

PROCEDURAL SEDATION (PS) FOR NON-ANESTHESIOLOGISTS

1. INTRODUCTION

This policy is designed to provide specific recommendations for the safe care of adult and children (Appendix I) patients receiving sedation during diagnostic and therapeutic procedures performed by non-anesthesiologists. These guidelines apply to the parenteral administration of drugs in adults and all routes of administration of drugs in children for procedural sedation (PS).

1. DEFINITIONS

1.1. LEVELS OF SEDATION

- 1.1.1. **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.
- 1.1.2. **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 a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- 1.1.3. **Deep sedation** 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.
- 1.1.4. **General anesthesia** consists of general and regional anesthesia, but does not include local anesthesia (field blocks). General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

A continuum exists between these levels of sedation. The patient's age and preexisting medical conditions may significantly alter the dosing requirements needed for PS.

This policy includes procedural sedation for all patients with the following exceptions:

- The administration of anesthetics outside of the operating room by a member of the Department of Anesthesia and Critical Care (DACC), which is addressed by other policies and procedures. Preoperative pre-



medication of patients prior to their transport to the operating room is specifically excluded from this policy.

- The administration of anesthetics in dental operatories by members of the Department of Oral and Maxillofacial Surgery addressed by policies and procedures of their department in accordance with regulations and permits of the Massachusetts Department of Public Health.
 1. The administration of parenteral morphine (≤ 15 mg for adults and ≤ 0.1 mg/kg for children) or parenteral meperidine (≤ 100 mg for adults and ≤ 1 mg/kg for children) without the concomitant use of a benzodiazepine.
 2. The use of a benzodiazepine for minimal sedation without the concomitant use of an opioid.
 3. The administration of intravenous sedatives and analgesics according to approved therapeutic protocols, which are designed to serve as a primary treatment for and/or as an adjunct in the management of specified medical conditions. Such medical conditions typically consist of the use of narcotics via any route (including Patient Controlled Analgesia pumps) for the management of pain, dressing changes, burn care, chest pain (angina), and pulmonary edema and the use of benzodiazepines for anxiety, sleep, the management of delirium tremens, and seizures.

1.1.5. Medications given to patients in intensive care units, excluding those admitted solely for the administration of procedural sedation, and intubated patients on ventilators.

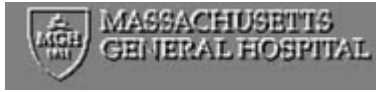
1.2. Operator (definition to be provided)

2. SOURCE/AUTHORITY FOR POLICY/PROCEDURES ON PS

A committee that was chaired by a member of the DACC and was approved by the Medical Policy and the General Executive Committees formulated this policy. All departments and services using procedural sedation will be responsible for the adherence to the requirements of the policy.

The DACC will:

- 1.3. educate practitioners of PS on the JCAHO and MGH standards for PS as set forth in this policy and in periodic revisions and privilege those who have met the appropriate requirements.
- 1.4. approve drugs used for PS (Appendix II, III)
- 1.5. provide consultation for questions on patient suitability for PS for any reason
- 1.6. ensure the availability of resuscitation support services at all times
- 1.7. provide a system of quality assurance (QA) for PS in the spirit of improved patient care.



3. PERSONNEL AND TRAINING

The practitioner responsible for the treatment of the patient and/or the administration of drugs for PS shall be appropriately trained. Because procedural sedation by non-anesthesiologists is a continuum from anxiolysis to inadvertent general anesthesia, it is not always possible to predict how an individual will respond to pharmacologic agents. Therefore, practitioners of PS must be capable of rescuing patients from an unexpected higher level of sedation, e.g. deep sedation progressing to apnea.

1.8.A minimum of two individuals privileged in PS is required: the **operator**, who performs the surgical or diagnostic procedure, and the **monitor** who administers drugs and monitors vital signs.

The operator will be immediately available to the patient until discharge from the recovery area.

The operator is a usually a physician who is required to maintain *competency* in advanced life support. This can be accomplished by continued certification in one or more of the advanced life supports listed below. Any certification must include a practicum in airway management. Computer and on-line courses are permitted if participation in an airway skills station is mandatory for certification.

1.8.1. Advanced Cardiac Life Support (ACLS) or Advanced Trauma Life Support (ATLS) is required for those who administer PS to adults (age > 19) and to pediatric patients of ages ≥ 15 years old.

1.8.2. Pediatric Advanced Life Support (PALS) is required for those who administer PS only to pediatric patients (age > neonates but < 19 y.o.). ACLS or ATLS and PALS are prerequisites for physicians who will administer PS to pediatric patients of age < 15 years and adults.

1.8.3. Neonatal Resuscitation Program (NRP) certification is required for those who administer PS to infants with corrected gestational ages ≤ 44 weeks.

1.8.4. Physicians who are board certified or candidates for board certification by a component of the American Board of Medical Specialties or an equivalent organization for international graduates in disciplines that require airway management and cardiopulmonary advanced life support skills for certification

1.8.5. Physicians who are board certified by a component of the American Board of Medical Specialties or an equivalent organization for international graduates in specialties that require cardiopulmonary advanced life support skills for certification without a requirement for airway management may satisfy the advanced life support requirement through a petition to the Procedural Sedation Committee and attendance at an airway management course provided by the DACC. The petition will include a copy of the board or subspecialty board requirements, evidence of continued maintenance of these skills, and evidence of board certification or candidacy.

1.8.6. The monitor must be an MD, DO, DMD, PA, RN, or RRT who will have no significant responsibilities; i.e., no tasks or duties that would compromise his/her ability to monitor the patient. Registered Respiratory Therapists may not administer medications. All monitors will be trained in airway



management, standards of PS, and pharmacology of approved drugs. Certification in advanced life support may be required in some areas.

1.8.7. A third individual is required when the procedure requires deep sedation, is particularly complex or the patient's medical condition may require management beyond the capacity of the practitioner(s). Each individual department or service will define these procedures.

1.9. Both the Medical Director and/or Nurse Manager of the patient care unit or service in which PS procedures are performed shall ensure that the providers of PS have the required credentials, knowledge, and skills.

1.10. The DACC will privilege practitioners of PS, through a comprehensive hospital-wide educational program that includes airway management, standards of care, patient evaluation, and the appropriate use and pharmacology of pertinent drugs

1.11. The MGH code operator number (6-2245) must be clearly displayed in all areas where PS is performed.

4. CLINICAL SITES APPROVED FOR PROCEDURAL SEDATION

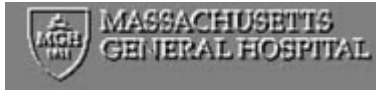
The administration of PS by privileged personnel is permitted only in designated areas that have been approved by the Medical Policy Committee (Appendix II). PS is prohibited in any other location. Practitioners should work with the respective nurse managers and physician leaders to propose in writing any requests for additional clinical sites for PS to be performed. The Medical Policy Committee will review and approve these proposals.

5. TRANSPORT AND CARE OF SEDATED PATIENTS

1.12. It is prohibited to initiate PS in a non-approved location prior to transport to an approved site.

1.13. Patients in approved locations who have received PS, when transported to and from another location (e.g. ICU to radiology), must be fully monitored (Section IX) and be accompanied by a health care provider with PS privileges including advanced life support (Section III.1.). The availability of a bag-valve-mask and oxygen are the minimal equipment requirements for transport. This PS-approved health care provider must remain with the patient until a second PS-credentialed provider can assume care.

1.14. Patients who have received PS for diagnostic and therapeutic procedures immediately prior to a surgical procedure can be transported to the OR by personnel only after discharge criteria are fully met and documented. Patients not meeting discharge criteria must be transported to the OR by a PS-credentialed professional who must stay with the patient until the attending anesthesiologist or his designee agrees to the transfer of care. In this instance, continued documentation of vital signs and state of consciousness is mandatory. Because the anesthesia team is often administering to other patients, the RN and/or MD accompanying the patient may be required to monitor the patient for an extended period. Patients transferred to other areas for additional procedures following an anesthetic in the OR must be accompanied by an anesthesiologist unless



discharge criteria have been met. The anesthesiologist will remain with the patient until transfer of care is agreed upon. Attending to attending physician communication is central to the success of these transfers.

6. EQUIPMENT AND MAINTENANCE

The functional status of all equipment will be checked prior to each procedure. The following are the minimal equipment requirements for PS in both procedure and recovery areas:

- 1.15. bag/valve masks (often called and Ambu bags); pediatric sizes in areas performing sedation for children; an oxygen source capable of delivering 90% oxygen at a 15 liter/minute flow rate for at least 60 minutes must be available for each patient.
- 1.16. suction (portable or wall) with the vacuum capability of removing thick secretions. and Yankauer (tonsillar) suction catheters.
- 1.17. a pulse oximeter.
- 1.18. a device for taking blood pressure (manual or automatic), with a variety of cuff sizes to accommodate arms of varying circumference.
- 1.19. an ECG monitor.
- 1.20. a capnograph when the patient cannot be directly observed. Capnography is recommended for all patients undergoing deep sedation.
- 1.21. Standard hospital resuscitation carts (“code carts”) and the reversal agents flumazaniil and naloxone.

7. CONSENT

The patient/guardian must be informed about the risks of and alternatives to sedation as a component of the planned procedure. Documentation of consent should be placed on the procedural record prior to the procedure.

8. PRE-PROCEDURE ASSESSMENT

It is preferable to document the pre-procedure assessment of the patient using the MGH form designed for this purpose (Appendix III). If this form is not employed, the following are the minimal requirements that must be prospectively documented in written and/or computerized records:

- 1.22. The baseline health evaluation includes:
 - allergies and previous adverse drug reactions
 - current medications (including chronic use of benzodiazepines and/or tricyclic antidepressants)
 - diseases, disorders and abnormalities
 - prior hospitalizations
 - pertinent family history of diseases or disorders



- review of systems

1.23. The physical examination includes:

- height and weight
- vital signs
- baseline oxygen saturation
- chest and cardiac examination
- state of consciousness

1.24. An evaluation of the airway (Appendix IV) including the presence of obstructive sleep apnea (Appendix V) that is documented is mandatory.

1.25. An electrocardiogram (ECG) obtained within six months of the procedure, read by a physician, with results documented, is required for patients with American Society of Anesthesiologists (ASA) physical status categories III, IV, and V and for all patients 65 years of age or greater. In addition, an ECG is required of ASA II patients who have risk factors for myocardial disease as evidenced by another disease process (Appendix V).

1.26. risk assessment:

- American Society of Anesthesiologists (ASA) Physical Status Category (Appendix IV)
- Patients classified as ASA I, II, or III are eligible for PS by all credentialed providers. However, an evaluation of each patient, and not the ASA physical status, should be the determinant for the appropriateness of PS (Appendix V).
- Patients classified as ASA IV or V, and any patient for whom there is a question of medical stability, inability to tolerate the procedure under PS, and questions of airway suitability, require consultation with a member of the DACC (page 32888). Patient care units with significant expertise and experience in providing PS to ASA IV and V patients may petition the Chief of Anesthesia and Critical Care or his/her designee on an annual basis for an exemption to this requirement.
- Patients should not be scheduled for procedures greater than four hours secondary to the added effects of the drugs used for PS and patient tolerance of long procedures.
- PS mandates a cooperation between physicians and the nursing staff. The attending physician bears the responsibility for evaluating and screening patients for PS in advance of the procedure. When there is a question about the suitability of a patient for PS, a member of the DACC will objectively evaluate with the ultimate goal of patient safety. Although the DACC will attempt to provide anesthesia for those patients who are not appropriate for PS, rescheduling the procedure may be necessary. In the event that a self-pay patient for an elective procedure is not evaluated



as suitable for PS on the day of surgery, he/she should be informed by the attending physician that their procedure will require an anesthetic that will be at their expense.

- Specific conditions that have been problematic for PS are described in Appendix VI.

1.27.NPO status (Appendix VII)

1.28.rationale for sedation and sedation plan.

1.29.patient's referring physician and telephone number

9. MONITORING, DRUG ADMINISTRATION, AND DOCUMENTATION

Whenever drugs for PS are administered, a licensed health care professional will monitor the patient continually by direct observation and by indirect physiologic measurement such as pulse oximetry. The monitor may also perform other tasks, which do not detract from his/her ability to observe the patient. If the administration of drugs for PS for planned or unplanned deep sedation, the monitor will remain with the patient. It is the physician under whose care procedural sedation is administered who is ultimately responsible for the resuscitation of an unstable patient.

- 1.30.Heart rates, respiratory rates, and blood pressure must be assessed at least every five minutes and documented. Blood pressure should be measured and recorded prior to the initiation of sedation and measured at least every five minutes thereafter. Planned drug-induced hypotension is a complex procedure, imposes risks, and usually requires invasive monitoring. It is not permitted under PS. A stethoscope for monitoring heart rate, respiratory rate, and adequacy of tidal volume is considered to be minimum monitoring equipment needed.
- 1.31.An ECG monitor with appropriate alarms should be used on all patients with ASA classifications of III, IV, and V and on those with a history of cardio-pulmonary disease.
- 1.32.The level of consciousness requires assessment and documentation according to a standard sedation scale (Appendix X)
- 1.33.Head position should be checked frequently to ensure a patent airway.
- 1.34.Oxygen saturation shall be monitored non-invasively on a continuous basis by pulse oximeter and documented. Supplemental oxygen is mandatory for all patients with sustained saturations below 90% regardless of the procedure. PS is not approved for procedures during which supplemental oxygen cannot be administered. When supplemental oxygen, repositioning of the airway, and the administration of naloxone and/or flumazaniil are ineffective in maintaining adequate ventilation, anesthesia assistance must be summoned.
- 1.35.All adult patients receiving sedation should have a functioning intravenous line or heparin lock.



- 1.36. Drugs given (route, site, time, drug and dose), including oxygen therapy in liters/minute and means delivered (e.g., nasal prongs, re-breathing mask, etc.) should be recorded at the time of administration.
- 1.37. Privileged physicians are required to sign physician orders for procedural sedation medications and these must be obtained prior to the start of the procedure.
- 1.38. All staff involved in a procedure are required to complete the Universal Protocol Time Out per the MGH Universal Protocol policy(link to be added).

10. PROVISIONS FOR PATIENT CARE FOLLOWING THE PROCEDURE AND DISCHARGE PLANNING

Objective criteria will be used following a procedure to evaluate the suitability of the patient for discharge or to a lower level of care. This can be facilitated by using a scale similar to that presented in Appendix XI to document the following minimal criteria:

- 1.39. maintenance of stable heart rate, respiratory rate, oxygen saturation and additional criteria per unit protocol. Any patient receiving naloxone or flumazenil will require a minimum two-hour period of observation following the last administration of the reversal agent.
- 1.40. return to pre-procedural state of consciousness as assessed by the scale in Appendix X
- 1.41. the patient can sit unaided, if appropriate to baseline and procedure.
- 1.42. the patient can walk with assistance, if appropriate to baseline and procedure.
- 1.43. The state of hydration is adequate.
- 1.44. Patients discharged to home must be under the care of a competent adult. The time of discharge, patient's condition, discharge plan (name of responsible party, patient's location), and written instructions to patient to include an explanation of potential or anticipated post- sedation effects and any limitation on activities and behavior including dietary precautions must be documented. A 24-hour emergency contact telephone number should be provided to all patients.
- 1.45. If patients are to be transferred to further care within the institution, standard criteria shall be applied for transfer of care.

11. QUALITY ASSESSMENT

- 1.46. A QA form, either in paper or electronic form, will be submitted for each patient undergoing PS. The MGH PS Quality Assessment Committee will evaluate/review all PS delivered within the organization.
- 1.47. The Medical Director and Nurse Manager of the care unit or service using PS will be responsible for implementing the MGH PS Quality Assessment Plan. The Department of Anesthesia through the PS Medical Director will oversee quality assessment and improvement activities throughout the organization. The focus of assessment includes, but is not limited to:



- Selection of appropriate procedures
- Preparation of patients for procedures
- Procedure performance and patient monitoring
- Provision of post procedure care including patient education
- Investigation of critical incidents

APPENDICES

- I. Statement on Procedural Sedation for Children at Massachusetts General Hospital
- II. Clinical Sites Approved for Procedural Sedation
- III. Pre-Sedation Assessment Form
- IV. Airway Assessment for Procedural Sedation
- V. Sedation Algorithm for Patients with Obstructive Sleep Apnea
- VI. American Society of Anesthesiologists Physical Status Classification
- VII. NPO Guidelines for Adult and Pediatric Patients
- VIII. Approved Drugs and Dosage Guidelines for Adult IV Procedural Sedation
- IX. Approved Drugs and Dosage Guidelines for Pediatric Procedural Sedation
- X. MGH Sedation Assessment During Procedural Sedation
- XI. Procedural Sedation Recovery Assessment Tool

(ref: Revisions to Anesthesia Care Standards, Comprehensive Accreditation Manual for Ambulatory Care, Standards and Intents for Sedation and Anesthesia Care, JCAHO)

Reviewed/revised: Procedural Sedation Committee (10/25/06)

Approved: Clinical Policy and Record Committee (11/01/02)(11/17/06)

Approved: Medical Policy Committee (11/06/02) (12/06/06)



APPENDIX I

STATEMENT ON PROCEDURAL SEDATION FOR CHILDREN AT MASSACHUSETTS GENERAL HOSPITAL

The following modifications for children under 15 years of age reflect the special features to be considered when children undergo procedural sedation at the Massachusetts General Hospital for Children.

Cardiovascular Monitoring

Standard monitoring is carried out except that a modification is required for young children in the application of blood pressure monitoring. At moderate sedation levels for ASA I and II category patients, intermittent inflation of the blood pressure cuff may disturb the young



child and disrupt investigative procedures. Given the physiological status of these children and the depth of sedation employed, the cardiac monitoring of heart rate and pulse oximetry would suffice to ensure adequate perfusion for the procedure carried out.

Sedation for Diagnostic Radiology and Electroencephalography

The following modifications are for pediatric patients who require procedural sedation for non-invasive diagnostic radiological procedures without interventions (e.g. CT, MRI) and electroencephalography (EEG) whereby the “operator” is a machine:

1. In addition to the required baseline health evaluation, physical examination, ASA risk assessment, NPO status, and sedation plan there must be a clear documentation of a physician within MGH who will be responsible for the patient if further medical management or an unexpected hospital admission is needed.
2. The monitor RN will administer drugs ordered by a physician. The physician does not have to be present during diagnostic procedures of a patient with an ASA physical status of I or II (Appendix V) provided that the monitor RN has current Pediatric Advanced Life Support (PALS) and/or Neonatal Resuscitation Program (NRP) certification appropriate for age and a second health care provider with equal qualifications is nearby. A physician trained in advanced life support must always be available during these diagnostic procedures.
3. Capnography, in addition to the standard monitors (see below), is required when the monitor cannot directly observe the child’s respiratory pattern and rate.

Drugs

Appendix IX is the list of approved drugs and their appropriate doses for conscious sedation in children.

NPO Guidelines

See Appendix VII

APPENDIX II

CLINICAL SITES APPROVED FOR PROCEDURAL SEDATION

The administration of PS by credentialed personnel is permitted only in designated areas that have been approved by the Medical Policy Committee. These locations are:

Bronchoscopy Suite
Cardiology Laboratories:
 Cardiac Catheterization
 Echocardiology
 Electrophysiology
 Pacemaker
Emergency Department
Endoscopy Suites (Blake 4; Charles River Plaza for ASA I and II only)



only) General Clinical Research Center (GCRC; research protocols

Intensive Care Units:

CCU

CSICU

MICU

NICU

PICU

Transplant ICU (ICU areas only; does not include Blake
6 non-ICU beds)

Radiology Suites (ASA I and II only for Yawkey Bldg)

Same Day Surgical Unit

Special Care Nursery (SCN), Blake 13

1. Sedation of patients who are admitted to ICUs is excluded from the PS policy (Section I.D).
2. The ICUs listed above and the Emergency Department may provide a temporary location for patients admitted to general hospital floors who require procedural sedation. This is subject to bed availability and the approval of the physicians in charge of the ICU/Emergency Department and the respective nurse managers. The selection of patients may be limited to those who would normally be admitted to that ICU. For example, the CCU may accept a patient who requires PS for a cardioversion or transesophageal echocardiogram but not for a reduction of a hip dislocation.
3. In the event of the unavailability of an approved location for procedural sedation for an in-patient, the sedation consultant should be paged (32888) for guidance.
4. Requests for non-scheduled anesthesia assistance can be made at 6-8995. Requests for anesthetics in non-operating room locations on nights, weekends, and holidays at any hour should be made by the patient's attending physician to the staff anesthesiologist on call. The procedure will be placed on the wait list that is ranked in order of booking time and severity of illness.
5. PS is prohibited in any other location. Practitioners of PS should work with the respective nurse managers and physician leaders to propose in writing requests for additional clinical sites for PS to be performed. The Medical Policy Committee will review and approve these proposals.

Patients in Isolation

Patients in strict isolation for whom movement to an approved location may compromise their health status or endanger the health of others, may have procedural sedation performed in the isolation area. It is the responsibility of the service performing the procedure to provide a credentialed monitor for the procedure and until there is complete



recovery to baseline. The physician performing the procedure must be immediately available until the recovery is complete.



APPENDIX III

Massachusetts General Hospital

12. PRE-SEDATION ASSESSMENT

Date: _____

Planned procedure: _____

Procedure discussed with patient or parent/guardian and CONSENT OBTAINED: Yes No N/A

MEDICATION ALLERGIES: No Known Yes (list) _____

Current MEDICATIONS: None Yes (list) _____

Pre-Procedure DIAGNOSIS/INDICATION: _____

PERTINENT MEDICAL HISTORY: Benign past medical history (If possible describe below)

Cardiac _____ CNS _____ Bleeding problem _____

HTN _____ Endocrine _____ Pregnant _____

Vascular _____ Renal _____ Complication with sedation _____

Asthma _____ Hepatitis _____ Other: _____

PHYSICAL EXAMINATION:

Airway: adequate o anesthesia consult o	Lungs: _____	Other: _____
Heart: _____	Mental Status: _____	

LABS: (None required) (Results acceptable) (Other) _____

EKG: (None required) (Results acceptable) (Other) _____

- As a PHYSICAL CLASSIFICATION:** (Select one)
- ASA I - (normally healthy patient)
 - ASA II - (mild systematic disease; e.g. HTN, mild asthma)
 - ASA III - (moderate systematic disease under control; e.g. Type 2 DM+HTN+mild COPD)
 - ASA IV - (life-threatening disease that is a constant threat to life; e.g. cardiomyopathy, severe COPD)
 - ASA V - (moribund patient, not expected to survive 24 hr with or without a procedure)
 - E - (denotes emergency; patients who need sedation and cannot wait for required NPO status)

SEDATION PLAN: 0 moderate sedation 0 deep sedation
 Sedation risks and options explained, questions answered, consent for sedation obtained
 Patient reassessed immediately prior to procedure
 Appropriate monitors applied, resuscitative and IV equipment available

NPO STATUS – Time of last intake: **Solids/Milk:** _____ **Clear Liquids:** _____

PROVIDER SIGNATURE: _____ M.D. DATE: _____

PATIENT REEVALUATED PRIOR TO PROCEDURE: (PROVIDER SIGNATURE): _____ M.D.



APPENDIX IV

AIRWAY ASSESSMENT FOR PROCEDURAL SEDATION

Positive pressure ventilation, with or without tracheal intubation, may be necessary if respiratory compromise develops during procedural sedation. 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. Listed below are factors that have been associated with difficulty in airway management. Each patient's airway should be assessed and documented during the preprocedural evaluation. Questions suitability for procedural sedation secondary to airway or any other issues should be referred to a member of the DACC (consult pager 32888; Gray OR desk, 6-8995).

1. History

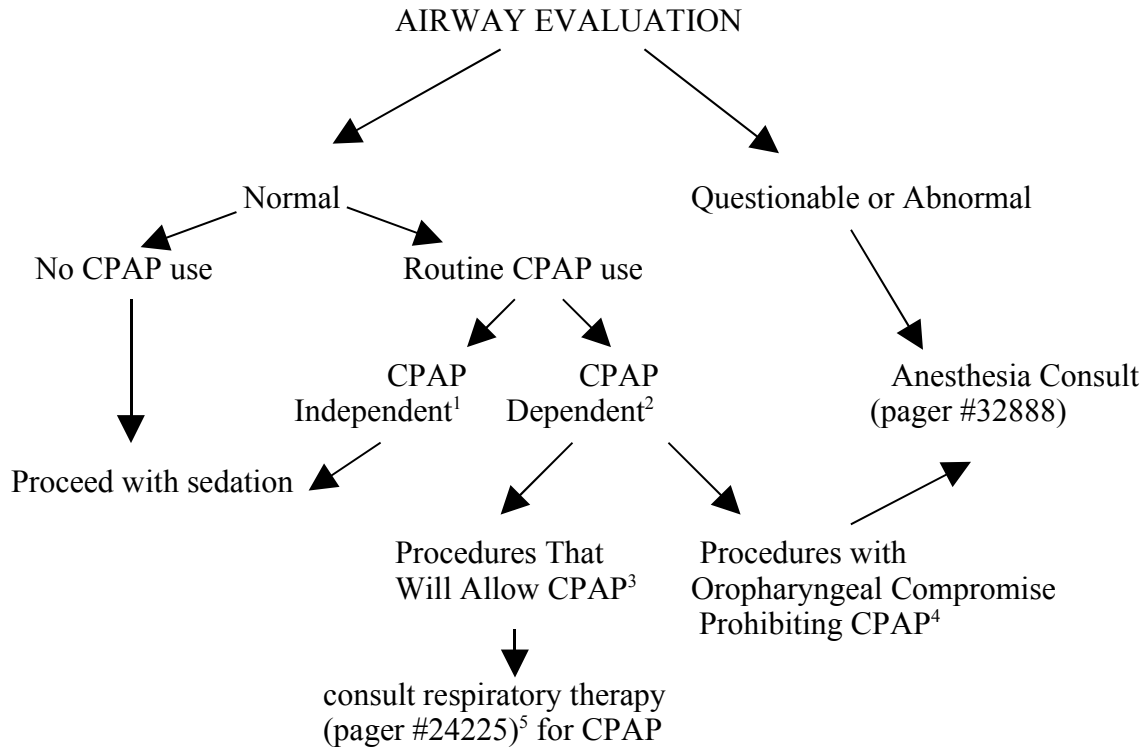
- a. previous problems with anesthesia or sedation
- b. stridor, snoring, sleep apnea
- c. advanced rheumatoid arthritis
- d. ankylosing spondylitis
- e. chromosomal abnormalities (e.g. trisomy 21)

2. Physical Examination

- a. body habitus:
 - significant obesity
- b. neck:
 - short neck
 - limited neck extension
 - neck mass
 - cervical spine disease or trauma
 - dysmorphic facial features
 - decreased thyro-mental distance
- c. mouth
 - small mouth opening (< 3 cm in adult)
 - edentulous
 - protruding incisors
 - presence of removable dental appliances
 - macroglossia
 - tonsillar hypertrophy
 - inability to see uvula
- d. jaw
 - micrognathia
 - retronathia

APPENDIX V

SEDATION ALGORITHM FOR PATIENTS WITH OBSTRUCTIVE SLEEP APNEA



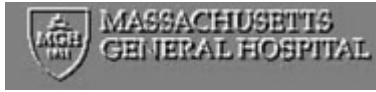
¹**CPAP-independent:** does not use CPAP routinely; does not bring CPAP machine on trips; functions well when CPAP not used.

²**CPAP-dependent:** cannot sleep without CPAP; always uses CPAP; brings CPAP on trips; has pulmonary artery HTN

³ For example: colonoscopy, cardiac catheterization, vascular access catheters

⁴ For example: upper GI endoscopy, EUS, ERCP, TEE

⁵Patients are not permitted to use home CPAP machines unless previously inspected by respiratory therapy. If CPAP dependent, page respiratory therapy (#24225) to set up CPAP machine via a physician's order for either the patient's known CPAP settings or 10 cm H₂O if the settings are unknown. Upon discharge, please page respiratory therapy to remove the CPAP machine.



APPENDIX VI

AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS CLASSIFICATION

Class I: no organic, physiological, biochemical or psychiatric disturbance; pathologic process for which the operation is to be performed is localized and is not a systemic disturbance.

Class II: mild to moderate systemic disturbance caused either by the condition to be treated or by other pathophysiologic processes.

Class III: severe systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability with finality.

Class IV: indicative of the patient with a severe systemic disorder already life-threatening, not always correctable by the operative procedure.

Class V: moribund patient who has little chance of survival but is submitted to operation in desperation.

The addition of the suffix “E” to the classification (e.g. IIIE) indicates an unplanned procedure for which the patient has not met the required NPO criteria.

Examples of Disease States That Should be Considered for the Appropriateness for PS on an Individual Basis

1. **Diabetes mellitus.** It is preferable to schedule diabetics early in the day for procedures. Most insulin-dependent diabetics will do well if half of their usual NPH dose is taken or as advised by their primary care physician. They should not be scheduled for prolonged procedures (greater than four hours) that require the frequent assessment and treatment of hyperglycemia or hypoglycemia.
2. **Obstructive Sleep Apnea (OSA).** OSA encompasses a wide spectrum. Some patients require nocturnal continuous positive airway pressure (CPAP) because they have mild obstruction. These can usually be safely done under PS. Other patients have morbid obesity, pulmonary artery hypertension, and significant co-morbidities. They may be acceptable short procedures if the CPAP can be employed. Appendix V is an algorithm for the evaluation of OSA patients.
3. **Chronic Obstructive Pulmonary Disease (COPD).** Patients with severe oxygen-dependent COPD are highly susceptible to the effects of drugs used for sedation. The associated co-morbidities should be considered before sedation is performed.



APPENDIX VII

NPO GUIDELINES FOR ADULT AND PEDIATRIC PATIENTS¹

ADULT NPO GUIDELINES

For patients seven years of age or older:

Clear liquids ²	2 hours
Solids ³	8 hours

PEDIATRIC NPO GUIDELINES

For Children 1 day to six years of age

Clear liquids ²	2 hours
Breast Milk	4 hours
Light Meal (dry toast or cereal only)	6 hours
Solids ³	8 hours

¹These guidelines are based on the 1999 ASA Practice Guidelines for Preoperative Fasting and the consensus of Team Leaders of the DACC. These recommendations are intended for healthy patients undergoing elective procedures. The guidelines may need to be modified for patients with conditions that might affect gastric emptying (e.g. gastroesophageal reflux disease, gastroparesis secondary to Type 1 diabetes mellitus) or gastric fluid volume.

²Clear liquids refers to water, clear juices without pulp (apple, cranberry), black tea, and tea without milk. Oral contrast media used for diagnostic purposes does not fall within the NPO guidelines and should be given per the protocol of the radiologic procedure.

³The chewing of gum is not allowed preoperatively. If swallowed, it is treated as a solid (NPO for 8 hours). If chewed but not swallowed, it is treated as a clear liquid (NPO 2 hours).



APPENDIX VIII

APPROVED DRUGS AND DOSAGE GUIDELINES FOR ADULT INTRAVENOUS PROCEDURAL SEDATION

1. The following table is intended as a resource for practitioners who need information on the group of drugs recommended for sedation. This is intended only as a rapid guide to appropriate dosing --- it is not a replacement for the hospital formulary or a textbook of pharmacology. Before administering any of these drugs, the clinician should be familiar with their appropriate uses in sedation as well as their therapeutic and toxic effects.
2. The most important element in providing safe and effective sedation is careful titration to an appropriate endpoint.
3. a. For minimal sedation and conscious sedation, these depressant drugs may be used to provide analgesia, drowsiness, relief of anxiety, and amnesia. Patients should remain responsive to voice command and retain control of breathing and protective airway reflexes. The use of higher doses will produce deep sedation and may lead to general anesthesia.
 - b. These recommended doses must be reduced when opioids and sedative-hypnotics are combined (lower dose by at least 50%), the patient is elderly, debilitated, or has significant organ system disease, and patient has received other respiratory and cardiac depressant medications.
 - c. The anesthetic induction drugs thiopental, propofol, methohexital, ketamine (adults), and etomidate are not permitted for use by non-anesthesiologists.



Drug	Average Dose (mg)	Incremental Dose (mg)	Time Between Doses (min)	Onset Time (min)	Duration of Effect (hr)	Comments
Meperidine (Demerol)	50-150	25	5	3-5	2-3	Not with MAOI
Morphine	5-15	2.5	5	5-10	3-4	
Fentanyl (Sublimaze)	0.025-0.15	0.025	3	1-2	0.5-1	
Butorphanol (Stadol)	0.5-2	0.5	3	2-3	3-4	Precipitates Withdrawal
Diazepam (Valium)	5-20	2.5	3	1-2	0.5-2	
Midazolam (Versed)	1-5	0.5-1	3	3-5	0.5-2	Slower onset than diazepam
Naloxone (Narcan)	0.4	0.04	2	1-2	.5-1	Resedation
Flumazenil (Romazicon)	1	0.2	2	1-2	.5-1.5	Resedation ¹

¹Flumazenil does NOT reliably reverse respiratory depression from benzodiazepines/narcotics. Flumazenil should be used with caution in patients with a history of chronic benzodiazepine use.

APPENDIX IX
APPROVED DRUGS AND DOSAGE GUIDELINES



FOR PEDIATRIC PROCEDURAL SEDATION

ALL DRUGS ADMINISTERED UNDER THE PRINCIPLE OF TITRATION TO EFFECT

DRUG	AVG. DOSE	INCREMENTAL DOSE	ONSET TIME	DURATION OF EFFECT	COMMENTS
Meperidine (Demerol)	1 mg/kg/IV	25% of initial dose	3-5 min	2-3 hrs	Reduce initial dose by 25-50% when used in combination with sedatives. Watch for rapid onset of respiratory depression.
Morphine	0.1 mg/kg/IV	25% of initial dose	5-10 min	3-4 hrs	Reduce initial dose by 25-50% when used in combination with sedatives. Watch for rapid onset of respiratory depression.
Ketamine: see section below chart for contraindications, doses, and approved locations for use.					
Fentanyl (Sublimaze)	1-3 mcg/kg/IV	25% of initial dose	1-2 min	30 min - 1 hr	Reduce initial dose by 25-50% when used in combination with sedatives. Watch for rapid onset of respiratory depression.
SEDATIVES					
Diazepam (Valium)	0.1 mg/kg/IV	25% of initial dose	1-2 min	30 min - 2 hrs	Valium may cause pain with IV administration. Reduce dose by 25-50% when used with narcotics.
Midazolam (Versed)	0.05-0.1 mg/kg/IV	25% of initial dose	1-3 min	30 min - 2 hrs	Reduce initial dose by 25-50% when used with narcotics.
Midazolam (oral)	0.5-0.75 mg/kg	50-100% of initial dose	20-30 min	60-90 min	
Midazolam (rectal)	0.5-1.0 mg/kg	50-100% of initial dose	5-10 min	30-60 min	Variable absorption with rectal route. Dilute with 5 cc normal saline.
Midazolam (Intranasal)	0.2-0.3 mg/kg	50-100% of initial dose	5-10 min	30-60 min	



Chloral Hydrate (oral or pr)	50-75 mg/kg to max. single dose of 1 gm	50-100% of initial dose	20-30 min	2-6 hrs	Maximum total dose PO = 1 gm
Pentobarbital (Nembutal)	2-6 mg/kg/IV	25-100% of initial dose	1-5 min	1 hr	Pts receiving barbiturates for seizure disorders may be refractory to usual sedative doses.
ANTAGONISTS					
Naloxone (Narcan)	0.01-0.1 mg/kg/IV		1-2 min	30-60 min	Only reverses narcotics. Rapid reversal may precipitate pain, nausea and vomiting and severe hypertension and tachycardia. Long acting narcotics may outlast reversal effects requiring multiple doses.
Flumazenil (Romazicon)	0.01-0.2 mg		1-2 min	30-90 min	Resedation



Ketamine provides reliable sedation, amnesia, and analgesia in children while preserving respiration, muscle tone, and cough/gag reflexes when administered appropriately. In addition to the standard evaluation, monitoring, and post-procedure recovery requirements as stated in this Policy for pediatric conscious sedation, the following are additional for ketamine administration:

1. Patients: ASA I and II pediatric patients > 6 months and < 15 year of age with the following exclusions that must be assessed and documented:
 - a. history of airway instability; tracheal surgery (including previous tracheostomy at any age; tracheal stenosis
 - b. craniofacial abnormality
 - c. upper respiratory tract infection
 - d. cardiovascular disease (angina, heart failure, hypertension, congenital abnormalities)
 - e. head injury
 - f. intracranial mass, hydrocephalus, glaucoma, seizure disorder
 - g. acute eye injury
 - h. psychiatric disorder
 - i. porphyria
 - j. thyroid disorder (even if euthyroid on replacement therapy).
2. Approved Locations: Pediatric Emergency Room (attending use only) Radiology
3. Personnel and Training: Ketamine use is limited to physicians and R.N.s who are credentialed in conscious sedation by the criteria outlined in this Policy and have received additional training by a member of the DACC.
4. Ketamine
 - a. Route of administration: intravenous (IV) and intramuscular (IM).
 - b. Concentration: 10 mg/ml for IV administration and 100 mg/ml for IM injections. [N.B. As for any medication, the concentration should be confirmed prior to administration].
 - c. Ketamine doses:
 - IV: 2 mg/kg (concentration: 10 mg/ml) with supplemental 1 mg/kg as needed. Atropine (0.01 mg/kg IV) or glycopyrrolate (0.01 mg/kg) should be administered to prevent hyper salivation.
 - IM: a single 4 mg/kg (concentration 100 mg/ml to limit pain on injection) with atropine 0.02 mg/kg in the same syringe. Supplemental doses of IM ketamine are not approved for any patient.
 - d. Midazolam 0.02 mg/kg IV or 0.1-0.1 mg/kg IM may be useful for occasional the child with emergence delirium from ketamine.

APPENDIX X



MGH Sedation Assessment During Procedural Sedation

1.48. The MGH Sedation Assessment tool is to be used as a guide to assess the patient's level of sedation before, during, and after a procedure when a patient is receiving sedation.

Scale Label	Description
A	1.49.Alert; Eyes may be closed but can respond to "can you tell me your name?" "Can you tell me where you are right now?"
D	Drowsy; Eyes may be closed, arouse only to verbal command: "(pt. name i.e. John), please open your eyes." Stable Vital signs prior to sedation assessment.
M	Mild physical stimulation (earlobe tug) produces patient response. Stable vital signs prior to sedation assessment
S	Stronger physical stimulation (sternal rub) produces patient response. MD notified of level of sedation.
U	Unresponsive. MD notified of level of sedation.



APPENDIX XI

Procedural Sedation Recovery Assessment Tool

Assessment Category	Assessment Findings	Assessment Scoring
Activity	Able to move 4 extremities on command	2
	Able to move two extremities on command	1
	Unable to move any extremities on command	0
Respiration	Able to breathe deeply and cough freely	2
	Dyspnea or spontaneous Resp rate less than 10 BPM	1
	Apneic	0*
Circulation	BP +/- 20 points of pre-procedure baseline value	2
	BP +/- 21-49 points of pre-procedure baseline value	1
	BP +/- 50 points pre-procedure baseline value	0 *
Consciousness	Fully awake	2
	Arousable to being called by name	1
	Not responding	0 *
Oxygen Saturation (O2 Sat)	Able to maintain O2 Sat. > 92% on room air	2
	Needs oxygen to maintain O2 Sat > 92%	1
	O2 Sat. < 90% even with Oxygen supplement	0 *
Pain	Pain free or level acceptable to patient	2
	Mild pain (pain level 3-6)	1
	Pain requiring parenteral medication	0

* Based upon overall nursing assessment of the patient, any patient with findings identified with a * indicates the need for further assessment and continuous monitoring.



Upon patient's transition from procedural area to recovery area frequency of vital signs, patient assessment and readiness for discharge will be evaluated based upon this Procedural Sedation Recovery Assessment Tool.

The following scoring values will dictate level of care and monitoring needs:

Total score of less than 7 or any item with a *: Continue to monitor per PS sedation guidelines (vital signs/assessment every five minutes) and continuous monitoring of patient

Total score between 8-9: Vital signs can be obtained every 15 minutes x 4, then every 30 minutes x 4, then every hour x 4 unless patient vital signs returns to pre-procedure baseline values.

Total score of 10-12: Patient has achieved return to pre-procedure baseline status and is ready for discharge

At any time during the patient assessment and care, based upon sound nursing judgment, the MD and RN will collaborate to provide intervention(s) if necessary. The frequency of monitoring of vital signs and patient assessment will be continuous and maintained at the procedural level monitoring standard of every five minutes including documentation.

Transfer to inpatient setting: When the patient achieves a total recovery assessment score of 10-12 and meets procedure specific criteria for transfer of care. Patient's can be transferred to an ICU area, prior to achieving a score of 10, based upon the determination of patient's readiness for transfer to the ICU by both a physician and nurse.

Discharge criteria from facility: The following elements are requirements for discharge from the procedural area.

1. Recovery assessment score of 10-12 has been met.
2. Mobility of patient is at pre-procedure baseline.
3. Tolerating P.O. intake (if applicable)
4. Procedural site intact (if applicable)
5. Escort available to take patient home.
6. Protective reflexes (cough and gag) are intact
7. The two-hour observation of the patient has been completed if a reversal agent has been administered. (If applicable)
8. Procedure specific discharge criteria must also be met prior to patient discharge.