RECOMMENDATIONS FOR SAFE ADMINISTRATION OF SEDATION AND ANALGESIA (CONSCIOUS SEDATION)

Patient Evaluation

Monitoring

Support Equipment and Emergency Training

Clinical Pharmacology

Recovery Care

The following content contained within is based upon the evidence-based American Society of Anesthesiologists Guidelines on Sedation and Analgesia by Non-Anesthesiologists.* (The complete guidelines may be obtained by calling your Roche representative at 1-800-LAROCHE)

*The guidelines have been endorsed by the governing board of the American Society for Gastrointestinal Endoscopy.

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Adapted from the American Society of Anesthesiologists Guidelines on Sedation and analgesia by Non-Anesthesiologists

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http://www.gasnet.org/apsf/clinical/sedation/
Patient Evaluation

Patient Consent

- Risks, benefits, expectations, and alternatives

Pre-Procedure History

- Major organ systems
  - Pre-existing cardiac or pulmonary disease may require reduced dosage because sedative and analgesic medications tend to cause cardiovascular and respiratory depression.
  - Hepatic and renal abnormalities may impair drug metabolism and excretion resulting in longer duration of drug action.

- Current medications
- Drug allergies
- Alcohol, tobacco, illicit substance use
  - Alcohol and/or other substance abuse may increase required effective dosage of sedatives and/or analgesics.
  - Smoking increases risk of airway irritability, bronchospasm, or cough during sedation.

- Previous experience with sedation/analgesia
  - Prior adverse reactions to sedation or anesthesia may increase risk of complications during subsequent sedation/analgesia.

Focused Physical Examination

- Cardiac
- Respiratory
- Airway

Example of Airway Assessment Procedures for Sedation and Analgesia:

Positive pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with atypical airway anatomy. Also, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Factors that may be associated with difficulty in airway management are:

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**History**

*Previous problems with anesthesia or sedation*

*Stridor, snoring, or sleep apnea*

*Dysmorphic facial features (e.g. Pierre-Robin syndrome, trisomy 21)*

*Advanced rheumatoid arthritis*

**Physical examination**

*Habitus*

*Significant obesity (especially involving the neck and facial structures)*

*Head and neck*

*Short neck, limited neck extension, decreased hyoid-mental distance (<3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation*

*Mouth*

*Small opening (<3 cm in an adult); edentulous, protruding incisors; loose or capped teeth; high arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula*

*Jaw*

*Micrognathia, retrognathia, trismus, significant malocclusion*

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**Pre-Procedure Fasting**

- Sedative and analgesic medications tend to impair airway reflexes in proportion to the degree of sedation achieved. Patients may be at increased risk of aspirating gastric contents should regurgitation occur.
- For elective procedures, this risk may be minimized by allowing sufficient time for gastric emptying before the procedure begins.
- In emergent situations or with impaired gastric emptying (bowel obstruction, pregnancy, opioids, pain), pulmonary aspiration risk should be considered in determining timing of the procedure and target level of sedation.
**Example of Fasting Protocol for Sedation and Analgesia for Elective Procedures:**

Gastric emptying may be influenced by many factors, including anxiety, pain, abnormal autonomic function (e.g., diabetes), pregnancy, and mechanical obstruction. Therefore, the suggestions listed do not guarantee that complete gastric emptying has occurred. Unless contraindicated, pediatric patients should be offered clear liquids until 23 h before sedation to minimize the risk of dehydration.

<table>
<thead>
<tr>
<th>Solids and Nonclear Liquids*</th>
<th>Clear Liquids</th>
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<tbody>
<tr>
<td>Adults</td>
<td>68 h or none after midnight</td>
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<tr>
<td>Children older than 36 months</td>
<td>68 h</td>
</tr>
<tr>
<td>Children aged 6-36 months</td>
<td>6 h</td>
</tr>
<tr>
<td>Children younger than 6 months</td>
<td>46 h</td>
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</tbody>
</table>

* This includes milk, formula, and breast milk (high fat content may delay gastric emptying).

1 There are no data to establish whether a 68 h fast is equivalent to an overnight fast before sedation/analgesia.
Monitoring

Level of Consciousness

Patients' responses to verbal commands during a procedure performed with sedation/analgesia serve as a guide to their level of consciousness. An appropriate level of consciousness implies that patients will be able to control their own airways and take deep breaths as necessary.

- Level of consciousness should be assessed frequently (1-minute intervals) during the onset of sedation and whenever medications are being titrated.
- Once an appropriate safe level of sedation is established, patients may be aroused less frequently if this is necessary to avoid interfering with the diagnostic or therapeutic procedure.

- With administration of sedative/analgesic medications, patients' responses to verbal commands are delayed and are frequently slowed or slurred.
- Light, tactile stimulation may be required to get patients' attention.
- Once aroused, they respond appropriately to verbal commands.
- In cases where verbal response is not possible, seek other indications of consciousness in response to verbal or tactile stimulation.

Patients whose only response to verbal command is reflex withdrawal from painful stimuli are deeply sedated, approaching a state of general anesthesia, and special care must be taken to ensure the patency of the airway, adequacy of pulmonary ventilation, and hemodynamic stability. This is deep sedation, not conscious sedation.

Pulmonary Ventilation

Sedative and analgesic medications significantly depress ventilatory drive and decrease airway patency. Pulmonary ventilation should be monitored to provide the earliest indication of inadequate air exchange.

- Ventilatory function usually can be monitored by observation of spontaneous respiratory activity or continuous auscultation of breath sounds.
- In situations where patients are physically separated from the care giver, automated apnea monitoring (detection of exhaled carbon dioxide, nasal thermistor, etc.) is desirable.

Oxygenation

Pulse oximetry should be used on a continuous basis to provide the earliest warning of hypoxemia.
- There may be a delay of a minute or more between the onset of apnea and the
first decrease in oximeter reading, particularly if the patient is breathing supplemental oxygen.

Pulse oximetry should never replace evaluation of the patient. If the monitor indicates low oxygen saturation, check the patient first to ensure adequate ventilation and oxygenation. If the patient responds appropriately and appears to be ventilating adequately, consideration can be given to possible monitoring errors. Equipment failure is a diagnosis of exclusion.

Hemodynamics

Medications administered during sedation/analgesia may directly depress cardiac function. In addition, they may impair the ability of the autonomic nervous system to compensate for hemodynamic changes.

- Blood pressure and heart rate should be monitored at frequent intervals, especially during the onset of sedation/analgesia.
- If recognized early, hypotension may be treated by elevation of the legs, administration of intravenous fluids, and, in some cases, administration of a short acting vasoconstrictor.

- Obtain a baseline blood pressure and pulse reading prior to initiation of sedation.
- Obtain frequent readings (12 minute intervals) during the onset of sedation.
- Obtain readings regularly (5-10 minute intervals) during the procedure.
- Obtain readings at the end of the procedure and prior to discharge.

Continuous EKG Monitoring

Patients may be at increased risk for developing cardiac dysrhythmias during sedation and analgesia. Continuous electrocardiograph monitoring enables the practitioner to rapidly detect and diagnose dysrhythmias, so that any necessary intervention can be undertaken in a timely manner.

This is especially important in the following situations:

- Patients with underlying cardiovascular disease
- Patients who are suspected of having dysrhythmias because of irregular rhythm noted on the pulse oximeter or detected during auscultation of heart sounds
- Procedures with increased risk of dysrhythmia (those involving gastrointestinal distention or cardiovascular manipulations such as angioplasty and endocardial ablation)
Support Equipment and Emergency Training

- Supplemental oxygen administration reduces the risk of hypoxemia and provides an additional margin of safety.
- Age- and size-appropriate emergency equipment should be immediately available, including a defibrillator for patients with cardiovascular disease.
- A person trained in basic life support and airway management should be present and available to initiate resuscitation if respiratory and/or cardiovascular depression occurs.
- An individual with advanced life support skills should be immediately available.

Emergency Algorithm

- Identify inadequate ventilation (observation, auscultation, capnography) or hypoxemia (pulse oximetry).
- Instruct the patient to take a "deep breath." If no response, apply painful stimulus. Repeat instructions to take a "deep breath."
- Is spontaneous breathing present?
  - Yes: Apply supplemental oxygen. Check airway reflexes. Check breath sounds.
  - No: Establish an airway a. jaw thrust b. nasal airway c. oral airway (Consider chemical reversal naloxone/flumazenil).
- Reassess clinical status—is the patient breathing?
  - Yes: Continue supplemental oxygen. Monitor vital signs/ventilation.
  - No: Apply positive pressure ventilation with mask/bag. Consider intubation.
- Assess ventilatory adequacy, level of consciousness, vital signs, skin color, lung sounds, airway reflexes, pulse oximetry.
Use of Appropriate Sedative/Analgesic Agents

- Combinations of sedatives and analgesic drugs may increase the likelihood of adverse outcomes, including ventilatory depression and hypoxemia.
  - The tendency for synergism between sedatives and analgesics reinforces the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function.

- Sedative and analgesic agents should be administered individually to achieve the desired effect rather than in fixed combinations.
- Intravenous sedatives/analgesic drugs should be given in small incremental doses titrated to desired endpoints.
- It is important to allow adequate time for peak drug effects to occur before administration of subsequent doses.

Reversal Agents

- Specific antagonists are available for opioids (i.e., naloxone) and benzodiazepines (e.g., flumazenil).

**Flumazenil** reverses the sedative and respiratory depressant effects of benzodiazepines.

- Dose: 0.2 mg IV; if desired effect is not achieved, an additional dose may be administered.
- It generally does not cause hypertension or tachycardia.
- Seizures may occur in patients who are receiving benzodiazepines for seizure control.

**Naloxone** effectively reverses opioid-induced respiratory depression; however, analgesia is also antagonized.

- Dose: 0.5 1. 0 μg/kg IV; if desired effect is not achieved, an additional dose may be administered.

*Both flumazenil and naloxone have shorter durations of action than the benzodiazepines and opioids which they antagonize. Patients must be observed for an appropriate period of time (up to 2 hours) after the last dose of an antagonist to ensure that respiratory depression does not recur.*
Recovery Care

- Patients must be monitored during recovery to ensure that any adverse events are rapidly recognized and treated.
- Vital signs should be recorded at regular intervals and pulse oximetry should be continued until the patient is no longer at risk of hypoxemia.
- Monitoring should include observation by a person trained in recognition of post-procedure/post-sedation complications.
- Appropriate discharge criteria should be met prior to discharge.

Example of Recovery and Discharge Criteria after Sedation and Analgesia:

Each patient care facility in which sedation/analgesia is administered should develop recovery and discharge criteria that are suitable for its specific patients and procedures. Some of the basic principles that might be incorporated in these criteria are enumerated.

General Principles

1. All patients receiving sedation/analgesia should be monitored until appropriate discharge criteria are satisfied. The duration of monitoring must be individualized depending on the level of sedation achieved, overall condition of the patient, and nature of the intervention for which sedation/analgesia was administered.

2. The recovery area should be equipped with appropriate monitoring and resuscitation equipment.

3. A nurse or other trained individual should be in attendance until discharge criteria are fulfilled. An individual capable of establishing a patient airway and providing positive pressure ventilation should be immediately available.

4. Level of consciousness and vital signs (including frequency and depth of respiration in the absence of stimulation) should be recorded at regular intervals during recovery. The responsible practitioner should be notified if vital signs fall outside of the limits previously established for each patient.

Guidelines for Discharge

1. Patients should be alert and oriented; infants and patients whose mental status was initially abnormal should have returned to their baseline. Practitioners must be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat.

2. Vital signs should be stable and within acceptable limits.

3. Sufficient time (up to 2 h) should have elapsed after last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become re-sedated after reversal effects have abated.
4. Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any post-procedure complications.

5. Outpatients should be provided with written instructions regarding post-procedure diet, medications, and activities, and a phone number to use in case of emergency.