Conscious Sedation
Provider Training Binder

10th Medical Group
USAFA, CO 80840

Version 1 FEB 2003

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Providers Credentialed For Performance of Conscious Sedation

Location	Providers
Emergency Svcs	Dr. McLaughlin Dr. Young Dr. Pendon Dr. Anderson Dr. Muechen Dr. Smith Dr. Gregory
USAFA Dental Clinic	Dr. Miller Dr. Delo Dr. Dossett Dr. DeVeau Dr. Casey Dr. Kirkpatrick
Oral Surgery	Dr. Miller Dr. Delo
Peterson Dental Clinic	Dr. Leake Dr. Plamondon Dr. Malthaner
General Surgery	Dr. Boyer Dr. Dixon Dr. Kim Dr. Timothy Dr. Desai
Special Care Unit	*Providers listed above may perform procedures in the SCU with appropriate support personnel*

21 May 2003 update

PURPOSE

The purpose of this publication is to familiarize providers with hospital policies and procedures for the practice of sedation and analgesia by non-anesthesiologists. This booklet is not intended to act as a substitute for initial sedation/analgesia training, which should only be accomplished during an accredited residency program. This reference presents the medical group instruction along with select literature to assist providers in the safe administration of sedation and analgesia.

It is currently accepted that the training and credentialing process to perform a procedure includes the ability to deliver appropriate sedation and analgesia. This is accepted within the 10th Medical Group. **However, this sedation/analgesia provider's package has been created to ensure that non-anesthesiologists performing sedation and analgesia are familiar with institutional guidelines and requirements.** This binder will be read annually by **all** non-anesthesia providers involved in the administration of sedation and analgesia for invasive procedures.

Should any questions arise, please do not hesitate to contact the department of anesthesia for guidance.

HARRY L. ERVIN, Major, USAF, MC
Medical Director, Anesthesia

DEPARTMENT OF THE AIR FORCE
10TH MEDICAL GROUP
UNITED STATES AIR FORCE ACADEMY COLORADO

12 June 2002

MEMORANDUM FOR RECORD

FROM: SGOSA (MAJOR HARRY L. ERVIN)

SUBJECT: Sedation and Analgesia Credentialing Process

1. **Standardization.** In an effort to standardize the process of sedation and analgesia (conscious sedation), all areas practicing conscious sedation in the 10th Medical Group and its associated geographically separated units have been identified. These areas have revised their respective practice guidelines (departmental instructions) to reflect changes to Medical Group Instruction 44-75. Individual department instructions are included as attachment 1 to this provider package.
2. **Required Reading.** All providers performing conscious sedation are required to read this provider handbook. The purpose of this is threefold; (1) familiarization with a recently updated and revised medical group instruction, (2) educational updates in the current practice of conscious sedation, and (3) familiarization with the conscious sedation instruction for the provider's specific area.
3. **Sign-Off Sheet.** Once a provider has read this handbook, a sign off sheet is forwarded to the provider's department chief for inclusion in the Provider Activity File. One conscious sedation handbook will be provided to all departments participating in the conscious sedation program.
4. **Departmental Provider Listing.** The department chief is responsible for maintaining a listing of each provider who has read the provider handbook. This listing will be forwarded to the department of anesthesia for verification and inclusion on the comprehensive list which is posted on the 10th Medical Group Intranet.

HARRY L. ERVIN, Major, USAF, MC
Medical Director, Anesthesia

DEPARTMENT OF THE AIR FORCE *10 MDG INSTRUCTION 44-75*
10TH MEDICAL GROUP *16 Dec 2002*
USAF ACADEMY CO *Medical*

Standards and Procedures for Use of Sedation/Analgesia

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

OPR: 10 MDOS/SGOSA (Maj Ervin) **Certified by: 10 MDG/CD (Col Davis)**
Supersedes: 10 MDGI 44-75, *11 Feb 02* **Pages: 18**
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This instruction implements Air Force Policy Directive (AFPD 44-1, *Medical Operations* and AFPD 46-1, *Nursing Services)*. It defines and establishes standards and procedures for the use of sedation/analgesia and monitoring of patients during invasive, diagnostic or painful procedures outside of the operating room by non-anesthesia personnel. It applies to procedures in which supplemental sedatives, anxiolytics and/or narcotics are administered to produce sedation and analgesia. It is not meant to be applied to procedures that are limited to the use of non-toxic doses of local anesthetics without supplemental sedation. It applies to all personnel assigned/attached to the 10th Medical Group (10 MDG).

SUMMARY OF CHANGES: Changed 2.1-2.3 definitions to reflect revised JCAHO definitions. Added 2.4 to the definitions to reflect the new JCAHO standards. 6.1.6 Added statement regarding review of medical history prior to sedation if history performed other than day of sedation.

1. References:

1.1. AFI 44-102, *Community Health Management*.

1.2. AFI 44-119, *Medical Service Quality Improvement and Risk Management*.

1.3. AFI 46-101, *Nursing Operations*.

1.4. AFI 46-102, *Nursing Care*.

1.5. *JCAHO Accreditation Manual for Hospitals*, current edition, JCAHO, Chicago, Illinois.

1.6. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: *An Updated Report by the American Society of Anesthesiology Task Force on Sedation and Analgesia by Non-Anesthesiologists*. Anesthesiology 2002; (96) 1004-17.

1.7. Wiener-Kronish JP ed. Anesthesia Clinics of North America. Philadelphia; Harcourt, Brace and Co., 1999; 355-63.

1.8. American Society of Postanesthesia Nurses: *Standards of Perianesthesia Nursing Practice*, 1995., Holzman, R.S., et.al. Guidelines for Sedation by Non-anesthesiologists During Diagnostic and Therapeutic Procedures.

1.9. *Journal of Clinical Anesthesiology* 1994; 6: 265-276., Somerson, S.J., et. al. Insights Into Conscious Sedation. AJN 1995; June, pp. 26-33., Bell, G.D. et al. Recommendations for Standards of Sedation and Patient Monitoring During Gastrointestinal Endoscopy. Gut 1991; 7:823-827., Cote, Charles, J. Sedation for the Pediatric Patient.

1.10. *Pediatric Clinics of North America*, 1994; 41:31-51., Committee on Drugs. Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

1.11. *Kost M. Manual of Conscious Sedation*. Philadelphia; W.B. Saunders, 1998.

1.12. 10 MDG Instruction 41-39, *Informed Consent and Treatment of Minors*.

1.13. Schuttler J, Zsigmond EK. *Textbook of IV Anesthesia*. Baltimore; Williams and Wilkins, 1997: 171-88.

2. Definitions:

2.1. Minimal sedation (anxiolysis) is 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.

2.2. Moderate sedation/analgesia ("conscious sedation") is 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 patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

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

2.4. 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 to painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

2.5. The standards for sedation and anesthesia care apply when patients receive moderate or deep sedation as well as general, spinal, or other major regional anesthesia.

3. Responsibilities.

3.1. The Chief of Medical Staff will ensure that policies and procedures are designed to ensure care of the highest caliber for all patients receiving sedation/analgesia.

3.2. Department Chiefs of areas administering sedation/analgesia will ensure:

3.2.1. Providers are appropriately credentialed to perform the therapeutic or diagnostic procedure and that documentation is approved and documented in their credentials folder. The Department of Anesthesia, in coordination with the Group Education office, will maintain a list of providers credentialed to perform conscious sedation on the 10 MDG Intranet homepage.

3.2.2. Non-credentialed personnel have completed the Competency Verification Program for conscious sedation (maintained in Group Education and Training Office), have received adequate training, experience, and are current in their training requirements in the delivery of conscious sedation. The attending provider is certified in Advanced Cardiac Life Support (ACLS) for adults, and Pediatric Advanced Life Support (PALS) for children (age 13 and under).

3.2.3. Conscious sedation reviews will be documented in the provider's activity file (PAF).

3.3. The Medical Director of Anesthesia will support the Chief of Medical Staff by:

3.3.1. Providing consultation for section chiefs and individual practitioners in implementing the standards detailed in this regulation regarding sedation/analgesia.

3.3.2. Verifying completion of initial testing and annual conscious sedation training (provider training package) for all providers administering sedation and analgesia.

3.3.3. Establishing and periodically updating medical facility standards for monitoring patients receiving sedation/analgesia.

3.3.4. Providing a review of conscious sedation administration and reporting appropriateness, outcomes data to critical care committee monthly.

3.3.5. Ensuring that the med web site is maintained with the most up-to-date list of providers credentialed and privileged to perform sedation and analgesia.

4. Qualifications For Administering Conscious Sedation.

4.1. All departments, units and clinics will develop an operating instruction (OI) that defines the scope of care that may be performed in their inpatient or outpatient setting using conscious sedation. Individual departments, units and clinics will submit these OIs to the Department of Anesthesia.

4.2. Only properly credentialed and privileged providers are qualified to prescribe, order, or select the medications to be used to achieve conscious sedation after completion of appropriate training package.

4.3. An appropriately privileged provider or trained registered nurse may administer the initial medication. Follow-on supplemental doses of medication may be administered by individuals in the following priority: the primary operating provider; another privileged provider; a registered nurse qualified by appropriate education, experience, and competence; a 4NOX1 (General Surgery) or 4Y0X1 (Oral Surgery) technician only with a waiver from MAJCOM, documented completion of competency training program, and only under the direct, physical observation of a privileged provider. This procedure, when performed by technicians, must be added in their Career Field Education and Training Plan (CFEP).

5. Patient Care Guidelines.

5.1. Pre-Procedure Evaluation.

5.1.1. All patients requiring conscious sedation will have a pre-procedure assessment done in two phases.

5.1.1.1. The first phase will be performed by a privileged provider or designee to determine that the patient is a candidate for conscious sedation. At a minimum this should include the patient's relevant history (including abnormalities of major organ systems, previous adverse reactions to conscious sedation, current medications, allergies, tobacco, alcohol or substance use or abuse) and an appropriately focused physical assessment to include cardiovascular and respiratory systems. Also, a brief assessment of the airway noting the patient's body habitus, neck, head, mouth and jaw abnormalities that may affect airway patency is recommended (see attachment 4). Laboratory testing is ordered based on the patient's underlying medical conditions and the likelihood that the results will affect the management of conscious sedation (see attachment 7). This information is to be documented on the AF Form 1417.

5.1.1.2. The second phase of assessment is performed immediately prior to administering conscious sedation. The purpose of this assessment is twofold. First, any interval changes (respiratory infection, recent MI, inappropriate fasting interval, etc.) that may represent contraindications to sedation must be excluded. Second, a clinical baseline is established to facilitate patient assessment throughout the sedation period. The assessment will be performed by or authenticated by a privileged provider prior to administering conscious sedation. Accomplishment of the second phase allows for initiation of conscious sedation.

5.1.1.3. If the procedure is an emergency and no time is available to document a complete assessment, a note should be placed in the chart stating such.

5.1.2. Arrangements for an appropriate recovery area will be made prior to the initiation of conscious sedation.

5.2. Patient Counseling. Prior to sedative medication administration, the risks, benefits, limitations and alternatives to the planned procedure will be discussed with the patient. Informed consent will be obtained in accordance with MDGI 41-39.

5.3. Pre-Procedure Fasting.

5.3.1. For elective procedures sufficient time for gastric emptying should be allowed. One should also be cognizant of patients who have conditions that do not allow for complete gastric emptying such as diabetes, bowel obstructions, pain and the use of narcotics. For urgent or emergent situations the benefits of conscious sedation must be weighed against the potential risk of regurgitation and aspiration of gastric contents. Suggested guidelines are:

5.3.1.1. Age 0 to 5 months: no milk or solid foods for 4 hours before sedation.

5.3.1.2. Age 6 to 36 months: no milk or solid foods for 6 hours before sedation.

5.3.1.3. Age greater than 36 months: no milk or solid foods for 6 to 8 hours before sedation.

5.3.1.4. Oral intake of clear liquids may continue, but in no instance should oral intake of clearliquids occur less than 2 hours before sedation medication is administered. NOTE: breast milk is not considered a clear liquid.

5.4. Monitoring.

5.4.1. Monitoring of the patient is to be continuous throughout the procedure and will include documentation of vital signs. The blood pressure, pulse, oxygen saturation, and respiratory rate will be recorded on the chart prior to the initiation of conscious sedation, during the procedure, and at the end of the procedure. Vital signs will be documented in the patient's sedation record at regular intervals during the procedure, at a minimum of every five minutes unless otherwise ordered more frequently by the provider. Oxygen saturation will be monitored continuously during the procedure and documented at 15-minute intervals on the record. Ventilatory function and the patient's response to verbal commands will be monitored and documented throughout the procedure. Continuous electrocardiogram (EKG) monitoring is performed in patients with significant cardiovascular disease or when dysrhythmias are anticipated or detected.

5.5. Documentation.

5.5.1. Post-procedure documentation of the patient's pain tolerance, level of consciousness, vital signs and *Aldrete* score will be recorded on the AF Form 1417. Prior to discontinuing the post-procedure monitoring, patient's vital signs must be stable compared to baseline (pre-procedure readings).

5.5.2. Documentation of all conscious sedation procedures will be done on AF Form 1417.

5.5.3. Medication dosages and the time they are given will be recorded on AF Form 1417.

5.6. Personnel.

5.6.1. Staffing during conscious sedation consists of a minimum of one provider and one qualified nurse (if medications will be administered by other than provider) or a qualified technician. One person must be devoted to monitoring the patient. The individual monitoring may assist the provider with brief interruptible tasks while maintaining constant visual monitoring. Additional monitoring personnel may be used according to clinical needs and complexity of the procedure. Additional monitoring personnel may include trained assistants

(technicians) who have been skills verified by their department as competent to monitor patients undergoing conscious sedation.

5.6.2. An individual capable of establishing an airway must be immediately available at all times. An individual with advanced life support skills will be available at the sedation procedure.

5.7. Training.

5.7.1. The credentialed provider responsible for managing the patient receiving conscious sedation must be experienced in the use of conscious sedation techniques for that procedure. The provider must be able to provide a level of monitoring that includes respiratory rate, oxygen saturation, blood pressure, cardiac rate, and rhythm (when determined necessary), and determining the patient's level of consciousness. The provider must be able to manage complications that may occur related to the administration of conscious sedation. The provider must maintain current training in Basic Life Support (BLS) and ACLS/PALS for adult and pediatric (age 13 and under) conscious sedation respectively (IAW AFI 44-102).

5.7.2. The individual assisting in the care of a patient receiving conscious sedation must meet the following criteria: (1) BLS biennial training; (2) training in airway management, recognition of the cardiopulmonary and respiratory effects of sedatives, and dysrhythmia recognition; (3) understanding of the pharmacology of the medications administered is required to include recognition of cardiovascular and respiratory side effects of sedatives; (4) ACLS/PALS is recommended for adult and pediatric conscious sedation respectively.

5.7.3. General competency for the qualified individual monitoring the care of the patient receiving conscious sedation includes the ability to: (1) demonstrate basic knowledge of complications related to conscious sedation and medications; (2) assess patient care status during sedation and recovery, to include respiratory rate, oxygen saturation, blood pressure, cardiac rate and the patient's level of consciousness; (3) demonstrate the ability to use oxygen delivery devices; (4) demonstrate skill in airway management and resuscitation according to BLS guidelines and (5) demonstrate understanding of Aldrete scoring system.

5.7.4. Training of personnel assisting with conscious sedation procedures will be uniform throughout the 10 MDG and under the direction of the Anesthesia Department. Registered Nurses and medical/dental technicians assisting with conscious sedation procedures and/or the recovery of such patients shall complete the self-learning packet entitled "Care of the Patient Receiving IV Conscious Sedation", complete the post-test, and show competency by completing the Competency Verification Record (Performance Checklist, AF Form 2519). The self-learning packet is available through the Group Education and Training Office while the coordination of the Competency Verification Record will be under the direction of anesthesia with practical/didactic direction from the Anesthesia Department. Reverification will be annual. Medical technicians not administering medications can consider that portion of the performance checklist not applicable.

5.7.5. Training of registered nurses will culminate with completion of three observed conscious sedation cases, during which, a fully trained registered nurse will act as a preceptor. After all

training requirements have been met, a copy of all training documentation will be forwarded to the Department of Anesthesia for review and certification.

5.8. Emergency equipment must be immediately accessible to every location where conscious sedation is administered. At a minimum it must include: intravenous equipment, defibrillator, suction device, oxygen, basic airway equipment (airways, self-inflating bag), basic resuscitative medications, reversal agents (flumazenil and naloxone), intubation equipment, and EKG monitor.

5.9. Equipment to administer supplemental oxygen should be present when conscious sedation is administered. If hypoxemia is anticipated or develops during conscious sedation, supplemental oxygen will be administered.

5.10. Medication selection is based on the desired effect. Sedatives decrease anxiety and analgesics relieve pain. Both types of drugs promote somnolence. Medications should be given incrementally with sufficient time between doses to assess effects. Appropriate dose reduction is encouraged if sedatives and analgesics are used together because their effects may be synergistic. Recommended doses of commonly administered medications can be found in attachment 1.

5.11. IV access must be maintained in all patients receiving intravenous sedatives and analgesics both during the procedure and until the patient is no longer at risk for cardiopulmonary depression. Providers may employ clinical judgment when determining if intravenous access is indicated in patients receiving conscious sedation by other than IV routes.

5.12. Reversal Agents. Specific antagonists must be available in units and clinics where conscious sedation is being performed. Patients who become apneic or hypoxic during a procedure may be given reversal agents such as naloxone and/or flumazenil to improve spontaneous respirations. Once reversal agents have been used, the patient should be observed long enough to ensure cardio-respiratory depression does not recur. The pharmacological half-life of currently available reversal agents suggests this period of time should approach two hours.

6. Recovery.

6.1. Post Procedure**.** Vital signs will be taken and recorded. The provider will confirm the appropriate location to monitor the patient's recovery. The patient will be assessed using the Aldrete Score (note: the Aldrete score may not be applicable to all patients, i.e., those with paraplegia, mental retardation, infants, etc.):

Physical Signs & Criteria	**Score**	**Aldrete Score**
Activity:		_____
Able to move 4 extremities	2	
Able to move 2 extremities	1	
Not able to move any extremity	0	

Respiration:		_____
Able to breathe deeply and cough	2	
Limited respiration effort- dyspnea	1	
No spontaneous respiratory effort	0	
Circulation:		_____
BP +/- 20% pre-sedation level	2	
BP +/- 20-30% pre-sedation level	1	
BP outside the range of +/- 30% pre-sedation level	0	
Consciousness:		_____
Fully alert, able to answer questions	2	
Arousable on calling	1	
Not responding	0	
Color:		_____
Normal, pink	2	
Pale, dusky, blotchy	1	
Frank cyanosis	0	
		+ _____

The sum of each Category = Aldrete Score.

6.2. If any section score is 0, or if there is a question of a patient's status, an anesthesia provider will be immediately notified via the paging system for consultation and appropriate disposition. In the rare circumstance the Aldrete System is not used, the provider will document the patient's condition in the patient's chart. The credentialed provider does not have to be present with the patient during recovery, but must be immediately available should problems arise.

6.3. Monitoring in the recovery areas.

6.3.1. All patients will be recovered in a location where direct visualization can occur with access around the patient for emergency conditions.

6.3.2. Vital signs (blood pressure, pulse, respiratory rate and oxygen saturation) will be documented upon arrival to recovery area and documented every 15 to 20 minutes until patient meets discharge criteria.

6.3.3. Recovery area personnel must be trained to recognize hypo/hypertension, airway obstruction, respiratory depression, and hypoxia as detected by pulse oximetry. An individual capable of treating any complications that might occur should be immediately available.

6.4. Discharge From Conscious Sedation Recovery Area.

6.4.1. The 10 MDG adopts the Aldrete Score as an objective scoring system for assessing patients during recovery. A score of 8-10 is required for discontinuation of monitoring and discharge. The Aldrete Score will be documented on the AF Form 1417. All patients will be assessed by a provider prior to discharge from the area where they are recovering from conscious sedation. This provider assessment must be at least 30 minutes after the last dose of intravenous conscious sedation medication. The provider assessment will take place 60 minutes after utilization of intramuscular sedatives. When reversal agents have been administered, this provider assessment will be 2 hours after the last dose of reversal agent and 15 minutes after discontinuing supplemental oxygen.

6.4.2. The patient discharged to home will be discharged in the presence of a responsible adult escort who will accompany him/her home and be able to report any post-procedural complications. The patient and adult escort must receive all necessary written instructions (activity, diet, danger signs, medications, emergency phone number, follow-up instructions, etc.). An "escort" is defined as an adult at least 18 years of age who voluntarily assumes attendant responsibilities for observing the sedated patient for the remainder of the day post-procedure.

7. Special Situations.

7.1. Certain classes of patients are at increased risk for developing complications related to conscious sedation unless special precautions are taken. Examples include uncooperative patients, extremes of age, cardiopulmonary disease, hepatorenal disease, central nervous system (CNS) disease, morbid obesity, sleep apnea, pregnancy, and drug/alcohol abuse. Procedural risks may be reduced by pre-procedural consultation with an appropriate specialist, depending on the nature of the underlying condition and the urgency of the situation.

7.2. Patients undergoing non-invasive procedures where anxiety would preclude performance or completion of the procedure (for example, magnetic resonance imagery scanning in a patient with claustrophobia) may be prescribed oral anxiolytics. Providers may exclude this subgroup from the monitoring stipulations of this MDGI based on the patient's individual health profile.

7.3. Support for After Hours Conscious Sedation.

7.3.1. Support for procedures requiring conscious sedation will be arranged by the department performing the procedure. If additional support staffing is required, the Senior Nurse On Call (SNOC) will be contacted by pager and additional nursing or technician personnel will be assigned to assist with the procedure. If the SNOC is unable to provide the required personnel emergently, the anesthesia provider on call may be contacted. If the anesthesia department is

unable to provide emergent assistance, the staff physician performing the procedure will call in additional physicians as necessary from his/her service to fulfill staffing requirements to meet patient monitoring standards.

8. Credentialing, Quality Assurance, and Risk Management.

8.1. Credentialing. Each provider who performs conscious sedation will read the conscious sedation provider package and forward a signed verification to their department chairperson for inclusion in their PAF. The conscious sedation provider's package is available in each department and from the Department of Anesthesia upon request. Credentialing for conscious sedation will be reviewed at the departmental level by the department chairperson after the provider requesting privileges reads the conscious sedation package and forwards a signed copy to the department chairperson. At the time of biannual renewal of privileging, conscious sedation performance and outcome will be evaluated by the department chairperson, as a component of procedure performance and outcomes (see 3.2.3). Conscious sedation performance and outcome evaluation will be documented in the PAF on AF Form 22.

8.2. Quality Assurance.

8.2.1. Monitoring and Evaluation: Each department will monitor, evaluate, and identify problems associated with their care (sedation/analgesia) utilizing Pharmacy and Therapeutics Review, Medical Records Audit, Morbidity and Mortality Review, Incident Reports, Patient Questionnaires, periodic studies and Anesthesia Consults.

8.2.2. The Department of Anesthesia will provide quality oversight of the Conscious Sedation Program. The Conscious Sedation Monitor (SGOSA) will audit 10% of Conscious Sedation Records every month and give feedback to those areas administering sedation/analgesia. The Chief of Medical Staff may mandate a higher audit percentage in areas of increased patient acuity. The quality assurance and performance improvement data will be aggregated/analyzed by department and individual provider. This information will be reported to the critical care committee.

8.2.3. Quality Assurance will be retrospective. Each department will forward monthly reports to the Department of Anesthesia Quality Assurance section summarizing quarterly cases performed and all cases with positive indicators for performance improvement. The monthly report form is found as Attachment 5 and can be used as an overprint.

8.2.4. Each department will report within two working days, the cases with positive indicators to the Department of Anesthesia Quality Assurance section for evaluation. The report form is found as attachment 3 and can be overprinted. A copy of the conscious sedation record will also accompany the report. The Quality Assurance section of the Department of Anesthesia will evaluate the records of the patients whose procedures triggered a positive indicator. Appropriate feedback will be forwarded to the provider, and a copy will be forwarded to the provider's Departmental QI Committee and the hospital Quality Assurance Department.

8.2.5. Performance improvement indicators for adverse events or reactions are listed on attachment 2. All reversal agent administration will be documented as an indicator, with documentation of Aldrete score at time of reversal. Performance improvement indicators for

adverse events or reactions are listed on drug administration as well as elective or emergent use of the drugs.

DOUGLAS J. ROBB, Col, USAF, MC, CFS
Commander

Attachments:
1. Recommended Dosages for Sedation and Analgesia
2. Performance Improvement Indicators
3. Performance Improvement Form
4. Airway Assessment
5. Conscious Sedation Monthly Report Form
6. American Society of Anesthesiologists Physical Status Classes
7. Recommended Laboratory Studies

RECOMMENDED DOSAGES FOR SEDATION AND ANALGESIA

Midazolam (Versed)- IV Increments of 1-2 mg., Induction of General Anesthesia: 0.1mg/kg. Titrate slowly to desired effect. (e.g. onset of slurred speech)
- Onset IV 30 - 60 seconds, peak effect 3-5 min, duration 15-80 minutes.
- Reduce doses in elderly, hypovolemic, when given concurrently with opiates, and in pts with COPD.

Fentanyl - IV, Increments of 25 - 50 ucg IV, Be prepared to manage airway consequences if administering over 1-2 ug/kg. Titrate slowly.
- Onset within 30 seconds, peak effect 5-15 minutes, duration 30 - 60 minutes.
- Adverse reactions include: hypotension, bradycardia, respiratory depression, apnea, dizziness, nausea, emesis, and muscle rigidity.

Morphine - IV, increments of 1-2.5 mg, be prepared to manage airway consequences if administering over 0.1 mg/kg.
- Onset, 1 minute, peak effect 5-20 minutes, duration 2-7 hours.
- Adverse reactions similar to fentanyl and also include bronchospasm, pruritis, and urticaria.
- Long duration of action.

Meperidine (Demerol)- IV, Increments 25-50 mg, be prepared to manage airway consequences if administering over 1-2mg/kg.
- Peak effect 15 minutes, duration 3-4 hours.
- Adverse reactions similar to other narcotics, also includes seizure, delirium and hypertension when given to a pt on a MAO inhibitor.

Naloxone (Narcan)- Reversal of narcotic induced respiratory depression.
- Incremental dose 10-40 ucg titrated to effect at 2-3 minute intervals, maximum dose 1-4 mg.
- Patients should be carefully monitored after and during reversal with naloxone, some opiates duration of action may exceed that of naloxone.
- Adverse reactions include: tachycardia, hypertension, dysrhythmias, pulmonary edema, and seizures. Abrupt reversal of opiate effect **may precipitate severe reactions and extreme caution** is recommended with its use.

Flumazenil (Romazicon)- Reversal for benzodiazepines.
- Increment dose 0.2mg IV at 1 minute intervals; titrate to patient response; maximum dose 3 mg in 1 hour.
- Duration of action of flumazenil may be exceeded by the duration of the benzodiazepine reversed. These patients need to be monitored up to 120 minutes after reversal.
- Adverse reactions include dysrhythmias, hypertension, angina, and seizure. **Extreme caution should be used when reversing benzodiazepines; a severe reaction may be precipitated**.

Patients receiving propofol or methohexital by any route should receive care consistent with that required for deep sedation. Patients receiving ketamine should be cared for in a manner consistent with achieved level of sedation.

PERFORMANCE IMPROVEMENT INDICATORS

The following items are **required** to be assessed for each conscious sedation case. Each department or service will report quarterly the cases with positive indicators to the Quality Assurance section of the Department of Anesthesia for evaluation. This may be reported with each Department's Invasive Procedure Review or attachment 3 can be utilized as an overprint.

Respiratory Problems:	Sustained O2 saturation less than 90% greater than five min. Respiratory Arrest Pulmonary Aspiration of Gastric Contents
Cardiovascular Problems:	Acute Myocardial Infarction Cardiac Arrest
Central Nervous System:	Stroke Failure to return to baseline mental status within 1-2 hours
Medical Problems:	Allergic/Anaphylactoid Reaction Unplanned admission to SCU (if due to sedation) Unplanned admission after outpatient procedure (if due to sedation) Death
All reversal agent usage	Elective Emergent Aldrete score at time of reversal

Conscious Sedation Performance Improvement Report Form
(Forward to Quality Assurance Section of Department of Anesthesiology)

Department: _____ Date:_____

Hospital Registration Number (patient): _____

Provider Name & Number: _____

Reversal agent use:	Elective or emergent Aldrete score at time of use	_____	
Respiratory Problems:	Sustained O2 saturation less than 90% for greater then five min.	_____	☐
	Pulmonary Aspiration	_____	☐
	Respiratory Arrest	_____	☐
Cardiovascular Problems:	Acute Myocardial Infarction	_____	☐
	Cardiac Arrest	_____	☐
Central Nervous System:	Stroke	_____	☐
	Failure to return to baseline mental status within 1-2 hours	_____	☐
Medical Problems:	Allergic/Anaphylactoid Reaction	_____	☐
	Unplanned admission to SCU (if due to sedation)	_____	☐
	Unplanned outpatient surgical admission (if due to sedation)	_____	☐
	Death	_____	☐

Outcome: _____
_____
_____

Opportunities to Improve: _____
_____
_____

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AIRWAY ASSESSMENT PRIOR TO CONSCIOUS SEDATION

Factors that may be associated with difficulty in airway management are outlined below:

1. **History**

   Previous problems with anesthesia or sedation
   Stridor, snoring, or sleep apnea
   Advanced rheumatoid arthritis

2. **Physical Examination**

   Significant obesity, especially the neck and facial areas
   Short neck, limited neck extension, neck mass, cervical spine disease or trauma, tracheal deviation.
   Small mouth, edentulous, protruding incisors, loose or capped teeth, high arched palate, Macroglossia, enlarged tonsils, nonvisible uvula.
   Jaw- Micrognathia, retrognathia, trismus, significant malocclusion

Conscious Sedation Monthly Report Form
(Forward to Quality Assurance Section of Department of Anesthesiology)

Department: _____ Date: _____

Fiscal Year: _____ Month: _____

Conscious Sedation Cases in Last Month: _____

Number of Cases Triggering Quality Assurance Indicators: _____

Number of Cases Employing Reversal Agent Use: _____

Elective Reversal: _____

Emergent Reversal: _____

Quality Assurance Material
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AMERICAN SOCIETY OF ANESTHESIOLOGISTS
PHYSICAL STATUS CLASSES

Class I: A healthy patient

Class II: A patient with mild systemic disease

Class III: A patient with severe systemic disease that limits activity but is not incapacitating

Class IV: A patient with an incapacitating systemic disease that is a constant threat to life

Class V: A moribund patient not expected to survive 24 hours with or without surgery

PREOPERATIVE LAB RECOMMENDATIONS

AGE:	**< 1 YR**	**CBC**
	> 40	CBC ECG
	> 65	CBC ECG CHEM 7

Fertile females: Beta-HCG

Major blood loss expected, or has occurred:	CBC T&S/T&C
COPD, Emphysema, Significant RAD:	PFT

(If PFTs done within 2 years with no change functional status, none required)

Significant Pulmonary Disease (Max. benefit with age >75)	CXR
Liver Disease or Significant Alcohol History	LFT
Diabetes or Renal Disease	Chem. 7
Diuretics	Chem. 7
Digoxin, Theophylline, Dilantin, etc.	Drug Level

If patients are at baseline health, and medications are unchanged, lab work is good for 6 months, and ECG/CXR for 1 year. If patient, or medication has changed, lab work should be within 1 month.

Patients requiring Urgent or Emergent procedure MUST have the appropriate studies performed. The only exception is a "true" LIFE or LIMB threatening condition.

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Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists

An Updated 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 for diagnostic and therapeutic procedures. To assist in this process, the American Society of Anesthesiologists (ASA) has developed these "Guidelines for Sedation and Analgesia by Non-Anesthesiologists."

Practice guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. The guidelines provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data.

This revision includes data published since the "Guidelines for Sedation and Analgesia by Non-Anesthesiologists" were adopted by the ASA in 1995; it also includes data and recommendations for a wider range of sedation levels than was previously addressed.

Additional material related to this article can be found on the ANESTHESIOLOGY Web site. Go to the following address, click on Enhancements Index, and then scroll down to find the appropriate article and link. http://www.anesthesiology.org

Developed by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists: Jeffrey B. Gross, M.D. (Chair), Farmington, CT; Peter L. Bailey, M.D., Rochester, NY; Richard T. Connis, Ph.D., Woodinville, WA; Charles J. Coté, M.D., Chicago, IL; Fred G. Davis, M.D., Burlington, MA; Burton S. Epstein, M.D., Washington, DC; Lesley Gilbertson, M.D., Boston, MA; David G. Nickinovich, Ph.D., Bellevue, WA; John M. Zerwas, M.D., Houston, TX; Gregory Zuccaro, Jr., M.D., Cleveland, OH.

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The accompanying Web site enhacement is a bibliography.

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

Definitions

"Sedation and analgesia" comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia. Definitions of levels of sedation–analgesia, as developed and adopted by the ASA, are given in table 1. These Guidelines specifically apply to levels of sedation corresponding to moderate sedation (frequently called conscious sedation) and deep sedation, as defined in table 1.

Focus

These Guidelines are designed to be applicable to procedures performed in a variety of settings (*e.g.*, hospitals, freestanding clinics, physician, dental, and other offices) by practitioners who are not specialists in anesthesiology. Because minimal sedation (anxiolysis) entails minimal risk, the Guidelines specifically exclude it. Examples of minimal sedation include peripheral nerve blocks, local or topical anesthesia, and either (1) less than 50% nitrous oxide (N_2O) in oxygen with no other sedative or analgesic medications by any route, or (2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. The Guidelines also exclude patients who are not undergoing a diagnostic or therapeutic procedure (*e.g.*, postoperative analgesia, sedation for treatment of insomnia). Finally, the Guidelines do not apply to patients receiving general or major conduction anesthesia (*e.g.*, spinal or epidural/caudal block), whose care should be provided, medically directed, or supervised by an anesthesiologist, the operating practitioner, or another licensed physician with specific training in sedation, anesthesia, and rescue techniques appropriate to the type of sedation or anesthesia being provided.

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. Se-

Table 1. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

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

Minimal Sedation (Anxiolysis) = a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (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.

Deep Sedation/Analgesia = a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia = a drug-induced loss of consciousness during which patients are not 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.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering *Moderate Sedation/Analgesia (Conscious Sedation)* should be able to rescue patients who enter a state of *Deep Sedation/Analgesia*, while those administering *Deep Sedation/Analgesia* should be able to rescue patients who enter a state of general anesthesia.

* Reflex withdrawal from a painful stimulus is not considered a purposeful response.

Developed by the American Society of Anesthesiologists; approved by the ASA House of Delegates October 13, 1999.

dation/analgesia provides two general types of benefit: (1) sedation/analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain; and (2) in children and uncooperative adults, sedation–analgesia may expedite the conduct of procedures that are not particularly uncomfortable but that require that the patient not move. At times, these sedation practices may result in cardiac or respiratory depression, which 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 or psychological response to stress.

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 a deeper level of sedation than anticipated. Because it is not always possible to predict how a specific patient will respond to sedative and analgesic medications, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. For moderate sedation, this implies the ability to manage a compromised airway or hypoventilation in a patient who *responds purposefully* after repeated or painful stimulation, whereas for deep sedation, this implies the ability to manage respiratory or cardiovascular instability in a patient who *does not respond purposefully* to painful or repeated stimulation. Levels of sedation referred to in the recommendations relate to the level of sedation intended by the practitioner. Examples are provided to illustrate airway assessment, preoperative fasting, emergency equipment, and recovery procedures; however, clinicians and their institutions have ultimate responsibility for selecting patients, procedures, medications, and equipment.

Task Force Members and Consultants

The ASA appointed a Task Force of 10 members to (1) review the published evidence; (2) obtain the opinion of a panel of consultants, including non-anesthesiologist physicians and dentists who routinely administer sedation–analgesia, as well as of anesthesiologists with a special interest in sedation–analgesia (see Appendix I); and (3) build consensus within the community of practitioners likely to be affected by the Guidelines. The Task Force included anesthesiologists in both private and academic practices from various geographic areas of the United States, a gastroenterologist, and methodologists from the ASA Committee on Practice Parameters.

This Practice Guideline is an update and revision of the ASA "Guidelines for Sedation and Analgesia by Non-

Anesthesiologists."[1] The Task Force revised and updated the Guidelines by means of a five-step process. First, original published research studies relevant to the revision and update were reviewed and analyzed; only articles relevant to the administration of sedation by nonanesthesiologists were evaluated. Second, the panel of expert consultants was asked to (1) participate in a survey related to the effectiveness and safety of various methods and interventions that might be used during sedation–analgesia, and (2) review and comment on the initial draft report of the Task Force. Third, the Task Force held open forums at two major national meetings to solicit input on its draft recommendations. National organizations representing most of the specialties whose members typically administer sedation–analgesia were invited to send representatives. Fourth, the consultants were surveyed to assess their opinions on the feasibility and financial implications of implementing the revised and updated Guidelines. Finally, all of the available information was used by the Task Force to finalize the Guidelines.

Availability and Strength of Evidence

Evidence-based Guidelines are developed by a rigorous analytic process. To assist the reader, the Guidelines make use of several descriptive terms that are easier to understand than the technical terms and data that are used in the actual analyses. These descriptive terms are defined below.

The following terms describe the strength of scientific data obtained from the scientific literature:

Supportive: There is sufficient quantitative information from adequately designed studies to describe a statistically significant relationship ($P < 0.01$) between a clinical intervention and a clinical outcome, using metaanalysis.

Suggestive: There is enough information from case reports and descriptive studies to provide a directional assessment of the relationship between a clinical intervention and a clinical outcome. This type of qualitative information does not permit a statistical assessment of significance.

Equivocal: Qualitative data have not provided a clear direction for clinical outcomes related to a clinical intervention, and (1) there is insufficient quantitative information or (2) aggregated comparative studies have found no quantitatively significant differences among groups or conditions.

The following terms describe the *lack* of available scientific evidence in the literature:

Inconclusive: Published studies are available, but they cannot be used to assess the relation between a clinical intervention and a clinical outcome because the studies either do not meet predefined criteria for content as defined in the "Focus" of these Guidelines, or do not provide a clear causal interpretation of findings because of research design or analytic concerns.

Insufficient: There are too few published studies to investigate a relationship between a clinical intervention and clinical outcome.

Silent: No studies that address a relationship of interest were found in the available published literature.

The following terms describe survey responses from the consultants for any specified issue. Responses were solicited on a five-point scale, ranging from 1 (strongly disagree) to 5 (strongly agree), with a score of 3 being neutral.

Strongly Agree: median score of 5
Agree: median score of 4
Equivocal: median score of 3
Disagree: median score of 2
Strongly Disagree: median score of 1

Guidelines

Patient Evaluation

There is insufficient published evidence to evaluate the relationship between sedation–analgesia outcomes and the performance of a preprocedure patient evaluation. There is suggestive evidence that some preexisting medical conditions may be related to adverse outcomes in patients receiving either moderate or deep sedation/analgesia. The consultants strongly agree that appropriate preprocedure evaluation (history, physical examination) increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes for both moderate and deep sedation.

Recommendations. Clinicians administering sedation/analgesia should be familiar with sedation-oriented aspects of the patient's medical history and how these might alter the patient's response to sedation/analgesia. These include: (1) abnormalities of the major organ systems; (2) previous adverse experience with sedation/analgesia as well as regional and general anesthesia; (3) drug allergies, current medications, and potential drug interactions; (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 vital signs, auscultation of the heart and lungs, and evaluation of the airway. (Example I). 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. These evaluations should be confirmed immediately before sedation is initiated.

Example I. Airway Assessment Procedures for Sedation and Analgesia

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

History
- Previous problems with anesthesia or sedation
- Stridor, snoring, or sleep apnea
- Advanced rheumatoid arthritis
- Chromosomal abnormality (*e.g.*, trisomy 21)

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, dysmorphic facial features (*e.g.*, Pierre-Robin syndrome)
- Mouth
  - Small opening (< 3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula
- Jaw
  - Micrognathia, retrognathia, trismus, significant malocclusion

Preprocedure Preparation

The literature is insufficient regarding the benefits of providing the patient (or legal guardian, in the case of a child or impaired adult) with preprocedure information about sedation and analgesia. For moderate sedation the consultants agree, and for deep sedation the consultants strongly agree that appropriate preprocedure counseling of patients regarding risks, benefits, and alternatives to sedation and analgesia increases patient satisfaction.

Sedatives and analgesics tend to impair airway reflexes in proportion to the degree of sedation–analgesia achieved. This dependence on level of sedation is reflected in the consultants opinion: They agree that preprocedure fasting decreases risks during moderate sedation, while strongly agreeing that it decreases risks during deep sedation. In emergency situations, when preprocedure fasting is not practical, the consultants agree that the target level of sedation should be modified (*i.e.*, less sedation should be administered) for moderate sedation, while strongly agreeing that it should be modified for deep sedation. The literature does not provide sufficient evidence to test the hypothesis that preprocedure fasting results in a decreased incidence of adverse outcomes in patients undergoing either moderate or deep sedation.

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, including its benefits, risks, and limitations associated with this therapy, as well as possible alternatives. 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 before their procedure, as recommended by the ASA "Guidelines for Preoperative Fasting"[2] (Example II). In urgent, emergent, or other situations in which gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed, or (3) whether the trachea should be protected by intubation.

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 deeply sedated, approaching a state of general anesthesia, and should be treated accordingly. The literature is silent regarding whether monitoring patients' level of consciousness improves patient outcomes or decreases risks. The consultants strongly agree that monitoring level of consciousness reduces risks for both moderate and deep sedation. The members of the Task Force believe that many of the complications associated with sedation and 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). Patients given sedatives or analgesics in unmonitored settings in anticipation of a subsequent procedure may be at increased risk of these complications.

Example II. Summary of American Society of Anesthesiologists Preprocedure Fasting Guidelines[2]*

Ingested Material	Minimum Fasting Period†
Clear liquids‡	2 h
Breast milk	4 h
Infant formula	6 h
Nonhuman milk§	6 h
Light meal‖	6 h

* These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the Guidelines does not guarantee a complete gastric emptying has occurred.

† The fasting periods apply to all ages.

‡ Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

§ Since nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

‖ A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

Pulmonary Ventilation. It is the opinion of the Task Force that the primary causes of morbidity associated with sedation/analgesia are drug-induced respiratory depression and airway obstruction. For both moderate and deep sedation, the literature is insufficient to evaluate the benefit of monitoring ventilatory function by observation or auscultation. However, the consultants strongly agree that monitoring of ventilatory function by observation or auscultation reduces the risk of adverse outcomes associated with sedation/analgesia. The consultants were equivocal regarding the ability of capnography to decrease risks during moderate sedation, while agreeing that it may decrease risks during deep sedation. In circumstances in which patients are physically separated from the caregiver, the Task Force believes that automated apnea monitoring (by detection of exhaled carbon dioxide or other means) may decrease risks during both moderate and deep sedation, while cautioning practitioners that impedance plethysmography may fail to detect airway obstruction. The Task Force emphasizes that because ventilation and oxygenation are separate though related physiologic processes, monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function.

Oxygenation. Published data suggest that oximetry effectively detects oxygen desaturation and hypoxemia in patients who are administered sedatives/analgesics. The consultants strongly agree 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 Task Force agrees that hypoxemia during sedation and analgesia is more likely to be detected by oximetry than by clinical assessment alone.

Hemodynamics. Although there are 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. On the other hand, if sedation and analgesia are inadequate, patients may develop potentially harmful autonomic stress responses (*e.g.*, hypertension, tachycardia). 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 these complications. The consultants strongly agree that regular monitoring of vital signs reduces the likelihood of adverse outcomes during both moderate and deep sedation. For both moderate and deep sedation, a majority of the consultants indicated that vital signs should be monitored at 5-min intervals once a stable level of sedation is established. The consultants strongly agree that continuous electrocardiography reduces risks during deep sedation, while they were equivocal regarding its effect during moderate sedation. However, the Task Force believes that electrocardiographic monitoring of selected patients (*e.g.*, with significant cardiovascular disease or dysrhythmias) may decrease risks during moderate sedation.

Recommendations. Monitoring of patient response to verbal commands should be routine during moderate sedation, except in patients who are unable to respond appropriately (*e.g.*, young children, mentally impaired or uncooperative patients), or during procedures where movement could be detrimental. During deep sedation, patient responsiveness to a more profound stimulus should be sought, unless contraindicated, to ensure that the patient has not drifted into a state of general anesthesia. During procedures where 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, corresponding to a state of moderate sedation. Note that a response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

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. In addition, ventilatory function should be continually monitored by observation or auscultation. Monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and for patients whose ventilation cannot be directly observed during moderate sedation. When possible, blood pressure should be determined before sedation/analgesia is initiated. Once sedation–analgesia is established, blood pressure should be measured at 5-min intervals during the procedure, unless such monitoring interferes with the procedure (*e.g.*, pediatric magnetic resonance imaging, where stimulation from the blood pressure cuff could arouse an appropriately sedated patient). Electrocardiographic monitoring should be used in all patients undergoing deep sedation. It should also be used during moderate sedation in patients with significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated.

Recording of Monitored Parameters

The literature is silent regarding the benefits of contemporaneous recording of patients' level of consciousness, respiratory function, or hemodynamics. Consultant opinion agrees with the use of contemporaneous recording for moderate sedation and strongly agrees with its use for patients undergoing deep sedation. It is the consensus of the Task Force that, unless technically precluded (*e.g.*, uncooperative or combative patient), vital signs and respiratory variables should be recorded 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 may disclose trends that could prove critical in determining the development or cause of adverse events. In addition, manual recording ensures that an individual caring for the patient is aware of changes in patient status in a timely fashion.

Recommendations. For both moderate and deep sedation, patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables should be assessed and recorded at a frequency that depends on the type and amount of medication administered, 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) at regular intervals during the procedure, (4) during initial recovery; and (5) just before discharge. If recording is performed automatically, device alarms should be set to alert the care team to critical changes in patient status.

Availability of an Individual Responsible for Patient Monitoring

Although the literature is silent on this issue, the Task Force recognizes that it may not be possible for the individual performing a procedure to be fully cognizant of the patient's condition during sedation/analgesia. For moderate sedation, the consultants agree that the availability of an individual other than the person performing the procedure to monitor the patient's status improves patient comfort and satisfaction and that risks are reduced. For deep sedation, the consultants strongly agree with these contentions. During moderate sedation, the consultants strongly agree that the individual monitoring the patient may assist the practitioner with interruptible ancillary tasks of short duration; during deep sedation, the consultants agree that this individual should have no other responsibilities.

Recommendation. A designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation/analgesia. During deep sedation, this individual should have no other responsibilities. However, during moderate sedation, this individual may assist with minor, interruptible tasks once the patient's level of sedation–analgesia and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.

Training of Personnel

Although the literature is silent regarding the effectiveness of training on patient outcomes, the consultants strongly agree that education and training in the pharmacology of agents commonly used during sedation–analgesia improves the likelihood of satisfactory sedation and reduces the risk of adverse outcomes from either moderate or deep sedation. Specific concerns may 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. Because sedation/analgesia constitutes a continuum, practitioners administering moderate sedation should be able to rescue patients who enter a state of deep sedation, whereas those intending to administer deep sedation should be able to rescue patients who enter a state of general anesthesia. Therefore, the consultants strongly agree that at least one qualified individual trained in basic life support skills (cardiopulmonary resuscitation, bag-valve-mask ventilation) should be present in the procedure room during both moderate and deep sedation. In addition, the consultants strongly agree with the immediate availability (1–5 min away) of an individual with advanced life support skills (*e.g.*, tracheal intubation, defibrillation, use of resuscitation medications) for moderate sedation and in the procedure room itself for deep sedation.

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 (within 5 min) for moderate sedation and within the procedure room for deep sedation.

Availability of Emergency Equipment

Although the literature is silent, the consultants strongly agree that the ready availability of appropriately sized emergency equipment reduces risks associated with both moderate and deep sedation. The literature is also silent regarding the need for cardiac defibrillators during sedation/analgesia. During moderate sedation, the consultants agree that a defibrillator should be immediately available for patients with both mild (*e.g.*, hypertension) and severe (*e.g.*, ischemia, congestive failure) cardiovascular disease. During deep sedation, the

consultants agree that a defibrillator should be immediately available for all patients.

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. Suction, advanced airway equipment, and resuscitation medications should be immediately available and in good working order (Example III). A functional defibrillator should be immediately available whenever deep sedation is administered and when moderate sedation is administered to patients with mild or severe cardiovascular disease.

Example III. 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 lists 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 [24-22-gauge]
- Intravenous tubing [pediatric "microdrip" (60 drops/ml)]
- Intravenous fluid
- Assorted needles for drug aspiration, intramuscular injection [intraosseous bone marrow needle]
- Appropriately sized syringes [1-ml 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]
- Lubricant

Advanced airway management equipment (for practitioners with intubation skills)
- Laryngeal mask airways [pediatric]
- Laryngoscope handles (tested)
- Laryngoscope blades [pediatric]
- Endotracheal tubes
  - Cuffed 6.0, 7.0, 8.0 mm ID
  - [Uncuffed 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm ID]
- Stylet (appropriately sized for endotracheal tubes)

Pharmacologic Antagonists
- Naloxone
- Flumazenil

Emergency medications
- Epinephrine
- Ephedrine
- Vasopressin
- Atropine
- Nitroglycerin (tablets or spray)
- Amiodarone
- Lidocaine
- Glucose, 50% [10 or 25%]
- Diphenhydramine
- Hydrocortisone, methylprednisolone, or dexamethasone
- Diazepam or midazolam

Use of Supplemental Oxygen

The literature supports the use of supplemental oxygen during moderate sedation and suggests that supplemental oxygen be used during deep sedation to reduce the frequency of hypoxemia. The consultants agree that supplemental oxygen decreases patient risk during moderate sedation, while strongly agreeing with this view for deep sedation.

Recommendations. Equipment to administer supplemental oxygen should be present when sedation/analgesia is administered. Supplemental oxygen should be considered for moderate sedation and should be administered during deep sedation unless specifically contraindicated for a particular patient or procedure. If hypoxemia is anticipated or develops during sedation/analgesia, supplemental oxygen should be administered.

Combinations of Sedative–Analgesic Agents

The literature suggests that combining a sedative with an opioid provides effective moderate sedation; it is equivocal regarding whether the combination of a sedative and an opioid may be more effective than a sedative or an opioid alone in providing adequate moderate sedation. For deep sedation, the literature is insufficient to compare the efficacy of sedative–opioid combinations with that of a sedative alone. The consultants agree that combinations of sedatives and opioids provide satisfactory moderate and deep sedation. However, the published data also suggest that combinations of sedatives and opioids may increase the likelihood of adverse outcomes, including ventilatory depression and hypoxemia; the consultants were equivocal on this issue for both moderate and deep sedation. 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 while reducing the associated risks.

Recommendations. Combinations of sedative and analgesic agents may 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 cause respiratory depression and airway obstruction emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function.

Titration of Intravenous Sedative–Analgesic Medications

The literature is insufficient to determine whether administration of small, incremental doses of intravenous sedative/analgesic drugs until the desired level of sedation or analgesia is achieved is preferable to a single dose based on patient size, weight, or age. The consultants strongly agree that incremental drug administration improves patient comfort and decreases risks for both moderate and deep sedation.

Recommendations. Intravenous sedative/analgesic drugs should be given in small, incremental doses that are titrated to the desired end points 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, transmucosal), allowance should be made for the time required for drug absorption before supplementation is considered. Because absorption may be unpredictable, administration of repeat doses of oral medications to supplement sedation/analgesia is not recommended.

Anesthetic Induction Agents Used for Sedation/Analgesia (Propofol, Methohexital, Ketamine)

The literature suggests that, when administered by non-anesthesiologists, propofol and ketamine can provide satisfactory moderate sedation, and suggests that methohexital can provide satisfactory deep sedation. The literature is insufficient to evaluate the efficacy of propofol or ketamine administered by non-anesthesiologists for deep sedation. There is insufficient literature to determine whether moderate or deep sedation with propofol is associated with a different incidence of adverse outcomes than similar levels of sedation with midazolam. The consultants are equivocal regarding whether use of these medications affects the likelihood of producing satisfactory moderate sedation, while agreeing that using them increases the likelihood of satisfactory deep sedation. However, the consultants agree that avoiding these medications decreases the likelihood of adverse outcomes during moderate sedation and are equivocal regarding their effect on adverse outcomes during deep sedation.

The Task Force cautions practitioners that methohexital and propofol can produce rapid, profound decreases in level of consciousness and cardiorespiratory function, potentially culminating in a state of general anesthesia. The Task Force notes that ketamine also produces dose-related decreases in level of consciousness, culminating in general anesthesia. Although it may be associated with less cardiorespiratory depression than other sedatives, airway obstruction, laryngospasm, and pulmonary aspiration may still occur with ketamine. Furthermore, because of its dissociative properties, some of the usual signs of depth of sedation may not apply (*e.g.*, the patient's eyes may be open while in a state of deep sedation or general anesthesia). The Task Force also notes that there are no specific pharmacologic antagonists for any of these medications.

Recommendations. Even if moderate sedation is intended, patients receiving propofol or methohexital by any route should receive care consistent with that required for deep sedation. Accordingly, practitioners administering these drugs should be qualified to rescue patients from any level of sedation, including general anesthesia. Patients receiving ketamine should be cared for in a manner consistent with the level of sedation that is achieved.

Intravenous Access

Published literature is equivocal regarding the relative efficacy of sedative–analgesic agents administered intravenously as compared with those administered by nonintravenous routes to achieve moderate sedation; the literature is insufficient on this issue for deep sedation. The literature is equivocal regarding the comparative safety of these routes of administration for moderate sedation and is insufficient for deep sedation. The consultants strongly agree that intravenous administration of sedative and analgesic medications increases the likelihood of satisfactory sedation for both moderate and deep sedation. They also agree that it decreases the likelihood of adverse outcomes. For both moderate and deep sedation, when sedative–analgesic medications are administered intravenously, the consultants strongly agree with maintaining intravenous access until patients are no longer at risk for cardiovascular or respiratory depression, because it increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes. In situations where sedation is initiated 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.

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 respiratory depression. Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema. The literature supports the ability of flumazenil to antagonize benzodiazepine-induced sedation and ventilatory depression in patients who have received benzodiazepines alone or in combination with an opioid. The consultants strongly agree that the immediate availability of reversal agents during both moderate and deep sedation is associated with decreased risk of adverse outcomes. 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. The consultants disagree that the use of sedation regimens that are likely to require routine reversal with flumazenil or naloxone improves the quality of sedation or reduces the risk of adverse outcomes.

Recommendations. Specific antagonists should be available whenever opioid analgesics or benzodiazepines are administered for sedation/analgesia. Naloxone or flumazenil may be administered to improve spontaneous ventilatory efforts in patients who have received opioids or benzodiazepines, respectively. This may be especially helpful in cases where 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 supplemental oxygen; and (3) receive positive pressure ventilation if spontaneous ventilation is inadequate. After pharmacologic reversal, patients should be observed long enough to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates. The use of sedation regimens that include routine reversal of sedative or analgesic agents is discouraged.

Recovery Care

Patients may continue to be at significant risk for developing complications after their procedure is completed. Decreased procedural stimulation, delayed drug absorption following nonintravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period. Examples include intramuscular meperidine–promethazine–chlorpromazine mixtures and oral or rectal chloral hydrate. When sedation–analgesia is administered to outpatients, it is likely that there will be no medical supervision once the patient leaves the medical facility. Although there is not sufficient literature to examine the effects of postprocedure monitoring on patient outcomes, the consultants strongly agree that continued observation, monitoring, and predetermined discharge criteria decrease the likelihood of adverse outcomes for both moderate and deep sedation. It is the consensus of the Task Force that discharge criteria should be designed to minimize the risk for cardiorespiratory depression after patients are released from observation by trained personnel.

Recommendations. Following sedation/analgesia, patients should be observed in an appropriately staffed

Example IV. 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 below.

General principles

1. Medical supervision of recovery and discharge after moderate or deep sedation is the responsibility of the operating practitioner or a licensed physician.
2. The recovery area should be equipped with, or have direct access to, appropriate monitoring and resuscitation equipment.
3. Patients receiving moderate or deep sedation should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending on the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.
4. Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals.
5. A nurse or other individual trained to monitor patients and recognize complications should be in attendance until discharge criteria are fulfilled.
6. An individual capable of managing complications (*e.g.*, establishing a patent airway and providing positive pressure ventilation) should be immediately available until discharge criteria are fulfilled.

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 status. Practitioners and parents 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. Use of scoring systems may assist in documentation of fitness for discharge.
4. 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 worn off.
5. Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any postprocedure complications.
6. Outpatients and their escorts should be provided with written instructions regarding postprocedure diet, medications, activities, and a phone number to be called in case of emergency.

and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression. Oxygenation should be monitored periodically until patients are no longer at risk for hypoxemia. Ventilation and circulation 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 (Example IV).

Special Situations

The literature suggests and the Task Force members concur that certain types of patients are at increased risk for developing complications related to sedation/analgesia unless special precautions are taken. In patients with significant underlying medical conditions (*e.g.*, extremes of age; severe cardiac, pulmonary, hepatic, or renal disease; pregnancy; drug or alcohol abuse) the consultants agree that preprocedure consultation with an appropriate medical specialist (*e.g.*, cardiologist, pulmonologist) decreases the risks associated with moderate sedation and strongly agree that it decreases the risks associated with deep sedation. In patients with significant sedation-related risk factors (*e.g.*, uncooperative patients, morbid obesity, potentially difficult airway, sleep apnea), the consultants are equivocal regarding whether preprocedure consultation with an anesthesiologist increases the likelihood of satisfactory moderate sedation, while agreeing that it decreases adverse outcomes. The consultants strongly agree that preprocedure consultation increases the likelihood of satisfactory outcomes while decreasing risks associated with deep sedation. The Task Force notes that in emergency situations, the benefits of awaiting preprocedure consultations must be weighed against the risk of delaying the procedure.

For moderate sedation, the consultants are equivocal regarding whether the immediate availability of an individual with postgraduate training in anesthesiology increases the likelihood of a satisfactory outcome or decreases the associated risks. For deep sedation, the consultants agree that the immediate availability of such an individual improves the likelihood of satisfactory sedation and that it will decrease the likelihood of adverse outcomes.

Recommendations. Whenever possible, appropriate medical specialists should be consulted before administration of sedation 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 severely compromised or medically unstable patients (*e.g.*, anticipated difficult airway, severe obstructive pulmonary disease, coronary artery disease, or congestive heart failure), or if it is likely that sedation to the point of unresponsiveness will be necessary to obtain adequate conditions, practitioners who are not trained in the administration of general anesthesia should consult an anesthesiologist.

†Readers with special interest in the statistical analysis used in establishing these Guidelines can receive further information by writing to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

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2. Practice Guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: A report by the American Society of Anesthesiologist Task Force on Preoperative Fasting. ANESTHESIOLOGY 1999; 90:896–905

Appendix I: Methods and Analyses†

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

1. A preprocedure patient evaluation, (i.e., history, physical examination, laboratory evaluation, consultation)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
2. Preprocedure preparation of the patient (*e.g.*, counseling, fasting)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
3. Patient monitoring (*i.e.*, level of consciousness, pulmonary ventilation [observation, auscultation], oxygenation [pulse oximetry], automated apnea monitoring [capnography], hemodynamics [electrocardiogram, blood pressure, heart rate])
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
4. Contemporaneous recording of monitored parameters (*e.g.*, level of consciousness, respiratory function, hemodynamics) at regular intervals in patients receiving sedation or analgesia
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
5. Availability of an individual who is dedicated solely to patient monitoring and safety
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

6a. Education and training of sedation and analgesia providers in the pharmacology of sedation–analgesia agents
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

6b. The presence of an individual(s) capable of establishing a patent airway, positive pressure ventilation, and resuscitation (*i.e.*, advanced life-support skills) during a procedure
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

7. Availability of appropriately sized emergency and airway equipment (*e.g.*, laryngeal mask airway, defibrillators)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)

b. Reduces adverse outcomes

8. The use of supplemental oxygen during procedures performed with sedation or analgesia
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
9. Use of sedative agents combined with analgesic agents (*e.g.*, sedative–analgesic cocktails, fixed combinations of sedatives and analgesics, titrated combinations of sedatives and analgesics)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
10. Titration of intravenous sedative–analgesic medications to achieve the desired effect
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
11. Intravenous sedation–analgesic medications specifically designed to be used for general anesthesia (*i.e.*, methohexital, propofol, and ketamine)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

12a. Administration of sedative–analgesic agents by the intravenous route
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

12b. Maintaining or establishing intravenous access during sedation or analgesia until the patient is no longer at risk for cardiorespiratory depression
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

13. Availability of reversal agents (naloxone and flumazenil only) for the sedative or analgesic agents being administered
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
14. Postprocedural recovery observation, monitoring, and predetermined discharge criteria reduce adverse outcomes.
15. Special regimens (*e.g.*, preprocedure consultation, specialized monitoring, special sedatives–techniques) 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)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

Scientific evidence was derived from aggregated research literature and from 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 36-yr period from 1966 through 2001. The manual search covered a 44-yr period from 1958 through 2001. More than 3,000 citations were initially identified, yielding a total of 1,876 nonoverlapping articles that addressed topics related to the 15 evidence linkages. After review of the articles, 1,519 studies did not provide direct evidence and were subsequently eliminated. A total of 357 articles contained direct linkage-related evidence.

A directional result for each study was initially determined by a literature count, classifying each outcome as either supporting a linkage, refuting a linkage, or neutral. The results were then summarized to obtain a directional assessment of support for each linkage. Literature pertaining to three evidence linkages contained enough studies with well-defined experimental designs and statistical information to conduct formal metaanalyses. These three linkages were: linkage 8 [supplemental oxygen], linkage 9 [benzodiazepines combined with opioids *vs.* benzodiazepines alone], and linkage 13 [naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine-opioid combinations].

Combined probability tests were applied to 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 weighted representation of the studies by weighting each of the standard normal deviates by the size of the sample. An odds-ratio procedure based on the Mantel–Haenszel method for combining study results using 2×2 tables was used with outcome frequency information. An acceptable significance level was set at $P < 0.01$ (one-tailed), and effect size estimates were calculated. Tests for heterogeneity of the independent studies were conducted to assure consistency among the study results. Der Simonian-Laird random-effects odds ratios were calculated when significant heterogeniety was found. To assess potential publishing bias, a "fail-safe 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 performed.

Metaanalytic results are reported in table 2. The following outcomes were found to be significant for combined probability tests: (1) *oxygen saturation*, linkage 8 (supplemental oxygen); (2) *sedation recovery*, linkage 13 (naloxone for antagonism of opioids and flumazenil for antagonism of benzodiazepine–opioid combinations); (3) *psychomotor recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (4) *respiratory–ventilatory recovery*, linkage 13 (naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine–opioid combinations). To be considered acceptable findings of significance, both the Fisher and weighted Stouffer combined test results must agree. Weighted effect size values for these linkages ranged from $r = 0.19$ to 0.80, representing moderate to high effect size estimates.

Mantel–Haenszel odds ratios were significant for the following outcomes: (1) *hypoxemia*, linkage 8 (supplemental oxygen) and linkage 9 (benzodiazepine–opioid combinations *vs.* benzodiazepines alone); (2) *sedation recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (3) *recall of procedure*, linkage 9 (benzodiazepine–opioid combinations). To be considered acceptable findings of significance, Mantel–Haenszel odds ratios must agree with combined test results when both types of data are assessed.

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a Kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.25$–0.64; (2) type of analysis, $\kappa = 0.36$–0.83; (3) evidence linkage assignment, $\kappa = 0.78$–0.89; and (4) literature inclusion for database, $\kappa = 0.71$–1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.45, Var (Sav) = 0.012; (2) type of analysis, Sav = 0.51, Var (Sav) = 0.015; (3) linkage assignment, Sav = 0.81 Var (Sav) = 0.006; (4) literature database inclusion, Sav = 0.84 Var (Sav) = 0.046. These values represent moderate to high levels of agreement.

The findings of the literature analyses were supplemented by the opinions of Task Force members as well as by surveys of the opinions of a panel of consultants drawn from the following specialties where sedation and analgesia are commonly administered: Anesthesiology, 8; Cardiology, 2; Dental Anesthesiology, 3; Dermatology, 2; Emergency Medicine, 5; Gastroenterology, 9; Intensive Care, 1; Oral and Maxillofacial Surgery, 5; Pediatrics, 1; Pediatric Dentistry, 3; Pharmacology, 1; Pulmonary Medicine, 3; Radiology, 3; Surgery, 3; and Urology, 2. The rate of return for this Consultant survey was 78% (n = 51/65). Median agreement scores from the Consultants regarding each linkage are reported in table 3.

Table 2. Meta-analysis Summary

Linkages	No. Studies	Fisher Chi-square	*P*	Weighted Stouffer Zc	*P*	Effect Size	Mantel-Haenszel Chi-square	*P*	Odds Ratio	Heterogeneity Significance	Heterogeneity Effect Size
Supplemental oxygen											
Oxygen saturation*	5	71.40	<0.001	5.44	<0.001	0.40	—	—	—	>0.90 (NS)	>0.50 (NS)
Hypoxemia*	7	—	—	—	—	—	44.15	<0.001	0.20	—	>0.50 (NS)
Sedatives/Opioids combined:											
Benzodiazepines + opioids											
Sedation efficacy	7	—	—	—	—	—	3.79	>0.05 (NS)	1.87§	—	<0.01
Recall of procedure	6	—	—	—	—	—	18.47	<0.001	2.18§	—	<0.01
Hypoxemia	5	—	—	—	—	—	11.78	<0.001	2.37	—	>0.05 (NS)
Naloxone for opioids											
Sedation recovery at 5 min*,†,‡	5	38.36	<0.001	3.13	<0.001	0.23	—	—	—	>0.30 (NS)	>0.02 (NS)
Respiration/ventilation*,†,‡	5	38.72	<0.001	3.97	<0.001	0.33	—	—	—	>0.10 (NS)	<0.001
Flumazenil for benzodiazepines											
Sedation recovery at 5 min	6	—	—	—	—	—	104.76	<0.001	8.15	—	>0.10 (NS)
Psychomotor recovery											
at 15 min	5	41.80	<0.001	1.69	0.046 (NS)	0.20	—	—	—	>0.70 (NS)	>0.50 (NS)
at 30 min	5	43.02	<0.001	3.36	<0.001	0.19	—	—	—	>0.90 (NS)	>0.50 (NS)
Respiration/ventilation†,‡	6	53.25	<0.001	5.03	<0.001	0.80	—	—	—	<0.01	<0.001
Flumazenil for benzodiazepine-opioid combinations											
Sedation recovery at 5 min	5	72.12	<0.001	6.76	<0.001	0.37	—	—	—	<0.001	<0.001
Respiration/ventilation†,‡	6	55.06	<0.001	5.11	<0.001	0.25	—	—	—	>0.10 (NS)	<0.001
Nausea/vomiting	5	—	—	—	—	—	0.28	>0.80 (NS)	1.22	—	>0.70 (NS)

* Nonrandomized comparative studies are included; † Studies in which anesthesiologist administered benzodiazepines, opioids, or reversal agents are included; ‡ Studies in which subjects consist of intensive care unit patients, postoperative patients, or volunteers with no procedures are included.

§ Der Simonian-Laird random-effects odds ratio.

For moderate sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 3 (electrocardiogram monitoring and capnography), linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives for improving satisfactory sedation), linkage 13b (routine administration of naloxone), linkage 13c (routine administration of flumazenil), and linkage 15b (anesthesiologist consultation for patients with medical conditions to provide satisfactory moderate sedation). In addition, Consultants were equivocal regarding whether postgraduate training in anesthesiology improves moderate sedation or reduces adverse outcomes.

For deep sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives), linkage 13b (routine administration of naloxone), and linkage 13c (routine administration of flumazenil).

The Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the updated Guidelines were instituted. The rate of return was 57% (n = 37/65). The percent of responding Consultants expecting no change associated with each linkage were as follows: preprocedure patient evaluation, 94%; preprocedure patient preparation, 91%; patient monitoring, 80%; contemporaneous recording of monitored parameters, 91%; availability of individual dedicated solely to patient monitoring and safety, 91%; education and training of sedation–analgesia providers in pharmacology, 89%; presence of an individual(s) capable of establishing a patent airway, 91%; availability of appropriately sized emergency and airway equipment, 94%; use of supplemental oxygen during procedures, 100%; use of sedative agents combined with analgesic agents, 91%; titration of sedatives–analgesics, 97%; intravenous sedation–analgesia with agents designed for general anesthesia, 77%; administration of sedative–analgesic agents by the intravenous route, 94%; maintaining or establishing intravenous access, 97%; availability–use of flumazenil, 94%; availability–use of naloxone, 94%; observation and monitoring during recovery, 89%; special care for patients with underlying medical problems, 91%; and special care for uncooperative patients, 94%. Seventy-four percent of the respondents indicated that the Guidelines would have no effect on the amount of time spent on a typical case. Nine respondents (26%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of these Guidelines. The amount of increased time anticipated by these respondents ranged from 1 to 60 min.

Table 3. Consultant Survey Summary

Intervention or Linkage	Outcome	Moderate Sedation N	Moderate Sedation Median* or Percent	Deep Sedation N	Deep Sedation Median* or Percent
1. Preprocedure patient evaluation	Satisfactory sedation	51	5	51	5
	Adverse outcomes	51	5	51	5
2. Preprocedure fasting	Satisfactory sedation	51	4	51	5
	Adverse outcomes	51	4	51	5
3. Monitoring					
a. Level of consciousness	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
b. Breathing (observation/auscultation)	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
c. Pulse oximetry	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
d. Blood pressure/heart rate	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
e. Electrocardiogram	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	49	5
f. Capnography	Satisfactory sedation	50	3	48	4
	Adverse outcomes	50	3	49	4
4. Contemporaneous recording	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
5. Individual for patient monitoring	Satisfactory sedation	49	4	48	5
	Adverse outcomes	49	4	48	5
6a. Education and training	Satisfactory sedation	50	5	49	5
	Adverse outcomes	50	5	49	5
6b. Individual with basic life support skills present in room		50	5	49	5
6c. Availability of advanced life support skills					
In the procedure room		2	4.2%	39	79.6%
Immediate vicinity (1–5 min)		27	56.2%	8	16.3%
Same building (5–10 min)		14	29.2%	2	4.1%
Outside provider		5	10.4%	0	0.0%
7. Emergency intravenous and airway equipment	Adverse outcomes	51	5	49	5
8. Supplemental oxygen	Adverse outcomes	50	4	49	5
9. Sedatives combined with analgesics	Satisfactory sedation	50	4	49	4
	Adverse outcomes	50	3	49	3
10. Titration	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
11. Avoiding general anesthetic sedatives	Satisfactory sedation	50	3	49	2
	Adverse outcomes	50	4	49	3
12a. Intravenous sedatives	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	4	50	4
12b. Intravenous access	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
13a. Immediate availability of naloxone or flumazenil	Adverse outcomes	51	5	51	5
13b. Routine administration of naloxone	Satisfactory sedation	37	2	37	2
	Adverse outcomes	37	2	37	2
13c. Routine administration of flumazenil	Satisfactory sedation	37	1	37	2
	Adverse outcomes	37	2	37	2
14. Observation, monitoring, and discharge criteria	Adverse outcomes	50	5	49	5
15a. Medical specialist consultation, patients with underlying medical conditions	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	4	49	5
15b. Anesthesiologist consultation, patients with underlying medical conditions	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	4	50	5
15c. Anesthesiologist consultation, patients with significant sedation risk factors	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
16. Postgraduate training in anesthesiology	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	50	4
17. In emergency situations, sedate patients less deeply		51	4	51	5

* Strongly agree: Median score of 5; Agree: Median score of 4; Equivocal: Median score of 3; Disagree: Median score of 2; Strongly disagree: Median score of 1.

Appendix II: Summary of Guidelines‡

Except as noted, recommendations apply to both moderate and deep sedation.

1. Preprocedure evaluation
   - Relevant history (major organ systems, sedation–anesthesia history, medications, allergies, last oral intake)
   - Focused physical examination (to include heart, lungs, airway)
   - Laboratory testing guided by underlying conditions and possible effect on patient management
   - Findings confirmed immediately before sedation
2. Patient counseling
   - Risks, benefits, limitations, and alternatives
3. Preprocedure fasting
   - Elective procedures—sufficient time for gastric emptying
   - Urgent or emergent situations—potential for pulmonary aspiration considered in determining target level of sedation, delay of procedure, protection of trachea by intubation
   - See ASA Guidelines for Preoperative Fasting[2]
4. 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)
   - Exhaled carbon dioxide monitoring considered when patients separated from caregiver
   - Blood pressure and heart rate at 5-min intervals unless contraindicated
   - Electrocardiograph for patients with significant cardiovascular disease

   For deep sedation:
   - Response to verbal commands or more profound stimuli unless contraindicated
   - Exhaled CO_2 monitoring considered for all patients
   - Electrocardiograph for all patients
5. Personnel
   - Designated individual, other than the practitioner performing the procedure, present to monitor the patient throughout the procedure
   - This individual may assist with minor interruptible tasks once patient is stable

   For deep sedation:
   - The monitoring individual may not assist with other tasks
6. Training
   - Pharmacology of sedative and analgesic agents
   - Pharmacology of available antagonists
   - Basic life support skills—present
   - Advanced life support skills—within 5 min

   For deep sedation:
   - Advanced life support skills in the procedure room
7. Emergency Equipment
   - Suction, appropriately sized airway equipment, means of positive-pressure ventilation
   - Intravenous equipment, pharmacologic antagonists, and basic resuscitative medications
   - Defibrillator immediately available for patients with cardiovascular disease

   For deep sedation:
   - Defibrillator immediately available for all patients
8. Supplemental Oxygen
   - Oxygen delivery equipment available
   - Oxygen administered if hypoxemia occurs

   For deep sedation:
   - Oxygen administered to all patients unless contraindicated
9. Choice of Agents
   - Sedatives to decrease anxiety, promote somnolence
   - Analgesics to relieve pain
10. Dose Titration
    - Medications given incrementally with sufficient time between doses to assess effects
    - Appropriate dose reduction if both sedatives and analgesics used
    - Repeat doses of oral medications not recommended
11. Use of anesthetic induction agents (methohexital, propofol)
    - Regardless of route of administration and intended level of sedation, patients should receive care consistent with deep sedation, including ability to rescue from unintended general anesthesia
12. Intravenous Access
    - Sedatives administered intravenously—maintain intravenous access
    - Sedatives administered by other routes—case-by-case decision
    - Individual with intravenous skills immediately available
13. Reversal Agents
    - Naloxone and flumazenil available whenever opioids or benzodiazepines administered
14. Recovery
    - Observation until patients no longer at risk for cardiorespiratory depression
    - Appropriate discharge criteria to minimize risk of respiratory or cardiovascular depression after discharge
15. Special Situations
    - Severe underlying medical problems—consult with appropriate specialist if possible
    - Risk of severe cardiovascular or respiratory compromise or need for complete unresponsiveness 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.

ASA Classification

- **ASA I. A healthy patient**
- **ASA II. A patient with mild systemic disease**
- **ASA III. A patient with severe systemic disease that limits activity, but is not incapacitating**
- **ASA IV. A patient with an incapacitating systemic disease that is a constant threat to life**
- **ASA V. A moribund patient not expected to survive 24 hours with or without operation**

Mortality risk associated with anesthesia:

ASA I: 0.08%
ASA II: 0.27%
ASA III: 1.8%
ASA IV: 7.8%
ASA V: 9.4%

CANDIDATES FOR CONSCIOUS SEDATION

- Those who are considered ASA I or ASA II
- Those who are ASA III or ASA IV may be considered for such procedures as cardiac catheterization, cataract surgery, or pacemaker insertion. Such high risk patients must be adequately prepared preoperatively and cared for in areas of the facility where the personnel are both experienced and capable (ICU, Cath Lab, OR, ED, etc.)
- Additional consideration should be given to those patients over 65 years of age. The bioavailability of drugs, particularly benzodiazepines, changes dramatically with age.

AIRWAY ASSESSMENT

Basic Assessment:

1. Mallampati Classification
2. Thyromental Distance
3. Mouth Opening
4. Neck Range of Motion
5. Dentition

Anatomic Characteristics Associated with Difficult Airway

1. Short, Muscular Neck
2. Receding Mandible
3. Protruding Maxillary incisors
4. Inability to visualize uvula
5. Limited temporomandibular joint mobility
6. Limited cervical spine mobility

RECOMMENDED PREOPERATIVE LABORATORY TESTING

Preoperative Condition	WBC	Hgb		PT/ PTT	Plt/ BT	Lytes	Creat/ BUN	Glucose or Hgb A_{1c}	AST/ Alk Phos	CXR	EKG	HCG	Albumin	T/S
		M	F											
Neonates		X	X											
Age ≥ 40											X			
Age ≥ 65		X	X			X	X	X		X	X			
Type C Procedure		X	X				X	X			X		X	X
Cardiovascular Disease							X			X	X			
Pulmonary Disease										X	X			
Malignancy	*	X	X	*										
Radiation Therapy	X									X	X			
Hepatic Disease				X					X					
Exposure to Hepatitis									X					
Renal Disease		X	X			X	X							
Bleeding Disorder				X	X									X
Diabetes						X	X	X			X			
Smoking ≥ 20 pack-years		X	X							X				
Fertile Females		X	X									X		
Diuretic Use						X	X							
Digoxin Use						X	X				X			
Steroid Use						X		X						
Anticoagulant Use		X	X	X										
CNS Disease	X					X	X	X			X			

Notes: * - order for leukemia only; Drug Levels should be ordered for medications such as Theophylline, Digoxin, and Dilantin
Type C Procedure – major blood loss or significant hemodynamic changes possible (i.e. – total joint arthroplasty, hysterectomy, bowel resection, lung resection)

CONSCIOUS SEDATION

BY
Major Harry Ervin
Staff Anesthesiologist, USAFA

HISTORY

- The term *conscious sedation* was first described by Dr. C. R. Bennett in 1978.
- In a paper entitled "Conscious Sedation in Dental Practice," he presented information related to the administration of intravenous sedative medications in conjunction with local anesthetics.

DEFINITIONS

- Conscious sedation is defined as the administration of pharmacological agents to produce a medically controlled state of depressed consciousness that:
  - allows protective reflexes to be maintained;
  - retains the patient's ability to maintain a patent airway independently and continuously;
  - permits appropriate responses by the patient

GOALS OF CONSCIOUS SEDATION

- To facilitate performance of a procedure
- Control behavior, including anxiety
- Relief from pain and other noxious stimuli
- Return the patient to a state in which safe discharge is possible

BACKGROUND

- Numerous medical services will utilize some form of conscious sedation, either parenteral or oral, for many diverse procedures or patient manipulations.

CANDIDATES FOR CONSCIOUS SEDATION

- Those who are considered ASA I* or ASA II
- Those who are ASA III or ASA IV may be considered for such procedures as cardiac catheterization, cataract surgery, or pacemaker insertion. Such high risk patients must be adequately cared for in areas of the facility where the personnel are both experienced and capable (ICU, Cath Lab, OR, ED, etc.)
- Additional consideration should be given to those patients over 65 years of age. The bioavailability of drugs, particularly benzodiazepines, changes dramatically with age

* American Society of Anesthesiologists Classification System

REVIEW OF ASA CLASSIFICATION

- *ASA I.* A healthy patient
- *ASA II.* A patient with mild systemic disease
- *ASA III.* A patient with severe systemic disease that limits activity but is not incapacitating
- *ASA IV.* A patient with an incapacitating systemic disease that is a constant threat to life
- *ASA V.* A moribund patient not expected to survive 24 hours with or without operation

ASA CLASS: *Why do we care?*

Physical Status	Anesthetics	Deaths	Mortality (%)	Increased Mortality
I	50,703	43	0.08	N/A
II	12,601	34	0.27	3.4
III	3,626	66	1.8	22
IV	850	66	7.8	97.5
V	608	57	9.4	117.5

FACILITIES AND EQUIPMENT

- Any area in which conscious sedation is performed should have the following equipment present and ready for use:
  - oxygen
  - suction apparatus
  - oxygen delivery devices
  - noninvasive blood pressure device
  - electrocardiograph
  - pulse oximeter

CONSCIOUS SEDATION PERSONNEL

- The physician/dentist responsible for administering the drugs and treating the patient must remain immediately available until the patient is stable/alert.
- At least one other individual (MD, dentist, RN) trained to monitor the appropriate parameters should be present to assist the responsible person with the procedure or management of any problems that may arise.

DOCUMENTATION: PRE-PROCEDURAL

- Patient consent to the procedure. In the case of a child, consent should be obtained from the parent or legal guardian. Similar issues are pertinent when dealing with an incompetent patient.
- Compliance with NPO guidelines which are consistent with accepted norms for general anesthesia (6-8 hours for solids, 2-3 hours for clear liquids).
- A medical history
- The general health of the patient as noted from a prior physical examination.

PRE-PROCEDURAL ASSESSMENT

- Accomplished in two phases
- The physician who plans conscious sedation for a patient has a medicolegal responsibility to perform the following:
  - history and physical exam
  - patient counseling and consent
  - ensure that patient is properly prepared for procedure
  - confirm that no contraindications to sedation exist
  - obtain baseline vital signs

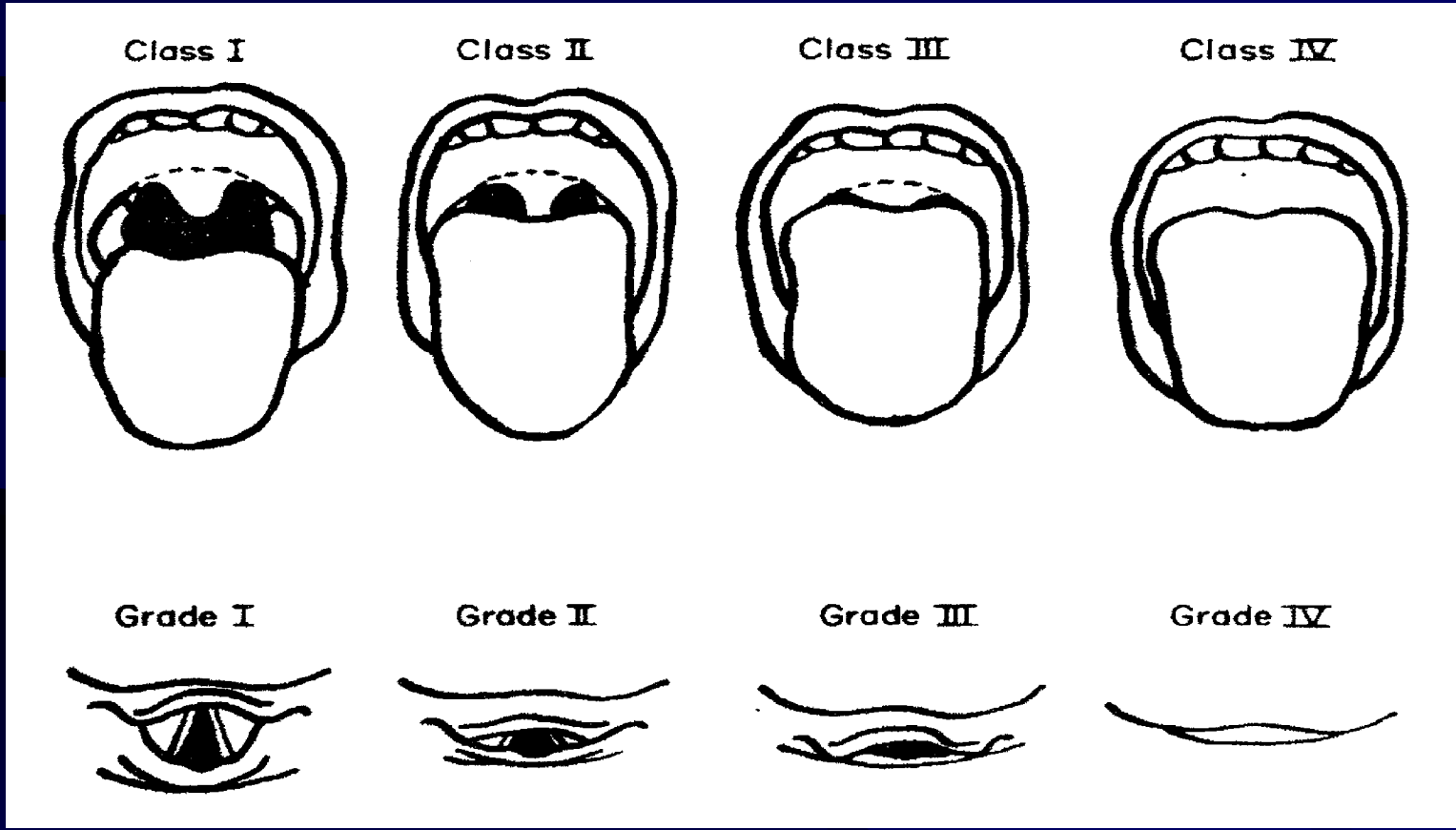
HISTORY

- A thorough history and review of systems is essential to proper patient care.
- Additional issues that warrant attention when preparing a patient for conscious sedation include the following:
  - allergies and drug reactions
  - anesthetic history
  - family history of adverse anesthetic outcomes
  - identify patients who have a history of recent respiratory infection, hypertension, angina, gastroesophageal reflux or are of childbearing age

PHYSICAL EXAMINATION

- As a minimum, the physical exam should consist of the following:
  - Vital signs (including height and weight to allow for estimation of appropriate drug dosages)
  - HEENT (including airway assessment)
  - Cardiopulmonary
  - Abdomen
  - Extremities
  - Neurologic

AIRWAY ASSESSMENT: MALLAMPATI CLASSIFICATION



ANATOMIC CHARACTERISTICS ASSOCIATED WITH DIFFICULT AIRWAY

- Short, muscular neck
- Receding mandible
- Protruding maxillary incisors
- Inability to visualize uvula
- Limited temporomandibular joint mobility
- Limited cervical spine mobility

EPIDEMIOLOGY OF DIFFICULT AIRWAY

- Intubation requiring multiple attempts and/or blades; probable grade II or III ~ 1-18%
- Intubation requiring multiple attempts and/or blades and/or laryngoscopists; grade III ~ 1-4%
- Intubation unsuccessful; grade III or IV ~ 0.05-0.35%
- Cannot ventilate by mask, cannot intubate; transtracheal jet ventilation, tracheostomy, brain damage, or death ~ 0.01-2.0 per 10,000

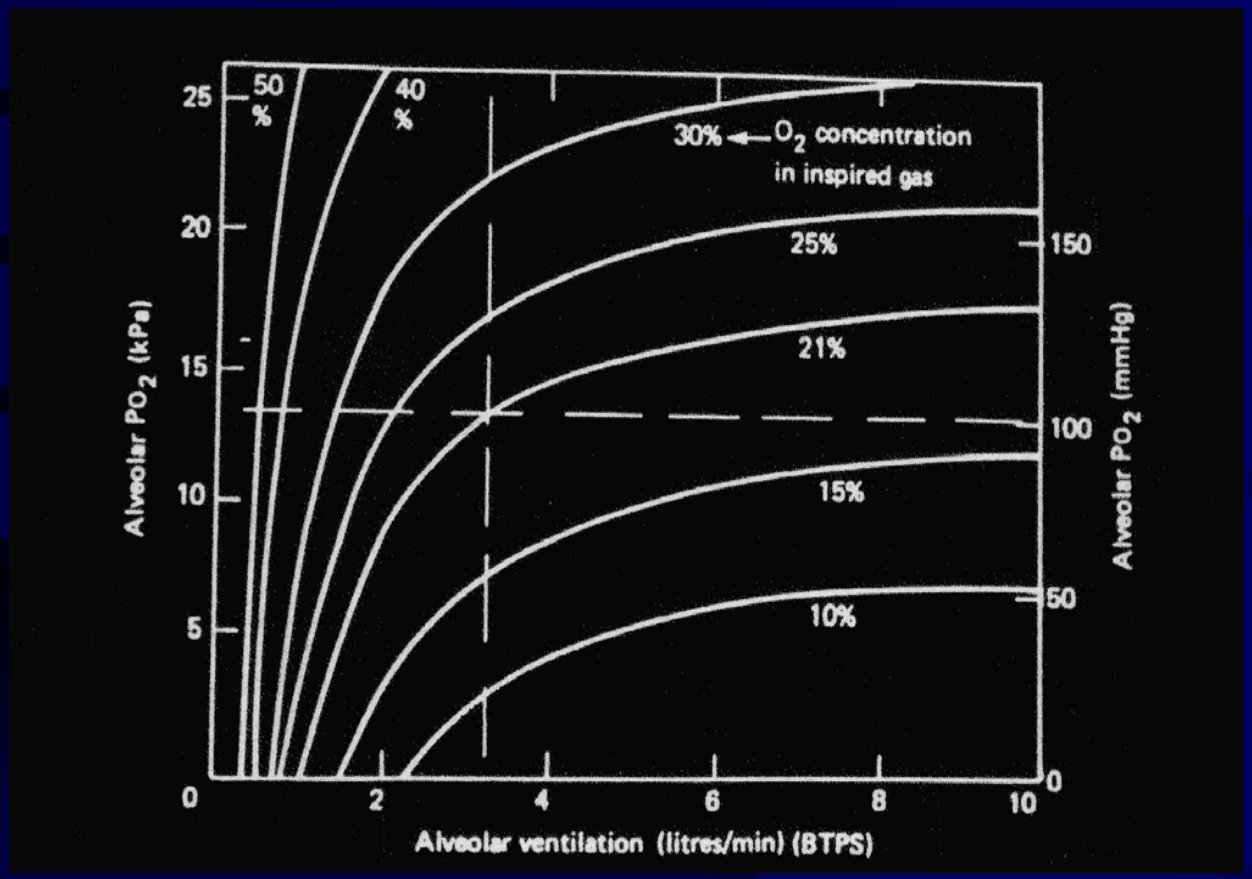
PROCEDURAL ASSESSMENT

- Continuous monitoring of appropriate parameters including respiratory rate, oxygen saturation, blood pressure, cardiac rate and rhythm, level of consciousness
- Documentation of vital signs by appropriate frequency during procedure.
- Complete documentation of the procedure, medications and their effect and any untoward incidence is mandatory

PRECAUTIONARY MEASURES

- Use of supplemental oxygen by nasal cannula
- Use of pulse oximetry. The alarms should be set very close to the room air saturation of the individual patient
- Constant one-on-one supervision, especially in the patient with multiple medical problems
- Appropriate airway and resuscitation equipment should be immediately accessible

RESPONSE OF ALVEOLAR OXYGEN TENSION TO SUPPLEMENTAL OXYGEN



POST-PROCEDURAL OBSERVATION

- Following conscious sedation, the patient:
  - should be observed where the level of consciousness (LOC), saturation, pulse rate, blood pressure and gait can be monitored
  - should only be discharged once the discharge criteria is met. This includes return to pre-procedural LOC, vital signs and gait
  - If there is concern about a patient following 30 minutes of observation and assessment, the observation period should be extended until appropriate criteria are met
  - patient discharge is accomplished by a physician

DISCHARGE

- Discharge instructions should be similar to that required for the Same Day Surgery Program. This includes the following precautions because the effects of the medications can last up to 24 hours.
  - Strongly recommend to the patient that an escort take the patient home either by car or taxi.
  - Strongly recommend to the patient that an escort stay with the patient overnight the day of surgery

ADDITIONAL AGE-SPECIFIC INSTRUCTIONS

- Adult patients are instructed not to:
  - drive a car, operate machinery, or power tools
  - drink alcoholic beverages
  - make important decisions or sign legal documents
- Guardians of pediatric patients are instructed:
  - patient avoidance of activities that may endanger the child if loss of balance is possible (e.g. bike riding, climbing stairs, playing on swings, etc.)

PHARMACOLOGY

- Benzodiazepines
- Opiates
- Flumazenil
- Naloxone

BENZODIAZEPINES

- Receptors are located on the alpha subunit of GABA receptors.
- BNZ enhance the chloride-gating function of GABA resulting in hyperpolarization of cell membranes, making them more resistant to excitation.
- The anatomic distribution of GABA receptors (almost exclusively CNS) is consistent with the minimal effects on other organ systems (e.g. cardiovascular).
- Minimal depression of ventilation or cardiovascular system at appropriate doses.

BENZODIAZEPINES

- **Diazepam** is the standard with which all BNZ are compared.
  - Highly lipid soluble, high protein binding
  - Metabolized in liver, active metabolites (desmethyldiazepam) contribute to prolonged sedation in elderly or those with hepatic impairment (*$t_{1/2}$ ~ 20-30 hours*)
  - Onset < 2 min (IV), dose: 0.1-0.2 mg/kg IV/PO/PR for sedation
  - Induction of general anesthesia: 0.3-0.5 mg/kg IV (to be considered ceiling dose, will be lower if used in combination with other CNS depressants)

BENZODIAZEPINES

- **Midazolam** is approximately 2-3 times as potent as diazepam.
  - Imidazole structure which leads to hydrophilic properties in bottle, but exposure to blood pH make it lipophilic ~ less venous irritation
  - Hydroxylation in liver, metabolites are excreted in urine; elimination half-life (1-4 hrs) not altered significantly by renal failure
  - Onset 30-60 sec (IV), Dose: 0.025-0.1 mg/kg IV (titrated) for sedation
  - Induction of general anesthesia: 0.1-0.2 mg/kg IV (will be lower in elderly patients or if other CNS depressants are present)

OPIATES

- Act at receptors (mu, kappa, delta) located in central and peripheral nervous system
- Activity at various receptors is responsible for beneficial (analgesia, sedation) as well as deleterious (nausea, ileus, hypoventilation, bradycardia, urinary retention, miosis) effects.
- All are potent respiratory depressants.
- Have noteworthy property of minimal cardiovascular depression; with exception of narcotics that cause histamine release.

OPIATES

- **Morphine** is the standard by which all opiates are compared.
  - Naturally occurring compound, hydrophilic properties which lead to delayed onset and prolonged action.
  - Causes histamine release, use with caution in asthmatics.
  - Conjugated in liver to Morphine-6-glucuronide, a potent opiate, elimination of metabolite is impaired in those with renal failure. Normal half-life ~ 114 min
  - Onset 5-10 min (IV), Dose: 0.075-0.15 mg/kg (titrated)

OPIATES

- **Meperidine** is an opiate that possesses 1/10th the potency of morphine.
  - Semi-synthetic compound with a faster onset of action than morphine. Originally developed as an anti-cholinergic and as a result, has atropine-like structure. Causes histamine release. $T_{1/2} \sim 180\text{-}260$ min
  - The only narcotic that is a direct myocardial depressant.
  - Metabolized to normeperidine in liver. Normeperidine is a CNS stimulant that causes delerium, myoclonus and seizures in those who have been on the drug for prolonged periods or have renal insufficiency.
  - Onset < 1 min (IV), Dose: 0.5-2 mg/kg IV (titrated)

OPIATES

- **Fentanyl** is a synthetic lipophilic compound that is approximately 100 times as potent as morphine.
  - VERY narrow therapeutic window--the difference between sedative/analgesic levels and respiratory depressant levels is much less than that observed with meperidine or morphine.
  - No histamine release, metabolized to norfentanyl in liver which is also dependent renal elimination. Has been associated with delerium. $T_{1/2} \sim 185\text{-}219$ min
  - Onset 3-5 min (IV), Dose: 0.5-2 mcg/kg IV (titrated)
  - One should not use over 1 mcg/kg unless you are prepared to deal with potential airway consequences.

FLUMAZENIL

- Specific benzodiazepine antagonist that reverses CNS depressant effects.
- The drug has a high affinity for BNZ receptors where it exerts weak agonist activity.
- The duration of antagonism is relatively brief (45-90 min) in comparison to the drugs that it reverses. Patients that receive flumazenil should be monitored up to 120 min for resedation, respiratory depression, or other residual BNZ effects.
- May cause hypertension, tachycardia, seizures, myocardial ischemia in predisposed patients.
- Onset 1-2 min (IV), Dose: 4-20 mcg/kg IV (0.2 mg/min in adults to 1 mg, may repeat in 20 min intervals until endpoint)

NALOXONE

- Pure opioid antagonist with no agonist activity
- Competitive inhibition of opiate agonists at mu, delta and kappa receptors.
- Duration of action is approximately 30-45 min which is substantially shorter than the opiates that it reverses. Consider observation of the patient for 120 minutes to assess for renarcotization.
- Reversal of opiates has resulted in hypertension, tachycardia, myocardial ischemia, nausea/vomiting, and pulmonary edema.
- Onset 1-2 min (IV), Dose:1-4 mcg/kg IV, technique for adult dosing: 0.4 mg diluted in 10 ml syringe (Saline), 1 ml (40 mcg) IV every 3-5 min until desired effect.

CONCLUSION

- Conscious sedation is a safe practice in a setting with proper monitoring, adequate IV access, and experienced personnel.
- The physician administering the medications should be familiar with them and their possible side-effects.
- One should establish a “comfort zone” that they will accept in conscious sedation and once that level is reached, consider consulting anesthesia.
- The patient will thank you for alleviation of discomfort and anxiety, but not for hypoxia and injury.