

Best Practice Guidelines	Guideline Name: Guidelines for Moderate (Conscious) Sedation and GI Endoscopy Procedures		Page 1 of 12
	Date: December 13, 2010	Supercedes: New	

1. Purpose:

- To provide healthcare professionals with guidelines for the safe administration of moderate (conscious) sedation during endoscopic procedures.
- To provide healthcare professionals with guidelines for the recovery of patients receiving moderate (conscious) sedation for endoscopic procedures.
- To provide guidelines for the safe discharge of patients receiving moderate (conscious) sedation for endoscopic procedures.

2. General:

Sedation and analgesia are generally considered to be an integral component of the endoscopic examination¹. Implementation of evidence informed moderate (conscious) sedation guidelines may improve the quality of care and reduce the incidence of sedation-related adverse events. The use of sedation for endoscopy is resource intensive. In the US, it has been estimated that sedation is responsible for 75% of patient time in the endoscopy units and 40% of the procedure costs³.

The purpose of sedation is:

- to reduce a patient's anxiety and discomfort;
- improved tolerance for the procedure;
- provide patient satisfaction;
- minimize patient's risk for injury during the examination; and
- improve performance of endoscopy (for example sedation can enhance colonoscopy completion rate and colonic polyp detection rate)².

Negative outcomes of sedation include¹:

- delayed recovery from the procedure;
- increased overall costs; and
- increased risk of cardiopulmonary complications.

The amount of sedation required for an endoscopic procedure is patient specific. Also, patients may require varying levels of sedation during a single procedure. For example, a patient undergoing colonoscopy may experience greater pain and require more analgesia/sedation at points in the procedure when the colon wall is being stretched. In prolonged, complex procedures, or in select circumstances, deeper levels of sedation may be required. Routine diagnostic, and uncomplicated gastrointestinal (GI) endoscopic procedures, can generally be performed under moderate (conscious) sedation.

Indications for Analgesia and Sedation¹⁴

Type of Procedure	Level of Sedation
Rigid or flexible (procto) sigmoidoscopy; rectal endoscopic ultrasound	Sedation is not routinely required. Moderate (conscious) sedation is optional for anxious patients, anticipation of pain, or therapeutic procedures.
Diagnostic and uncomplicated upper GI endoscopy and colonoscopy	Moderate (conscious) sedation required.
Prolonged or complex procedures (e.g. endoscopic retrograde cholangiopancreatography (ERCP) or endoscopic ultrasound)	Deeper levels of sedation may be required.

3. Pre-procedure Assessment⁸:

Prior to administration of intravenous sedation a patient history and physical examination designed to identify aspects that could adversely affect the outcome of endoscopic sedation. The medical history shall include, but not be limited to:

- significant cardiac or pulmonary disease;
- neurologic or seizure disorder;
- anticipated airway problems (sleep apnea, thick neck, severe obesity);
- adverse reaction to sedation or anesthesia;
- current medications, drug and food allergies;
- alcohol or drug abuse;
- time of last oral intake; and
- the American Society for Anesthesiology (ASA) physical status classification.
 - ASA class I–III patients may have sedation administered by an endoscopist or Registered Nurse.
 - Anesthesiology should be considered for:
 - ASA classes IV and V patients requiring sedation;
 - emergency endoscopic procedures in unstable patients;
 - complex endoscopic procedures such as ERCP, endoscopic ultrasound; and
 - patients with a history of adverse reaction to sedation, alcohol or substance abuse, or inadequate response to moderate (conscious) sedation, prior problems with procedural sedation, prior use of high dose sedatives and narcotic analgesics
 - Patients at higher risk for Obstructive sleep Apnea (OSA) (e.g. obese patients with ASA Class IV or V, diagnosed sleep apnea requiring CPAP, , , procedures that will require deep sedation, problematic or altered oropharyngeal anatomy¹⁶)

Note: Use of anesthesiologist is not mandatory in these circumstances. In individual cases it is appropriate for sedation to be administered by an endoscopist or Registered Nurse.

ASA Classification - Class Description⁹

I	The patient is normal and healthy
II	The patient has mild systemic disease that does not limit their activities (e.g., controlled hypertension or controlled diabetes without systemic sequelae)
III	The patient has moderate or severe systemic disease, which does limit their activities (eg, stable angina or diabetes with systemic sequelae)
IV	The patient has severe systemic disease that is a constant potential threat to life (eg, severe congestive heart failure, end-stage renal failure)
V	The patient is morbid and is at substantial risk of death within 24 hours (with or without a procedure)
E	Emergency status: in addition to indicating underlying ASA status any patient undergoing an emergency procedure is indicated by the suffix "E"

4. Factors Involved in the Choice of Sedation Regimen¹⁴:

The level of sedation targeted and the agents chosen will depend on:

- Characteristics of the procedure including:
 - length of procedure;
 - level of anxiety; and
 - degree of invasiveness.
- Individual patient factors including:
 - age;
 - existing medical conditions;
 - prior experience with endoscopic procedures;
 - patient anxiety; and
 - current use of opiates or other sedatives.
- Patient preferences
- Need for patient cooperation

5. Moderate (Conscious) Sedation Agents:

A report on a recent survey of Canadian endoscopists related to sedation during colonoscopy in Canada, concludes that two-thirds of Gastroenterologists use a combination of benzodiazepines and opioids for sedation during colonoscopy⁴. The dosing regimen is variable; however, more than 60% of endoscopists surveyed use 3 – 5 mg of Midazolam while more than 70% use 50 – 100 mcg of Fentanyl during the procedure. Endoscopy Re-Design within WRHA requires an electronic format of data collection (including medication administration) and be capable of generating reports. Once this has been established, it should be possible to extract provider sedation practices and patient outcomes. The goal will be to develop a more specific protocol for standardized application of administration of moderate (conscious) sedation agents. Current recommendation is as in the table below:

Usual doses of common sedative agents for moderate (conscious) sedation for endoscopy (adapted from the AGA institute review of endoscopic sedation¹)

Drug	Initial dose	Supplemental dose	Usual maximum dose	Average dose	Average dose for colonoscopy from the survey of CAG clinicians ⁴	Comments
Fentanyl	50-100 ugm	25 ugm q 2-5 mins	200 ugm		50-100 ugm	Dose reduction of 50% or more is indicated in the elderly
Midazolam	0.03 mg/kg	1 mg q 2mins	6 mg		3-5 mg	Dose reduction of 20% or more for pts > 60 yrs and/or ≥ ASA III
Propofol	5-15 mg	5-15 mg		Colonoscopy : 65-100 mg EGD: 35-70 mg		Pre-induction Fentanyl: 25-75 Midazolam: 0.5-2.5 mg

Propofol

A recent review and position statement, “Nonanesthesiologist administration of Propofol (NAAP) for GI endoscopy” compiled by multiple gastroenterology and endoscopy societies in the US concluded that the administration of Propofol by nonanesthesiologists is comparable to sedation using benzodiazepines and an opioid with respect to their sedation efficacy and safety profiles⁵. The NAAP sedation is superior to sedation using benzodiazepines and an opioid with regards:

- to time to sedation;
- time to recovery; and
- patient satisfaction (for colonoscopy)^{5,6}.

An opioid and a benzodiazepine can be administered each as a single dose and followed up with small incremental doses of propofol to achieve a target level of moderate (conscious) sedation⁵.

As emphasized in the position statement, proper training and patient selection are crucial for the safe practice of NAAP sedation⁵. Canadian Association of Gastroenterology has published a similar position statement⁷. Currently the anesthesiology societies do not support the use of Propofol by nonanesthesiologists.

The position of the WRHA Anesthesiology Program is that Propofol should be used by professionals trained in the provision of general anesthesia with proper supervision by a physician trained in anesthesia and qualified to provide rescue in the event that too much drug

is given. Patients requiring Propofol need appropriate monitoring by a dedicated practitioner who is not involved in the diagnostic/therapeutic procedure¹⁷.

Usual Dose of Reversal Agents:

Medication overdoses or adverse reactions may cause respiratory depression, hypotension, or impaired cardiovascular function.

Drug	Intended Use	Initial Dose	Supplemental Dose	Usual Maximum Dose	Comments
Naloxone (Narcan)	Reverse effects of Narcotic	0.05-0.1 mg over 2-3 minutes	Repeat at 2-3 min. intervals until RR is greater than 10/min.	0.4 mg	Use with caution in patients with coronary artery disease.
Flumazenil (Anexate)	Reverse sedative effects of Benzodiazepines	0.3 mg	Repeat at 60 second intervals	1 mg	Use incremental doses of 0.1mg in elderly patients as often receive smaller doses of benzodiazepines

6. Choosing a Sedative agent:

Implementation of an evidence based sedation protocol can improve the quality of practice and reduce the incidence of sedation related adverse events. The practice of moderate (conscious) sedation is a dynamic activity that may result in the introduction of agents not currently widely used in Winnipeg for endoscopy (e.g. Propofol). Moderate (conscious) sedation practice will require ongoing evaluation of outcomes including, but not limited to:

- procedure time;
- procedure completion rate;
- complication rate; and
- patient experience, including a willingness to return for repeat endoscopy if indicated

7. Sedation Levels and Definitions:

Sedation and analgesia includes a continuum of states of consciousness ranging from minimal sedation (anxiolysis) to general anesthesia. When determining the level of sedation required during gastrointestinal procedures, it is important to identify the desired outcome of the level of sedation. For example, with gastroscopy and colonoscopy, the desired outcome is to achieve minimal to moderate (conscious) sedation that will allow the patient to tolerate a noxious procedure. In contrast, during an ERCP, moderate sedation may be required to achieve the same outcome. When minimal sedation is the intent, however the patient is unable to tolerate the procedure, and deep sedation is required for the remainder of the procedure, it is important to mobilize a 2nd nurse to the procedure room. (Personal email communication, Joanne Cabrera, April 16, 2009, Alberta Health Services).

ASA Definitions of General Anesthesia and Levels of Sedation/Analgesia

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

Minimal sedation:

- also known as anxiolysis;
- a drug-induced state during which the patient responds normally to verbal commands;
- cognitive function and coordination may be impaired; and
- Ventilatory and cardiovascular functions are unaffected.

Moderate (conscious) sedation:

- a drug-induced depression of consciousness during which the patient responds purposefully to verbal command; either alone or accompanied by light tactile stimulation;
- no interventions are necessary to maintain a patent airway;
- spontaneous ventilation is adequate; and
- cardiovascular function is usually maintained.

Deep sedation/analgesia:

- a drug-induced depression of consciousness during which the patient cannot be easily aroused, but responds purposefully (reflex withdrawal from a painful stimulus is NOT considered a purposeful response) following repeated or painful stimulation;
- independent ventilatory function may be impaired;
- the patient may require assistance to maintain a patent airway;
- spontaneous ventilation may be inadequate; and
- cardiovascular function is usually maintained.

Cautionary Note: During intended deep sedation, the RN should have no other responsibilities and a 2nd nurse or assistant is required to assist the physician¹⁰.

General anesthesia:

- a drug-induced loss of consciousness during which the patient is not arousable, even to painful stimuli;
- the ability to maintain independent ventilatory function is often impaired;
- assistance is often required in maintaining a patent airway;
- positive pressure ventilation may be required due to depressed spontaneous ventilation or drug-induced depression of neuromuscular function; and

- cardiovascular function may be impaired.

8. Target Level of Sedation:

Moderate (conscious) sedation/analgesia is the most common target level of sedation used in the outpatient/ambulatory setting. Pain: Clinical Manual¹¹ states that optimal moderate (conscious) sedation is achieved when the patient:

- Maintains consciousness;
- Independently maintains airway ;
- Retains protective reflexes (swallow and gag);
- Responds to verbal and physical commands;
- Is not anxious or afraid;
- Experiences acceptable pain control;
- Has a minimal change in vital signs;
- Remains cooperative during the procedure;
- Has mild amnesia for the procedure; and
- Recovers to baseline (pre-procedure) status safely and promptly.

Several sedation scales and scoring systems have been developed to describe the level of consciousness. The Modified Observer’s Assessment of Alertness and Sedation (MOAA/S) is one such tool. This scale does not take into account cardio-respiratory status (which also needs to be recorded, as below) and there is some subjectivity as to what MOAA/S levels constitute moderate (conscious) or deep sedation (deep sedation is defined as when score is less than 2 or 1). It is important that there is a uniform assessment and subsequent assignment of a sedation scale score.

Modified Observer’s Assessment of Alertness/Sedation Scale ¹

Responsiveness	Score
Agitated	6
Responds readily to name spoken in normal tone (alert)	5
Lethargic response to name spoken in normal tone	4
Responds only after name is called loudly and/or repeatedly	3
Responds only after mild prodding or shaking	2
Does not respond to mild prodding or shaking	1
Does not respond to deep stimulus	0

9. Patient Monitoring:

ASA Guidelines for monitoring during sedation

- Continuous O₂ Saturation (oxygenation);
- Continuous Pulse (circulation);
- Respirations (ventilation) by observation and/or auscultation at regular intervals;
- Blood Pressure measurements at appropriate intervals;
- Level of Consciousness (LOC) at regular intervals using verbal stimuli for moderate sedation, with more profound stimuli used for deep sedation;
- Electrocardiograph (EKG) monitoring should be used
 - during moderate sedation in patients with **significant** cardiovascular disease;
 - during moderate sedation in patients undergoing procedures where dysrhythmias are anticipated; or
 - in patients receiving deep sedation.

- End-tidal CO₂ (capnography) should be considered for patients
 - Receiving moderate sedation where ventilation cannot be observed directly; and
 - Receiving deep sedation.

Note: End-tidal CO₂ monitoring is a practice that is being evaluated in the literature; however is not yet an accepted evidence-based practice.

10. Documentation:

Pre-procedure Documentation^{8 *}

The registered nurse (RN) shall perform and document a patient assessment. Assessment factors should include physical, psychosocial, current medications, treatment(s), and previous medical/ surgical, and drug history. Review of the patient's symptoms and history will provide pertinent information (pacemaker, COPD, hepatitis etc.) required to be documented. Documentation shall include the time that the patient assessment was performed and name of the person performing the assessment or intervention.

Documentation shall include but not be limited to:

- Patient's name, birth date age and PHIN;
- Date and Time of arrival;
- Time of assessment;
- Patient stated reason for procedure, planned procedure and name of physician performing the procedure;
- Patient/family teaching-including discharge criteria;
- Signed informed consent;
- Baseline vital signs (Temperature, Pulse, Respiratory status, Blood pressure, and Oxygen saturation prior to procedure);
- Actual height and weight (not based on patient report);
- Warmth, dryness and color of skin;
- NPO status;
- Bowel prep compliance (if applicable i.e. for colonoscopy);
- Current medications and time of last dose- including ASA, anticoagulants, anti-platelet agents(e.g. clopidogrel) nonsteroid anti-inflammatories, sleeping pills, tranquilizers;
- Allergies to foods or medications;
- Presence of prosthetic devices;
- Physical disabilities;
- Intravenous line, type, site, inserted by, rate, or presence of intermittent lock;
- Lab results (if applicable);
- Pre-procedure pain;
- Patient concerns;
- Emotional status;
- Base Line Aldrete Score; and
- Admitting nurse's signature.

*These pre-, intra-, and post- procedure guidelines are also followed by Alberta Health services

Intra-procedure Documentation⁸:

- Minimal monitoring includes BP, Heart rate and rhythm (if EKG monitoring indicated as above), respiratory rate and effort, O₂ Sat, and level of consciousness, and level of comfort.

The frequency of intra-procedural monitoring and associated documentation will vary dependent on the level of sedation achieved.

Minimal sedation: Requirement for vital signs monitoring and documentation every 15 minutes throughout the procedure and immediately following the procedure.

Moderate (conscious) sedation/analgesia: Place the patient on continuous oximetry. Monitor vital signs every 5 minutes throughout the procedure and immediately following and document a minimum of every 10 minutes.

Deep sedation/analgesia: Place patient on continuous oximetry. Monitor and document vital signs every 5 minutes throughout the procedure and immediately following.

- Procedure performed;
- Physician, nurse and support staff involved in the procedure;
- Name of drug(s)/agent(s) (including Oxygen), dosage, administration time, route of administration, person administering and patients response;
- IV fluids administered or discontinued including blood and blood products;
- Equipment including, but not limited to:
 - Scope including serial # ;
 - Dilators, make and size;
 - Ligation bands;
 - Cautery including # of machine setting of cut and coagulation, pad placement, skin condition pre and post procedure; and
 - Any other special equipment used.
- Unusual events (including adverse events), interventions and outcomes;
- Patient status at end of procedure;
- Specimens obtained and disposition;
- Post procedure diagnosis; and
- Signature of procedure nurse.

Post-procedure Documentation⁸:

- Date and Time of arrival in post-procedure area;
- Minimal monitoring includes BP, Heart rate, respiratory rate and effort, O2 Sat, level of consciousness, and level of comfort;
Minimal Sedation: Monitor and document vital signs every 30 minutes and/or until the patient reaches Aldrete score of 8 or returns to baseline Aldrete score.
Moderate (conscious) sedation/analgesia: Monitor and document vital signs every 15 minutes for at least 30 minutes and/or until the patient reaches Aldrete score of 8 or returns to baseline Aldrete score.
Deep sedation/analgesia: Monitor and document vital signs every 15 minutes for at least 30 minutes and/or until the patient reaches Aldrete score of 8 or returns to baseline Aldrete score.
- Name of drug(s)/agent(s) (including Oxygen), dosage, administration time, route of administration, person administering and patients response;
- IV fluids administered or discontinued including blood and blood products;
- Unusual events (including adverse events), intervention and outcomes;
- Abdominal assessment/pulmonary assessment;
- Mode of transportation for discharge;
- Person responsible for patient at discharge i.e. (wife, son, significant other);
- Discharge instructions given to outpatient and/or patients family and comprehension of instructions- signed by person responsible for patient;
- Discharge criteria applied;

- Time of discharge; and
- Signature of discharge nurses and designation.

11. Discharge Criteria:

Standardized discharge criteria shall be used to assess recovery from sedation. This practice is designed to facilitate safe and efficient discharge. Several recovery scales have been developed, most using similar criteria to assess eligibility for discharge. One such example is the Aldrete scoring system, which evaluates five (5) physiologic parameters:

- Respiration;
- oxygen saturation;
- blood pressure;
- consciousness; and
- activity.

In addition to a physiologic assessment, suitability for discharge includes an ability to dress and walk independently. Patients do not need to be assessed for their ability to tolerate fluids or solids before discharge home¹.

Aldrete Scoring System¹³:

Respiration

Able to take deep breath and cough	2
Dyspnea/shallow breathing	1
Apnea	0

Oxygen saturation

SaO ₂ > 95% on room air	2
SaO ₂ = 90 – 95% on room air	1
SaO ₂ < 90% even with supplemental O ₂	0

Consciousness

Fully awake	2
Arousable on calling	1
Not responding	0

Circulation

BP +/- 20 mmHg baseline	2
BP +/- 20 – 50 mm Hg baseline	1
BP +/- 50 mm Hg baseline	0

Activity

Able to move 4 extremities	2
Able to move 2 extremities	1
Able to move 0 extremities	0

NOTE. Monitoring may be discontinued and patient discharged to home or appropriate unit when Aldrete score is ≥ 9 OR returns to baseline Aldrete Score.

12. Discharge Instructions:

All patients being discharged shall:

- receive verbal and written instructions outlining diet, activity, medication, and follow-up evaluation;

- receive contact information for the endoscopist/endoscopist's office, Health Links-Info Sante and/or other agency as applicable with availability 24 hours/day in the event of a complication related to the endoscopic procedure; and
- be discharged home, accompanied by a responsible individual.

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