Washington Adventist Hospital

MEDICAL STAFF OFFICE

7600 Carroll Avenue
Takoma Park
Maryland 20912

Tel: 301 891 5056
Fax: 301 891 5912
TTY: 301 891 5081

November 11, 2008

Dear Physicians:

The Washington Adventist Patient Care Sedation Analgesia Policy (#5655) has been revised to reflect current standard of care and to be in compliance with the **Joint Commission (JC) regulations**.

The policy is as follows:

1. Credentialing: Please see enclosure "Requirements for Physician (Non-Anesthesiologist) Clinical Privileges for Moderate Sedation/Analgesia". These Requirements must be met as part of your application/reapplication for privileges:

   - Read the material in the attached WAH Sedation Analgesia Self Study Packet.
   - Answer the 15- question exam, sign and return to the Medical Staff Office.
   - Complete a ACLS/BLS course or
   - Complete the airway management competency.

2. The Pre-Sedation/Analgesia Assessment Form is available on all units where Sedation/analgesia is performed and **MUST BE COMPLETED PRIOR TO EACH PROCEDURE** for which sedation/ analgesia is planned.

Please contact Omid Moayed, Chairman, Department of Anesthesia (X5520) if there are questions. Thank you for your co-operation.

Sincerely,

Omid Moayed, MD, Chairman
Department of Anesthesia

OM/shl

Washington Adventist Hospital
Sedation Analgesia Credentialing
Self-Study Packet for Physicians (Non-Anesthesiologists)

TABLE OF CONTENTS

4. Anesthesia: Consists of general anesthesia and spinal or major regional anesthesia. It does *not* include local anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory 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.

Since sedation/analgesia states are a continuum, it is possible for patients to slip into deep sedation/analgesia when only moderate sedation/analgesia was intended. Therefore, practitioners who are credentialed to provide moderate sedation/analgesia must be qualified to rescue patients from deep sedation/analgesia. Additionally, the physician/LIP must be competent to manage a compromised airway and to provide adequate oxygenation and ventilation. Careful patient evaluation is an extremely important part of the safe administration of sedation and analgesia drugs.

Patients Considered at Increased Risk for Sedation/Analgesia Complications:

1. Patients at extremes of age
2. Patients in poor physiologic conditions, e.g. patients with ASA status III, IV, V, or "E" (refer Table 1), including patients with COPD, asthma, coronary artery disease undergoing non-cardiac procedures, congestive heart failure, advanced renal disease and end stage renal disease

Table 1: ASA Classifications

| | |
|---|---|
| Class I | A normally healthy patient |
| Class II | A patient with mild systemic disease |
| Class III | A patient with severe systemic disease |
| Class IV | A patient with severe systemic disease that is a constant threat to life |
| Class V | A moribund patient who is not expected to survive without the operation |
| Class E | An emergency |

3. Patients who have increased potential to develop airway obstruction/complications:
   - patients with morbid obesity
   - patients with history of sleep apnea or heavy snoring
   - patients with abnormal airway anatomy (refer Table 2), particularly Class III and IV
   - Patients with short neck, reduced thyromental distance (distance from bottom of chin to thyroid cartilage, < 3 cm), obese head/neck area, etc.
     - *Also, these patients may be difficult to ventilate or intubate if airway obstruction occurs.*

Washington Adventist Hospital
Sedation Analgesia Credentialing
Self-Study Packet for Physicians (Non-Anesthesiologists)

I. Criteria

As required by Medical Executive Committee and Patient Care Policy #5655 "Sedation Analgesia", the following criteria have been established for physician (non-anesthesiologists) credentialing in Moderate Sedation Analgesia:

1. Completion of the Washington Adventist Hospital Sedation/Analgesia Self Study Module which consists of the following:

   a) Pertinent anesthesiology journal articles on sedation/analgesia

   b) Pharmacology review

   c) Review of Airway Management Video

   d) WAH Sedation/Analgesia Test
   The test must be returned to Medical Staff Office. The physician must score 90%. If the score is below 90%, the physician may retake the test once. If the second score is below 90%, the physician must consult with the Chairman of the Department of Anesthesia for individual instruction.

   e) BCLS or

   f) Airway Management Course

2. These requirements must be met at the time of initial application for privileges and every 2 years thereafter as part of the re-credentialing process.

II. Review of Sedation/Analgesia

Objective of *Moderate Sedation/Analgesia* (formerly "conscious sedation")

1. To safely administer sedative and analgesic agents to a patient so they can safely tolerate (both physiologically and psychologically), an operative, invasive or diagnostic procedure that may otherwise be unpleasant, painful or anxiety provoking.

2. The physician (non-anesthesiologist) can most safely accomplish this goal by achieving #1 or #2 of the following and avoiding #3 and certainly #4.

Definitions:
The four levels of sedation and anesthesia are:

1. **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;

2. **Moderate sedation/analgesia ("conscious sedation"):** A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained;

3. **Deep sedation/analgesia:** A drug-induced depression of consciousness during which patients cannot be easily aroused by respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function maybe impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained; and

Table 2: Abnormal Airway Anatomy [1]

| Class I | Class II | Class III | Class IV |
|---|---|---|---|
|  |  |  |  |
| *Soft palate, fauces, uvula, anterior and posterior tonsillar pillars | *Soft palate, fauces, uvula | *Soft palate, base of uvula | *Soft palate not visible |
| No difficulty | No difficulty | Moderate difficulty | Severe difficulty |

*Anatomic Structures Visualized

References:
1. Mallampati signs as indicators of difficulty of intubation. (Adapted from Mallampati, Samsoon, and Young. [http://www.kwpub.com/mallampati.html])

4. Patients who have a history of complications with prior anesthesia or sedation/analgesia
5. Patients who are unusually anxious and might require a large amount of medication
6. Patients with "at risk" NPO status (risk of pulmonary aspiration of gastric contents):
   - Patients who have had solid food within 8 hours of the procedure
   - Patients who have had non-clear liquids within 6 hours
   - Patients who have had clear liquids within 4 hours of the procedure

These patients carry a significant morbidity and potential mortality secondary to the increased potential for aspiration of gastric contents. Therefore strict adherence to NPO guidelines is important. In non-elective situations, ideally the procedure would be delayed until guidelines are met. If the clinical conditions do not allow for this, other options include:

- Consulting with an anesthesiologist;
- Administering all of the following (adult dosing below):
  - Metoclopramide (Reglan): 10 mg IV 30 minutes to one hour prior to procedure increases gastric emptying and increases lower esophageal sphincter tone
  - H2 antagonist IV: one to 1 ½ hrs. prior to procedure
  - Sodium citrate (Bicitra): 30 ml PO 15 minutes prior to the procedure to increase gastric pH
- Administering minimal amounts of sedatives to minimize the potential for loss of protective reflexes

None of these measures absolutely prevents aspiration of gastric contents.

## III. Pharmacology Review (Please refer to Appendix A: Adult Dosing Guidelines)

Introduction

The most important practice for the safe administration of sedation/analgesic medications is incremental titration of the dosing. Further, doses should be appropriately reduced in patients who are:

- Over the age of 60
- Generally debilitated
- At risk for airway complications

- Sensitive to the medications such as those with COPD or sleep apnea

Commonly Used Medications

1. Hypnotic Sedatives

Midazolam (Versed)

- Used for amnesia, sedation, anxiolytic, skeletal muscle relaxant, not an analgesic.
- 2-3 times more potent than diazepam (Valium).
- Elimination half-life is 1-4 hours which may be doubled in the elderly.
- Metabolism – midazolam (Versed) undergoes hydroxylation by hepatic oxidative mechanisms. The metabolites are excreted unchanged in the urine. The elimination of half-life is unaltered in renal failure.

**Apnea and airway obstruction may occur with rapid bolus administration especially in the presence of opioids.**

Diazepam (Valium)

- IV use is discouraged for sedation/analgesia due to long half-life.
- May be used as oral pre-medication prior to procedure.

2. Narcotic Opioids

Morphine

- Prototype opioid agonist
- Produces analgesia, sedation and sometimes euphoria
- Peak analgesic effects and peak respiratory depressant effects may occur 20 minutes after IV injection
- Elimination half-life approximately 114 minutes
- Plasma morphine concentrations are greater in the elderly
- Respiratory effects: depression of ventilation; decreased rate of breathing and sometimes increased tidal volume

**Apnea and airway obstruction may occur with rapid bolus administration especially in the presence of hypnotic sedatives.**

- Cardiovascular effects: not a myocardial depressant, reduces sympathetic tone to peripheral veins, also may produce:
  - Orthostatic hypotension
  - Bradycardia secondary to increased vagal activity
  - Histamine release

Meperidine (Demerol)

- Elimination half-life is 3-4 hours
- Metabolism: demethalation in liver to normeperidine which can cause CNS stimulation.
- Normeperidine half-life is 15-40 hours
- May accumulate in patients with renal disease
- Respiratory effects: depression of ventilation; decreased rate of breathing and sometimes increased tidal volume

**Apnea and airway obstruction may occur with rapid bolus administration especially in the presence of hypnotic sedatives.**

- Cardiovascular effects
  - Large doses produce direct myocardial depressant effects
  - Hypotension is more frequent and more profound than with comparable doses of morphine or fentanyl
  - May increase heart rate
  - Contraindicated in patients taking MAO inhibitors

Fentanyl
- More rapid onset time than morphine or meperidine (within 30 seconds)
- Its greater potency and rapid onset reflects its greater lipid solubility
- Metabolism: Hepatic to inactive metabolites that are excreted in the urine
- Elimination half-life 185-219 minutes. The short duration of action reflects rapid redistribution to inactive tissue sites in fat and skeletal muscle. The slow reuptake from these sites account for persistant effects that parallel the slow elimination half-life.
- Does not cause histamine release
- Does not cause myocardial depression
- Less likely to cause hypotension
- Higher doses may result in skeletal muscle rigidity making adequate ventilation impossible
- Potent respiratory depressant and must be carefully titrated (as with all opioids).
- Respiratory effects: depression of ventilation; decreased rate of breathing and sometimes increased tidal volume.

Apnea and airway obstruction may occur with rapid bolus administration especially in the presence of hypnotic sedatives.

3. Reversal Agents
- This group of drugs should be readily available but is rarely used because serious side effects may occur. They should be reserved for emergency situations or inadvertent overdose only. Sedation/analgesics should be properly titrated so that reversal agents are not needed.
- Note: Post Moderate Sedation Monitoring: Due to the short duration of these drugs, the minimum period for monitoring post moderate sedation is one hour after administration of reversal agents. If the patient shows any signs or symptoms of re-sedation or re-narcotization, they should be monitored until these signs or symptoms have resolved.
- Opoid Antagonists: Naloxone (Narcan)
  - Onset: 1-2 minutes
  - Duration: 30-45 minutes
  - Half-life: Approximately 1 hour
  - Administration: Dilute 0.4 mg in 9 ml NSS (total volume = 10 ml, 0.04 mg/ml); giving no more than 1.0 ml over 2 minutes. May give up to 0.8 mg.
  - If patient is apneic or has severely depressed ventilations, more rapid administration may be necessary
- Benzodiazepine Antagonist: Flumazenil (Romazicon)
  - 0.2 mg over 1-3 minutes
  - Repeat 0.2 mg if desired response is not attained s/p additional 45 seconds
  - Repeat at 1 minute intervals to a maximum dose of 1 mg.
  - If excessive sedation occurs, does may be repeated every 20 minutes to a maximum of 3 mg in any 1 hour
  - If no response to cumulative dosing of 1-5 mg over 2-10 minutes, look for another cause of increased sedation

- Can cause life-threatening seizures in patients receiving benzodiazepines on a long-term basis and in those who have overdosed on barbiturates or tricyclic antidepressants.

IV. Quality Assurance Indicators

The Department of Anesthesia monitors several Quality Assurance (QA) indicators for IV Sedation/Analgesia (refer Table 3). For occurrences, please forward the following to the Systems Improvement Department: patient's name, patient account number, the incident, and, if an anesthesiologist is paged, the name of the responding anesthesiologist. A confidential voice message may be left at X6248.

Table 3: QA Indicators for IV Sedation/Analgesia

| |
|---|
| 1. Loss of responsiveness to verbal command after S/A |
| 2. Loss of airway (obstruction) post S/A |
| 3. Respiratory depression / respiratory arrest / intubation post S/A |
| 4. Marked deviation from pre-op vital signs; e.g.:<br>▪ Systolic BP < 89 AND BP 30-40% variation from baseline<br>▪ $SPO_2$ <88% |
| 5. Use of reversal agent |
| 6. Cardinal events:<br>▪ CP arrest<br>▪ CVA w/in 72 hrs*<br>▪ Aspiration |
| 7. Cardiac arrest w/in 24 hrs* |
| 8. Seizures w/in 24 hrs* |
| 9. Peri-op MI w/in 24 hrs* |

*Time-specific indicators taken from initial administration of sedative and/or analgesic agent

V. Discharge Criteria: Modified Aldrete Scoring

Post-Procedure Phase: Identify post-procedure requirements and discharge criteria.

Post-procedure monitoring and documentation begin at the completion of the procedure. Vital signs should stabilize, and oxygen saturation should return to normal or baseline limits on room air. The patient's return to an alert level of consciousness – with intact protective reflexes and an acceptable comfort level with minimal nausea – are necessary before discharge. The physician who performed the procedure will be immediately notified of any changes in the patient's condition, such as a drop in oxygen saturation, a 20% drop or rise in systolic BP, or a decreased LOC. Satisfactory surgical site and dressing condition, return of pre-procedural ambulation abilities, and the presence of a responsible adult are required for discharge to home care. Patients and significant others should receive written and verbal discharge instructions. Pre-procedural education is encouraged due to the amnesic effects of sedative drugs. Post-procedural site care, pain control measures, prescriptions, home care needs, and follow-up medical care should be reviewed. Post-procedure phone calls by staff within 72 hours are suggested to ensure continuity of care and for quality improvement. Patients who receive S/A should not drive themselves home. A second person for transportation from the facility should be identified before the procedure starts (see Sedation / Analgesia Policy Post Procedure section for patient remaining in hospital after the procedure.)

The duration of the post-procedure recovery period may vary depending on the type and amount of sedative / analgesia administered, age, medical history, and procedure performed.

- Aldrete scoring is initiated immediately post procedure
- Monitor vitals, oxygen saturation and level of consciousness every 15 minutes until patient meets discharge criteria. ECG monitoring is included when indicated.
- Any patient receiving a drug antagonist (i.e. flumazeril, naloxone) shall have recovery monitoring for a minimum of 1 hour after administration and until the patient is fully awake and alert. This time is necessary to ensure that the patient does not become resedated after reversal effects have abated.
- If resedation or renarcotization occurs, the patient should remain under close monitoring in the recovery area until these effects have resolved.
- At no time should the sedated patient be left unattended.

Discharge Criteria / Aftercare Instructions

- Vital signs, oxygen saturation and level of consciousness are stable compared to presedation baseline.
- Patients requiring supplemental oxygen must meet pre-procedure baseline levels prior to discharge or transfer to a non-monitored area.
- Aldrete scoring system (refer Table 4) is used to determine readiness for discharge or transfer. The score range of "10" for complete recovery to "0" in comatose patients.
- Patients may be discharged with score of "9" or above providing that activity, respiration, and color on the scale are scored at "2" and circulation and level of consciousness are scored at "1" or "2".
- Complete written discharge instructions regarding post-procedure diet, medications, activity and contact telephone number in case of emergency should be given to the ambulatory patient and/or responsible adult following recovery from sedation/analgesia.
- Outpatients should be discharged to a responsible adult who assumes responsibility for transport and is able to report any post-procedure complications.
- Document and advise patient/family that following sedation/analgesia that the patient must not drink alcohol, drive an automobile, operate any dangerous machinery or undertake any responsible business matters for 24 hours.
- The qualified individual managing the patient during the recovery phase shall give report to the inpatient staff taking care of the patient.

Aldrete Scoring System

| Modified Aldrete Score | | Time | | | | |
|---|---|---|---|---|---|---|
| | | ADM | 15 Min | 30 Min | 45 Min | END |
| Activity | | | | | | |
| 2 | Moves all extremities on command | | | | | |
| 1 | Moves two extremities on command | | | | | |
| 0 | Unable to move extremities on command | | | | | |
| Respiration | | | | | | |
| 2 | Able to breathe deeply and cough freely | | | | | |
| 1 | Dyspnea or limited breathing | | | | | |
| 0 | Apneic | | | | | |
| Circulation | | | | | | |
| 2 | BP/HR = ± 20% of pre-op level | | | | | |
| 1 | BP/HR = ± 21% - 29% of pre-op level | | | | | |
| 0 | BP/HR = ± 30% pre-op level | | | | | |
| Consciousness | | | | | | |
| 2 | Fully awake | | | | | |
| 1 | Arousable on command | | | | | |
| 0 | Not responding to verbal stimulation | | | | | |
| $O_2$ Saturation | | | | | | |
| 2 | $SPO_2$ > 94% or = pre-op level | | | | | |
| 1 | $SPO_2$ > 92% or = pre-op level | | | | | |
| 0 | $SPO_2$ < 92% or = pre-op level | | | | | |
| Total: | | | | | | |

LEGEND:
10 = Total Score; Score ≥ 9 Needed for PACU Discharge/Bypass
*Note: Return to base line status score as "2"

# APPENDIX A: ADULT AND PEDIATRIC DOSING GUIDELINES

# Washington Adventist Hospital

## Sedation and Analgesia

| Drug | Indication | Dose* | Onset* | Peak* | Duration* | Technique |
|---|---|---|---|---|---|---|
| hloral lydrate, | Sedative/hypnotic for pediatric patients | *Peds:* 25-100mg/kg/dose PO/PR; maximum dose 120mg/kg or total dose 1gm<br>*(Adults:* N/A) | 15-60 minutes | 0.5-1 hour | 4-6 hours | • Administer 30-60 minutes prior to the procedure; may repeat in 30 minutes if necessary |
| entanyl Sublimaze) | To induce conscious sedation prior to a diagnostic or therapeutic procedure | *Peds (1-12 years):*<br>0.7-1.0mcg/kg/dose IV/IM<br>Total dose ⇧2mcg/kg IV/IM<br><br>*Adults:* 25-50mcg/dose IV/IM<br>Total dose 150mcg IV/IM | Immediate (IV)<br>7-8 minutes (IM) | 3-5 minutes (IV)<br>No data (IM) | 30-60 minutes(IV)<br>1-2 hours (IM) | • Administer very slowly over 1-2 minutes<br>• Rapid IV injection may cause chest wall rigidity |
| Meperidine (Demerol) | Preoperative medication, Support of anesthesia, relief of moderate to severe pain | *Peds:* 0.25-0.5mg/kg/dose IV<br>Total Dose ⇧1mg/kg IV<br><br>*Adults:* 25-50mg IV<br>Total dose 100mg IV | 5-10 minutes | 10-15 minutes | 2-4 hours | • Administer in 10mg increments every 5-10 minutes for adults<br>•Administer 5 minutes prior to procedure in pediatric patients |
| Midazolam (Versed) | Sedation/anesthesia prior to or during diagnostic, therapeutic or endoscopic procedures | *Peds:* 0.025-0.05mg/kg IV/IM<br>– total dose 0.1 mg/kg IV/IM<br><br>0.25-0.75mg/kg po<br>– total dose 0.75mg/kg po<br><br>*Adults <60 years old:* 0.5mg-1.0mg IV, ⇧2.5mg over 3-5 minutes- total dose ⇧7.5mg<br><br>*Adults ≥60 years old:* 0.5mg-1.0mg IV, ⇧1.5mg over 3-5 minutes- total dose ⇧5mg | 1-5 minutes | 20-60 minutes | 1-2 hours;<br>6 hours<br>(maximum) | • Titrate slowly over 3-5 minutes.<br>• Evaluate sedative effect in 3 minutes or more<br>• Allow 3 minutes between doses to assess full sedative effect |

*May vary depending upon the complexity and duration of the procedure or individual patient characteristics.
** Should opiate overdose occur during conscious sedation, the dose would be 0.1mg/kg/dose up to 5 year or 20kg; if no response; repeat in 3-5 minutes.
*** Higher doses require a consult from anesthesia

## Appendix A: ADULT & PEDIATRIC DOSING GUIDELINES

| Drug | Indication | Dose* | Onset* | Peak* | Duration* | Technique |
|---|---|---|---|---|---|---|
| ketamine**** Ketalar)<br><br>KETAMINE IS ADMINISTERED BY MD/CRNA only. | Used in moderate sedation for diagnostic or surgical procedures that do not require skeletal muscle relaxation.<br><br>(Also used for induction of anesthesia prior to administration of other general anesthetics) | *KETAMINE IS ADMINISTERED BY MD/CRNA only.*<br><br>*Peds:*<br>Sedation & analgesia:<br>2-10mg/kg IM<br><br>*Adults:*<br>Sedation & analgesia:<br>0.6mg/kg IM (35-70mg) | Sedation<br>30-40 seconds (IV)<br>3-4 minutes (IM)<br><br>Analgesia<br>10-15 minutes (IM) | 15-30 minutes (IM)<br>No data (IV) | Sedation<br>5-10 minutes (IV)<br>12-25 minutes (IM)<br><br>Sedation<br>15-30 minutes (IM) | • Physician/CRNA only administers dose(s) slowly, over 60 seconds, to prevent respiratory depression and enhanced pressor response<br>• Increments of one-half to the full induction dose may be repeated as necessary to maintain sedation. The larger the total dose administered, the longer the time to complete recovery. |

**** Information on Ketamine is given as guidelines for clinical monitoring only – KETAMINE is to be administered by a physician or CRNA only per MD Nurse Practice Act.

Antidotes/Reversal Agents

| Drug | Indication | Dose* | Onset* | Peak* | Duration* | Technique |
|---|---|---|---|---|---|---|
| Naloxone (Narcan) | For complete or partial reversal of narcotic depression, including respiratory depression induced by opioids | *Peds:* 0.005-0.01mg IV q 2-3 min. till desired response**<br><br>*Adults:* 0.1mg IV q 2-3 min. with 0.1mg increments to a max. dose of 1mg q 5 min. | 1-2 minutes | N/A | <60 minutes depends on route of administration | • Inject at 2-3 minutes intervals until desired degree of reversal.<br><br>• Repeat in 1-2 hour intervals if needed |
| Flumazenil (Romazicon) | For complete or partial reversal of benzodiazepine sedation | *Peds:* 0.01 mg/kg IV q 1 min. max. total dose 0.05mg/kg - 1mg<br><br>*Adults:* 0.2-1mg total dose 3mg | 1-2 minutes | 6-10 minutes | 60 minutes | • Repeat at 1 minute intervals to desired effect into running IV |

*May vary depending upon the complexity and duration of the procedure or individual patient characteristics.
** Should opiate overdose occur during conscious sedation, the dose would be 0.1mg/kg/dose up to 5 year or 20kg; if no response; repeat in 3-5 minutes.
*** Higher doses require a consult from anesthesia

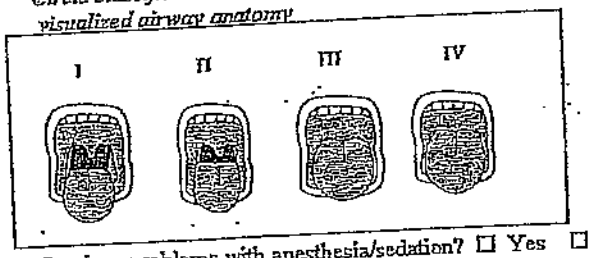
## APPENDIX B: PRE-SEDATION/ANALGESIA ASSESSMENT FORM

# Pre-Sedation/Analgesia Assessment Form

This supplemental form must be completed and signed by the physician in addition to the History and Physical examination prior to implementation of sedation/analgesia.

1. Please check box for appropriate ASA status classification:
   - ☐ Status I — No organic disease
   - ☐ Status II — Mild or moderate systemic disease without functional impairment
   - ☐ Status III — Organic disease with definite functional impairment
   - ☐ Status IV — Severe disease that is life threatening
   - ☐ Status V — Moribund patient, not expected to survive

2. Airway Evaluation:
   *Circle classification that corresponds to visualized airway anatomy*




Check appropriate box (es):

Neck: ☐ Normal ☐ Restricted neck motion ☐ Short Neck ☐ Obese head/neck area

Mouth: ☐ Normal ☐ Loose teeth ☐ Broken teeth ☐ Capped teeth ☐ Dentures

Other/comments: _____

3. Previous problems with anesthesia/sedation? ☐ Yes ☐ No Comments: _____

4. Any history of sleep apnea or snoring? ☐ Yes ☐ No Comments: _____

5. Last oral intake: NPO since _____ (time)

6. Sedation/Analgesia Plan: _____

In light of the above evaluation, I believe this patient is an acceptable candidate for sedation/analgesia and have discussed the sedation/anesthesia alternatives, indications for, and risks of sedation with the patient/parent/guardian, who understands and consents. ☐ Yes ☐ No

*Additionally, the patient will be reevaluated immediately prior to the administration of sedation/analgesic medications.

Signature of MD: _____ Date/Time: _____

## *IMMEDIATE PREOPERATIVE ASSESSMENT

I have re-evaluated the patient immediately prior to the administration of sedation/analgesia medication and: (check appropriate box)

☐ The status is unchanged and I consider the patient an acceptable candidate for the procedure/anesthetic.

☐ Status has changed but still consider the patient to be an appropriate candidate for the procedure/anesthetic.

Comment: _____

☐ Due to a change in status the procedure will be canceled at the current time.

Comment: _____

Signature of MD: _____ Date/Time: _____



Patient Identification:

## APPENDIX C: WAH SEDATION / ANALGESIA TEST

# APPENDIX D: SELECTED READINGS

PRACTICE GUIDELINES

Anesthesiology
1996; 84:459–71


# *Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists*

## *A Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists*

ANESTHESIOLOGISTS possess specific expertise in the pharmacology, physiology, and clinical management of patients receiving sedation and analgesia. For this reason, they are frequently called on to participate in the development of institutional policies and procedures for sedation and analgesia in nonoperating-room settings. To assist in this process, the American Society of Anesthesiologists developed these Guidelines for Sedation and Analgesia by Non-Anesthesiologists.

Practice guidelines are systematically developed recommendations that assist practitioners in making decisions about health care. These recommendations may be adopted, modified, exceeded, or rejected according to clinical needs and constraints, and they are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice. Practice guidelines are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome.

Developed by the Task Force on Sedation and Analgesia by Non-Anesthesiologists: Jeffrey B. Gross, M.D. (Chair), Farmington, Connecticut; Peter L. Bailey, M.D., Salt Lake City, Utah; Robert A. Caplan, M.D., Seattle, Washington; Richard T. Connis, Ph.D. (Methodologist), Woodinville, Washington; Charles J. Coté, M.D., Chicago, Illinois; Fred G. Davis, M.D., Burlington, Massachusetts; Burton S. Epstein, M.D., Washington, D.C.; Patricia A. Kapur, M.D., Los Angeles, California; John M. Zerwas, M.D., Houston, Texas; and Gregory Zuccaro, Jr., M.D., Cleveland, Ohio.

Accepted for publication November 28, 1995. Supported by the American Society of Anesthesiologists, under the direction of James F. Arens, M.D., Chairman of the Committee on Practice Parameters. Approved by the House of Delegates, October 25, 1995. These guidelines received official endorsement by the Governing Board of the American Society for Gastrointestinal Endoscopy. A list of the references used to develop these guidelines is available by writing to the American Society of Anesthesiologists.

Address correspondence to Dr. Gross: Department of Anesthesiology (M/C 2015), University of Connecticut School of Medicine, Farmington, Connecticut 06030-2015.

Address reprint requests to the American Society of Anesthesiologists: 520 North Northwest Highway, Park Ridge, Illinois 60068-2573.

Key words: Analgesia. Practice guidelines: analgesia; sedation. Sedation: conscious.

The practice guidelines enumerated below have been developed using systematic literature summarization techniques. Results of the literature analyses have been supplemented by the opinions of the Task Force members and a panel of more than 60 consultants, drawn from a variety of medical specialties in which sedation and analgesia are commonly provided. In those instances when the literature does not provide conclusive data, there is an explicit statement that the guidelines are based on the opinion of the consultants or the consensus of the Task Force members. A detailed description of the analytic methods is included in appendix 1.

### *A. Definition*

"Sedation and analgesia" describes a state that allows patients to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation. The Task Force decided that the term "sedation and analgesia" (sedation/analgesia) more accurately defines this therapeutic goal than does the commonly used but imprecise term "conscious sedation." Note that patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by "sedation/analgesia."

### *B. Purpose*

The purpose of these guidelines is to allow clinicians to provide their patients with the benefits of sedation/analgesia while minimizing the associated risks. Sedation/analgesia provides two general types of benefit: First, sedation/analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain. Second, in children and uncooperative adults, sedation/analgesia may expedite the conduct of procedures that are not particularly uncomfortable but require that the patient not move. Excessive sedation/analgesia may result in cardiac or respiratory depression that must be rapidly recognized and appropriately

managed to avoid the risk of hypoxic brain damage, cardiac arrest, or death. Conversely, inadequate sedation/analgesia may result in undue patient discomfort or patient injury because of lack of cooperation or adverse physiologic response to stress.

*C. Focus*

These guidelines have been designed to be applicable to procedures performed in a variety of settings (*e.g.*, hospitals, free-standing clinics, physicians' offices) by practitioners who are not specialists in anesthesiology. The guidelines specifically exclude the following: (1) patients who are not undergoing a diagnostic or therapeutic procedure (*e.g.*, postoperative analgesia, sedation for treatment of insomnia); (2) otherwise healthy patients receiving peripheral nerve blocks, local or topical anesthesia, and/or no more than 50% $N_2O$ with oxygen and no other sedative or analgesic agents administered by any route; (3) situations when it is anticipated that the required sedation will eradicate the purposeful response to verbal commands or tactile stimulation (as distinct from reflex withdrawal from a painful stimulus); such patients require a greater level of care than recommended by these guidelines; and (4) perioperative management of patients undergoing general anesthesia or major conduction anesthesia (spinal or epidural/caudal blockade).

*D. Application*

These guidelines are intended to be general in their application and broad in scope. The appropriate choice of agents and techniques for sedation/analgesia is dependent on the experience and preference of the individual practitioner, requirements or constraints imposed by the patient or procedure, and the likelihood of producing unintended loss of consciousness. Templates are provided as examples to illustrate principles; clinicians and their institutions have ultimate responsibility for selecting patients, procedures, medications, and equipment.

## Guidelines

*I. Patient Evaluation*

Published data suggest and consultant opinion strongly supports the contention that appropriate preprocedure evaluation of patients' histories and physical findings reduces the risk of adverse outcomes. Additionally, consultant opinion supports the contention that an appropriate history, physical examination, and laboratory evaluation leads to improved patient satisfaction.

*Recommendations:* Clinicians administering sedation/analgesia should be familiar with relevant aspects of the patient's medical history including: (1) abnormalities of the major organ systems, (2) previous adverse experience with sedation/analgesia, as well as regional and general anesthesia, (3) current medications and drug allergies, (4) time and nature of last oral intake, and (5) history of tobacco, alcohol, or substance use or abuse. Patients presenting for sedation/analgesia should undergo a focused physical examination including auscultation of the heart and lungs and evaluation of the airway (template 1). Preprocedure laboratory testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia.

*II. Preprocedure Preparation*

*Patient Counseling:* There is insufficient evidence in the literature to establish the benefit of providing the patient (or her/his guardian, in the case of a child or impaired adult) with preprocedure information about sedation/analgesia. However, the consultants strongly support the contention that appropriate preprocedure counseling improves patient satisfaction and reduces risks; they also support the view that costs may be reduced. The Task Force members concur that patients undergoing sedation/analgesia should be informed of the benefits, risks, and limitations associated with this therapy, as well as possible alternatives.

*Preprocedure Fasting:* Because sedatives and analgesics tend to impair airway reflexes in proportion to the degree of sedation/analgesia achieved, members of the Task Force support the concept of preprocedure fasting before sedation/analgesia for elective procedures. However, the literature provides insufficient data to test the hypothesis that preprocedure fasting results in a decreased incidence of adverse outcomes in patients undergoing sedation/analgesia (as distinct from patients undergoing general anesthesia).

*Recommendations:* Patients (or their legal guardians in the case of minors or legally incompetent adults) should be informed of and agree to the administration of sedation/analgesia before the procedure begins. Patients undergoing sedation/analgesia for elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying

**Template 1. 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:

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

before their procedure (template 2). In urgent, emergent, or other situations when gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining the timing of the intervention and the degree of sedation/analgesia.

*III. Monitoring*

*Level of Consciousness:* The response of patients to commands during procedures performed with sedation/analgesia serves as a guide to their level of consciousness. Spoken responses also provide an indication that the patients are breathing. Patients whose only response is reflex withdrawal from painful stimuli are likely to be deeply sedated, approaching a state of general anesthesia, and should be treated accordingly. The consultants strongly support the contention that monitoring level of consciousness reduces risks and support the concept that overall costs may be reduced. The members of the Task Force believe that many of the complications associated with sedation/analgesia can be avoided if adverse drug responses are detected and treated in a timely manner (*i.e.*, before the development of cardiovascular decompensation or cerebral hypoxia); this may pose a special risk to patients given sedatives/analgesics in unmonitored settings in anticipation of a subsequent procedure.

*Pulmonary Ventilation:* It is the opinion of the Task Force that a primary cause of morbidity associated with sedation/analgesia is drug-induced respiratory depression. The literature suggests and consultant opinion strongly supports the observation that monitoring of ventilatory function reduces the risk of adverse outcomes associated with sedation/analgesia. Ventilatory function usually can be effectively monitored by observation of spontaneous respiratory activity or auscultation of breath sounds. In circumstances where patients are physically separated from the caregiver, the consultants support and the Task Force members con-

**Template 2. 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 2–3 h before sedation to minimize the risk of dehydration.

| | Solids and Nonclear Liquids* | Clear Liquids |
|---|---|---|
| Adults | 6–8 h or none after midnight† | 2–3 h |
| Children older than 36 months | 6–8 h | 2–3 h |
| Children aged 6–36 months | 6 h | 2–3 h |
| Children younger than 6 months | 4–6 h | 2 h |

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

† There are no data to establish whether a 6–8-h fast is equivalent to an overnight fast before sedation/analgesia.

cur that automated apnea monitoring (by detection of exhaled carbon dioxide or other means) may decrease risks; the consultants suggest that such monitoring will not reduce overall costs. The Task Force cautions practitioners that impedance plethysmography may fail to detect airway obstruction.

*Oxygenation:* Published data suggest and the consultants strongly support the view that early detection of hypoxemia through the use of oximetry during sedation/analgesia decreases the likelihood of adverse outcomes, such as cardiac arrest and death. The literature suggests, the consultants strongly support, and Task Force members agree that hypoxemia during sedation and analgesia is more likely to be detected by oximetry than by clinical assessment alone. The Task Force emphasizes that oximetry is not a substitute for monitoring ventilatory function.

*Hemodynamics:* Although there is insufficient published data to reach a conclusion, it is the opinion of the Task Force that sedative and analgesic agents may blunt the appropriate autonomic compensation for hypovolemia and procedure-related stresses. Early detection of changes in patients' heart rate and blood pressure may enable practitioners to detect problems and intervene in a timely fashion, reducing the risk of cardiovascular collapse. The consultants support the concept that regular monitoring of vital signs reduces risks and suggest that it decreases costs. Although the literature provides no guidance, the consultants suggest the use of continuous electrocardiographic monitoring in patients with hypertension and strongly support its use in patients with significant cardiovascular disease or dysrhythmias; the consultants suggest that electrocardiographic monitoring is not required in patients without cardiovascular disease.

*Recommendations:* Monitoring of patient response to verbal commands should be routine, except in patients who are unable to respond appropriately (*e.g.*, young children, mentally impaired or uncooperative patients) or during procedures in which facial movement could be detrimental. During procedures in which a verbal response is not possible (*e.g.*, oral surgery, upper endoscopy), the ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation suggests that the patient will be able to control his airway and take deep breaths if necessary. Note that a response limited to reflex withdrawal from a painful stimulus represents a greater degree of sedation/analgesia than addressed by this document.

Ventilatory function should be continually monitored by observation and/or auscultation. When ventilation cannot be directly observed, exhaled carbon dioxide detection is a useful adjunct to these modalities. All patients undergoing sedation/analgesia should be monitored by pulse oximetry with appropriate alarms. If available, the variable pitch "beep," which gives a continuous audible indication of the oxygen saturation reading, may be helpful. When possible, blood pressure should be determined before sedation/analgesia is initiated. Once sedation/analgesia is established, blood pressure should be measured at regular intervals during the procedure, as well as during the recovery period. Electrocardiographic monitoring should be used in patients with significant cardiovascular disease as well as during procedures in which dysrhythmias are anticipated.

### *IV. Recording of Monitored Parameters*

Both the literature and consultant opinion suggest that contemporaneous recording of patients' level of consciousness, respiratory function, and hemodynamics reduces the risk of adverse outcomes. Although consultant opinion suggests that recording of this information may not improve patient comfort or satisfaction, the consultants suggest that it may reduce costs resulting from adverse events. The consultants strongly support recording of vital signs and respiratory variables before initiating sedation/analgesia, after administration of sedative/analgesic medications, at regular intervals during the procedure, on initiation of recovery, and immediately before discharge. It is the opinion of the Task Force that contemporaneous recording (either automatic or manual) of patient data provides information that could prove critical in determining the cause of any adverse events that might occur. Additionally, manual recording ensures that an individual caring for the patient is aware of changes in patient status in a timely fashion.

*Recommendations:* Patients' ventilatory and oxygenation status and hemodynamic variables should be recorded at a frequency to be determined by the type and amount of medication administered as well as the length of the procedure and the general condition of the patient. At a minimum, this should be: (1) before the beginning of the procedure, (2) after administration of sedative/analgesic agents, (3) on completion of the procedure, (4) during initial recovery, and (5) at the time of discharge. If recording is performed automat-

ically, device alarms should be set to alert the care team to critical changes in patient status.

*V. Availability of a Staff Person Dedicated Solely to Patient Monitoring and Safety*

Although there are insufficient data in the literature to provide guidance on this issue, the Task Force recognizes that it is difficult for the individual performing a procedure to be fully cognizant of the patient's condition during sedation/analgesia. The consultants support the contention that the availability of an individual other than the person performing the procedure to monitor the patient's status improves patient comfort and satisfaction; they also strongly support the view that risks are reduced. The consultants support the observation that this would not decrease overall costs. It is the consensus of the Task Force members that the individual monitoring the patient may assist the practitioner with interruptible ancillary tasks of short duration once the patient's level of sedation/analgesia and vital signs have stabilized, provided that adequate monitoring is maintained.

*Recommendations:* A designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation/analgesia. This individual may assist with minor, interruptible tasks.

*VI. Training of Personnel*

Although there is insufficient literature to determine the effectiveness of training on patient outcomes, the consultants strongly support the observation that providing appropriate training in clinical pharmacology for individuals administering sedative/analgesic medications reduces the risk of adverse outcomes; they also support the views that patient comfort is improved and overall costs are reduced. Specific concerns include: (1) potentiation of sedative-induced respiratory depression by concomitantly administered opioids; (2) inadequate time intervals between doses of sedative or analgesic agents, resulting in a cumulative overdose; and (3) inadequate familiarity with the role of pharmacologic antagonists for sedative and analgesic agents.

Because the primary complications of sedation/analgesia are related to respiratory or cardiovascular depression, it is the consensus of the Task Force that the individual responsible for monitoring the patient should be trained in the recognition of complications associated with sedation/analgesia. In addition, at least one qualified individual, capable of establishing a patent airway and maintaining ventilation and oxygenation, should be present during the procedure.

*Recommendations:* Individuals responsible for patients receiving sedation/analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines. Individuals monitoring patients receiving sedation/analgesia should be able to recognize the associated complications. At least one individual capable of establishing a patent airway and positive pressure ventilation, as well as a means for summoning additional assistance, should be present whenever sedation/analgesia is administered. It is recommended that an individual with advanced life-support skills be immediately available.

*VII. Availability of Emergency Equipment*

The literature suggests and the consultants strongly support the view that the ready availability of appropriately sized emergency equipment reduces the risk of sedation and analgesia. The consultants also support the contention that overall costs, including those associated with adverse outcomes, may be reduced. The literature does not address the need for cardiac defibrillators during sedation/analgesia. The consultants strongly support the availability of a defibrillator whenever sedation/analgesia is administered.

*Recommendations:* Pharmacologic antagonists as well as appropriately sized equipment for establishing a patent airway and providing positive pressure ventilation with supplemental oxygen should be present whenever sedation/analgesia is administered. Advanced airway equipment and resuscitation medications should be immediately available (template 3). A defibrillator should be immediately available when sedation/analgesia is administered to patients with significant cardiovascular disease.

*VIII. Use of Supplemental Oxygen*

The literature supports the use of supplemental oxygen during sedation/analgesia: There is a decreased incidence and severity of hypoxemia among sedation/analgesia patients given oxygen as compared to those breathing room air. However, it must be appreciated that, by delaying the onset of hypoxemia; supplemental oxygen will delay the detection of apnea by pulse oximetry, emphasizing the importance of monitoring pulmonary ventilation by other means (see above). Consultant opinion supports the view that supplemental oxygen decreases patient

Template 3. Example of Emergency Equipment for Sedation and Analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The table below should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated.

- Intravenous equipment
  - Gloves
  - Tourniquets
  - Alcohol wipes
  - Sterile gauze pads
  - Intravenous catheters [24- or 22-G]
  - Intravenous tubing [pediatric "microdrip" (60 drops/ml)]
  - Intravenous fluid
  - Three-way stopcocks
  - Assorted needles for drug aspiration, intramuscular injection [intraosseous bone marrow needle]
  - Appropriately sized syringes
  - Tape
- Basic airway management equipment
  - Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)
  - Source of suction
  - Suction catheters [pediatric suction catheters]
  - Yankauer-type suction
  - Face masks [infant/child]
  - Self-inflating breathing bag-valve set [pediatric]
  - Oral and nasal airways [infant/child-sized airways]
  - Lubricant
- Advanced airway management equipment (for practitioners with intubation skills)
  - Laryngoscope handles (tested)
  - Laryngoscope blades [pediatric]
  - Endotracheal tubes
    - Cuffed; 6.0, 7.0, or 8.0 mm ID [Uncuffed; 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, or 6.0 mm ID]
  - Stylet (appropriately sized for endotracheal tubes)
- Pharmacologic antagonists
  - Naloxone
  - Flumazenil
- Emergency medications
  - Epinephrine
  - Ephedrine
  - Atropine
  - Lidocaine
  - Glucose, 50% [10% or 25%]
  - Diphenhydramine
  - Hydrocortisone, methylprednisolone, or dexamethasone
  - Diazepam or midazolam
  - Ammonia splints

risk, while suggesting that routine use of supplemental oxygen may increase costs.

*Recommendations:* Equipment to administer supplemental oxygen should be present when sedation/analgesia is administered. If hypoxemia is anticipated or develops during sedation/analgesia, supplemental oxygen should be administered.

*IX. Use of Multiple Sedative/Analgesic Agents*

The literature supports the observation that combinations of agents may be more effective than single agents in certain circumstances. However, the published data also suggest and consultant opinion supports the observation that combinations of sedatives and opioids may increase the likelihood of adverse out-

comes, including ventilatory depression and hypoxemia. Although not evaluated in the literature, it is the consensus of the Task Force that fixed combinations of sedative and analgesic agents may not allow the individual components of sedation/analgesia to be appropriately titrated to meet the individual requirements of the patient and procedure.

*Recommendations:* Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (*e.g.*, additional analgesic medication to relieve pain, additional sedative medication to decrease awareness or anxiety). The propensity for combinations of sedative and analgesic agents to potentiate respiratory depression emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function.

*X. Titration of Sedative/Analgesic Medications to Achieve the Desired Effect*

The literature suggests that the administration of small, incremental doses of intravenous sedative/analgesic drugs until the desired level of sedation and/or analgesia is achieved is preferable to a single dose based on patient size, weight, or age. The consultants support the concept that incremental drug administration improves patient comfort and decreases costs; they strongly support the contention that the potential risks associated with excessive doses are reduced.

*Recommendations:* Intravenous sedative/analgesic drugs should be given in small, incremental doses that are titrated to the desired endpoints of analgesia and sedation. Sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (*e.g.*, oral, rectal, intramuscular), allowance should be made for the time required for drug absorption before supplementation is considered.

*XI. Intravenous Access*

Published data suggest that, in cooperative patients, administration of sedative/analgesic agents by the intravenous route improves patient comfort and satisfaction. The consultants strongly support the importance of intravenous access in reducing patient risks. In situations when sedative/analgesic medications are to be administered intravenously, it is the consensus of the Task Force that maintaining intravenous access until the patient is no longer at risk for cardiorespiratory depression improves patient safety. In those situations when sedation is begun by nonintravenous routes (*e.g.*, oral, rectal, intramuscular), the need for intravenous access is not sufficiently addressed in the literature. However, initiation of intravenous access after the initial sedation takes effect allows additional sedative/analgesic and resuscitation drugs to be administered if necessary.

*Recommendations:* In patients receiving intravenous medications for sedation/analgesia, vascular access should be maintained throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression. In patients who have received sedation/analgesia by nonintravenous routes or whose intravenous line has become dislodged or blocked, practitioners should determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis. In all instances, an individual with the skills to establish intravenous access should be immediately available.

*XII. Reversal Agents*

Specific antagonist agents are available for the opioids (*e.g.*, naloxone) and benzodiazepines (*e.g.*, flumazenil). The literature supports the ability of naloxone to reverse opioid-induced sedation and ventilatory depression during sedation/analgesia. However, the Task Force reminds practitioners that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema. The literature supports the ability of flumazenil to reverse benzodiazepine-induced sedation and its effectiveness in reversing ventilatory depression in patients who have received benzodiazepines alone. In patients who have received both benzodiazepines and opioids, published data support the ability of flumazenil to reverse sedation; however, there are insufficient data to establish the effectiveness of flumazenil in reversing ventilatory depression under these circumstances. The consultants strongly support the contention that the availability of reversal agents is associated with decreased risk. It is the consensus of the Task Force that respiratory depression should be initially treated with supplemental oxygen and, if necessary, positive pressure ventilation by mask.

*Recommendations:* Specific antagonists should be available whenever opioid analgesics or benzodiazepines are administered for sedation/analgesia. Naloxone and/or flumazenil may be administered to improve

Template 4. 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 patent 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 the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated 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.

spontaneous ventilatory efforts in patients who have received opioids or benzodiazepines, respectively. This may be especially helpful in cases in which airway control and positive pressure ventilation are difficult. Before or concomitantly with pharmacologic reversal, patients who become hypoxemic or apneic during sedation/analgesia should: (1) be encouraged or stimulated to breathe deeply, (2) receive positive pressure ventilation if spontaneous ventilation is inadequate, and (3) receive supplemental oxygen. After pharmacologic reversal, patients should be observed long enough to ensure that cardiorespiratory depression does not recur.

*XIII. Recovery Care*

Patients may continue to be at significant risk for complications after their procedure is completed. Decreased procedural stimulation, prolonged drug absorption after oral or rectal administration, and post-procedure hemorrhage may contribute to cardiorespiratory depression. When sedation/analgesia is administered to outpatients, one must assume there will be no medical supervision once the patient leaves the medical facility. Although there is not sufficient literature to examine the effects of post-procedure monitoring on patient outcomes, the consultants suggest that appropriate monitoring of patients during the recovery period will improve patient comfort and strongly support the view that adverse outcomes may be reduced. It is the consensus of the Task Force that discharge criteria should be established that minimize the risk for cardiorespiratory depression after patients are released from observation by trained personnel.

*Recommendations:* After sedation/analgesia, patients should be observed until they are no longer at increased risk for cardiorespiratory depression. Vital signs and respiratory function should be monitored at regular intervals until patients are suitable for discharge. Discharge criteria should be designed to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel (template 4.)

*XIV. Special Situations*

The literature suggests, the consultants strongly support, and the Task Force members concur that certain classes of patients (e.g., uncooperative patients; extremes of age; severe cardiac, pulmonary, hepatic, renal, or central nervous system disease; morbid obesity; sleep apnea; pregnancy; drug or alcohol abuse) are at increased risk for developing complications related to sedation/analgesia unless special precautions are taken. However, the consultants support the view

that risks may be reduced by preprocedure consultation with appropriate specialists (*e.g.*, cardiologist, pulmonologist, nephrologist, obstetrician, pediatrician, anesthesiologist) before administration of sedation/analgesia to these individuals. The consultants support the concept that patient comfort is improved and risks are reduced by consultation with an anesthesiologist before administering sedation/analgesia to patients who are likely to develop complications (*e.g.*, inadequate spontaneous ventilation, loss of airway control, cardiovascular compromise) or in whom sedation/analgesia alone is not expected to provide adequate conditions (*e.g.*, young children, uncooperative patients). However, the consultants also support the contention that such consultation will not reduce costs.

*Recommendations:* Whenever possible, appropriate medical specialists should be consulted before administration of sedation/analgesia to patients with significant underlying conditions. The choice of specialists depends on the nature of the underlying condition and the urgency of the situation. For significantly compromised patients (*e.g.*, severe obstructive pulmonary disease, coronary artery disease, congestive heart failure) or if it appears likely that sedation to the point of unresponsiveness or general anesthesia will be necessary to obtain adequate conditions, practitioners who are not specifically qualified to provide these modalities should consult an anesthesiologist.

## Appendix 1: Methods and Analyses

The scientific assessment of these guidelines was based on the following statements or evidence linkages. These linkages represent directional hypotheses about relationships between sedation/analgesia by non-anesthesiologists and clinical outcomes.

1. A preprocedure patient evaluation (*i.e.*, history, physical examination, laboratory evaluation) improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
2. Preprocedure preparation of the patient (*e.g.*, counseling, fasting) improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
3. Patient monitoring (*i.e.*, level of consciousness, pulmonary ventilation, oxygenation, hemodynamics) improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
4. Contemporaneous recording of monitored parameters (*e.g.*, level of consciousness, respiratory function, hemodynamics) improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
5. Availability of a staff person dedicated solely to patient monitoring and safety improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
6. Education and training of (sedation/analgesia) providers improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
7. Availability of appropriately sized emergency and airway equipment, including trained staff, improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
8. Use of supplemental oxygen improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
9. Use of multiple sedative/analgesic agents improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
10. Titration of sedative/analgesic medications to achieve the desired effect improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
11. Administration of sedative/analgesic agents by the intravenous route improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
12. Availability of reversal agents (*e.g.*, naloxone, flumazenil) improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
13. Post-procedure monitoring (*e.g.*, during duration of recovery stay, postdischarge) improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.
14. Special regimens for patients with special problems (*e.g.*, uncooperative patients; extremes of age; severe cardiac, pulmonary, hepatic, renal, or central nervous system disease; morbid obesity; sleep apnea; pregnancy; drug or alcohol abuse; emergency/unprepared patients; metabolic and airway difficulties) improves patient satisfaction, increases clinical benefits, and reduces adverse outcomes.

Scientific evidence was derived from multiple sources, including aggregated research literature (with metaanalyses when appropriate), surveys, open presentations, and other consensus-oriented activities. For purposes of literature aggregation, potentially relevant clinical studies were identified *via* electronic and manual searches of the literature. The electronic search covered a 29 yr, from 1966 through 1994. Manual searches covered 48 yr, from 1947 through 1994. More than 3,000 citations were initially identified, yielding 1,315 nonoverlapping articles that addressed topics related to the 14 evidence linkages. After review of the articles, 1,046 studies did not provide direct evidence and were subsequently eliminated, yielding 269 articles containing direct linkage-related evidence. Journals represented by the 269 articles included the following disciplines: anesthesiology, 59; oncology, 5; cardiology, 12; oral/maxillofacial/dental, 71; emergency medicine, 19; gastroenterology, 50; lithotripsy, 4; obstetrics/gynecology, 5; pediatrics, 4; pharmacology, 7; pulmonary medicine, 4; radiology, 17; surgery, 8; and urology, 4.

A directional result for each study was initially determined by classifying the outcome as: (1) supporting a linkage, (2) refuting a linkage, or (3) neutral. The results were averaged to obtain a directional assessment of support for each linkage. The literature relating to linkages 8 (supplemental oxygen); 9 (multiple agents); and 12a, 12b, and 12c (naloxone to reverse opioids, flumazenil to reverse benzodiazepines, and flumazenil to reverse benzodiazepines combined with opioids, respectively) contained enough studies with well defined experimental designs and statistical information to conduct formal metaanalyses. Combined probability tests were applied when studies reported continuous data, and an odds-ratio procedure was applied to dichotomous study results.

Two combined probability tests were employed as follows: (1) the Fisher combined test, producing chi-square values based on logarithmic transformations of the reported $P$ values from the independent studies, and (2) the Stouffer combined test, providing representation of the studies by weighting each of the standard normal deviates by the size of the sample. A procedure based on the Mantel-Haenszel method for combining study results using $2 \times 2$ tables was used when sufficient outcome frequency information was available. An acceptable significance level was set at $P < 0.01$ (one-tailed), and effect size estimates were calculated. Interobserver agreement was established through assessment of interrater reliability testing. Tests for heterogeneity of the independent samples were conducted to ensure consistency among the study results. To control for potential publishing bias, a "failsafe" N value was calculated for each combined probability test. No search for unpublished studies was conducted, and no reliability tests for locating research results were done.

Results of the combined probability tests are reported in table 1. Significance levels from the weighted Stouffer combined tests for clinical efficacy were $P < 0.001$ for four linkages: 9 (multiple agents), 12a (naloxone for opioid reversal), 12b (flumazenil for benzodiazepine reversal), and 12c (flumazenil for benzodiazepine-opioid combinations). Weighted effect size estimates ranged from $r = 0.20$ to $r = 0.42$, demonstrating small-to-moderate effect size estimates. Significance levels from the weighted Stouffer combined tests for beneficial outcomes were $P < 0.001$ for two linkages, 8 (supplemental oxygen) and 12a (naloxone). Significance levels for adverse outcomes ($P < 0.001$) were found for linkage 9 (multiple agents). Linkage 12b was not significant. Weighted effect size estimates ranged from $r = 0.30$ to $r = 0.36$. Sufficient data were available to conduct Mantel-Haenszel analyses for linkages 8 (supplemental oxygen) and 9 (multiple agents). Significant differences in the odds of hypoxemia (assessed by $Sp_{O_2}$ levels) were found between patients breathing supplemental oxygen *versus* those breathing room air (odds ratio 4.68, 99% confidence limits 4.13–5.23, $Z = 6.51$, $P < 0.001$). The odds of an adverse outcome for multiple agents were found to be nonsignificant.

Tests for heterogeneity of statistical tests and effect size were nonsignificant in all cases ($P > 0.01$) except linkage 9 (multiple agents) and 12c (flumazenil to reverse benzodiazepines combined with opioids), indicating that the majority of pooled studies provided common estimates of significance and population effect sizes for the linkages. The two significant effect size estimates for heterogeneity may be due to a variety of factors (*e.g.*, methodologic differences among the various studies), dissimilar outcome measures, or other mediating effects.

Agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.69–0.95$; (2) type of analysis, $\kappa = 0.48–0.81$; (3) evidence linkage assignment, $\kappa = 0.65–0.90$; and (4) literature inclusion for database, $\kappa = 0.35–1.00$. Three-rater chance-corrected agreement values were: (1) design, $S_{av} = 0.79$, Var ($S_{av}$) = 0.06; (2) analysis, $S_{av} = 0.61$, Var ($S_{av}$) = 0.06; (3) linkage identification, $S_{av} = 0.74$, Var ($S_{av}$) = 0.01; and (4) literature inclusion, $S_{av} = 0.53$, Var ($S_{av}$) = 0.02. These values represent moderate to high levels of agreement.

The findings of the literature analyses were supplemented by the opinions of Task Force members and surveys of the opinions of a panel of consultants drawn from the following specialties in which sedation/analgesia are commonly administered: anesthesiology, 9; cardiology, 5; dental-anesthesiology, 3; dermatology, 1; emergency medicine, 3; gastroenterology, 6; hematology/oncology, 2; intensive care, 2; oral and maxillofacial surgery, 5; pediatric dentistry, 2; pediatric oncology, 1; pharmacology, 2; plastic surgery, 1; pulmonary medicine, 5; radiology, 8; surgery, 4; and urology, 2. Consultants, in general, were highly supportive of the linkages (*i.e.*, agreed that they resulted in improvement of patient comfort/satisfaction, reduced risk of adverse outcomes, reduced overall costs, and were important issues for the guidelines to address). Responses were given on a 5-point scale, ranging from 1, strongly disagree, to 5, strongly agree; support for a linkage was defined as the fraction of consultants responding "4" or "5" to a given linkage. The percentage of consultants reporting support for each linkage is reported in table 2. Additional responses from consultants are listed as follows: (1) percentage of consultants supporting continuous electrocardiographic monitoring of different classes of patients was, for all patients, 23%; patients with hypertension, 51%; patients with cardiovascular disease, 91%; and patients with cardiac dysrhythmias, 94%; (2) percentage of consultants supporting the immediate availability of a defibrillator for different classes of patients was: for all patients, 64%; patients with hypertension, 68%; patients with cardiovascular disease, 83%; and patients with dysrhythmias, 85%; and (3) percentage of consultants supporting determination of vital signs and respiratory variables at the following times was: before sedation, 91%; immediately after sedation initiated, 79%; at regular intervals during procedure, 83%; at beginning of recovery, 89%; at intervals during recovery, 81%; and just before discharge, 87%.

The feasibility of implementing these guidelines into clinical practice was assessed by an opinion survey of those respondents from the consultant panel who were non-anesthesiologists ($N = 37$). Responses for feasibility of implementation of the guidelines were as follows: Seventy-five percent of these consultants indicated that implementation of the guidelines would not result in the need to purchase new equipment, supplies, or pharmaceuticals. Among the 25% who stated that purchases would be required, the median anticipated cost was $3,750 (mean $6,167; range $1,500–$20,000). Anticipated new costs included: hiring and training (*e.g.*, ACLS) personnel, the presence of a nurse during procedures, establishing intravenous access as a routine procedure, exhaled carbon dioxide monitoring equipment, defibrillator, more attention to preprocedure needs (*e.g.*, NPO status), and additional personnel time during recovery.

The non-anesthesiologist consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the guidelines were instituted. Percentages of consultants expecting no change associated with each linkage were as follows: preprocedure history, 81%; preparation of the patient, 76%; direct monitoring of respiration, 89%; automated ventilatory monitoring, 38%; pulse oximetry, 95%; cardiovascular monitoring, 95%; patient-dedicated staff, 89%; education and training, 95%; emergency equipment, 95%; supplemental oxygen, 95%; multiple classes of agents, 95%; titration, 92%; i.v. access, 89%; reversal agents, 92%; post-procedure monitoring, 89%; and preprocedure consultation with an anesthesiologist, 84%.

Sixty-six percent of the respondents indicated that the guidelines would have no effect on the amount of time spent on a typical case. None reported that the guidelines would reduce the amount of time spent per case. For all respondents, the mean increase in the amount of time spent on a typical case was 4.8 min. Of the 32% of respondents who reported an anticipated increase in time spent on a typical case, the mean was 14.0 min (range 5.0–30.0 min).

Table 1. Statistical Summary

| Combined Test Results | | P | df |
|---|---|---|---|
| Sedation efficacy | | | |
| Linkage 9: Multiple agents | $\chi^2 = 92.54$ | <0.001 | 38 |
| Fisher's combined test | Zc (weighted) = 5.270 | <0.001 | |
| Stouffer combined test | r (weighted) = 0.20 | | |
| Effect size estimate | Nfs 0.01 = 117.9 | | |
| Failsafe n value | | | |
| Reversal efficacy | | | |
| Linkage 12a: Naloxone to reverse opioids | $\chi^2 = 50.66$ | <0.001 | 10 |
| Fisher's combined test | Zc (weighted) = 3.894 | <0.001 | |
| Stouffer combined test | r (weighted) = 0.36 | | |
| Effect size estimate | Nfs 0.01 = 24.6 | | |
| Failsafe n value | | | |
| Linkage 12b: Flumazenil to reverse benzodiazepines | $\chi^2 = 220.54$ | <0.001 | 48 |
| Fisher's combined test | Zc (weighted) = 6.450 | <0.001 | |
| Stouffer combined test | r (weighted) = 0.32 | | |
| Effect size estimate | Nfs 0.01 = 628.4 | | |
| Failsafe n value | | | |
| Linkage 12c: Flumazenil to reverse benzodiazepines + opioids | $\chi^2 = 80.39$ | <0.001 | 12 |
| Fisher's combined test | Zc (weighted) = 3.183 | <0.001 | |
| Stouffer combined test | r (weighted) = 0.42 | | |
| Effect size estimate | Nfs 0.01 = 79.4 | | |
| Failsafe n value | | | |
| Adverse outcomes | | | |
| Linkage 9: Multiple agents | $\chi^2 = 86.17$ | <0.001 | 28 |
| Fisher's combined test | Zc (weighted) = 3.716 | <0.001 | |
| Stouffer combined test | r (weighted) = 0.32 | | |
| Effect size estimate | Nfs 0.01 = 127.9 | | |
| Failsafe n value | | | |
| Beneficial respiratory outcomes | | | |
| Linkage 8: Supplemental oxygen | $\chi^2 = 73.95$ | <0.001 | 14 |
| Fisher's combined test | Zc (weighted) = 7.227 | <0.001 | |
| Stouffer combined test | r (weighted) = 0.30 | | |
| Effect size estimate | Nfs 0.01 = 61.3 | | |
| Failsafe n value | | | |
| Linkage 12a: Naloxone to reverse opioids | $\chi^2 = 45.94$ | <0.001 | 10 |
| Fisher's combined test | Zc (weighted) = 4.487 | <0.001 | |
| Stouffer combined test | r (weighted) = 0.36 | | |
| Effect size estimate | Nfs 0.01 = 24.7 | | |
| Failsafe n value | | | |
| Linkage 12b: Flumazenil to reverse benzodiazepines | $\chi^2 = 29.07$ | <0.001 | 10 |
| Fisher's combined test | Zc (weighted) = 0.740 | >0.010 | NS |
| Stouffer combined test | r (weighted) = 0.35 | | |
| Effect size estimate | Nfs 0.01 = 9.8 | | |
| Failsafe n value | | | |

Readers with special interest in the statistical analyses used in establishing these guidelines can receive further information by writing to: Jeffrey B. Gross, M.D., Department of Anesthesiology (M/C 2015), University of Connecticut School of Medicine, Farmington, Connecticut 06030-2015.

## Appendix 2: Definition of Terms

In these guidelines, the following terms are used to express the strength of the evidence relating various interventions and the associated outcomes.

Table 2. Proportion of Consultants Indicating Support for Linkages (%)

| Linkage | Patient Comfort/ Satisfaction | Reduced Risk | Reduced Costs | Important Topic |
|---|---|---|---|---|
| 1. Patient evaluation | 57 | 92 | 63 | 62 |
| 2. Preprocedure preparation | 92 | 85 | 63 | 65 |
| 3a. Level of consciousness | 70 | 87 | 52 | 71 |
| 3b. Ventilation monitoring, observation/auscultation | 45 | 85 | 43 | 70 |
| 3c. Automated apnea monitoring | 32 | 74 | 30 | 72 |
| 3d. Pulse oximetry | 77 | 96 | 56 | 81 |
| 3e. Heart rate, blood pressure | 55 | 83 | 45 | 66 |
| 4. Contemporaneous recording of monitored parameters | 23 | 67 | 38 | 67 |
| 5. Staff availability | 58 | 65 | 31 | 75 |
| 6. Training of personnel | 69 | 94 | 67 | 77 |
| 7. Availability of emergency equipment | 42 | 96 | 54 | 63 |
| 8. Supplemental oxygen | 35 | 50 | 19 | 67 |
| 9. Multiple agents | 48 | 13 | 7 | 71 |
| 10. Titration | 87 | 81 | 55 | 70 |
| 11. Intravenous access | 42 | 85 | 33 | 67 |
| 12. Reversal agents | 35 | 85 | 29 | 71 |
| 13. Post-procedure monitoring | 67 | 92 | 52 | 81 |
| 14a. Special regimens | 71 | 88 | 37 | 67 |
| 14b. Anesthesia consultation | 70 | 74 | 34 | 68 |

Literature review

Insufficient data: There are insufficient published data to provide an indication of the relationship between intervention and outcome.

Suggests: There is qualitative evidence in the form of case reports or descriptive studies, but there is insufficient quantitative evidence to establish a statistical relationship between intervention and outcome.

Supports: Quantitative data indicate a significant relationship between intervention and outcome ($P < 0.01$), and qualitative data are supportive.

Consultant opinion

The consultants' questionnaire was based on a 5-point scale ranging from "1" (strongly disagree) to "5" (strongly agree), with a score of "3" being neutral.

Suggests: The number of individuals responding "4" or "5" exceeds the number responding "1" or "2."

Supports: 50% or more of the responses were "4" or "5."

Strongly supports: 50% or more of the responses were "5."

## Appendix 3: Summary of Guidelines*

- Preprocedure evaluation
  - Relevant history
- Focused physical examination (to include heart, lungs, airway)
- Laboratory testing when indicated
- Patient counseling
  - Risks, benefits, limitations, and alternatives
- Preprocedure fasting
  - Elective procedures
    - Sufficient time for gastric emptying
  - Urgent or emergent situations
    - Benefits of sedation/analgesia must be weighed against the potential risk of regurgitation and aspiration of gastric contents
- Monitoring
  - Data to be recorded at appropriate intervals before, during, and after procedure
    - Pulse oximetry
    - Response to verbal commands when practical
    - Pulmonary ventilation (observation, auscultation, other means)
    - Blood pressure and heart rate at appropriate intervals
    - Electrocardiograph for patients with significant cardiovascular disease
- Personnel
  - Designated individual, other than the practitioner performing the procedure, present to monitor the patient throughout the procedure
- Training
  - Pharmacology of sedative and analgesic agents
  - Pharmacology of available antagonists
  - Basic life support skills present
  - Advanced life support skills immediately available
- Emergency equipment
  - Suction, appropriately sized airway equipment, means of positive-pressure ventilation
  - Intravenous equipment, pharmacologic antagonists, and basic resuscitative medications
- Supplemental oxygen
  - Oxygen delivery equipment available
  - Oxygen administered if hypoxemia occurs
- Choice of agents
  - Sedatives to decrease anxiety, promote somnolence
  - Analgesics to relieve pain
- Dose titration
  - Medications given incrementally with sufficient time between doses to assess effects
  - Appropriate dose reduction if both sedatives and analgesics are used
- Intravenous access
  - Sedatives administered intravenously, maintain intravenous access
  - Sedatives administered by other routes, case-by-case decision
- Recovery
  - Observation until patients are no longer at risk for cardiorespiratory depression
  - Appropriate discharge criteria
- Special situations
  - Severe underlying medical problems, consult with appropriate specialist
  - Risk of severe cardiovascular or respiratory compromise or need for deep sedation/general anesthesia to obtain adequate operating conditions, consult anesthesiologist

* This is a summary of the guidelines. The body of the document should be consulted for complete details.

Anesthesiology
73:826–830, 1990

# Frequent Hypoxemia and Apnea after Sedation with Midazolam and Fentanyl



Peter L. Bailey, M.D.,* Nathan L. Pace, M.D.,† Michael A. Ashburn, M.D.,* Johan W. B. Moll, drs.,‡ Katherine A. East, M.S.,§ Theodore H. Stanley, M.D.†

More than 80 deaths have occurred after the use of midazolam (Versed®), often in combination with opioids, to sedate patients undergoing various medical and surgical procedures. We investigated the respiratory effects of midazolam (0.05 mg·kg$^{-1}$) and fentanyl (2.0 μg·kg$^{-1}$) in volunteers. The incidence of hypoxemia (oxyhemoglobin saturation <90%) and apnea (no spontaneous respiratory effort for 15 s) and the ventilatory response to carbon dioxide were evaluated. Midazolam alone produced no significant respiratory effects. Fentanyl alone produced hypoxemia in half of the subjects and significant depression of the ventilatory response to $CO_2$, but did not produce apnea. Midazolam and fentanyl in combination significantly increased the incidence of hypoxemia (11 of 12 subjects) and apnea (6 of 12 subjects), but did not depress the ventilatory response to $CO_2$ more than did fentanyl alone. Adverse reactions linked to midazolam and reported to the Department of Health and Human Services highlight apnea- and hypoxia-related problems as among the most frequent adverse reactions. Seventy-eight per cent of the deaths associated with midazolam were respiratory in nature, and in 57% an opioid had also been administered. All but three of the deaths associated with the use of midazolam occurred in patients unattended by anesthesia personnel. We conclude that combining midazolam with fentanyl or other opioids produces a potent drug interaction that places patients at a high risk for hypoxemia and apnea. Adequate precautions, including monitoring of patient oxygenation with pulse oximetry, the administration of supplemental oxygen, and the availability of persons skilled in airway management are recommended when benzodiazepines are administered in combination with opioids. (Key words: Hypnotics, benzodiazepines: midazolam. Anesthetics, opioids: fentanyl. Drug interaction. Complications: hypoxemia/apnea.)

MORE THAN 80 DEATHS have been associated with the use of midazolam (Versed®) to sedate patients undergoing various diagnostic or therapeutic medical and surgical procedures in the United States (Department of Health and Human Resources). In many of these cases, opioids had been simultaneously administered. Most deaths occurred in patients who were breathing spontaneously, usually without receiving supplemental oxygen. In addition, monitoring of patient oxygenation and ventilation, although usually not stated in adverse drug reaction reports, was most likely quite variable. Outside the specialty of anesthesiology, no minimal monitoring standard is established or applied in patients who receive drugs with the potential to cause significant respiratory depression. Thus, there may be one or more possible explanations for these apparently drug-related deaths.

Although hypnotic doses of midazolam and other benzodiazepines have been shown to decrease spontaneous minute ventilation and the slope of the ventilatory response to $CO_2$,[1] this effect does not consistently occur with sedative doses of these drugs.[2,3] In fact, the respiratory effects of benzodiazepines are quite variable.[4] All opioids, however, consistently produce dose-dependent depression of the ventilatory response to $CO_2$. In addition, both benzodiazepines and opioids significantly blunt the ventilatory response to hypoxemia.[5–7] Although opioids and benzodiazepines are often used together for preanesthetic medication, there are no available descriptions of the effects of combinations of these two drugs on ventilation and oxygenation. Much of the reported morbidity and mortality associated with the use of midazolam may be related not only to its own respiratory actions, but also to interactions with other drugs given simultaneously. We therefore designed this study to evaluate the respiratory effects of sedative doses of midazolam and analgesic doses of the opioid fentanyl (Sublimaze®), separately and in combination, in healthy young adult volunteers.

## Materials and Methods

The investigation was approved by the University of Utah Health Sciences Center Institutional Review Board for Human Research, and written and oral informed consent was obtained from each subject. The subjects were 12 healthy adult males between the ages of 18 and 40 yr. They had no significant medical conditions, were receiving no chronic medications, and had no history of alcohol or tobacco abuse. The subjects refrained from caffeine and aspirin consumption for at least 12 hr and had nothing to eat or drink for at least 8 hr prior to the commencement of the study. All study sessions began at 7:30 AM.

Each subject was evaluated at three separate sessions at least 48 hr apart. During each session, subjects received either fentanyl (2 μg·kg$^{-1}$ iv), midazolam (0.05 mg·kg$^{-1}$ iv), or fentanyl (2 μg·kg$^{-1}$) plus midazolam (0.05 mg·kg$^{-1}$) iv. The experimental design was completely balanced for the possible sequences of drug administra-

* Assistant Professor of Anesthesiology.
† Professor of Anesthesiology.
‡ Visiting Medical Student.
§ Research Assistant.

Received from the Department of Anesthesiology, University of Utah School of Medicine, Salt Lake City, Utah. Accepted for publication May 29, 1990. Supported by Stanley Research Foundation, Salt Lake City, Utah.

Address reprint requests to Dr. Bailey: Department of Anesthesiology, University of Utah School of Medicine, 50 North Medical Drive, Salt Lake City, Utah 84132.

esthesiology
71, No 5, Nov 1989

on. Two subjects were assigned to each of the six possible ermutations of the order of drug administration at the hree sessions. Subjects were assigned to their permutation roup by a computer-generated, permuted-block, re- tricted randomization table; block size was six subjects. During each session, both subject and investigators were blinded to the study drug(s) being administered.

On the morning of each study session a 20-G catheter was inserted into an arm vein after the subcutaneous administration of 0.1 ml 1% lidocaine. Intravenous lactated Ringer's solution was then begun at a rate of 125 ml · hr$^{-1}$. Systemic blood pressure (Critikon Dinamap vital signs monitor) and heart rate and oxyhemoglobin saturation ($Spo_2$) *via* pulse oximetry (Criticare Systems, Inc.) were recorded while subjects were breathing room air. Subjects then performed an initial $CO_2$ rebreathing challenge to familiarize themselves with the test. Subjects wore comfortable head phones emitting white noise to standardize auditory stimuli and soft nose clips to prevent nasal breathing during each $CO_2$ challenge. Subjects were instructed to keep their eyes closed during each test session. Fifteen minutes later, resting end-tidal carbon dioxide partial pressure ($PET_{CO_2}$ mmHg) was measured by a Beckman LB-2 infrared $CO_2$ analyzer while the subject breathed room air. This was followed by a control $CO_2$ rebreathing challenge.

After another 15-minute rest period, the study drug(s) was given intravenously over 1 min while subjects breathed room air. The respiratory rate and $Spo_2$ were then continuously monitored by visual inspection and finger pulse oximetry, respectively. Hypoxemic episodes were defined as $Spo_2$ <90% and lasting at least 10 s. Apnea was defined as the absence of any spontaneous respiratory effort for at least 15 s. If apnea occurred, spontaneous respiration was encouraged by vocal or tactile stimuli. After a 5-min observation period for hypoxemia and apnea, a $CO_2$ rebreathing challenge was performed. Additional $CO_2$ rebreathing challenges were completed 20, 40, 60, 90, 120, 180, 240, and 300 min after drug administration. Continuous observation for additional hypoxemia and apnea was made between $CO_2$ challenges.

## Rebreathing Circuit and Measurement

We used a modified Read rebreathing circuit as previously described.[4] The rebreathing apparatus has a 7.5-l neoprene rebreathing bag enclosed in a Lucite box; to measure ventilatory flow, a Validyne differential pressure transducer measures the pressure drop across a Fleisch pneumotachograph at the outlet of the box. Flow was directed either into the bag or through the pneumotachograph by a three-way valve located at the mouth of the box, permitting the subject to breathe directly into the room when not rebreathing $CO_2$. Inspiratory and expiratory limbs of the circuit were separated by a Collins J-Valve. $CO_2$ concentration was measured by a Beckman LB-2 infrared $CO_2$ analyzer, which sampled gas at the mouthpiece at a rate of 200 ml · min$^{-1}$ and returned it to the central chamber of the Collins valve. Inspiratory circuit resistance was 1.7 cm $H_2O \cdot l^{-1} \cdot s^{-1}$. Expiratory circuit resistance was 1.7 cm $H_2O \cdot l^{-1} \cdot s^{-1}$ and remained constant between flow rates of 15 and 135 l · min$^{-1}$. Flow and $CO_2$ were sampled by a microcomputer (Motorola Exorciser II) 12-bit analog-to-digital (A/D) convertor (Burr-Brown MP7208 Data Acquisition System) with a resolution of 4.8 mV per A/D unit and a range of ±10 V.

## Rebreathing Data Collection and Analysis

After allowing the subject to breathe quietly through the mouthpiece with the nose clip in place, the resting $PET_{CO_2}$ was recorded and the three-way valve was switched to the rebreathing bag previously filled with 7.0% $CO_2$ and 93.0% $O_2$. For each breath, the following data were displayed on the video terminal and stored electronically: inspiratory time ($T_I$); breath duration ($T_{TOT}$); fractional inspired $CO_2$ concentration $\%IN_{CO_2}$ and end-tidal $CO_2$ concentration $\%ET_{CO_2}$; tidal volume ($V_T$); minute ventilation ($\dot{V}_E$); and elapsed time since start of $CO_2$ rebreathing. All gas volumes were corrected to BTPS. Subjects were encouraged to rebreathe as long as possible, but could stop at any time. The desired goal was to reach a $PET_{CO_2}$ of 65 mmHg. The increase in $PET_{CO_2}$ during $CO_2$ rebreathing tests was always at least 15 mmHg, but not more than 25 mmHg.

After completion of each $CO_2$ challenge, plots of $\dot{V}_E$ *versus* $PET_{CO_2}$ were displayed on the video display terminal. To ensure that the regression line reflected only data from the linear portion of ventilatory response, data from the first ten breaths were excluded from analysis. Data from all other breaths were used for least-squares linear regression. The slope of the ventilatory response to $CO_2$ ($\dot{V}_E/CO_2$, l · min$^{-1}$ · mmHg$^{-1}$) and the estimated $\dot{V}_E$ at a $PET_{CO_2}$ of 50 mmHg ($\dot{V}_E50$, l · min$^{-1}$) were the parameters chosen to depict each subject's response to $CO_2$.

Descriptive and graphic statistics included line graphs of mean ± standard error for the variables slope $\dot{V}_E/CO_2$ and $\dot{V}_E50$ at baseline and 5, 20, 40, 60, 90, 120, 180, 240, and 300 min after drug(s) for each of the three sessions. Inferential statistics were calculated for both frequency counts and continuous variables. A $P < 0.05$ was considered statistically significant. Analysis of the difference in the incidence of hypoxemia and apnea during the three study sessions was made by a small-sample procedure, contingency-table test for three dependent samples.[5] Comparison of $\dot{V}_E/CO_2$ and $\dot{V}_E50$ was by repeated measurement multivariate analysis of variance (ANOVA) us-

ing restricted maximum likelihood estimation. The P5V module of BMDP was used, allowing use of a data matrix with missing values; the test statistic was a Wald chi-squared statistic, $X^2_{df}$, where df = the degrees of freedom of the test statistic.

## Results

Baseline values for $\dot{V}_E/CO_2$ ($X^2_2 = 1.18$; $P = 0.554$) and $\dot{V}_E50$ $X^2_2 = 0.79$; $P = 0.674$) were not significantly different for the three study sessions. There was a significant difference (fig. 1) in drug effects on $\dot{V}_E/CO_2$ ($X^2_2 = 19.59$; $P = 0.000$). Both fentanyl and fentanyl plus midazolam depressed $\dot{V}_E/CO_2$ for at least 60 min ($X^2_2 = 56.08$; $P = 0.000$). There was also a significant difference (fig. 2) in drug effects on $\dot{V}_E50$ ($X^2_2 = 12.55$; $P = 0.002$). Both fentanyl and fentanyl plus midazolam depressed $\dot{V}_E50$ for at least 60 min ($X^2_2 = 87.78$; $P = 0.000$). The effects of fentanyl and fentanyl plus midazolam were essentially similar for $\dot{V}_ECO_2$ ($X^2_1 = 0.96$; $P = 0.326$) and for $\dot{V}_E50$ ($X^2_1 = 0.14$; $P = 0.708$).

No subject receiving midazolam alone became hypoxemic, whereas hypoxemia occurred in half (6 of 12) of those receiving fentanyl and nearly all (11 of 12) of those given both midazolam and fentanyl. All but one episode of hypoxemia occurred within 5 min of drug administration. Differences in the incidence of hypoxemia were statistically significant between midazolam and fentanyl ($P < 0.05$) and between midazolam and fentanyl plus midazolam ($P < 0.05$). Although neither midazolam nor fentanyl alone resulted in apnea, the combination of the drugs resulted in apnea in half (6 of 12) the subjects ($P < 0.05$). All episodes of apnea occurred within 5 min of injection of the drug combination and were always associated with hypoxemia. All hypoxemic and apneic subjects responded to verbal or tactile stimulation.

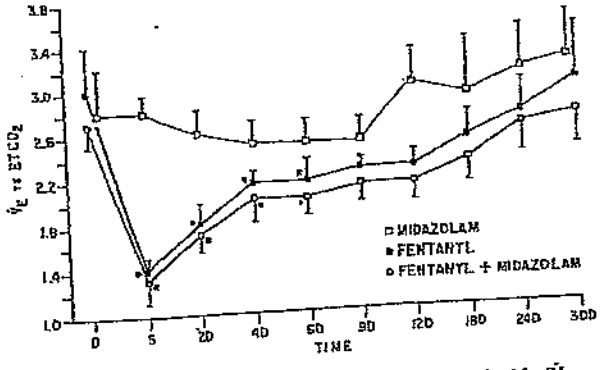



FIG. 1. Slope of the ventilatory response to carbon dioxide ($\dot{V}_E$ vs. $ET_{CO_2}$, $l \cdot min^{-1} \cdot mmHg^{-1}$) before (time 0) and minutes after midazolam, fentanyl, and midazolam plus fentanyl. (*$P < 0.05$; see results.)

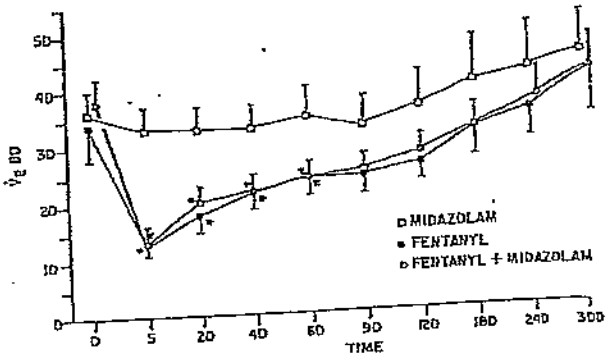



FIG. 2. Minute ventilation at an end-tidal carbon dioxide of 50 mmHg ($\dot{V}_E50$, $l \cdot min^{-1}$) before (time 0) and minutes after midazolam, fentanyl, and midazolam plus fentanyl. (*$P < 0.05$; see results.)

## Discussion

This study evaluated the effects of sedative doses of midazolam and analgesic doses of fentanyl, alone and in combination, on the incidence of hypoxemia and apnea and on the ventilatory response to carbon dioxide in young healthy adult volunteers. Fentanyl alone, 2.0 $\mu g \cdot kg^{-1}$, produced the expected decrease in $\dot{V}_E/CO_2$ and $\dot{V}_E50$ seen with analgesic doses of opioids. On the other hand, midazolam 0.05 $mg \cdot kg^{-1}$ did not produce any change from baseline in $\dot{V}_E/CO_2$ or $\dot{V}_E50$. Combining midazolam with fentanyl produced no greater depression of the ventilatory response to $CO_2$ than did fentanyl alone. The $CO_2$ response we observed after midazolam is comparable with the response seen by Power *et al.*,[3] who found that midazolam 0.075 $mg \cdot kg^{-1}$ caused no statistically significant depression of the ventilatory response to $CO_2$. Gross *et al.*,[1] using higher doses of midazolam (0.2 $mg \cdot kg^{-1}$), found significant depression of the ventilatory response to $CO_2$ in normal adults. These results suggest that a dose-dependent relationship may exist and that higher (hypnotic) doses of midazolam may be more likely to depress the ventilatory response to $CO_2$ and spontaneous ventilation than lower doses. In addition, older patients may be more prone to ventilatory depression after any dose of midazolam.[9]

Other investigators have documented changes in respiratory function even after small, sedative doses of midazolam. Using a noninvasive technique to measure ventilatory parameters, Forster *et al.*[2] and Berggren *et al.*[10] documented a decrease in tidal volume and an increase in respiratory rate but no change in $\dot{V}/_E$ in adult volunteers after the administration of midazolam 0.05–0.2 $mg \cdot kg^{-1}$. Both Forster's group and Berggren's group suggested that they were able to identify significant changes in ventilation with small doses of midazolam because their techniques for measuring ventilatory variables

did not stimulate subjects. The presence of a respiratory measuring equipment device, such as a mouthpiece or a nose clip, which is frequently used during $CO_2$ rebreathing tests, can itself increase ventilation.[11] Thus, our assessment technique may have obscured some of the actions of midazolam on the $CO_2$ response. However, the effect of nose clips and mouthpieces did not prevent depression of the $CO_2$ response induced by small doses of fentanyl and therefore is probably of little real significance.

We also documented that low doses of midazolam (0.05 $mg \cdot kg^{-1}$) alone do not produce hypoxemia or apnea in healthy young adults breathing room air. This result was obtained even though our hospital is approximately 5,000 feet above sea level, with an average dry barometric pressure of 595 mmHg. The inspired partial pressure of oxygen is thus significantly lower (125 mmHg) than at sea level (150 mmHg) and would bias our results toward hypoxemia. Again, older subjects or patients may be more prone to hypoxemia. Midazolam did, however, increase the incidence of hypoxemia and apnea produced by fentanyl when these drugs were given in combination. Whereas fentanyl alone produced hypoxemia in 50% (6 of 12) of the subjects studied and apnea in none, the addition of midazolam to fentanyl produced hypoxemia in almost all (11 of 12) and apnea in half (6 of 12) of the subjects. Thus, although we found no further depression of the ventilatory response to $CO_2$ after combining midazolam with fentanyl, we did document marked increases in hypoxemia and apnea when the two drugs were combined.

The mechanism probably underlying these respiratory effects is the significant blunting of hypoxic ventilatory drive by both benzodiazepines[5] and opioid narcotics.[6,7] Moreover, it appears from our results that depression of hypoxic ventilatory drive occurs sooner and to a greater degree than does the ventilatory response to hypercarbia after combinations of these drugs. This hypothesis is supported by the synergistic effects of the combination of midazolam and fentanyl on hypoxemia and apnea without any alteration of $CO_2$ responsiveness: whereas midazolam alone did not cause hypoxemia and neither midazolam nor fentanyl alone resulted in apnea, the effects of the drug combination were more than additive. Thus, combining midazolam with fentanyl, and most likely other opioids, can result in an absence of an effective ventilatory response to hypoxemia and can lead to severe arterial oxygen desaturation within 1–2 min in patients breathing room air.[12] In such situations, arterial oxygen partial pressure drops to critically low levels before blood $CO_2$ tensions can rise adequately to stimulate breathing. Sleep, too, may destabilize ventilation and oxygenation, especially in pain-free individuals receiving sedatives or analgesics.[13]

TABLE 1. The Ten Most Frequently Reported Adverse Reactions to Midazolam*

| Reaction | Number of Reports | Per Cent of Total |
|---|---|---|
| Apnea | 138 | 9 |
| Hypotension | 104 | 6 |
| Somnolence/stupor | 73 | 5 |
| Cardiac arrest | 68 | 4 |
| Hypoventilation | 52 | 3 |
| Agitation | 50 | 3 |
| Hypoxia/cyanosis | 48 | 3 |
| Hostility | 46 | 3 |
| Bradycardia | 45 | 3 |
| Confusion | 35 | 2 |
| Other | 977 | 60 |

* Department of Health and Human Services, Office of Epidemiology and Biostatistics, Center for Drug Evaluation and Research, Data Retrieval Unit HFD-737, June 27, 1989.

The clinical significance of our findings is confirmed by review of the adverse drug reactions reported to the Department of Health and Human Services. A total of 1,615 adverse reactions or events (215 types) after use of midazolam have been reported to the Department of Health and Human Services as of June 27, 1989.§ The dose of midazolam reportedly administered most often ranged from 1 to 10 mg. Four patients received higher doses. These reactions ranged in severity from hiccup to death. The single most frequently reported adverse reaction was apnea (table 1). Cyanosis or hypoxia specifically were reported 50 times. However, 17 other types of adverse reactions, totalling 623 events, including agitation, hostility, convulsions (which can be caused by hypoxemia and so may also indicate the occurrence of hypoxemia in these reports), were also reported. A total of 86 deaths occurred in the adverse drug reaction reports in the United States. All but three of these deaths occurred outside the operating room, in clinical situations where patients are typically unattended by anesthesia personnel. Sixty-seven (78%) of these deaths were associated with oxygenation difficulties or ventilation difficulties and in 57% of these respiratory deaths various opioids (most commonly meperidine and fentanyl) had been used with midazolam. It is also possible that cardiovascular depression and hypotension (table 1) also contributed to respiratory insufficiency because of inadequate medullary blood flow.[14]

The clinical implications of our findings are relevant for anesthesiologists and nonanesthesia-trained specialists as well. Midazolam and other benzodiazepines are frequently used in combination with an opioid for sedation, not only during the administration of operative regional

§ Department of Health and Human Services, Office of Epidemiology and Biostatistics, Center for Drug Evaluation and Research, Data Retrieval Unit HFD-737, June 27, 1989.

anesthesia, but also during many medical office procedures, including gastrointestinal endoscopy. In a recent review of cardiac arrests during spinal anesthesia,[15] over half of the patients who experienced sudden cardiac arrest had received both diazepam and fentanyl. Inadequately recognized hypoxemia and apnea secondary to sedation was believed to be a crucial factor in these mishaps.[15,16] Endoscopists are also beginning to document the risk of hypoxemia in their environment.[17,18] Most of the midazolam-associated adverse drug reaction reports have involved patient care outside the operating room, where standards for the assessment of ventilation and oxygen have not been defined and therefore are variable.

Our results demonstrate that midazolam, when combined with an opioid, is likely to place patients at high risk for hypoxemia and apnea. Adequate precautions, including monitoring of patient oxygenation with pulse oximetry, the application of supplemental oxygen, and the availability of persons skilled in airway management are recommended when these or similar type drugs are combined for patient sedation in any clinical setting.

## References


1. Gross JB, Zebrowske ME, Carrl WD, Gardner S, Smith TC: Time course of ventilatory depression after thiopental and midazolam in normal subjects and in patients with chronic obstructive pulmonary disease. ANESTHESIOLOGY 58:540–544, 1983
2. Forster A, Morel D, Bachmann M, Gemperle M: Respiratory depressant effects of different doses of midazolam and lack of reversal with naloxone: A double-blind randomized study. Anesth Analg 62:920–924, 1983
3. Power SJ, Morgan M, Chakrabarti MK: Carbon dioxide response curves following midazolam and diazepam. Br J Anaesth 55: 837–841, 1983
4. Bailey PL, Andriano KP, Goldman M, Stanley TH, Pace NL: Variability of the respiratory response to diazepam. ANESTHESIOLOGY 64:460–465, 1986
5. Alexander CM, Gross JB: Sedative doses of midazolam depress hypoxic ventilatory responses in humans. Anesth Analg 67:377–382, 1988
6. Weil JV, McCullough RE, Kline JS, Sodal IE: Diminished ventilatory response to hypoxia and hypercapnia after morphine in normal man. N Engl J Med 292:1103–1106, 1975
7. Kryger MH, Yacoub O, Dosman J, Macklem PT, Anthonisen NR: Effect of meperidine on occlusion pressure responses to hypercapnia and hypoxia with and without external inspiratory resistance. Am Rev Respir Dis 114:333–340, 1976
8. Krauth J: Distribution free statistics: An application-oriented approach. Elsevier, Amsterdam, 1988, pp 268–279
9. Greenblatt DJ, Abernethy DR, Locniskar A, Harmatz JS, Limjuco RA, Shader RI: Effect of age, gender, and obesity on midazolam kinetics. ANESTHESIOLOGY 61:27–35, 1984
10. Berggren L, Eriksson I, Mollenholt P, Sunzel M: Changes in respiratory pattern after repeated doses of diazepam and midazolam in healthy subjects. Acta Anaesthesiol Scand 31:667–672, 1987
11. Askanazi J, Silverberg P, Hyman A, Foster R, Yaremchuk M, Kinney JM: Effects of the mask and mouthpiece plus nosedip on spontaneous breathing pattern. Crit Care Med 6:143–146, 1978
12. Nunn JF: Applied Respiratory Physiology, third edition. Butterworths, Boston, 1987, p 229
13. Knill RL: Cardiac arrests during spinal anesthesia: Unexpected? (letter). ANESTHESIOLOGY 69:629, 1988
14. Greene NM: The central nervous system, Physiology of Spinal Anesthesia. Edited by Greene NM. Williams & Wilkins, Baltimore, 1981, pp 45–48
15. Caplan RA, Ward RJ, Posner K, Cheney FW: Unexpected cardiac arrest during spinal anesthesia: A closed claims analysis of predisposing factors. ANESTHESIOLOGY 68:5–11, 1988
16. Keats AS: Anesthesia mortality: A new mechanism. ANESTHESIOLOGY 68:2–4, 1988
17. Lavies NG, Creasy T, Harris K, Hanning CD: Arterial oxygen saturation during upper gastrointestinal endoscopy influence of sedation and operator experience. Am J Gastroenteriology 83:618–622, 1988
18. Bell GD, Speckett GP, Reeve PA, Morden A, Logan RFA: Intravenous midazolam for upper gastrointestinal endoscopy: A study of 800 consecutive cases relating dose to age and sex of patient. Br J Clin Pharmacol 23:241–243, 1987

APPENDIX E: Airway Management Competency

ADVENTIST HEALTHCARE

# Competency Validation Form

| NAME: | UNIT: |
|---|---|
| SOCIAL SECURITY #: | DATE: |

*Instructions:* Date/Initial each box as performance criteria is observed. If performance criteria not met, the comment/plan section must be completed with date of expected completion. An asterisk (*) in front of performance criteria indicates the behavior is a critical behavior and is required to successfully complete this competency. When form is complete, it becomes part of the employee's permanent record.

**Competency Title: Airway Management Competency**

**Outcome:** (Expected behavior when competency is completed correctly)
**Attendee will be able to perform proper airway management as demonstrated by successful completion of 90% of the performance criteria.**

*Key for Competency Validation Method*
O = Observation S = Simulation
SP = Self learning packet

| Performance Criteria | Competency Validation Met (Please sign off each line) Initial | Date | Circle Key | Competency Validation Not Met (refer Comments a. through g.) |
|---|---|---|---|---|
| 1. Demonstrates proper head tilt-chin lift-jaw thrust technique for opening obstructed airway | | | O S SP | |
| 2. Demonstrates proper placement of Oropharyngeal airway | | | O S SP | |
| 3. Demonstrates proper mouth-to-mask rescue breathing | | | O S SP | |
| 4. Demonstrates proper Bag-Valve technique for rescue breathing | | | O S SP | |
| 5. | | | O S SP | |
| 6. | | | O S SP | |
| 7. | | | O S SP | |

Age Specific Considerations:
____ Neonate ____ Pediatric ____ Adult ____ Geriatric

Age Specific Performance Criteria: Above criteria met with the following additional requirements.
(If more than three criteria needed here or if above criteria do not apply, create separate competency.)

| | | | | |
|---|---|---|---|---|
| 1. | | | O S SP | |
| 2. | | | O S SP | |
| 3. | | | O S SP | |

Measurement Criteria:

References:

Comments: (Performance qualifiers, etc.)
____ Role model, excellent performer
____ Needs improvement, as noted below
____ a. Excessive time needed to complete procedure
____ b. Broke aseptic or sterile technique
____ c. Significant inaccuracy noted
____ d. Technique may be harmful to patient
____ e. Incorrect procedure/sequence
____ f. Incorrect equipment assembly/usage
____ g. Unable to correctly answer questions about rationale or theory related to the procedure
____ Other (specify) _____

| Circle one: **Validated** **Not Validated** see below | Signature: | Date: |
|---|---|---|

Remedial Plan: (address issues from Comments Section if not validated)

I understand that I must repeat this competency and complete it by (date): _____
Employee Signature: _____

| Date Developed: | Written by: | Approved by: |
|---|---|---|
| Date Revised: | | |

# Airway Control & Adjuncts

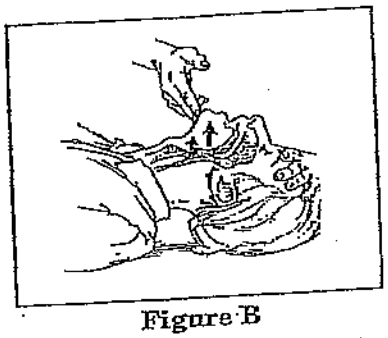


Figure B

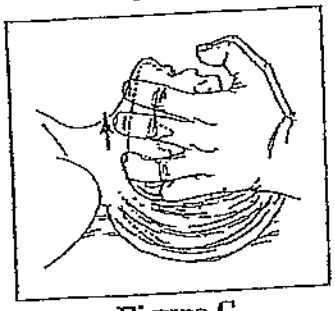


Figure C

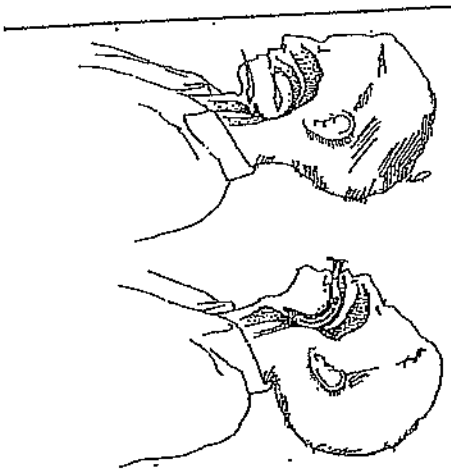
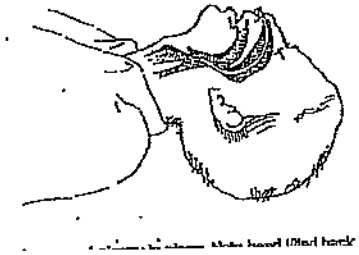


Fig 2. Placement of correctly inserted oropharyngeal airway. Top, Before insertion, incorrect head position. Bottom, After insertion, showing head tilted and oropharyngeal airway in place.



Action notes

To Open Airway

*Head tilt – chin lift*
On hand on forehead to tilt head back, fingers of other hand to lift lower jaw. (See Fig. B)

*Jaw-thrust:* (for suspected neck injury)
Place fingers under each side of lower jaw and displace the mandible forward (See Fig. C)

Airway Adjuncts

*Oral Airway Insertion*

Step 1 Clear the airway of secretions, blood, vomit with Yankauer suction catheter.

Step 2 Insert Airway

A. Insert airway backward as it enters the mouth. As the airway transverses the oral cavity and approaches the posterior wall of the pharynx, rotate the airway into proper position.

OR

B. Move tongue out of the way with a tongue blade depressor and insert the airway.

*Nasopharyngeal Airway Insertion*

Step 1 Clear the airway of secretions, blood, vomit with Yankauer suction catheter.

Step 2 Gently insert the proper-sized and lubricated airway close to the midline along the floor of the nostril into the posterior pharynx behind the tongue. If resistance is encountered, slight rotation of the tube may facilitate insertion at the

## Rescue Breathing

### Action Notes

Mouth-to-mouth

Step 1 Keep airway open

Step 2 Pinch nose with thumb and index finger on hand on the forehead

Step 3 Take a deep breath

Step 4 Plance mouth over mouth & form and tight seal

Step 5 Give 2 slow breaths (1-1/2 to 2 sec./breath) with adequate volume to make the chest rise.

Step 6 Take a breath after each ventilation and listen and feel for air escaping during exhalation


Fig 10. Mouth-to-mask ventilation with a one-way valve.

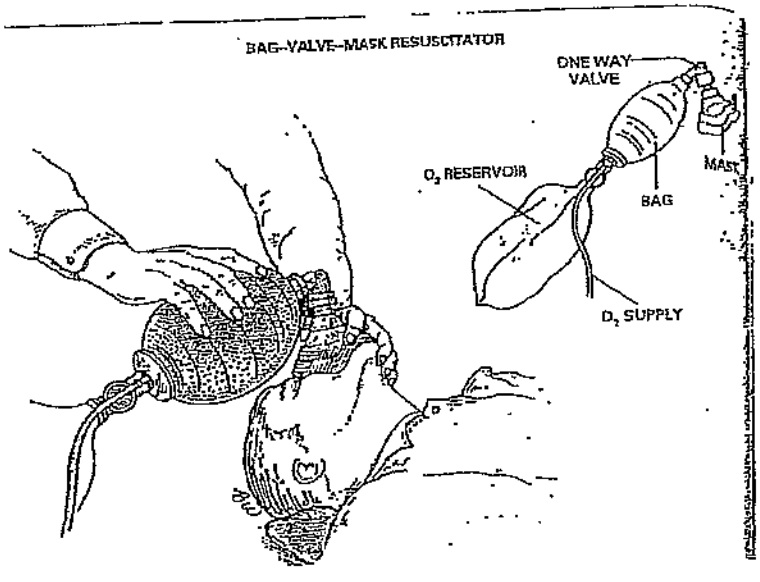
Mouth-to-Mask

Step 1 Place mask on patient's face after Head Tilt

Step 2 Apply pressure to both sides of the mask with your palms thumb side down

Step 3 Usin index, middle and ring fingers, apply upward pressure to the mandible

Step 4 Blow through the mask observing the rise and fall of the chest




Bag-valve Devices

Step 1 Position yourself at the top of the patient's head

Step 2 Apply head tilt manuever

Step 3 Deliver the selected tidal volume over 2 seconds

Note: Efective ventilation is more likely when two rescuers use these devices, one to hold the mask and one to squeeze the bag.

## Appendix C: WASHINGTON ADVENTIST HOSPITAL SEDATION/ANALGESIA TEST

Name _____ Date _____

DIRECTIONS: CIRCLE ONE ANSWER FOR EACH QUESTION. (Return completed test to Medical Staff Office)

1. The goals of administering sedation/analgesia from an unpleasant and painful procedure are to:
a) Provide amnesia and analgesia
b) For patient to maintain a patent airway
c) Ensure patient remains arousable
d) All of the above

2. Midazolam (Versed) may provide all of the following except:
a) Amnesia for the procedure
b) Analgesia
c) Anxiolysis
d) Sedation

3. Which of the following statements about using naloxone (Narcan) to reverse opioids is not true?
a) It antagonizes the respiratory depressant effects of the opioids
b) It can cause hypertension, pulmonary edema and dysrhythmia
c) The dose of Narcan is 0.1-0.8 mg in incremental doses
d) It does not reverse the analgesia

4. Which of the following patients is most likely to develop hypotension after the administration of narcotic opioids?
a) 45 year old male with well controlled hypertension
b) An elderly patient who has had a bowel prep and is likely dehydrated
c) 65 year old female with stable angina
d) A young otherwise healthy patient

5. If the above patient develops hypotension, what is the most effective treatment?
a) Administer naloxone (Narcan)
b) Administer midazolam (Versed)
c) Give fluids and stimulate the patient
d) Administer epinephrine in incremental doses

6. Which of the following medications are contraindicated in patients taking MAO inhibitors?
a) Meperidine (Demerol).
b) Droperidol (Inapsine)
c) Fentanyl (Sublimaze)
d) Midazolam (Versed)

7. Which of the following factors may be associated with difficult airway management?
a) Previous problems with sedation and anesthesia
b) Patient with a history of sleep apnea and heavy snoring
c) Patient with abnormal airway anatomy
d) All of the above

8. The reversal effects of naloxone (Narcan) last longer than the respiratory depressant effects of meperidine (Demerol).
a) True
b) False

9. An 85 year old female patient with a fracture of the radius underwent closed reduction under moderate (formerly "conscious") sedation. She was given 3 mg of Midazolam (Versed) and 50 mg of

meperidine (Demerol) IV. At the end of the procedure, patient was very sleepy and was given 0.2 mg of naloxone (Narcan). When the nurse went to reassess the patient 45 minutes later, the patient was found unresponsive with a respiratory rate of 8. The differential diagnosis is:

a) The patient probably had an MI
b) The patient had respiratory depression from renarcotization
c) The patient had a cerebral hemorrhage
d) The patient is too tired and is resting

10. The most lipid soluable and most rapid onset of action is associated with which of the following medications?

a) Meperidine (Demerol)
b) Fentanyl (Sublimaze)
c) Morphine
d) Dihydromorphone

11. The following are true regarding aspiration of stomach contents during moderate sedation:

a) May occur in patients who have a full stomach and are receiving moderate sedation
b) Increased incidence in patients with hiatal hernia and gastroesophageal reflux
c) Incidence may be reduced by waiting 8 hours after intake of solid food
d) All of the above

12. A decrease in oxygen saturation is an early sign of hypoventilation during moderate sedation:

a) true
b) false

13. Flumazenil is the reversal agent for benzodiazepines:

a) true
b) false

14. Which of the following statements about reversal agents is correct?

a) Flumazenil reverses analgesia
b) They have few side effects
c) They should be frequently used to speed recovery post procedure
d) They should be reserved for emergency situations or inadvertent overdose.

15. A 55 year-old 270-pound man has a history of loud snoring that frequently wakes him during the night. As a result he suffers from daytime somnolence and headaches. He is scheduled for a colonoscopy under moderate sedation. What is the most appropriate management?

a) Because of his size, increase the usual dose of sedatives
b) Avoid the use of supplemental oxygen
c) Obtain an anesthesia consult
d) Perform the procedure with no sedation.

I have read and reviewed the preceding independent study packet, including documentation requirements, pre-sedation assessment and consent form, and will incorporate these guidelines into my practice.

Signature _____ Date _____