

***Procedural Sedation and
Analgesia***

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Guidelines for Procedural Sedation and Analgesia

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Guidelines for Procedural Sedation and Analgesia

1.0 Objectives

- To establish guidelines for the administration of sedation and analgesia outside of the operating room (for non-anaesthetists)
- To standardize the monitoring of patients receiving procedural sedation and analgesia for diagnostic testing and therapeutic procedures.
- To ensure a safe environment for patients and staff in the use of these medications

2.0 Definition

“Procedural sedation and analgesia” is a description of a state that allows a patient to tolerate unpleasant procedures while maintaining adequate cardio-respiratory function. This is accomplished through administration of sedative and analgesic agents while allowing independent airway control throughout the procedure. The term “procedural sedation and analgesia”, is a more accurate description than the better known but imprecise term “conscious sedation”. Throughout this document, the term “procedural sedation” will be used to represent the concept of procedural sedation and analgesia.

3.0 Indications

Procedural sedation and analgesia is the administration of specific medication to minimally depress a patient’s level of consciousness, while at the same time allowing them to maintain a patent airway, protective reflexes and the ability to respond to verbal commands and/or physical stimulation. The goal is to provide sufficient analgesia and sedation to facilitate a procedure and improve comfort.

If these agents are used for reasons other than procedural sedation, this guideline does not apply.

There are a variety of situations requiring procedural sedation. Some of the most commonly seen situations include orthopedic procedures, endoscopy and cardioversions. Other examples of situations requiring procedural sedation include (but are not limited to):

ADULT	PEDIATRIC
Orthopedic Reduction fracture/dislocations Hand and fingertip repairs	Orthopedic Same indications as adults
Surgical I&D abscesses Chest tubes Burn or abrasion debridement	Surgical Same indications as adults Wound exploration / repair Complex or facial laceration Foreign body removal
Procedural Cardioversion Lumbar Puncture	Procedural Sexual assault exam Slit lamp exams

4.0 Level of Sedation

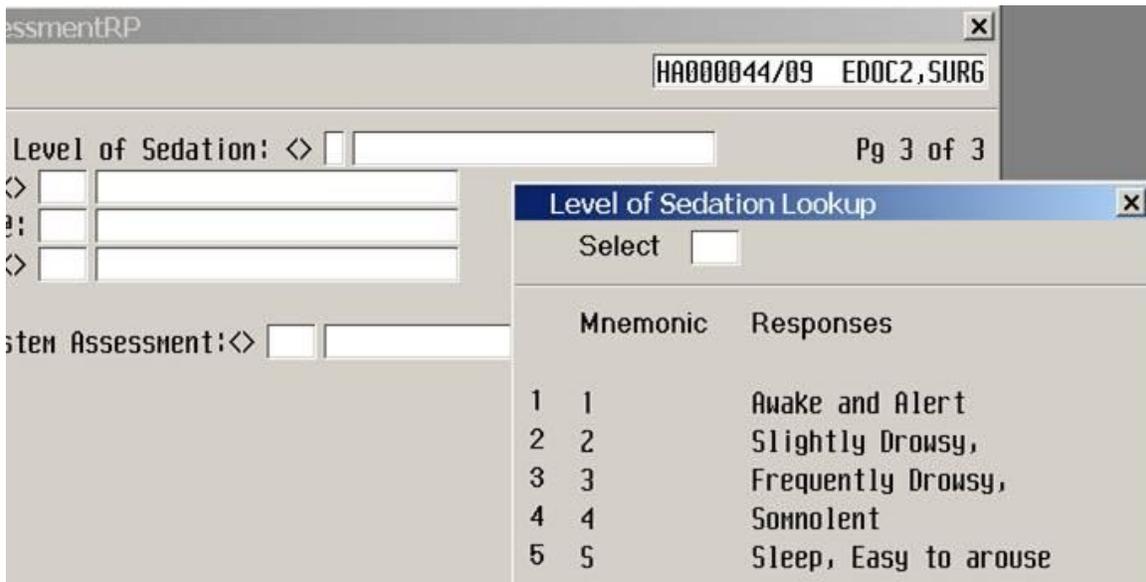
In 1999 the American Society of Anesthesiologists (ASA) adopted formal definitions for the level of sedation and analgesia and have incorporated them into the 2001 updated practice guidelines for sedation and analgesia by non-anesthesiologists (6). These levels range from minimal sedation (“Anxiolysis”) through to general anesthesia, and are found below:

LEVEL OF SEDATION	DEFINITION
Minimal Sedation (“Anxiolysis”)	A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
Moderate Sedation / Analgesia (“Procedural Sedation”)	A drug-induced depression of consciousness during which patients may respond purposefully to verbal commands (dependent on procedure), either alone or accompanied by tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
Deep Sedation / Analgesia	A drug-induced depression of consciousness during which the patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
General Anesthesia	A drug-induced loss of consciousness during which patients are not rousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance 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.

The goal of procedural sedation and analgesia will be to achieve a mild to moderate level of sedation. If deeper levels of sedation may be required, an anesthesiologist must be in attendance.

EXCEPTION: The presence of an anesthesiologist is not required when performed by Emergency Department or ICU attending staff or adult intensivists skilled in procedural sedation. If deeper sedation is anticipated, it is recommended that a second person trained in airway management be present.

At QHC the Pasero Opioid-induced Sedation Scale (POSS) has been adapted for nursing assessment of level of sedation. Frequency of assessing and documentation is in intra and post-procedure sections of this guideline.



5.0 Staffing

Because sedation is a continuum, it is impossible to predict individual patient response and therefore it is possible to “overshoot” the desired level of sedation. Practitioners providing sedation and analgesia must be able to **rescue** the patient from a level of sedation deeper than intended.

Staff during procedure must include a minimum of 2 – 3 personnel:

- Physician performing procedure
- Qualified Registered Nurse (RN), Respiratory Therapist (RT), Anaesthesia Assistant or physician to assess and maintain airway patency, adequacy of ventilation, vital signs, and monitoring devices in use. The primary responsibility of the second regulated health care professional is to monitor the patient during the procedure. During moderate sedation, the person responsible for patient assessment may also perform tasks that are interruptible and short; however, when in deep sedation, the person needs to be dedicated to monitoring the patient (American Society for Gastrointestinal Endoscopy, 2008).
- If the procedure itself requires more than one person to perform it, then another appropriately trained individual must be recruited to assist. This second individual must be competent in airway management and cardiac monitoring interpretation.
- The registered nurse managing the patient receiving procedural sedation must have no other responsibilities during and after the procedure that will compromise the nurse’s ability to adequately monitor the patient (the nurse patient ratio of 1:1 until a recovery score of **8** on the Modified Aldrete Scale is achieved).
- Additional personnel such as an RN, RT, Physician may be required to

assist with the procedure, administer medications, document and/or maintain the airway

- When using procedural sedation, at least one physician certified in advanced airway management or trained in general anesthesia must be on-site and available within 5 minutes.

For sedation given to a patient to undergo a diagnostic test, the nurse managing the patient receiving procedural sedation must have no other responsibilities during and after the procedure that will compromise the nurse's ability to adequately monitor the patient (the nurse patient ratio of 1:1 until a recovery score of 8 on the Modified Aldrete Scale is achieved). In these situations, the ordering physician may not be present but must be available (or an assigned designate) within the hospital to respond within 5 minutes.

NOTE: If the nature of the procedure itself would make it difficult for the physician to also manage patient outcomes resulting from a deeper level of sedation, recruiting another appropriately trained physician should be considered.

6.0 Pre-Procedure Assessment

6.1 Physician Responsibilities

Pre-procedure evaluation of patients has been proven to **reduce risk** of adverse outcomes in procedural sedation and analgesia. It is mandatory in all cases. The physician is responsible for the pre-procedure assessment of the patient, and documentation of the assessment on the patients health record.

At a minimum, this includes:

- Focused history and physical (vital signs, weight, cardiac and respiratory assessment, and baseline neurological status).
- Drug allergies and reactions, current medications and any previous adverse effect from anesthesia
- Airway evaluation – Specific note made of beards, facial and neck anatomy, teeth, dentures and mouth opening, congenital anomalies, obesity (**MALLAMPATI SCORE**)
- Fasting Status (See Appendix 1 for Fasting Guidelines)

Note: All Emergency Patients should be presumed to have a full stomach and this should be considered in the risk/benefit analysis regarding choice of agent as well as the depth of sedation. Once identified needing sedation they should remain NPO. If possible patients may benefit from delaying the procedure until NPO for at minimum 6 hours (ideally 8 hours). When proper fasting cannot be assured, the increased risks of sedation must be weighed against its benefits.

6.2 Nursing Responsibilities

The Nurse will:

- Prepare the patient and environment for procedural sedation
- Remain with the patient during the procedure;
- Facilitate the creation of a non-threatening environment;
- Consult other health care providers as appropriate
- Evaluate and record the patient's baseline physiologic and psychological parameters on the patient record, e.g., vital signs (HR, BP, RR), level of consciousness (5 point observation scale), oxygen saturation and weight (if not already recorded on the patient record).
- Initiate IV access with NS (as ordered by the physician), using appropriate size cannula;
- Connect the patient to appropriate monitoring equipment: cardiac monitoring (for high risk patients), non-invasive BP (NIBP) monitoring and O₂ saturation monitoring;
- Prepare the following equipment at the patient's bedside (and ensure the equipment is appropriate for the patient's size and age):
 - Oxygen (mask and prongs)
 - Oral Airways (AGE AND SIZE APPROPRIATE)
 - Resuscitation Bag (Ambubag)(DITTO)
 - Operational suction equipment
 - NIBP cuff
 - Pulse oximeter
 - Cardiac Monitor (as required)
 - Naloxone (at bedside, do not draw up unless requested)
 - Flumazenil (at bedside, do not draw up unless requested)
 - Other medication for procedure as ordered

Resuscitation equipment (adult and paediatric), including defibrillator, endotracheal tubes, airways, laryngoscope, advanced airway equipment, oxygen sources with positive pressure capabilities, emergency drugs and oxygen tanks or sources must be readily available.

Monitoring equipment (blood pressure apparatus, ECG and oximetry) must be tested daily and prior to the procedure.

6.3 Consent

The patient or their legal guardian (in the case of children or legally incompetent adults) must be informed of the indications for sedation, the risk and benefits associated with it and any alternatives. Obtaining a separate written consent is optional, but at minimum documentation that an informed verbal (or written) consent was obtained is required.

- Informed consent for the procedure (including the procedural sedation and analgesia) will be obtained by the physician prior to procedural sedation and analgesia. Either a verbal or written consent will be

recorded in the patient record. Please refer to the QHC Consent Policy for further detail as needed.

7.0 Intra-Procedure Assessment

Procedural sedation may result in cardio-respiratory depression or allergic reactions. Therefore, equipment and supplies should be readily available and the procedure should take place in an area that is large enough and equipped for resuscitation.

7.1 Patient Monitoring

Minimum monitoring of all patients when procedural sedation is used includes: blood pressure, pulse, respiration, level of consciousness, pulse oximetry, and pain tolerance at the initiation, during, and at the completion of the procedure.

Documentation of the patients' condition during the procedure is the responsibility of the second health care professional responsible for monitoring the patient. **The major complication from procedural sedation is respiratory depression and aspiration.** Any individual involved in procedural sedation must understand this and must know how to identify this complication and quickly intervene.

Monitoring the patient involves a dedicated nurse to assess, monitor, and document the following:

a) Visual observation – colour, respiratory rate and depth

b) Cardiac – heart rate and blood pressure

Note: Cardiac rhythm monitoring is encouraged for all patients, and required for all cases involving deep sedation. This subgroup of high-risk patients would include those who have a history of cardiac or pulmonary disease, the elderly, and those patients for whom a prolonged procedure is expected.

c) Level of consciousness – (5 point observation scale)

- 1) Awake and Alert
- 2) Drowsy, normal speech
- 3) Eyes closed, responds to voice / light touch
- 4) Eyes closed, responds to painful stimuli
- 5) Unresponsive (General Anesthesia)

d) Respiratory – airway patency, respiratory rate and pulse oximetry.

e) Frequency of Monitoring Vital Signs – Patients are at highest risk of respiratory depression within 5 to 20 minutes after receiving intravenous sedation and after removal of external painful stimuli upon completion of the procedure. Therefore, the patients' cardiac and respiratory vital signs should be recorded at a frequency determined by the type and amount of medications given, as well as the length of the procedure.

At a minimum this will include:

- Before procedure
- Every 3 – 5 minutes after administration of medications, and every 5 minutes during the procedure
- Vital signs recorded upon completion of the procedure
- Post Procedure – continue monitoring vital signs every 5 – 15 minutes for initial phase of recovery phase or until awake then proceed to vital signs every 15 – 30 minutes until discharge criteria met

Dependent on the patient's response, assessment may be needed more frequently. **“Please note that modern electronic monitoring may facilitate assessment but cannot replace well-trained assistants”** (Cancer Care Ontario, p10, 2007)

8.0 Post-Procedure Assessment

The post procedure phase, with the removal of painful stimuli and the ongoing effects of medications, is a high-risk time for respiratory depression and aspiration. Ongoing monitoring of the patients' level of consciousness and vital signs is important to ensure patient safety. The patients' vital signs are monitored continuously and documented at intervals until discharge criteria are met. **The physician must be immediately accessible within the department if the patient's status declines.**

8.1 Patient Monitoring

Following the procedure, constant nursing care is needed until the patient achieves a Modified Aldrete score of 8 or greater, including a respiratory score of 2 (see Appendix 2: Modified Aldrete Score). Monitor cardiac rhythm if patient deemed high risk (as assessed above).

Monitor vital signs (HR, BP, RR, LOC), oxygen saturation, level of sedation and record vital signs a minimum of:

- Every 15 minutes until the patient achieves a Modified Aldrete score of 8 or greater, including a respiratory score of 2 (see Appendix 2: Modified Aldrete Score);
- Vital signs are taken every 15 minutes for at least 2 hour if opioid or benzodiazepine reversal agents, such as naloxone and flumazenil are administered;
- If possible, post procedure position patient on their side until awake, if not, elevate head of bed to 30 degrees;
- Notify physician if any of the following occur:
 - Decreasing level of consciousness or seizing activity
 - SpO₂ less than 92% despite increased oxygen delivery
 - Change in cardiac rhythm or heart rate (greater than or less than 20%)
 - Abnormal vital signs for patient (greater than 20% difference from baseline)

- Patient unable to achieve recovery criteria
- Just prior to transfer to another patient care area, when applicable; and
- Just prior to discharge home, when applicable.

For patients who are unable to obtain a modified Aldrete Score of **8** or greater due to preexisting conditions, the physician can write patient specific discharge/transfer orders.

In addition the following:

- Assess and document any unexpected events and post-procedure complications as related to sedation and take interventions as required.
- Assist and accompany patient to bathroom, assessing presence of orthostatic hypotension
- Assess gait prior to discharge
- Reinforce pre-procedure teaching related to discharge instructions. The teaching should be provided in a written form and a copy given to the patient prior to discharge.

8.2 Discharge Criteria for Patients going home

The conditions below must be met prior to the nurse notifying the responsible physician that the patient is ready for discharge home.

- Discharge (Home) readiness has been confirmed by meeting the criteria listed below:
 - a) When patient is being discharged from endoscopy, a Post Anesthetic Discharge Scoring System (PADSS) of 9 out of 10 must be achieved. The PADSS evaluates ambulation, nausea and vomiting, pain and surgical bleeding). See Appendix 3.
 - b) Cardiovascular function and airway patency satisfactory and stable
 - c) Patient is easily rousable, oriented and protective reflexes intact
 - d) Patient can talk (if age/developmentally appropriate)
 - e) Patient can sit up unaided (if appropriate) and has a stable gait.
 - f) Pre-sedation level of responsiveness or level as close as possible to the norm in very young or handicapped children
 - g) Adequate state of hydration – minimal or no nausea or vomiting at the time of discharge.
 - h) Stable vital signs for a minimum of 60 minutes
 - i) No evidence of bladder distension
- If reversal agents were given, adequate time (minimum 2 hours) must be allowed for reversal agent to wear off and discharge criteria to be met.
- A responsible adult is present to transport the patient home (please see below).
- Verbal and written discharge instructions have been given to the patient and caregiver. The instructions must include:

- Do not drive an automobile or operate dangerous machinery for 12–24 hours (or day of procedure)
- No alcohol, sleeping pills, or medication that cause drowsiness for 24 hours unless discussed with physician (for example, prescribed pain management)
- If nausea occurs, take clear fluids only, then progress diet to solids as tolerated
- Take medications as directed by physician on discharge

All efforts will be made to ensure that the patient is accompanied home with a responsible adult. If all avenues have been exhausted and a responsible adult is not available post procedure, discharge safety is assessed by a period of observation as determined by the physician and includes assessment related to return to cognitive and functional baseline status, medications in use, and anticipated analgesic requirements.

9.0 Documentation

Document all assessments and interventions on the specific documentation forms and electronic health record. Ensure to document patients condition and disposition at discharge as well as discharge instructions given for follow-up care.

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Appendix 1 – ASA Fasting Guidelines

Ingested Material	Mandatory Fasting Period (hours)
Clear Fluids	2
Light Meal	6
Full Meal	8
Alcohol	24
NO gum, candy, lozenges	

Appendix 2 – Modified Aldrete Score

The Modified Aldrete Score is completed:

- Upon receiving the patient post-procedure in the designated recovery area (in some clinical units this may be the same area that the procedure occurred)
- As changes occur in the patient's condition
- When a change in frequency of vital signs occurs
- At discharge

O₂ Saturation	Able to maintain O ₂ saturation greater than 92% on room air	2
	Needs O ₂ inhalation to maintain O ₂ saturation greater than 90%	1
	O ₂ saturation less than 90% even with O ₂ supplement	0
Respiration	Able to breathe deeply and cough freely	2
	Dyspnea or limited breathing	1
	Apneic	0
Consciousness	Fully awake	2
	Arousal on calling	1
	Not responding	0
Activity	Able to move four extremities voluntarily or on command	2
	Able to move two extremities voluntarily or on command	1
	Unable to move extremities voluntarily or on command	0
Circulation	BP ± 20% of pre-anaesthetic level	2
	BP ± 20 – 49% of pre-anaesthetic level	1
	BP ± 50% of pre-anaesthetic level	0
RECOVERY SCORE: Before discharge, score should be 8-10 with a respiratory score =2		

Appendix 3 – Post Anesthetic Discharge Scoring System (PADSS)

Category	Description of Status	PADSS Score
Vital Signs	Within 20% range of pre-op value	2
	Within 20 to 40% range of pre-op value	1
	greater than 40% range of pre-op value	0
Ambulation	Steady gait/no dizziness	2
	Ambulates with assistance	1
	Not ambulating/dizziness	0
Nausea and Vomiting	Minimal, treated with PO medications	2
	Moderate, treated with parenteral medications	1
	Continues after repeated treatment	0
Pain	Acceptable to patient (PO medications)	2
	Pain not controlled/not acceptable to patient	1
Surgical Bleeding	Minimal/no dressing changes required	2
	Moderate bleeding	1
	Severe bleeding	0

Appendix 4 – Information of Commonly used Medications for Procedural Sedation

Drug	Administration Guidelines	Pharmacokinetics	Precautions Contraindications Adverse Affects	Notes
Midazolam (Versed): Sedative, Hypnotic, Anxiolytic	Adults: 1-2.5 mg (0.015 – 0.03 mg/kg) IV total dose 1-2 mg boluses Titrate to affect to Max. 10 mg total. Rarely need to exceed 5 mg in an adult. Max. in Elderly 3.5 mg (total) Paediatrics: ▪ 0.5 mg/kg PO (max. 10 mg total) ▪ 0.01 - 0.1 mg/kg IV total dose	Onset: 1-5 min. Peak: 20-30 min. Duration: 1-2 hrs. Metabolized: liver Excreted: Kidneys	P ▪ Renal failure, Elderly C ▪ Hypersensitivity A ▪ Respiratory depression, Hypotension, Paradoxical agitation	Reduce dosage - 30% (50% in elderly) when used in conjunction with a narcotic; Monitor Vitals closely
Fentanyl Action: Analgesic, Sedative at higher doses	Dosage: 0.5 - 1 mcg/kg IV per bolus Adults given as 25-50 mcg boluses q3-5 min to a max of 3 mcg/kg total	Onset: Immediate Peak: 2-3 min. Duration: 20-30 min (is dose related) Metabolized: Liver Excreted: Kidney	P ▪ Elderly, bradyarrhythmia C ▪ Hypersensitivity A ▪ Hypotension ▪ Respiratory depression ▪ Chest wall rigidity ▪ Bradycardia	Reduce dose when given with anxiolytics; Respiratory insufficiency; Reduce dose in the elderly
Propofol (Diprivan): Sedative, Hypnotic, Amnestic, mild anti-emetic	Dosage: ▪ Variable patient response, therefore Bolus at 0.15-0.5 mg/kg IV (total dose) titrated to effect. ▪ Total adult dose 0.5mg/kg - 1.5 mg/kg	Onset: 2-10 min. Peak: variable with boluses because of rapid clearance, steady state achievable with infusion. Metabolized: Lipophillic, rapidly cleared from plasma, therefore no dose adjustment in hepatic and renal failure (Note – long term administration in these patients has not been evaluated)	P ▪ Allow longer time between boluses in elderly due to decreased circulation time; May rapidly achieve deep sedation with IV boluses C ▪ Hypersensitivity to <u>egg</u> or <u>soy</u> A ▪ Local pain on injection; Hypotension; Respiratory depression, significant risk to airway intervention and ventilation	No analgesic effects; Premedicate with fentanyl for painful procedures; Addition of 10 mg (1mL) preservative free lidocaine to 20mL syringe of propofol reduces pain on injection; Supplied as 10 mg/ml

Drug	Administration Guidelines	Pharmacokinetics	Precautions Contraindications Adverse Affects	Notes
Ketamine (Ketalar) Action: Sedative, Analgesic, Amnestic, Dissociative properties, Maintenance of airway reflexes	Dosage: 0.5 – 1.0 mg/kg IV, slowly, titrated to effect. 3 mg/kg IM , Note: Small doses of Midazolam (0.01 mg/kg) prophylactically may Minimize emergence Phenomenon. Optional pretreatment with Atropine 0.01 mg/kg to reduce airway secretions.	Onset: IV 30 sec, IM 3-4 min. Duration: IV 20 min, IM 25-30 min. Recovery time may be prolonged (approx. 2 hrs) with IM route	P • IV slowly titrated may minimize Emergence Reaction; Hallucination and Agitation C • Increased ICP; Coronary artery disease; Psychotic disorders; Hypersensitivity A • Tachycardia, tremors, Hypersalivation, Laryngospasm, N/V during recovery.	•Post-sedation emesis, emergence reactions and prolonged recovery, limit its use to ED physicians who have experience with this agent.

Reversal Agents

Naloxone (Narcan) Action: • Opiate antagonist	Adults: 0.1 – 0.2 mg IV Paediatrics: 0.01 mg/kg IV	Onset: 1-2 min. Duration: 45 min.	P • Opiod dependency	• Monitor closely for recurrence of respiratory depression
Flumazenil	Adults: 0.2 mg q1 minute up to 1 mg ; 3 mg/hr maximum Paediatric: 0.01 mg/kg up to 0.2 mg IV bolus, may repeat q1-3 min. x 4 doses (0.05 mg/kg IV total)	Onset: 1-4 min. Duration: 1 hrs (usually).	P • Physical dependence on benzodiazepines A • Seizures	• Monitor for seizures. <i>Not</i> to be used to advance discharge.



DISCHARGE INSTRUCTIONS AFTER PROCEDURAL SEDATION/ANALGESIA

Procedural sedation is used when a painful procedure is being done. Sedatives (medications to help you relax) and analgesics (pain relievers) are given to help lessen the pain you might feel during the procedure. You or your child may still be a little sleepy or clumsy for the next 24 hours, so you will need to be extra careful.

For the next 24 hours:

<p>Adults:</p> <ol style="list-style-type: none"> 1. Do not do activities that require normal balance, strength and coordination (climbing ladders, swimming, cycling, etc) 2. No driving or operating mechanical equipment for the next 12-24 hours 3. Avoid alcohol, sleeping pills or other medications that cause drowsiness for 24 hours 4. Do not sign any legal or financial documents for 24 hours 5. Do not eat until completely awake (start with clear fluids such as water/juice and progress to solid foods when tolerating fluids) 6. If vomiting occurs, stop eating for 30-60 minutes then gradually resume clear fluids 	<p>Children:</p> <ol style="list-style-type: none"> 1. Have someone watch your child while riding in the car on the way home. If your child falls asleep at any time in the next 6 hours, watch him or her all the time to make sure that your child has no difficulty breathing. 2. Supervise all activities for the next 4 hours 3. Do not allow your child to do any activity that requires coordination such as riding a bike, tricycle, scooter, or skateboard for the next 24 hours 4. Do not allow your child to drive any motorized vehicle for 24 hours.
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RETURN TO THE EMERGENCY ROOM IF THE FOLLOWING OCCUR:

- Breathing problems
- Significant/prolonged weakness or sleepiness
- Frequent nausea and vomiting

The sedative(s) you have received are: _____

The analgesic(s) you have received are: _____

I have read and understand the above instructions and have been provided a copy to review after discharge home.

Signature of Patient/Guardian/Substitute Decision Maker

Date

Communication Pathway

Committee/Council	Date
Mental Health, Rehabilitation and Complex Continuing Care PAC	May 20, 2011.
Surgical Program Advisory Committee	October 13, 2011.
Maternal Child Program Advisory Committee	June 14, 2011.
Nursing Practice Committee	September 20, 2011.
Medicine and Critical Care Program Advisory Committee	September 6, 2011.
Emergency and Primary Care Program Advisory Committee	June 21, 2011; March 20, 2012.
Pharmacy and Therapeutics Council	December 20, 2011.
Medicine Advisory Committee	April 10, 2012.