professional and accrediting organizations provide education for clinicians who are involved in the administration or monitoring of moderate sedation. For example, the ASA developed "Sedation and analgesia by non-anesthesiologists," a multimedia course designed specifically for non-anesthesia providers.⁴⁷ As of 2012, the course

packet includes a video with information regarding basic CO₂ monitoring and advanced life support, in addition to basic knowledge about safe administration of sedative and analgesic medications that clinicians use to establish a moderate level of sedation. The course curriculum included the ASA practice guidelines for sedation and analgesia by nonanesthesiologists; the ASA standards for basic anesthetic monitoring, which were updated in 2010 to include the use of capnography for moderate sedation; and the ASA statement on respiratory monitoring during endoscopic procedures. In addition, the course provides tools such as quality assurance indicators and a sedation credentials checklist. Health care providers who participate in educational activities like this often are complying with competency requirements in the moderate sedation policy.

Checklists

The use of checklists in health care has significantly gained in popularity since the World Health Organization introduced safety checklists.⁴⁸ Checklists have been associated with decreased mortality and morbidity, lower health care costs,^{49,50} and fewer communication errors.⁵¹ More recently, the crisis checklist for the OR was introduced.⁵² Checklists can be developed for specific procedures and health care settings and modified accordingly. Checklist implementation should be a multidisciplinary effort and must be accomplished systematically. In 2012, the National Adult Sedation Consortium developed a moderate sedation checklist template that highlights key events during a procedure that requires sedation (Figure 1). This template addresses patient evaluation, important processes immediately before the procedure, patient recovery, and outcomes reporting. This template can be modified to meet the specific needs of the clinicians monitoring moderate sedation or those of the facility. As a tool for practitioners in the administration of moderate sedation, safety checklists should be incorporated into the sedation policy.

Sedation Checklist Template

<p>Assessment (ie, before entering the procedure room)</p> <p><i>Patient Factors</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> History and physical examination with associated progress notes <input type="checkbox"/> Consent obtained; explanation of sedation level given <input type="checkbox"/> NPO status verified <input type="checkbox"/> Patient confirmed as suitable for the level of sedation <input type="checkbox"/> Recovery and escort plans verified <p><i>Facilities/Emergency</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Medications (sedation + procedure + rescue) <input type="checkbox"/> Equipment (sedation + procedure + rescue) <input type="checkbox"/> Oversedation backup plan reviewed 	<p>Sedation (ie, before sedation)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Oxygen and suction <input type="checkbox"/> Monitors on and functioning <input type="checkbox"/> Necessary team members in attendance <p>Time Out</p> <ul style="list-style-type: none"> <input type="checkbox"/> Patient re-identified <input type="checkbox"/> Procedure confirmed <input type="checkbox"/> Antibiotics required? <input type="checkbox"/> Allergies confirmed <input type="checkbox"/> Open communication demonstrated 	<p>Recovery (ie, in the recovery area)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Hand over and transition of care performed <input type="checkbox"/> Pain assessment performed <p><i>Before Discharge</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Discharge criteria met? <input type="checkbox"/> Written instructions provided, including follow-up instructions <input type="checkbox"/> Is an escort available, if needed? 	<p>Outcomes (ie, after the procedure)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Unintended events <input type="checkbox"/> Clinician experience <input type="checkbox"/> Patient experience
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Figure 1. A sample checklist template for moderate sedation. Reprinted with permission from the National Adult Sedation Consortium, Boston, MA.

Simulation Training

Simulation has gained popularity in a variety of settings as a way to teach specific skills to practitioners, and there is emerging evidence about its efficacy.^{53,54} When simulators are used for simulation training, they are either mannequin based or computer screen based. Both simulator types have a place in sedation education and training. Drill scenarios can be developed for personnel to practice and address sedation competencies dealing with specific knowledge and skills, such as airway management, patient resuscitation, medication pharmacology, and team communication. In most cases, the learning objectives of a particular training course will help determine selection of an appropriate simulator or a combination of simulators.⁵³ In a 2013 study, Tobin et al⁵⁴ used simulation to teach clinicians about moderate sedation. The results showed a significant increase in participants' level of knowledge, skills, and clinical judgment.

CONCLUSION

As the number of procedures requiring moderate sedation continues to grow, each facility must establish evidence-based policies to ensure patient safety. A typical sedation policy should address the training and qualifications of personnel, monitoring requirements, pharmacological guidelines, patient recovery, quality assurance, and documentation requirements. Maintaining a robust sedation program requires the multidisciplinary involvement of clinicians, pharmacists, quality and risk managers, and hospital administrators. As the practice of moderate sedation continues to evolve, new developments, such as innovative medication delivery systems, the increased use of capnography, and a greater emphasis on both outcomes measurement and the use of safety checklists, all can help shape its future. **AORN**

Editor's notes: *The Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery is a trademark of The Joint*

Commission, Oakbrook Terrace, IL. SEDASYS is a registered trademark of Ethicon Endo-Surgery, Inc, West Somerville, NJ.

References

1. Are specific privileges to administer sedation required? The Joint Commission. Updated July 7, 2010. http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=457&ProgramId=47. Accessed December 19, 2013.
2. Centers for Medicare & Medicaid Services. Policies and procedures. 45 CFR §164.316. In: HIPAA Security Series. 2007;2(paper 5):6-8. <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/pprequirements.pdf>. Accessed December 18, 2013.
3. A position statement on safe medication administration. American Society of PeriAnesthesia Nurses. http://www.aspan.org/Portals/6/docs/ClinicalPractice/PositionStatement/1214/Pos_Stmt_6_Safe_Med_Admin.pdf. Accessed December 19, 2013.
4. Recommended practices for managing the patient receiving moderate sedation. In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, Inc; 2014:471-479.
5. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology*. 2002;96(4):1004-1017.
6. Caperelli-White L. Nursing considerations for sedation. In: Urman RD, Kaye AD, eds. *Moderate and Deep Sedation in Clinical Practice*. New York, NY: Cambridge University Press; 2012:102-114.
7. American Society of Anesthesiologists. Continuum of depth of sedation: definition of general anesthesia and levels of sedation/analgesia. 2009. <http://www.asahq.org/For-Members/~media/For%20Members/Standards%20and%20Guidelines/2012/CONTINUUM%20OF%20DEPTH%20OF%20SEDATION%20442012.ashx>. Accessed December 9, 2013.
8. American Association of Nurse Anesthetists. Registered nurses engaged in the administration of sedation and analgesia. 2013. <http://www.aana.com/resources2/professionalpractice/Documents/PPM%20Consid%204.2%20RNs%20Engaged%20in%20Sedation%20Analgesia.pdf>. Accessed December 9, 2013.
9. Propofol administration: who should administer? Institute for Safe Medication Practices. <http://www.ismp.org/Newsletters/acutecare/articles/20051103.asp>. Accessed December 18, 2013.
10. Fox C, Liu H, Yarborough M, Fox ME, Kaye AD. High-risk patients: sedation considerations in coexisting disease. In: Urman RD, Kaye AD, eds. *Moderate and Deep Sedation in Clinical Practice*. New York, NY: Cambridge University Press; 2012:120-134.
11. Aldrete JA, Kroulik D. A postanesthetic recovery score. *Anesth Analg*. 1970;49(6):924-934.
12. White PF, Song D. New criteria for fast-tracking after outpatient anesthesia: a comparison with the modified Aldrete's scoring system. *Anesth Analg*. 1999;88(5):1069-1072.

13. Brown I, Jellish W, Kleinman B, et al. Use of post-anesthesia discharge criteria to reduce discharge delays for inpatients in the postanesthesia care unit. *J Clin Anesth*. 2008;20(3):175-179.
14. Chung F, Chan VW, Ong D. A post-anesthetic discharge scoring system for home readiness after ambulatory surgery. *J Clin Anesth*. 1995;7(6):500-506.
15. The Joint Commission. *Comprehensive Accreditation Manual*. Oakbrook Terrace, IL: The Joint Commission; 2009:31.
16. American Society of Anesthesiologists. Statement on granting privileges for administration of moderate sedation to practitioners who are not anesthesia professionals. <http://www.asahq.org/For-Members/~media/For%20Members/Standards%20and%20Guidelines/2012/STATEMENT%20ON%20GRANTING%20PRIVILEGES%20FOR%20ADMINISTRATION.ashx>. Accessed December 9, 2013.
17. Apfelbaum JL, Connis RT, Nickinovich DG, et al. Practice advisory for preanesthesia evaluation: an updated report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation. *Anesthesiology*. 2012;116(3):522-538.
18. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: an updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters. *Anesthesiology*. 2011;114(3):495-511.
19. *Moderate and Deep Sedation Hospital Policy*. Boston, MA: Brigham and Women's Hospital; 2013.
20. Kaye AD, Gayle J, Kaye AM. Pharmacology principles. In: Urman RD, Kaye AD, eds. *Moderate and Deep Sedation in Clinical Practice*. New York, NY: Cambridge University Press; 2012:8-32.
21. Schilling D, Rosenbaum A, Schweizer S, Richter H, Rumstadt B. Sedation with propofol for interventional endoscopy by trained nurses in high-risk octogenarians: a prospective, randomized, controlled study. *Endoscopy*. 2009;41(4):295-298.
22. Rex DK, Deenadayalu VP, Eid E, et al. Endoscopist-directed administration of propofol: a worldwide safety experience. *Gastroenterology*. 2009;137(4):1229-1237.
23. Rex DK, Heuss LT, Walker JA, Qi R. Trained registered nurses/endoscopy teams can administer propofol safely for endoscopy. *Gastroenterology*. 2005;129(5):1384-1391.
24. University HealthSystem Consortium Consensus Group on Moderate Sedation. *Moderate Sedation Best Practice Recommendations*. Oak Brook, IL: University Health-System Consortium; 2005.
25. Cravero JP, Beach ML, Blike GT, Gallagher SM, Hertzog JHPediatric Sedation Research Consortium. The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the Pediatric Sedation Research Consortium. *Anesth Analg*. 2009;108(3):795-804.
26. Cravero JP, Blike GT, Beach M, et al; Pediatric Sedation Research Consortium. Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium. *Pediatrics*. 2006;118(3):1087-1096.
27. Pino RM. The nature of anesthesia and procedural sedation outside of the operating room. *Curr Opin Anaesthesiol*. 2007;20(4):347-351.
28. Bhananker SM, Posner KL, Cheney FW, Caplan RA, Lee LA, Domino KB. Injury and liability associated with monitored anesthesia care: a closed claims analysis. *Anesthesiology*. 2006;104(2):228-234.
29. Metzner J, Posner KL, Domino KB. The risk and safety of anesthesia at remote locations: the US closed claims analysis. *Curr Opin Anaesthesiol*. 2009;22(4):502-508.
30. Metzner J, Domino KB. Risks of anesthesia or sedation outside the operating room: the role of the anesthesia care provider. *Curr Opin Anaesthesiol*. 2010;23(4):523-531.
31. Metzner J, Domino KB. Outcomes, controversies, and future trends. In: Urman RD, Kaye AD, eds. *Moderate and Deep Sedation in Clinical Practice*. New York, NY: Cambridge University Press; 2012:150-158.
32. Urman RD, Grammer R, Gross W. Procedural sedation outcomes in a tertiary care academic institution. Presented at: The Anesthesiology 2013 Annual Meeting; October 15, 2013; San Francisco, CA.
33. Frieling T, Heise J, Kreysel C, Kuhlen R, Schepke M. Sedation-associated complications in endoscopy—prospective multicentre survey of 191142 patients. *Z Gastroenterol*. 2013;51(16):568-572.
34. Behrens A, Labenz J, Schuler A, et al. [How safe is sedation in gastrointestinal endoscopy? A multicentre analysis of 388,404 endoscopies and analysis of data from prospective registries of complications managed by members of the Working Group of Leading Hospital Gastroenterologists (ALGK)]. *Z Gastroenterol*. 2013;51(5):432-436.
35. American Society of Anesthesiologists. Standards for basic anesthetic monitoring. Effective July 1, 2011. Available at: <http://www.asahq.org/For-Members/~media/For%20Members/documents/Standards%20Guidelines%20Stmnts/Basic%20Anesthetic%20Monitoring%202011.ashx>. Accessed December 9, 2013.
36. Soto RG, Fu ES, Vila H Jr, Miguel RV. Capnography accurately detects apnea during monitored anesthesia care. *Anesth Analg*. 2004;99(2):379-382.
37. Krauss B, Hess DR. Capnography for procedural sedation and analgesia in the emergency department. *Ann Emerg Med*. 2007;50(2):172-181.
38. Qadeer MA, Vargo JJ, Dumot JA, et al. Capnographic monitoring of respiratory activity improves safety of sedation for endoscopic cholangiopancreatography and ultrasonography. *Gastroenterology*. 2009;136(5):1568-1576.
39. SEDASYS computer-assisted personalized sedation system - P080009. US Food and Drug Administration. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm353950.htm>. Accessed December 9, 2013.
40. Pambianco DJ, Vargo JJ, Pruitt RE, Hardi R, Martin JF. Computer-assisted personalized sedation for upper endoscopy and colonoscopy: a comparative, multicenter randomized study. *Gastrointest Endosc*. 2011;73(4):765-772.
41. Martin JF, Bridenbaugh P, Gustafson M. The SEDASYS System is not intended for the sedation of high-risk patients. *Gastrointest Endosc*. 2011;74(3):723.

42. Poon CM, Leung TL, Wong CW, Chan YL, Leung TC, Leong HT. Safety of nurse-administered propofol sedation using PCA pump for outpatient colonoscopy in Chinese patients: a pilot study. *Asian J Surg*. 2007;30(4):239-243.
43. Usta B, Türkay C, Muslu B, et al. Patient-controlled analgesia and sedation with alfentanil versus fentanyl for colonoscopy: a randomized double blind study. *J Clin Gastroenterol*. 2011;45(7):e72-e75.
44. Liu SY, Poon CM, Leung TL, et al. Nurse-administered propofol-alfentanil sedation using a patient-controlled analgesia pump compared with opioid-benzodiazepine sedation for outpatient colonoscopy. *Endoscopy*. 2009;41(6):522-528.
45. Mandel JE, Tanner JW, Lichtenstein GR, et al. A randomized, controlled, double-blind trial of patient-controlled sedation with propofol/remifentanyl versus midazolam/fentanyl for colonoscopy. *Anesth Analg*. 2008;106(2):434-439.
46. Rodrigo MR, Irwin MG, Tong CK, Yan SY. A randomised crossover comparison of patient-controlled sedation and patient-maintained sedation using propofol. *Anaesthesia*. 2003;58(4):333-338.
47. Sedation and analgesia by non-anesthesiologists 2012. American Society of Anesthesiologists. <https://www.asahq.org/For-Members/Practice-Management/Practice-Parameters/Guidelines-for-Sedation-and-Analgesia-by-Non-Anesthesiologists.aspx>. Accessed December 9, 2013.
48. Implementation manual WHO surgical safety checklist 2009. World Health Organization. http://whqlibdoc.who.int/publications/2009/9789241598590_eng.pdf. Accessed December 9, 2013.
49. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009;360(5):491-499.
50. Semel ME, Resch S, Haynes AB, et al. Adopting a surgical safety checklist could save money and improve the quality of care in U.S. hospitals. *Health Aff (Millwood)*. 2010;29(9):1593-1599.
51. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med*. 2006;355(26):2725-2732.
52. Arriaga AF, Bader AM, Wong JM, et al. Simulation-based trial of surgical-crisis checklists. *N Engl J Med*. 2013;368(3):246-253.
53. Kozmenko V, Riopelle J, Kaye AD, Kozmenko L. Simulation training for sedation. In: Urman RD, Kaye AD, eds. *Moderate and Deep Sedation in Clinical Practice*. New York, NY: Cambridge University Press; 2012:159-167.
54. Tobin CD, Clark CA, McEvoy MD, et al. An approach to moderate sedation simulation training. *Simu Healthc*. 2013;8(2):114-123.

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