Monitored Anesthesia Care

Description

Adequate sedation and analgesia are important parts of many diagnostic and therapeutic procedures. Various levels of sedation and analgesia (anesthesia) may be used, depending on the patient’s condition and the procedure being performed. This policy addresses the potential role of dedicated anesthesia providers during procedures performed in a properly-equipped and staffed outpatient setting.

Background

Overview of Monitored Anesthesia care

Monitored anesthesia care (MAC) is a spectrum of anesthesia services defined by the type of anesthesia personnel present during a procedure, not specifically by the level of anesthesia needed. The American Society of Anesthesiologists (ASA) has defined MAC. (1) The following is derived from ASA statements:

Monitored anesthesia care is a specific anesthesia service for a diagnostic or therapeutic procedure. Indications for monitored anesthesia care include the nature of the procedure, the patient’s clinical condition and/or the potential need to convert to a general or regional anesthetic.

Monitored anesthesia care includes all aspects of anesthesia care—a pre-procedure visit, intra-procedure care and post-procedure anesthesia management. During monitored anesthesia care, the anesthesiologist provides or medically directs a number of specific services, including but not limited to:

- Diagnosis and treatment of clinical problems that occur during the procedure.
- Support of vital functions.
- Administration of sedatives, analgesics, hypnotics, anesthetic agents or other medications as necessary for patient safety.
- Psychological support and physical comfort.
- Provision of other medical services as needed to complete the procedure safely.

MAC may include varying levels of sedation, analgesia, and anxiolysis as necessary. The provider of MAC must be prepared and qualified to convert to general anesthesia when necessary. If the patient
loses consciousness and the ability to respond purposefully, the anesthesia care is a general anesthetic, irrespective of whether airway instrumentation is required.

MAC refers to a particular type of physician service, and not to the level of anesthesia provided. MAC often involves the provision of sedatives and/or analgesics to induce moderate sedation, but may also involve the use of sedatives, hypnotics, analgesics, and anesthetic drugs which are commonly used for the induction and maintenance of general anesthesia. (2)

**Sedation Depth**

In 2004, the ASA defined 4 levels of sedation/analgesia as shown in Table 1. (3):

<table>
<thead>
<tr>
<th>Sedation Level</th>
<th>Definition</th>
<th>Physiologic Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal sedation (anxiolysis)</td>
<td>A drug-induced state during which patients respond normally to verbal commands.</td>
<td>Although cognitive function and coordination may be impaired, ventilator and cardiovascular function are unaffected.</td>
</tr>
<tr>
<td>Moderate sedation/analgesia</td>
<td>A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.</td>
<td>No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.</td>
</tr>
<tr>
<td>Deep sedation/analgesia</td>
<td>A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation.</td>
<td>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.</td>
</tr>
<tr>
<td>General anesthesia</td>
<td>A drug-induced depression of consciousness during which patients are not arousable, even by painful stimulation.</td>
<td>The ability to independently maintain ventilator 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.</td>
</tr>
</tbody>
</table>

Table 1: American Society of Anesthesiologists' Levels of Sedation/Analgesia
Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering moderate sedation/analgesia (conscious sedation) should be able to rescue patients who enter a state of deep sedation/analgesia, while those administering deep sedation/analgesia should be able to rescue patients who enter a state of general anesthesia.

Sedation for Diagnostic and Therapeutic Procedures

Multiple diagnostic and therapeutic procedures performed in the outpatient setting, including endoscopy, colonoscopy, bronchoscopy, and interventional pain management procedures, rely on some degree of sedation for anxiolysis and pain control. Regardless of sedation depth, sedation and anesthesia services that are provided in outpatient settings should be administered by qualified and appropriately trained personnel. Moderate sedation is generally sufficient for many diagnostic and uncomplicated therapeutic procedures. Moderate sedation using benzodiazepines, with or without narcotics, is frequently administered under the supervision of the proceduralist.

According to the American Society of Anesthesiologists’ (ASA) standard for monitoring, MAC should be provided by qualified anesthesia personnel, including physicians and nurse specialists. (4) By this standard, the personnel must be in addition to the proceduralist and must be present continuously to monitor the patient and provide anesthesia care. For patients at high risk of an unsuccessful procedure under moderate sedation, this allows for the safe continuation of the procedure under deep sedation or general anesthesia by trained personnel.

Moderate sedation can be achieved using pharmacologic agents for sedation, anxiolysis, and analgesia. A frequently used combination is an opioid and benzodiazepine, for example, fentanyl with midazolam at doses individualized to obtain the desired sedative effect. Other combinations have also been utilized for this purpose. While both benzodiazepines and opioids can cause respiratory depression, effective reversal agents exist for both.

Propofol is an agent that has been increasingly used to provide sedation for procedures. Propofol is associated with a rapid onset of action and fast recovery from sedation. However, there have been concerns about potential side effects and safety when used by non-anesthesiologists. Propofol has the potential to induce general anesthesia, and there is no pharmacologic antagonist to reverse its action. When used as moderate sedation, propofol may be administered by anesthesia personnel or under the direction of the proceduralist. ASA has offered practice guidelines for the provision of sedation by non-anesthesiologists, stating that personnel must be prepared to respond to deep sedation and loss of airway protection should these complications inadvertently occur during sedation. (5)

Regulatory Status

In October 1989, propofol “Diprivan®” (AstraZeneca) was first approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for the induction and maintenance of anesthesia. The current FDA-approved label for Diprivan® states that it is indicated for initiation and maintenance of monitored anesthesia care (MAC) sedation, combined sedation and regional anesthesia, or intensive care unit (ICU) sedation of intubated, mechanically ventilated patients (adults
It is also approved for induction of general anesthesia in patients older than or equal to 3 years of age and maintenance of general anesthesia in patients older than or equal to 2 months of age.

There are multiple other FDA approved medications for pain relief, anxiolysis and sedation that may be used in outpatient sedation.

Related Policies

8.01.40 Manipulation Under Anesthesia

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Use of monitored anesthesia care may be considered medically necessary for gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures, when there is documentation by the proceduralist and anesthesiologist that specific risk factors or significant medical conditions are present.

Those risk factors or significant medical conditions include any of the following:

- Increased risk for complications due to severe comorbidity (ASA P3* or greater)
- Morbid obesity (BMI [body mass index] >40)
- Documented sleep apnea
- Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment)
- Spasticity or movement disorder complicating procedure
- History or anticipated intolerance to standard sedatives, such as
  - Chronic opioid use
  - Chronic benzodiazepine use
- Patients with active medical problems related to drug or alcohol abuse
- Patients of extreme age, i.e., younger than age 18 or age 70 years or older
- Patients who are pregnant
- Patients with increased risk for airway obstruction due to anatomic variation, such as:
  - History of stridor
  - Dysmorphic facial features
  - Oral abnormalities (e.g., macroglossia)
  - Neck abnormalities (e.g., neck mass)
  - Jaw abnormalities (e.g., micrognathia)
- Acutely agitated, uncooperative patients
- Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation.
Use of monitored anesthesia care is considered not medically necessary for gastrointestinal endoscopic, bronchoscopic, or interventional pain procedures in patients at average risk related to use of anesthesia and sedation.

**Policy Guidelines**

This policy only addresses anesthesia services for diagnostic or therapeutic procedures involving gastrointestinal (GI) endoscopy, bronchoscopy and interventional pain procedures performed in the outpatient setting.

**Monitored Anesthesia**

Monitored anesthesia care can be provided by qualified anesthesia personnel with training and experience in:

- Patient assessment.
- Continuous evaluation and monitoring of patient physiological functions.
- Diagnosis and treatment (both pharmacological and non-pharmacological) of any and all deviations in physiological function.

**Procedural/Patient Risks**

Examples of prolonged endoscopy procedures that may require deep sedation include endoscopy in patients with adhesions post-abdominal surgery, endoscopic retrograde cholangiopancreatography, stent placement in the upper GI tract, and complex therapeutic procedures such as plication of the cardioesophageal junction.

The Mallampati score is considered a predictor of difficult tracheal intubation and is routinely used in preoperative anesthesia evaluation. (6) The score is obtained by having the patient extend the neck, open the mouth, and extend the tongue while in a seated position. Patients are scored from Class 1-4 as follows:

- Class I - the tonsils, uvula and soft palate are fully visible.
- Class 2 - the hard and soft palate, uvula and upper portion of the tonsils are visible.
- Class 3 - the hard and soft palate and the uvula base are visible.
• Class 4 - only the hard palate is visible.

Patients with Class 3 or 4 Mallampati scores are considered to be at higher risk of intubation difficulty. While the Mallampati score does not determine a need for monitored anesthesia care, it may be considered in determining risk for airway obstruction. Other tests to predict difficult tracheal intubation include the upper lip bite test, the intubation difficulty scale, and the Cormack-Lehane grading system.

Rationale

Literature Review

One updated systematic review on the use of propofol for sedation during colonoscopy has been published by the Cochrane Collaboration. One randomized controlled trial (RCT) has examined the use of moderate sedation with monitored anesthesia care (MAC) against moderate sedation without monitored care; it has been published in abstract form only. Many of the RCTs and comparative studies have focused on comparisons of agents for moderate sedation. Many recommendations for the indications for MAC are derived from narrative reviews and expert opinion. The following is a summary of the key literature to date:

Monitored Anesthesia Care in Endoscopy

Evidence Related to the Use of MAC for Endoscopy

An extensive review of the literature related to sedation for gastrointestinal (GI) endoscopy was published through the American Gastroenterological Association (AGA) Institute in 2007 some of which is relevant for this policy. (7) The review recommended that use of an anesthesia professional should be strongly considered for ASA physical status 3 through 5 patients. The authors noted that other possible indications for an anesthesia specialist include patients with pregnancy, morbid obesity, neurologic or neuromuscular disorders, a history of alcohol or substance abuse, and patients who are uncooperative or delirious. They also noted that endoscopic procedures that may require an anesthesia specialist include endoscopic retrograde cholangiopancreatography (ERCP), stent placement in the upper GI tract, and complex therapeutic procedures such as plication of the cardioesophageal junction. This review was used in formulating the initial conclusions of this policy.

Enestvedt et al retrospectively reviewed 1,318,495 patients who underwent 1,590,648 endoscopic procedures and found the risk for serious adverse events with endoscopy increased with higher ASA physical status classification, especially class 3 to 5. (8) These findings support the use of ASA physical status class as a predictor of periendoscopic adverse events and as a useful tool for risk stratification.

Agostoni et al evaluated a prospective database of 17,999 GI endoscopies performed under MAC during the period of October 2001 to December 2009. (9) The authors identified 6 variables predicting any sedation-related complication using multivariate logistic regression models: age (1-year OR=1.02; 95% CI, 0.01 to 1.02), BMI (1-point OR=1.03; 95% CI, 0.02 to 1.05), ASA score (“3-4” vs “1-2” OR=1.69; 95% CI, 1.44 to 1.99), Mallampati score (“3-4” vs “1-2” OR=1.33; 95% CI, 1.04 to 1.70), emergency nature of the procedure (OR=1.48; 95% CI, 1.13 to 1.94), length of the procedure
(OR=2.00; 95% CI, 1.78 to 2.24). The authors noted the Mallampati score is used to assess potential difficulty in tracheal intubation, and it is unclear why this score was predictive of any complication.

In a prospective cohort study of 470 ERCP patients receiving MAC, Berzin et al reported adverse respiratory events were strongly associated with higher BMI using multivariate regression models. (OR=1.08, p<0.001). Patients with obesity experienced respiratory events almost twice as often as nonobese patients (p=0.03). Higher ASA class was not associated with adverse respiratory events under MAC (OR=1.2, p=0.25) but was associated with cardiovascular events (OR=2.88, p<0.001).

Coté et al reported another prospective observational study on 766 patients undergoing advanced endoscopic procedures such as ERCP, endoscopic ultrasound, and small-bowel enteroscopy who received propofol. These procedures are notable for their duration and complexity compared with diagnostic EGD. The primary outcome measure was airway modifications (AM), with a comparison of defining characteristics of the group requiring at least 1 AM, such as chin lift or nasal airway, to those requiring no modification. No patients in the study required endotracheal intubation. BMI, male sex, and ASA class 3 or above were associated with a need for AM. Patients in this study received anesthesia from a certified registered nurse anesthetist and generally had a level of deep sedation, and thus their care continues to meet the definition of MAC.

Evidence Related to the Use of Propofol for Endoscopy

Given the interest in use of propofol, additional details are provided concerning its use in GI endoscopy.

Systematic Reviews

A Cochrane systemic review by Singh and colleagues (updated in June 2011), summarized the results of RCTs comparing the use of propofol and traditional agents for use during colonoscopy. (12) The review encompassed and enlarged on a prior review by McQuaid and Laine, in 2008, which reviewed a broader set of studies of all randomized trials of any agents used for sedation for endoscopic procedures. (13) The reviews come to largely similar conclusions, but certain comparisons were only performed in one or the other review.

The primary objective of the Cochrane review was to compare the relative effectiveness, patient acceptance, and safety of propofol compared to traditional sedatives for patients undergoing colonoscopy. (12) The secondary objective was to synthesize the studies comparing propofol administration by anesthesiologists to that by non-anesthesiologists for sedation during colonoscopy. This review is an update of a previously published Cochrane systematic review in 2008. The literature search for the updated review was undertaken up to December 2010. The outcome measures of interest were technical performance of colonoscopy (recovery time, discharge time, procedure time), patient satisfaction, pain control, and complication rates (cardio-respiratory events, colonic perforations and hospital admission rate after procedure, and death). (12)

Twenty-two studies met the inclusion criteria for the primary objective in this updated review. (12) Eight (of 22) eligible RCTs evaluated propofol as a single agent, and seven trials were published in only abstract format, including the largest trial from 2000 (n=7,286 patients), which reported on different rates of colonic perforation. Only one trial published in 2006 was a double blinded RCT, where all patients as well as all those involved in administering the medications and assessing the outcomes
were not aware of the intervention in different arms of the trial. The agents administered in the control arms across these trials included benzodiazepines alone (diazepam, midazolam) or a combination of a benzodiazepine and a narcotic (pethidine, fentanyl, remifentanil or alfentanil). One trial published in 2003 included only a narcotic (remifentanil) and all patients in the control arm of this study remained awake throughout the procedure. The dosage of the agents used varied across trials. The intended level of sedation when stated was defined in most studies as that needed for patients tolerance of the procedure. Many of the studies had a potential of moderate to high risk of bias and combining data for some of the outcomes for meta-analysis was problematic. Most studies included only healthy outpatients.

Recovery time (reported in 11 studies; 776 patients) was shorter with propofol compared to the control arm (weighted mean difference (WMD) -14.2 minutes; 95% confidence interval (CI) -17.6, -10.8), with no significant heterogeneity (p=0.41). Discharge time (seven studies; 542 patients) was also reported to be shorter with use of propofol (WMD -20.9 minutes; 95% CI -30.9, 10.8); however there was significant heterogeneity between studies (p<0.0001). There was higher patient satisfaction (10 studies, 819 patients) with use of propofol (odds ratio (OR) for dissatisfaction 0.35; 95% CI 0.23, 0.53). There was no difference in procedure time (nine studies; 736 patients) or complication rates. There was also no difference in pain control with non-patient controlled sedation (5 studies; 396 patients) between propofol and the control arm (OR 0.90; 95% CI 0.58, 1.39). (12)

The Cochrane review found only one RCT, reported in abstract format, for the secondary objective, comparison of propofol administration by anesthesiologists (Group A) to that by endoscopists (Group B). (12) This RCT has subsequently been published by Poincloux and colleagues. (14)

### Randomized Controlled Trials

In the single RCT included in the Cochrane review described above, Poincloux et al randomized 90 adult patients (from a university center in France) undergoing colonoscopy were randomized into the above two groups. The goal of propofol administration by anesthesiologists was anesthesia and that by endoscopists was sedation. There was no difference in procedure time (16.7 minutes for Group A and 17.7 minutes for Group B) or patient satisfaction (average score on Visual Analog Scale, 90.8 vs. 89). Subjects in Group A indicated greater willingness to undergo further colonoscopies under the same conditions (95% vs 79%; P=0.02). A higher proportion of patients administered propofol by an anesthesiologist experienced hypoxia, but no patient required an intervention.

An RCT published by Shen et al in 2014 evaluated the safety, complication rates, patient and examiner satisfaction with two different sedation regimens (etomidate-remifentanil and propofol-remifentanil) in patients aged 60-80 years undergoing outpatient diagnostic gastroscopy. (15) The study included a total of 720 patients randomized to either etomidate-remifentanil (n=360) or propofol-remifentanil (n=360). Five subjects in the etomidate-remifentanil group were excluded from analysis. Patients in the propofol-remifentanil group demonstrated decreases in their systolic and diastolic blood pressures (SBP and DBP, respectively) and heart rates (HR) during and after the procedure compared with baseline (P<0.05). For subjects in the propofol-remifentanil group, the average SBP dropped from approximately 125 mmHg preprocedure to 95 mmHg during the procedure, the average DBP dropped from approximately 67 mmHg to approximately 52 mmHg, and the average HR dropped from approximately 75 bpm to approximately 70 bpm (data extrapolated from graphs). The authors state that “the decrease of these cardiopulmonary function parameters led to adverse effects in older patients,” but the adverse
effects are not specified. Compared with those in the etomidate-remifentanil group, patients in the propofol-remifentanil group were more likely to have hypoxemia (21.39% vs 12.68%; P=0.002), injection pain (22.5% vs 0.85%; P<0.001), and body quiver (43.06% vs 19.15%; P<0.001). Those in the etomidate-remifentanil group were more likely to have myoclonus (4.51% vs 0.83%; P=0.002). There were no significant differences between groups for duration time, recovery time, and time to leave recovery room.

In a small block-randomized RCT, Treeprasertsuk et al randomized 48 patients undergoing double balloon enteroscopy to sedation with either propofol or combination meperidine-midazolam. (16) Twenty-eight patients were randomized to meperidine-midazolam, one of whom was excluded from the study due to hemodynamic instability prior to the procedure. Twenty-eight patients were randomized to propofol, but 5 were excluded due to hemodynamic instability and 2 were excluded due to refusal of treatment. Among included patients, recovery times and patient satisfaction scores did not differ significantly between groups. However, the study’s small size and high rates of drop out after randomization may have limited its ability to detect a significant between-group difference.

**Observational Studies**

There are numerous observational studies, and some of the representative publications are summarized here. Studies of propofol in endoscopy are frequently, but not uniformly specific to non-anesthesiologist, (ie, endoscopist or endocopy nurse) administration of propofol.

Horiuchi et al. reported an observational study from Japan. (17) Low-dose propofol was administered by nurses supervised by the endoscopist during diagnostic endoscopy. In this study, 10,662 patients were observed following receiving an age-dependent standard dose protocol of propofol, which was administered by bolus injection, with additional doses given when required for adequate sedation prior to esophagogastroduodenoscopy (EGD). The incidence of respiratory depression was the primary outcome for this study, and further measures of successful completion of the procedure and patient satisfaction were analyzed. Twenty-eight patients required transient supplemental oxygen supply, while none required mask or endotracheal intubation. All procedures were successful and 79.1% diagnostic EGDs were completed with a single bolus of propofol. The authors conclude that low-dose nurse-administered propofol sedation is safe when supervised by the endoscopist, and practical for diagnostic EGD. The study is limited by the lack of a comparison group. Patients with ASA classification 3 and 4 were excluded from the study, so these conclusions may not be generalized to that group.

Rex et al. reviewed case series of endoscopist-directed propofol sedation published in MEDLINE, CINAHL and EMBASE over the period of 1966 to 2008, resulting in 646,080 procedures in 28 studies published between 2002 and 2008. (18) Incidence of mask ventilations, endotracheal intubation, neurologic injuries, and death were collected from the published studies and calculated to reveal a death rate 0.62 per 100,000 cases. A direct comparison group was not included in this review. The authors note that this death rate compares favorably to published surveys of death rates of endoscopic procedures utilizing opioids and benzodiazepines of 11 per 100,000. They also compare this to published data on the general anesthesia overall death rate of 1-2 per 100,000. As mentioned, a direct comparison group is not available nor is death rates for endoscopic procedures under MAC. However, the incidence of published adverse events appears to be low.

Khan et al evaluated the safety of non-anesthesiologist-administered propofol sedation in 156 patients
undergoing endoscopy with ERCP. (19) Of the total, 86 (55.1%), 50 (32.1%) and 20 (13%) were considered ASA Class I, II, and III anesthesia risk, respectively. Two patients, both ASA class III, developed sedation-related complications, one minor requiring bag-mask ventilation and one major requiring endotracheal intubation and mechanical ventilation. Both were managed by the non-anesthesiologist and gastroenterologist at the site of the procedure.

Adeyemo et al conducted a retrospective, comparative study to evaluate colonoscopy perforation rates for patients who underwent sedation with and without propofol. (20) The study did not specify the administrator of the propofol. The authors reviewed all colonoscopies performed at their institution from 2003 to 2012 (N=118,004), including 37,480 cases performed with propofol sedation and 80,524 performed with nonpropofol sedation. Cases done with propofol sedation were more likely to be men (42.3% vs 48.2%; P<0.0001) and had a slightly lower mean age (60.1 vs 60.8 years; P<0.0001). Colonic perforation was more likely in the propofol group (incidence rate: 6.9 per 10,000 colonoscopies vs 2.7 per 10,000 colonoscopies; P=0.0015), for a relative risk of 2.5 (95% CI 1.38 to 4.70; P=0.0009). Perforation risks were higher for patients undergoing therapeutic colonoscopy; in that subgroup, the perforation rate was 8.7 per 10,000 colonoscopies in the propofol group compared with 2.6 per 10,000 colonoscopies in the nonpropofol group; P=0.0016. Among diagnostic colonoscopies, there was no difference in perforation rate by anesthesia type.

Nonaka et al conducted a retrospective study to evaluate the safety of endoscopist-directed propofol sedation for therapeutic endoscopy and to compare rates of adverse outcomes for older (≥75 years) and younger (<75 years) patients. (21) The study included 160 patients, 85 of whom were under 75 years. There were no differences between groups in terms of circulatory adverse events, procedure time, initial bolus infusion rate, number of bolus doses, number of changes in the maintenance rate, and the total infusion dose. However, older patients required a lower infusion rate (4.02 mg/kg/hour vs 4.76 mg/kg/hour; P=0.048).

In 2014, Sieg et al reported outcomes from a prospective, multicenter study of endoscopist-directed sedation with propofol in 53 German outpatient gastroenterology practices. (22) The study included 24,441 subjects who underwent 13,793 colonoscopies, 6467 esophagogastroduodenoscopies, and 4181 combination procedures. Propofol monosedation was used in 52.1% of the patients, while 47.9% received a combination of midazolam and propofol. Major adverse events occurred in four patients (0.016%), including 3 requirements for mask ventilation and 1 laryngospasm. Minor adverse events included hypoxemia in 93 patients (0.381%), intestinal bleeding in 12 patients (0.049%), bradycardia in 7 patients (0.029%), and persistent hypotension requiring intravenous fluids in 5 patients (0.02%). Propofol monosedation was associated with a higher probability of hypoxemia (0.50%) compared with propofolmidazolam sedation (0.5% vs 0.25%; P<0.0001). Patient questionnaires were available for 15,690 subjects. Of those, patients sedated with propofol had higher scores on a scale from 1 (very bad) to 9 (very good) describing how they felt compared with the previous day than those sedated with propofolmidazolam (mean 7.225 vs 7.216, P<0.02).

Kilgert et al prospectively evaluated patient satisfaction and procedural complications relative to sedation type among 307 patients undergoing endoscopic procedures at a single institution, 247 (80.5%) of whom were treated in the outpatient setting. (23) Sedation was directed by the endoscopist without knowledge of patient questionnaire responses. Compared with propofol monosedation, patients sedated with midazolam and meperidine were more likely to report fear during endoscopy (23.8% vs 0;
P=0.08120). In addition, propofol monosedation was less likely to be associated with pain during endoscopy (0% compared with 16.4% for propofol + meperidine [P<0.0001], 8.9% for midazolam + meperidine [P<0.0001], and 16.7% other agents or no sedation [P<0.0001]). Propofol sedation was less likely to be associated with cardiovascular events than meperidine with either propofol or midazolam, but rates of cardiovascular events are not specified.

**Section Summary**

Evidence-based guidelines about the use of sedation for endoscopy have addressed the use of MAC and subsequent studies have demonstrated higher sedation complication rates in higher ASA scored patients.

The evidence base comparing different anesthetic methods is not robust, consisting primarily of non-randomized comparisons and observational studies. A single RCT comparing propofol administration by anesthesiologists to that by non-anesthesiologists for sedation during colonoscopy did not show any differences in procedure time or patient satisfaction, and reported a higher rate of hypoxia in patients treated with propofol. However, a Cochrane review of randomized studies concluded that recovery time, discharge time, and patient satisfaction were all improved with propofol compared to alternative agents. This review did not find any evidence of increased complications. However, this evidence base does not rule out an increased complication rate with propofol, since there is a low complication rate in general, thus making it difficult to discern differences in the absence of large RCTs.

**Bronchoscopy**

In 2009, Silvestri and colleagues published an RCT comparing 2 doses of the sedative agent fospropofol in patients undergoing diagnostic bronchoscopy. (24) The study was performed by pulmonologists without anesthesia supervision. Patients (n=252) were randomly assigned to receive either 2 mg/kg or 6.5 mg/kg induction doses of fospropofol, followed by additional doses per protocol. All patients received a pre-procedural dose of fentanyl. The primary endpoint was sedation success using the Modified Observer’s Assessment of Alertness/Sedation (MOAA/S). A secondary endpoint was treatment success, as measured by percentage of patients who did not require alternate sedation or ventilation. The higher dose group had greater sedation success (88.7% vs. 27.5%, respectively; p<0.001). Treatment success also favored the higher dose group (91.3% vs. 41.25, respectively; p<0.001). Adverse events were higher for the higher dose group; for example, the number of patients requiring any type of airway assistance (33 vs. 14, or 21.5% vs. 13.6%, respectively). The trial does not compare alternate sedation approaches; that comparison is necessary to evaluate the clinical value of the fospropofol sedation strategy for bronchoscopic procedures.

The British Thoracic Society published guidelines for flexible bronchoscopy in 2001 (25) and updated these guidelines in 2013. (26) With respect to sedation, the guidelines state that sedation should be offered, patients should be monitored during and immediately after the procedure and that at least 2 assistants, at least 1 a qualified nurse, should be in attendance. Resuscitation equipment should be readily available. Sedation should be limited to a depth which permits verbal contact at all times. The preferred sedation agent is a benzodiazepine, intravenous midazolam.
Interventional Pain Management Procedures

In 2008, Bernards and colleagues published a review of the literature around neurologic complications of regional anesthesia in anesthetized or heavily sedated patients. (27) Some experts postulate that the inability of a sedated patient to express atypical symptoms during a regional block may lead to increased risk of injury. No comparative studies have been done, and limited information is available from registries. The American Society of Regional Anesthesia (ASRA) and Pain Medicine has acknowledged the scarce and conflicting literature on the topic and recommends carefully weighing the risks and benefits in considering performing those procedures while the patient is heavily sedated or anesthetized. (28)

Considerations for Anesthesia for All Procedure Types

Location of the Procedure

The American Society of Anesthesiologists (ASA) has recommended that any location providing MAC have the capability of cardiopulmonary resuscitation and monitoring equipment. (29,30) In 2004, Fleisher et al performed a retrospective claims data review on 564,267 outpatient surgical procedures: 360,780 at an outpatient department of a hospital, 175,288 at an ambulatory surgical center and 28,199 at a physician’s office. The rates of all-cause death, emergency department visits, and inpatient admissions within 7 days of the procedure were compared. The highest rates were seen among patients in the outpatient surgery department of the hospital, suggesting that patients evaluated to be at highest risk had their procedure in the location of lowest anesthesia risk. Multivariate analysis noted that increasing patient age, increasing procedural risk, and increasing past medical history of inpatient admissions were all independently predictive of adverse outcome. In 2013, Whippey et al published a case-control study of risk factors for unanticipated hospitalization following an outpatient procedure. The authors retrospectively identified 20,657 outpatient procedures and randomly selected 200 patients with an unanticipated hospitalization. (31) These patients were compared with 200 randomly selected control patients without an unanticipated hospitalization. Predictors of unanticipated hospitalization included procedures lasting longer than 1 hour, high ASA physical status classification, older age, and higher body mass index (BMI).

Pregnancy

Concerns regarding procedures and sedation during pregnancy are two-fold: sensitivity of the fetus to the agents and/or procedural hypotension and maternal factors that increase sensitivity to sedation and that make intubation more difficult in an emergency situation. In a large (n=720,000) Swedish registry of pregnant patients from the 1970s and 1980s, 5,405 operations took place. (32) Congenital malformations and stillbirths were not increased in the offspring of women having an operation. Incidence of low birth weight infants was increased as a result of both prematurity and intrauterine growth retardation. Neonatal death was also increased in the patients who had an operation. No specific types of anesthesia or operation were associated with these outcomes. The contribution of the underlying condition which led to the need for surgery could not be separated from the effects of the surgery or sedation/anesthesia.

Fetal heart rate monitoring is considered to be a more sensitive indicator of placental perfusion and fetal oxygenation than observations of maternal hemodynamic stability alone. The American College of
Obstetricians and Gynecologists (ACOG) has recommended that the use of intermittent or continuous fetal monitoring during surgery be individualized. (33)

Physiologic changes in pregnancy may require changes in standard doses of anesthetic or sedative agents. However, propofol does not generally require a change in loading dose for induction. (34) Physiologic changes in pregnancy may warrant MAC when airway protection becomes necessary, due to additional difficulties noted with emergent intubation in pregnant patients and the urgency to restore full oxygenation to the maternal and fetal patients. (35) Thus MAC can be considered medically necessary for procedures performed during pregnancy.

**Clinical Trials**

A search of the online database ClinicalTrials.gov on January 13, 2015, identified the following RCTs evaluating anesthesia options for endoscopy, bronchoscopy, or interventional pain procedures:

- **RCT of Efficacy and Safety of Sedation Compared to General Anesthesia for ERCP** (NCT02046590) – This is a randomized, double-blind, active-comparator trial to compare deep sedation with propofol with general anesthesia for therapeutic endoscopic retrograde cholangiopancreatography (ERCP). The primary outcome is ERCP success rate. Enrollment is planned for 132 subjects; the estimated study completion date is January 2015.

- **Moderate Sedation for Elective Upper Endoscopy With Balanced Propofol Versus Propofol Alone: a Randomized Clinical Trial** (NCT02174588) – This is a randomized, open-label trial to compare propofol alone with propofol plus midazolam for anesthesia for patients undergoing esophagogastroduodenoscopy. The primary outcome is patient satisfaction measured on a visual analogue scale. Enrollment is planned for 140 subjects; the estimated study completion date is November 2015.

- **Non-anesthesiologist Administered Propofol Sedation for Colonoscopy - a Randomized Clinical Trial** (NCT02067065) – This is a randomized, single-blinded, active comparator trial to compare non-anesthesiologist-administered propofol sedation with anesthesiologist-administered propofol sedation among patients undergoing elective total colonoscopy. The primary outcome measure is the rate of minor adverse events. Enrollment is planned for 400 subjects; the estimated study completion date was June 2014, but no published results were identified.

- **Satisfaction With Nurse Administered Propofol Sedation vs. Midazolam With Fentanyl Sedation for Endoscopy** (NCT01934088) – This is a randomized, open-label trial to compare nurse-directed anesthesia with propofol with nurse-directed anesthesia with midazolam/fentanyl among patients undergoing endoscopy. The primary outcome measure is patient satisfaction. Enrollment is planned for 200 subjects; the estimated study completion date was December 2014, but no published results were identified.

- **Nurse Administered Propofol Sedation vs. Midazolam With Fentanyl-sedation for Flexible Bronchoscopy: A Randomized, Single Blind, Controlled Study of Satisfaction and Safety** (NCT02226328) – This is a randomized, open-label trial to compare nurse-directed anesthesia with propofol with nurse-directed anesthesia with midazolam/fentanyl among patients undergoing elective flexible bronchoscopy endoscopy. The primary outcome measure is patient satisfaction.
satisfaction. Enrollment is planned for 128 subjects; the estimated study completion date is December 2015.

Practice Guidelines and Position Statements

In 2004, and amended in 2009, the American Society of Anesthesiologists released a statement on the safe use of propofol:

“The Society believes that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. However, when this is not possible, non-anesthesia personnel who administer propofol should be qualified to rescue patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state of general anesthesia.” (36)

The American Society released guidelines regarding sedation during endoscopy in 2008 for Gastrointestinal Endoscopy (ASGE). (37) These guidelines indicate, “Adequate and safe sedation can be achieved in most patients undergoing routine esophagogastroduodenoscopy [EGD] and colonoscopy by using an intravenous benzodiazepine and opioid combination.” These guidelines also include a discussion of use of propofol for routine endoscopy, and their overall conclusion is that “clinically important benefits in average-risk patients undergoing upper endoscopy and colonoscopy have not been consistently demonstrated with regard to patient satisfaction and safety. Therefore, the routine use of propofol in average-risk patients cannot be endorsed.” In addition to addressing the efficacy and safety of propofol, the guidelines discuss the issue of who is qualified to administer propofol. The ASGE endorses gastroenterologist-directed propofol use when adequate training for its use has been achieved. Numerous case series studies were cited showing very low rates of clinical adverse events when propofol was administered by registered nurses under gastroenterologist supervision.

In 2014, ASGE issued guidelines on the safety of the endoscopy unit that made several recommendations regarding procedural sedation: (38)

- Recommendations for Intraprocedure Staffing Based on Level of Sedation
  - No sedation - One assistant other than the physician performing the procedure should be present to assist with the technical aspects of the procedure.
  - Moderate sedation (also known as conscious sedation) - Sedation should be directed by a physician who is credentialed and privileged to do so. Moderate sedation can be administered by an RN. During the period in which the patient is sedated, the RN must monitor the patient for vital sign changes, hypoxemia, and comfort. The RN may assist with minor, interruptible tasks. In the event that more intense technical assistance is required, a second assistant (RN, LPN, or UAP) should be available to join the care team for the technical aspects of the procedure.
  - Deep sedation - Most institutions require that deep sedation be administered by an anesthesia professional such as an anesthesiologist, certified registered nurse anesthetist (CRNA), or anesthesiologist assistant who is credentialed and privileged to do so. In this situation, the anesthesia provider should be responsible for administering sedation and monitoring the patient. A second staff person is required to assist with technical aspects of the procedure.

- Recommendations for Patient Monitoring
All patients undergoing endoscopy should be monitored, the frequency of which depends on procedural and patient factors (e.g., type of sedation, duration and complexity of procedure, patient condition). At a minimum, monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery, and just before discharge.

Units should have procedures in place to rescue patients who are sedated deeper than intended.

When the target level is moderate sedation (also known as conscious sedation):

- The individual assigned responsibility for patient monitoring may perform brief, interruptible tasks.
- Minimal monitoring requirements include electronic assessment of blood pressure, respiratory rate, heart rate, and pulse oximetry combined with visual monitoring of the patient's level of consciousness and discomfort.
- Currently, there are inadequate data to support the routine or required use of capnography during endoscopic procedures in adults when moderate sedation is the target.

When deep sedation is targeted:

- The individual responsible for patient monitoring must be dedicated solely to that task and may not perform any other function during the procedure.
- The use of capnography in endoscopic ultrasound, ERCP, and colonoscopy to assess the adequacy of ventilation may reduce the incidence of hypoxemia and apnea, but its impact on the frequency of other sedation-related adverse events such as bradycardia and hypotension is unknown. As such, capnography may be considered for the performance of endoscopy under deep sedation. However, there is no safety data to date to support the universal use of capnography in such cases.
- Documentation of the clinical assessments and monitoring data during sedation and recovery is required.

In 2010, the European Society of Gastrointestinal Endoscopy released guidelines on non-anesthesiologist administration of propofol (NAAP) which stated, “Compared with traditional sedation, propofol-based sedation presents similar rates of adverse effects, provides higher postprocedure patient satisfaction for most endoscopic procedures, decreases time to sedation, and decreases recovery time (and may therefore decrease discharge time compared with traditional sedation). Propofol-based sedation may also increase the quality of endoscopic examination. There are no cost-effectiveness data directly comparing specifically NAAP with traditional sedation or monitored anesthesia care for gastrointestinal endoscopy. (Evidence level 1+.)” (39)

In 2005, ASA released a statement on anesthetic care during interventional pain procedures. (40) While recognizing that conditions exist which may make skilled anesthesia care necessary, most minor pain procedures, under most routine circumstances, do not require anesthesia care other than local anesthesia.

U.S. Preventive Services Task Force Recommendations
Not applicable.
Summary
Comparative evidence that supports the use of monitored anesthesia care in specific procedures is limited. Evidence from noncomparative studies indicate that physician-directed moderate sedation is a safe and effective alternative to monitored anesthesia care for the majority of patients undergoing procedures in which deep sedation or anesthesia is unnecessary, such as gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures. Propofol may be used both for general anesthesia and moderate sedation. The principal differences between propofol and the traditional agents used in these clinical trials of moderate sedation are a shorter recovery period (a mean of 14.2 minutes), shorter discharge time, and higher overall satisfaction scores. Pain control and incidence of complications appear to be similar overall, but the available evidence does not rule out small differences in these outcomes. Patient characteristics, such as comorbidities, airway features, or the ability to cooperate with the proceduralist may predict the need for greater depth of sedation or a greater likelihood of needing an intervention to support physiologic functions during sedation. The use of monitored anesthesia care may be considered medically necessary in cases with specific risk factors or significant medical conditions as indicated in the policy statement.

Medicare National Coverage
There are no Medicare national coverage determinations that address the use of monitored anesthesia care in GI endoscopy, bronchoscopy, or interventional pain procedures.

References
<table>
<thead>
<tr>
<th>Section: Surgery</th>
<th>Effective Date: July 15, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsection: Anesthesiology</td>
<td>Original Policy Date: June 7, 2012</td>
</tr>
<tr>
<td>Subject: Monitored Anesthesia Care</td>
<td>Page: 17 of 20</td>
</tr>
</tbody>
</table>


**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New Policy</td>
<td>Literature search update; references 5-7, 15-16 added. Policy updated with literature review: The following policy statements were changed: 1) The bullet point on severe sleep apnea was changed to “documented sleep apnea;” 2) In the bullet point on patients at increased risk for airway obstruction due to anatomic variation, “sleep apnea” was removed from the “history of sleep apnea or stridor” sub-bullet point; and 3) The bullet point on patients of extreme age was changed to “patients younger than 18 years or 70 years or older”.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Policy Update</td>
<td>References added.</td>
</tr>
</tbody>
</table>
unchanged.

Keywords

Propofol
MAC (Monitored Anesthesia Care), moderate sedation, general anesthesia

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 19, 2015 and is effective July 15, 2015.

Signature on File

Deborah M. Smith, MD, MPH