



UNIVERSITY *of* MARYLAND
MEDICAL SYSTEM

Adult Procedural Moderate and
Deep Sedation:
A Training Program for
Physicians

Adult Procedural Sedation by the Non-Anesthesiologist

Guidelines for adult procedural sedation promote safe and effective medical practice:

- Many procedures are more tolerable for the patient, and easier for the provider, if the patient receives sedation.
- In order to provide sedation safely, the American Society of Anesthesiologists (ASA) provides guidelines for patient selection and evaluation and in how we administer sedation, monitor patients and recover patients.
- Completing this presentation and successfully taking the knowledge test are parts of the credentialing process for providing procedural sedation.
- At UM SJMC, separate credentialing exists for adult procedural deep sedation and pediatric moderate sedation. No credentialing exists for pediatric deep sedation and an anesthesiology consult should be obtained in all patients 12 years of age or younger if it is determined that a deep level of sedation will be required.

Provider Credentialing for Adult Procedural Sedation

- **To perform a procedure while supervising a nurse providing moderate sedation, a provider must meet the following criteria**
- **Licensing and Training verification**
 - Hold an unrestricted state license (MD, DO, DPM, DDS, PA or NP)
 - Hold current DEA and state CDS registrations
 - Meet all other credentialing requirements
- **Successfully complete sedation specific training and demonstrate competence**
 1. Complete this presentation and successfully pass the accompanying test with 85% or greater
 2. Review the hospital sedation policy
 3. **Providers must have current certification in ACLS (Physicians board certified in Emergency Medicine are excepted as this is a core competency of the specialty)**

Maintaining Provider Credentialing for Procedural Sedation

- **Ongoing surveillance by the Performance Improvement Department is part of ongoing maintenance of credentials**
 - Number of cases performed
 - Number of adverse events
 - Nature and severity of adverse events
 - Peer review of cases
- **Providers also must demonstrate maintenance of skills**
 - Completion of sedation competency every two years
 - Completion of knowledge test (85% passing)
- **Assessment of ongoing skills competency**
 - Determined by provider's departmental chief

Objectives

At the completion of this Self-Study Guide, the applicant will be able to:

- Assess, monitor, manage, evaluate, and document patient care before, during and after sedation analgesia.
- Discuss techniques for administering pharmacologic agents, which will maintain the patient at the desired level of sedation and analgesia.
- Appropriately manage patients regardless of the level of sedation obtained.
- Discuss the rationale and process for ETCO₂ monitoring.

Applications for Procedural Sedation

Some of the Diagnostic and Therapeutic procedures that are appropriate for sedation include:

- Endoscopies
- Cardiac Catheterization
- Radiologic Studies
- Bronchoscopies
- Dental procedures
- Various procedures in the ED setting

Sedation versus Analgesia

- **Sedation** reduces the state of awareness
 - Many sedatives produce amnesia, the inability to remember
 - Benzodiazepines are sedative agents with no analgesic effects
- **Analgesia** reduces or eliminates the perception of pain, most have sedative effects
 - Opioids are primarily analgesics; examples include Morphine and Fentanyl

Continuum of Sedation

The American Society of Anesthesiologists and TJC define four levels of anesthesia:

1. Minimal sedation (anxiolysis): A drug-induced state during which patients respond to verbal commands. This level of sedation may impair cognitive function and coordination. Minimal sedation does not affect ventilatory or cardiovascular function.
2. Moderate sedation/analgesia (formerly called “conscious sedation”): A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or with light tactile stimulation. The patient requires no interventions to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Continuum of Sedation

The American Society of Anesthesiologists and TJC define four levels of anesthesia:

3. Deep sedation/analgesia: A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposely to repeated or painful stimulation. This level of sedation may impair the patient's ability to independently maintain ventilatory function. A patient may require assistance to maintain a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Continuum of Sedation

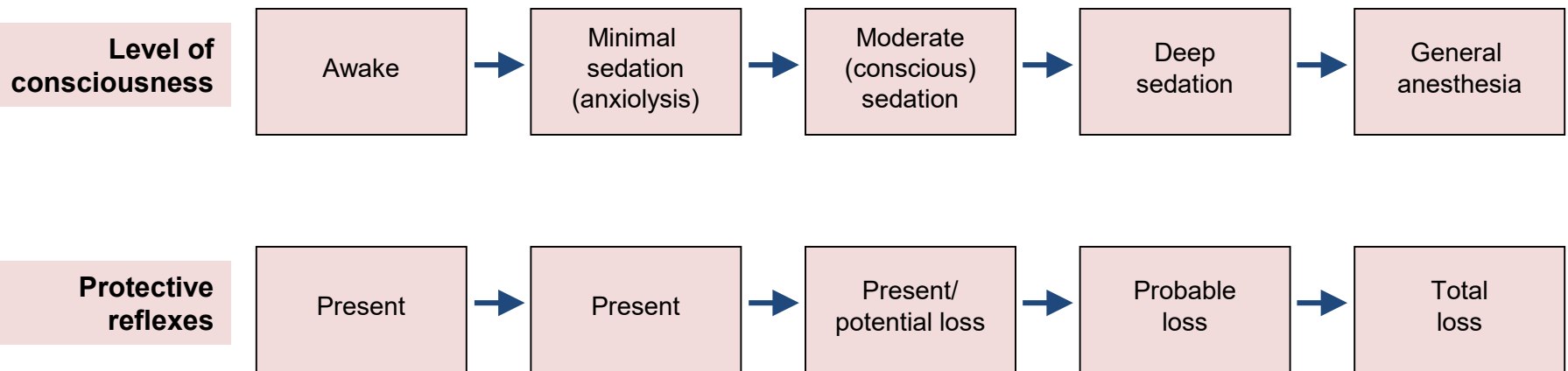
The American Society of Anesthesiologists and TJC define four levels of anesthesia:

4. General anesthesia: A drug-induced loss of consciousness during which patients cannot be aroused even by painful stimulation. It does not include local anesthesia. General anesthesia frequently impairs the ability to independently maintain ventilatory function. Patients often require assistance to keep their airway patent. Patients may need positive-pressure ventilation because general anesthetics may depress spontaneous ventilation and neuromuscular function. General anesthesia may impair cardiovascular function.

Continuum of Depths of Sedation

Patients may move between states of sedation based on medications administered and stimulation received.

Providers should be prepared to rescue patients if sedation is deeper than intended.



Moderately Sedated



A Moderately Sedated Patient:

- Looks like this and is arousable to verbal stimuli, able to answer your questions and respond to verbal commands (like “take a deep breath”).
- Is able to maintain his/her own airway and breathes adequately, taking full, **not shallow** breaths.

Moderate to Deep Sedation



If the patient goes from Moderate Sedation to Deep Sedation, the person monitoring the patient:

- Makes the MD doing the procedure aware
- Helps patient maintain open airway
(oral airway, head tilt-chin lift, jaw thrust)
- Assists with ventilations via Ambu Bag & Mask with 100% O₂ as needed
- Administers reversal agents if needed
- Supports BP & cardiac rhythm with fluids and meds if needed

Undesired Effects of Deep Sedation

1. Airway obstruction (tongue)
2. Respiratory depression->Apnea
3. Hypotension
4. Agitation
5. Unarousable sleep
6. Significantly slurred speech
7. Nystagmus

Consent for Procedure + Sedation

- Physician to explain risk & benefits to patient & family & obtain informed consent
- Obtain patient signature **prior** to administration of any sedative or opioid
 - Include time and date
- Witness's signature
 - Time and date should match patient's
 - Witnessing patient signed consent

ASA Classification

ASA Classification is completed by the physician

- ASA I - Healthy Patient
- ASA II - Patient with mild systemic disease
- ASA III - Patient with severe systemic disease

(For example; history of CVA, DM w/ end organ damage, CRF w/ dialysis, oxygen dependent COPD, CABG, multiple Cardiac Stents, Cardiomyopathy, MI, Cardiac or Respiratory Arrest, Pacemaker → Procedure MD to consult Anesthesia Provider prior to procedure → Procedure may become Monitored Anesthesia Care (MAC) or General Anesthesia, both provided by Anesthesiologist)

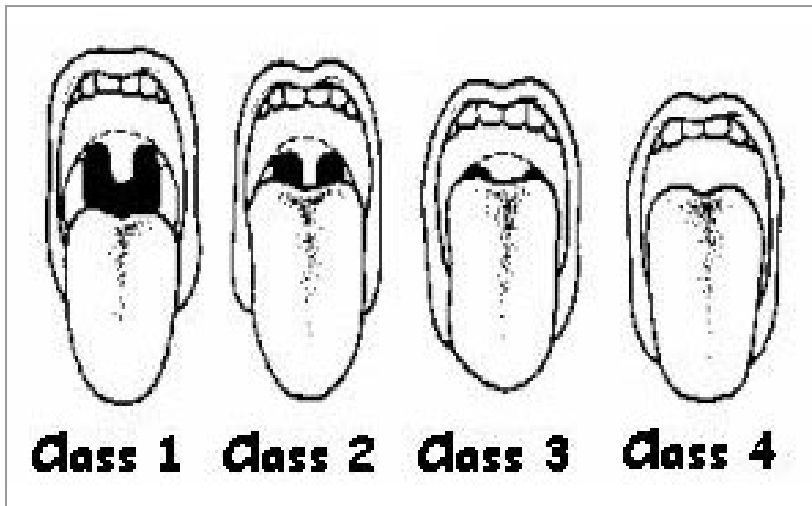
ASA Classification

These ASA levels require an Anesthesia Qualified Physician:

- ASA IV – Patient with Severe Systemic Disease that is a constant threat to life
- ASA V – Patient is moribund – not expected to survive without the procedure
- ASA VI – Patient declared brain dead whose organs are being removed for donor purposes

Airway Assessment

The Mallampati score predicts ease of intubation. Class 1 and 2 are likely easy to intubate while class 3 and 4 may be difficult to intubate.



Mallampati Classification

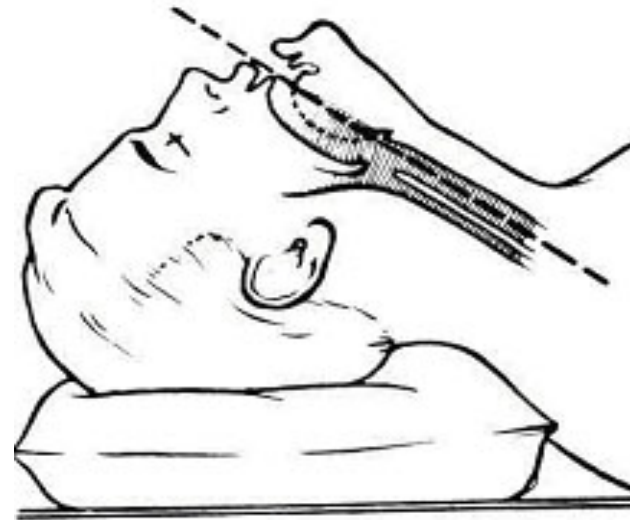
Scoring is as follows:

- Class 1: Full visibility of tonsils, uvula and soft palate
- Class 2: Visibility of hard and soft palate, upper portion of tonsils and uvula
- Class 3: Soft and hard palate and base of the uvula are visible
- Class 4: Only hard palate visible

Airway Assessment

Examine the patient and look for other features that may predict airway obstruction or difficult intubation.

- Morbid obesity
- Hx OSA, snoring
- Small mouth opening (<3 fingerbreadths)
- Large tongue
- Large overbite
- Short neck
- Arthritis of neck
- Previous tracheostomy
- History of neck irradiation



Identify Risk Factors

Potential risk factors identified during patient history & physical:

1. Communication barriers
2. Pregnancy
3. Hx drug, alcohol, tobacco use
4. Lack of patient prep (patient unable to be NPO)
5. Use of opioids w/in 24 hours of procedure
6. Previous adverse experience with sedation or anesthesia
7. Recent cold, flu or fever
8. Unstable Vital Signs (BP, HR, Rhythm, RR)
9. GI Bleed

NPO Guidelines

- Prior to Non-emergent procedure no:
 - 8 hours – Solid food
 - 6 hours – Light meal or particulate liquids
 - 4 hours – Breast milk
 - 2 hours – Clear liquids
- Emergency Dept. procedures: Assume full stomach, anticipate increased risk of aspiration
- If the patient is not NPO, consider the risk of aspiration vs the risk of waiting the appropriate time or waiting for an anesthesia provider. Expected level of sedation required to complete procedure should also be factored into the decision.

Pre-Procedure Assessment

- Consent -----→ • Includes the procedure (no abbreviations), plan for sedation, & signatures
- ASA Classification-----→ • Physician identifies candidates appropriate for Procedural Sedation
- Mallampati Score-----→ • Physician identifies patient with potential airway problem
- NPO status -----→ • Identifies patient with potential for aspiration
- Patient History & Physical---→ • Identifies conditions which affect patient response to Procedural Sedation

Equipment & Training Required

Always ensure that rescue equipment is readily available.

Equipment

- Patent IV
- Reversal Agents
- Monitor-continuous ECG rhythm, BP, O₂ sat, capnography
- Oxygen via NC/Mask
- BagValveMask (BVM)
- Oral & Nasal Airways
- Laryngeal mask airway
- Intubating equipment
- Operating Suction
- Stethoscope
- Code Cart with Defibrillator
- Cricothyrotomy Tray

Training

- **ACLS, or Code Blue Level 2 certified RN who has NO additional responsibilities other than administering sedation & monitoring the patient**
- Sedation and monitoring must be provided by a Registered Nurse who has successfully completed the moderate sedation education and competency

Intra-Procedure

Administering Meds & Monitoring the Patient Intra-Procedure

- Baseline vital signs (BP, HR, Respiration rate & depth, SAO₂, ETCO₂, Sedation Level, & Pain Score)
 - Monitor the above parameters every 5 minutes with continuous ECG rhythm
- Administer IV meds over recommended time periods, giving meds chance to take effect
- Titrate meds according to above parameters
- Assess level of sedation & pain score by asking patient to answer questions and to take deep breaths

Richmond Agitation and Sedation Scale (RASS)

+4 Combative

+3 Very Agitated

+2 Agitated

+1 Restless

0 Alert and Calm

-1 Drowsy

-2 Light Sedation

-3 Moderate Sedation

-4 Deep Sedation

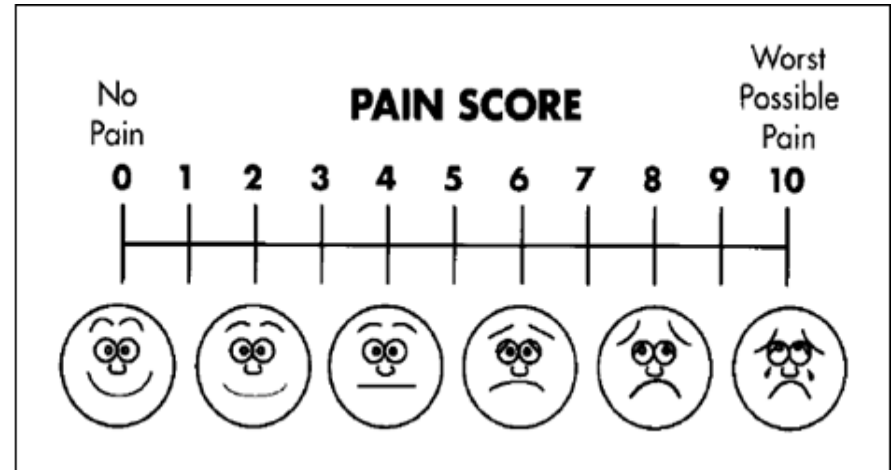
-5 Unarousable

Intra-Procedure Monitoring

- **Observe for signs and symptoms of airway obstruction**: tongue, soft palate collapse, snoring, loss of pharyngeal and laryngeal reflexes
- **Skin Condition**: color, turgor, temperature
- **Observe Neurological Activity**: Pupil activity, eyelid movement

Pain Score

- The goal is comfort with safety
- Pain score of 3 or less
- Vital signs stable
- Airway open, respirations adequate



Procedural Sedation-RN Administered

Medications the Moderate Sedation Competent RN may administer:

- Verbal sedation - reassuring the patient
- Opioids (Fentanyl, Morphine) produce analgesia
- Benzodiazepines (Midazolam, Diazepam, Lorazepam) produce amnesia
- Combined (small doses of both an opioid and a benzodiazepine) work synergistically to produce analgesia and amnesia=moderate sedation
- Ketamine – dissociative sedation

Opioids

- Opioids remain the gold standard for treatment of severe pain.
 - Fentanyl is a synthetic opioid. It is **50 to 100** times more potent and has a shorter duration than morphine.
 - An unusual complication, chest wall rigidity, may occur with large doses (usually >5 microgram/kg) given rapidly. You may need to use neuromuscular blockade and tracheal intubation to treat this complication.
- Morphine may also be used. Due to its histamine release, use caution in patients with Asthma.

- The most common adverse effects of opioids are:
 - RESPIRATORY DEPRESSION
 - Bradycardia
 - Pruritis
- Hemodynamically compromised patients (i.e, dehydration) may develop hypotension.

Benzodiazepines

- Benzodiazepines are sedative hypnotic agents that produce amnesia.
- Benzodiazepines can cause respiratory depression, especially with concomitant use of barbiturates or opioids. Occasionally a paradoxical excitatory reaction occurs. Hypotension occurs less frequently with these drugs than with barbiturates.
- For patients who are hemodynamically unstable (i.e., hypotensive or hypovolemic), you should decrease the recommended dose (typically by 50%).

Deep Sedation Medications

The following medications may NOT be used for moderate sedation and must be MD administered (RESTRICTED TO ED AND CRITICAL CARE PHYSICIANS FOR PROCEDURAL DEEP SEDATION):

- Propofol and Etomidate are administered by Anesthesia Qualified Physicians (Anesthesiologists, Intensivists in ICU & NICU, Emergency Dept. Physicians)
- Due to narrow therapeutic window these agents may only be used for procedural sedation when the intended goal is DEEP sedation
- These patients **also** require monitoring during the recovery to pre-procedure status by the RN

*****RN may NOT administer Propofol or Etomidate*****

Dissociative Anesthetics (Ketamine)

Ketamine is a dissociative agent that produces a cataleptic (i.e., trance- like) state in which the eyes remain open with a slow nystagmic gaze. Patients are non-communicative but they appear awake.

- Can produce general anesthesia when given in larger doses. Its duration of action is variable (15 to 60 minutes). Use the lower dose range for hemodynamically compromised patients.
- Adverse effects of Ketamine include increased systemic (BP), intracranial, and intraocular pressures; hallucinogenic emergence reactions ; **laryngospasm**; and excessive airway secretions.
- Produces potent analgesia and rapid sedation; it preserves respiratory drive and airway protective reflexes when used in appropriate doses.
- Given in 10-20mg incremental doses IV for moderate and deep sedation

Naloxone (Narcan)

- Naloxone is the prototypical narcotic receptor antagonist. When you suspect that respiratory depression is caused by opioid effect, use naloxone in small doses (0.005-0.01mg/kg). This dose will maintain some analgesia for the underlying pain.
- If the initial dose is ineffective, repeat titrated doses every 1 to 2 minutes.
- The maximum dose is 0.1mg per dose. You may give naloxone by the IV, IM or tracheal route.

(Note that this dose is intentionally much lower than the dose recommended for immediate and full reversal of narcotic poisoning.)

Flumazenil (Romazicon)

- Flumazenil, a benzodiazepine receptor antagonist, can reverse benzodiazepine-induced respiratory depression and paradoxical excitatory reactions. *It is ineffective for opioid narcotic reversal.*
- Providers generally give flumazenil in doses of 0.01 to 0.02 mg/kg; you may repeat these doses every 1 to 2 minutes up to a maximum dose of 1 mg.
- Use caution if the patient has a history of seizures because Flumazenil may induce seizures.

Recognize and Rescue

- **With recognition of adverse effects, stop the procedure in order to stabilize and support the patient.**
- If respiratory depression or airway obstruction occurs during sedation, you should immediately open and clear the airway. Then provide assisted ventilation and 100% oxygen as needed.
- If you decide to give a reversal agent, consider the following agents.
 - For opioid narcotic reversal: Naloxone (Narcan)
 - For benzodiazepine reversal: Flumazenil (Romazicon)
- Beware of the adverse effects of reversal agents. Weigh the benefit of immediate reversal against provision of respiratory assistance until the adverse effects of the narcotic or benzodiazepine dissipate.

Note that the half-life of the reversal agent is frequently shorter than the half-life of the sedative agent. Observe for recurrence of sedation after the effects of the reversal agent dissipate.

Suggested Sequential Management of Airway Obstruction

- Reposition the airway
- Perform a jaw thrust
- Insert oral airway
- Call for help
- Insert nasal airway
- Insert supraglottic airway device (LMA)
- Tracheal intubation
- Surgical airway (percutaneous cricothyrotomy)

Post-Procedure Care

- The expectation of post-procedure care is to verify the patient's return to baseline status.
- Constant observation with vital signs at least every 15 minutes until "Recovery Phase Completion Criteria" are met.
- The period of time in "Recovery Phase" should be at least 90 minutes after the last dose of reversal agent if given.

Completion of recovery phase criteria:

1. Alert, oriented x 3
2. No major discomfort
3. No active bleeding
4. Stable VS (within normal range or 20% of pre-procedure VS)
5. Adequate respirations $\text{SaO}_2 > 90\%$ on room air

Criteria for Discharge Home

- Patient is alert and oriented X3 or sensorium is essentially the same as pre-procedure
- Is ambulating without excessive dizziness; demonstrates good motor control or is back to pre-procedure status
- Is without major discomfort or significant bleeding
- Has stable vital signs for 30 minutes
- Tolerates PO fluids without nausea or vomiting, or nausea under control with medication

Discharge Instructions

- Receives written discharge instructions and a verbal review with their responsible adult companion
- Patient may not drive for 24 hours
- Instruct patient to avoid making any legally binding decisions/sign legal documents or operate heavy equipment for at least 24 hours
- No alcoholic beverages for at least 24 hours

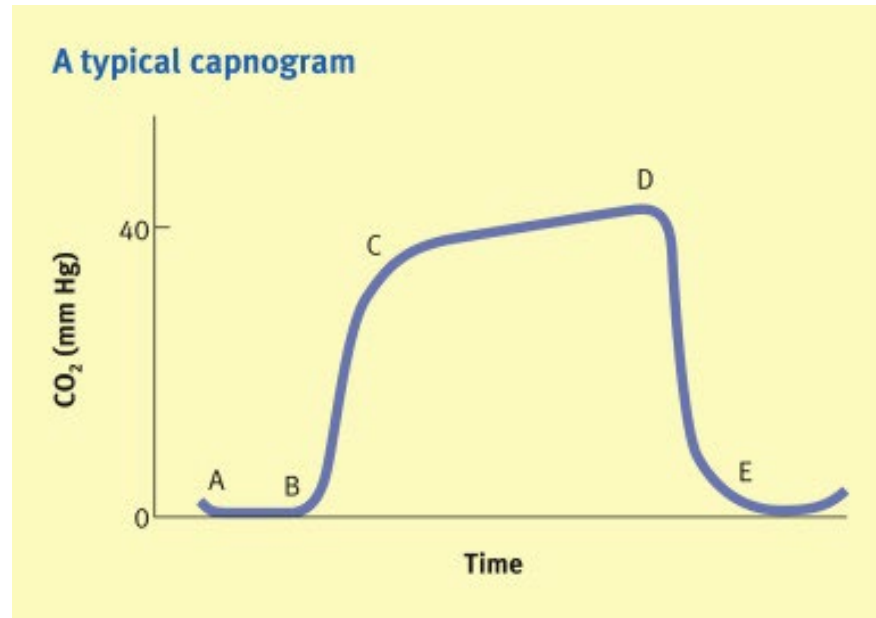
Post Procedure Documentation

- CMS requires all of the following to be included in a post procedure note:
 - Respiratory function, including respiratory rate, airway patency, and oxygen saturation
 - Cardiovascular function, including pulse rate and blood pressure
 - Mental status
 - Temperature
 - Pain
 - Nausea and vomiting
 - Post operative hydration

CO₂ is a Ventilation Vital Sign

- There are two components to breathing
 - Oxygenation – measured by SpO₂
 - Ventilation – elimination of CO₂ – measured by exhaled CO₂
- When breathing room air, oxygenation and ventilation are closely matched and measuring SpO₂ provides a good surrogate for ventilation.
- When supplemental oxygen is used, SpO₂ may be maintained while ventilation is inadequate. Treating a low SpO₂ by increasing oxygen flow rate may mask increasing hypercarbia.
- Monitoring CO₂ in addition to SpO₂ provides a direct measure of ventilation and early detection of airway obstruction.
- Monitoring of CO₂ is required by the Joint Commission and by the American Society of Anesthesiologists whenever moderate sedation is performed.

The End Tidal CO₂ Curve

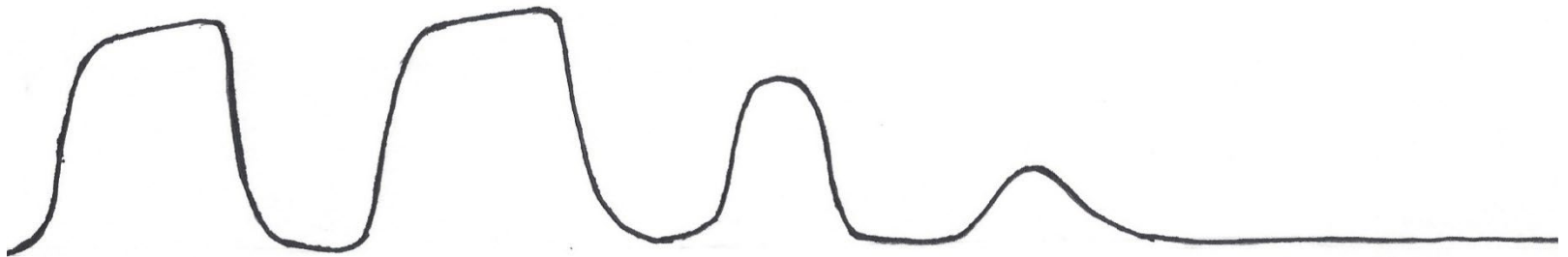


- A-B Inhalation
- B-C Dead Space exhalation
- C-D Alveolar Exhalation
- D-E End Exhalation

CO₂ in Clinical Use

- Early detection of hypoventilation and apnea
- CO₂ fall off may precede SpO₂ drop by as much as a minute

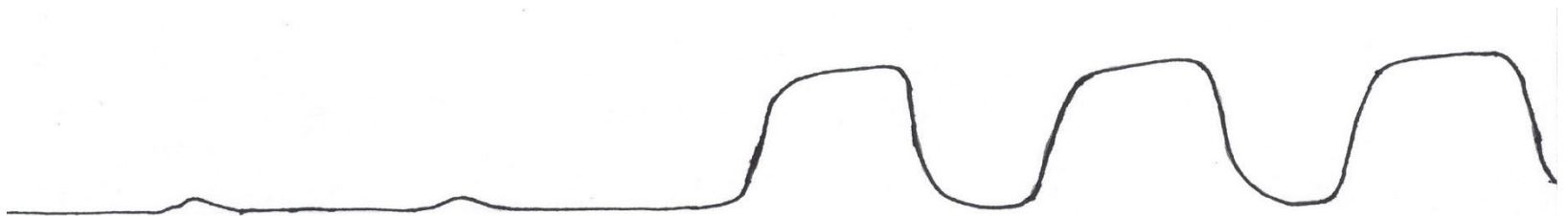
SpO₂ 100%



CO₂ in Clinical Use

- CO₂ provides early confirmation that ventilation has been restored
- SpO₂ will be restored in 10 – 20 seconds

SpO₂ 81%



CO₂ Interpretation

- With sampling from nasal cannula, the patients true ET CO₂ will be greater than that shown on the monitor because room air is entrained in the sample stream.
- The respiratory pattern is more important than the numerical value.
- The CO₂ waveform may be affected by mouth breathing or occlusion of the aspiration port on the nasal cannula.
- CO₂ sampling doesn't replace the requirement to Observe and Examine the Patient

Deep Sedation is Anesthesia

- CMS defines Deep Sedation as MAC Anesthesia
- Anesthesia may only be provided by:
 - A Physician (MD, DO)
 - A Dentist
 - A Podiatrist
- The only exception is within the Emergency Department and ICU
 - Board certified ED physicians and Board certified Critical Care physicians who are appropriately credentialed may provide Deep Sedation within the ED and ICU

Definitions of Deep and Dissociative Sedation

- **Deep sedation/analgesia:** A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposely to repeated or painful stimulation. This level of sedation may impair the patient's ability to independently maintain ventilatory function. A patient may require assistance to maintain a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- **Dissociative sedation:** A unique trancelike cataleptic state produced by ketamine and characterized by profound analgesia and amnesia. Airway reflexes, respiratory function and cardiovascular function are usually maintained.

Agents Used in Deep Sedation

- Deep sedation may be produced by the same agents used for moderate sedation (e.g. midazolam and fentanyl)
- Propofol and Etomidate are specifically used to produce deep sedation or general anesthesia. They may not be used to produce moderate sedation due to their narrow therapeutic window
- Ketamine is used to produce moderate sedation, deep sedation or general anesthesia

Propofol

- Propofol is a sedative/hypnotic agent without analgesic activity
- Onset of action ~ 40 seconds
- Titrate small amounts to desired effect
- May cause respiratory depression, apnea > 60 seconds, hypotension, bradycardia, and airway obstruction
- **Synergistically acts to intensify the respiratory depression caused by opioids**
- Propofol has amnestic and anti-emetic properties
- Recommended dosing is 1mg/kg bolus with repeat doses of 0.5mg/kg every 3-5 minutes
- Dosing must be adjusted downward for patients with hemodynamic compromise, frail or elderly, patients receiving adjunct sedation meds, and patients at high risk for airway obstruction
- Causes painful injection; larger veins preferred

Etomidate

- Etomidate is a hypnotic drug without analgesic activity
- Rapid onset (< 1minute), brief duration
- Greater cardiovascular stability than propofol. Maintains heart rate, blood pressure and cardiac output
- May cause apnea similar to propofol
- Associated with nausea/vomiting
- May cause adrenal suppression
- May cause myoclonus
- Recommended dosing 0.1-0.2mg/kg bolus followed by 0.05mg/kg boluses every 3-5 minutes
- Causes painful injection; larger veins preferred

Ketamine

- Ketamine produces dissociative sedation. This is a trance like state in which eyes may remain open and exhibit nystagmus. Patients are non-communicative but may appear awake.
- Ketamine may be titrated IV (10 -20 mg increments) or may be given as a single IM dose (4-5 mg/kg for pediatrics, 6.5 mg/kg for adults).
- Onset of action 30 seconds IV, 3-5 minutes IM.
- Reduces cardiac contractility. Use with caution in patients with CM.
- Maintains heart rate and blood pressure through sympathomimetic stimulation.
- Maintains spontaneous respiration.
- Causes vivid hallucinations, hypersalivation, increased intracranial and intraocular pressures, laryngospasm.
- Relatively contraindicated in patients with psychosis.

Monitoring Deep and Dissociative Sedation

- Moderate Sedation, Deep Sedation and General Anesthesia all require the same level of monitoring.
 - Continuous 3 lead EKG, SpO₂ and ETCO₂, NIBP every 5 minutes.
 - Qualitative monitoring of consciousness, respiration, and pain scale.

Post Procedure Care

- Patient to be monitored to PACU standards.
- As specified by Policy
- Supplemental oxygen as needed
- 3 lead EKG, NIBP and SpO₂ monitoring every 15 minutes
- Pain medication and warming as needed
- Patient and family education

Post Procedure Documentation

- CMS requires all of the following to be included in a post procedure note:
 - Respiratory function, including respiratory rate, airway patency, and oxygen saturation
 - Cardiovascular function, including pulse rate and blood pressure
 - Mental status
 - Temperature
 - Pain
 - Nausea and vomiting
 - Postoperative hydration

When to consider consultation with the anesthesia department for deep sedation:

- All ASA IV and ASA V patients
- Patients with full stomachs, especially those at increased risk for aspiration (diabetics, obese, pregnant, substance abuse)
- Patients at risk for airway obstruction (h/o OSA, morbidly obese, MPA Class III or IV, airway abnormalities)
- Patients with communication barriers
- Patients with a history of adverse experiences with anesthesia
- Patients with unstable vital signs or active bleeding
- Patients with severe heart valvular disease
- Patients with severe pulmonary HTN
- Any time it crosses your mind!

Review of Hospital Policy APC 20

Please review hospital policy APC 20: Procedural Sedation Analgesia by Non-Anesthesia Provider

After review, complete the competency exam. A score of 85% is required to pass the exam.