Deep Sedation Provider Course for Non-Anesthesiologists

San Antonio Regional Hospital

A Self-Directed Learning Module

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DEEP SEDATION PROVIDER COURSE
A SELF-DIRECTED LEARNING MODULE

Objectives

- The participant will be able to identify the common procedures in which deep sedation is appropriate.
- The participant will be able to explain the criteria for the proper level of sedation on the sedation continuum and be able to differentiate between the different levels of sedation.
- The participant will be able to identify common medications used in deep sedation and their effect/side effects.
- The participant will be able to understand when the need to "rescue" a patient from general anesthesia arises.
- The participant will be familiar with the proper reversal agents for opioids and benzodiazepines commonly used in deep sedation.
- The participant will be able to explain the proper monitoring of patients undergoing deep sedation.
- The participant will be familiar with the sources of guidance of practice regarding deep sedation.

Introduction to Deep Sedation

Sedation and analgesia follow a continuum ranging from anxiolysis to general anesthesia and the criteria for the different levels are outlined in a later section. The purpose of this series of models is to help credential non-anesthesia providers in providing safe and effective sedation.

Deep sedation is a state of sedation and analgesia in which the patient provides a purposeful response to repeated or painful stimulation, may require airway and ventilatory assistance, while usually maintaining his/her cardiovascular function. The growing number of outpatient procedures, advances in medical technology, and increasing population has lead to an increasing number of procedures being performed under Deep sedation. *While it is the position of the American Society of Anesthesiologists (ASA) that no one other than licensed anesthesia providers should perform Deep sedation, many facilities are now credentialing emergency room physicians to perform Deep sedation.*

Advanced cardiopulmonary resuscitation equipment and trained personnel should always be immediately available anytime Deep sedation is being performed. (American Association of Anesthesiologists Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, 2002)

Sedation Continuum

The American Association of Anesthesiologists (ASA) has adopted a continuum for the levels of sedation and analgesia from minimal sedation (anxiolysis) through general anesthesia. This continuum provides an easy to follow and fairly predictable course of patient sedation. It should be noted that not all patients will follow the continuum in exactly the same way and sedation/analgesia must be customized for each patient as an individual. The clinician must take into account each patients age, comorbidities, allergies, and physical characteristics.

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Criteria for this continuum is based upon the patients responsiveness, airway self preservation, spontaneous ventilation and cardiovascular function. It is important to point out that any practitioner should have the capabilities to rescue a patient from one level of deeper than the intended level of sedation. This means that in

order to provide deep sedation the practitioner must be able to rescue a patient from general anesthesia. (ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, 2002)

Sedation Level	**Meaning**
Minimal Sedation	Minimal sedation may be defined simply as anxiolysis. The patient has a normal response to verbal stimulation with their airway, spontaneous ventilation, and cardiovascular function unaffected. This may be illustrated by using a small amount of a benzodiazepine to a patient to relieve preoperative anxiety.
Moderate Sedation	Moderate sedation is commonly referred as conscious sedation. It is characterized when a patient has a purposeful response to verbal or tactile stimulation. The patient's airway management requires no intervention with spontaneous ventilation. Cardiovascular function is usually maintained.
Deep Sedation	Deep sedation is a state between moderate sedation and general anesthesia. The Deeply sedated patient provides a purposeful response to repeated or painful stimulation. The patient may require airway and ventilatory assistance. Cardiovascular function is usually maintained.
General Anesthesia	General anesthesia is characterized by a patient who is un- arousable to even painful stimuli. Airway intervention is often required and spontaneous ventilation is frequently impaired. Cardiovascular function may be impaired.

Factor	**Minimal Sedation**	**Moderate (Conscious) Sedation**	**Deep Sedation**	**General Anesthesia**
Consciousness	Relaxed, Awake, Impaired Cognition +/-	Sleepy, Drowsy	Asleep	Unconscious
Responsiveness	Verbally Responsive Responsive to Tactile Stimuli	Verbally Awakens Purposeful movement to stimuli May be amnestic	Verbally Unresponsive Responsive to Deep Stimuli(may be purposeful)	Unresponsive
Airway	Unaffected	Patent	+/- Impaired	Impaired
Ventilation	Unaffected	Adequate	Inadequate, O2 Supplement	Impaired
Cardiovascular	Unaffected	Stable	Stable	Impaired +/-

(Adapted from Colson, 2005)

Pharmacology of Deep Sedation

The goal of deep sedation is to allow the practitioner to perform the procedure with minimal pain and discomfort to the patient. While there is no standard recipe for deep sedation, a combination of intravenous sedatives/hypnotics are used most often. Opioids and benzodiazepines may also be used in different combinations and titrated to the desired level of sedation and analgesia. Propofol, etomidate, and ketamine are commonly used IV sedative/hypnotic drugs that are used during deep sedation. Midazolam alone or midazolam and fentanyl are also commonly used.

Medications for the deep sedation regimen should be based upon their effects, duration of action, ease of reversal, and relative safety. **It is important to keep in mind the widely varied individual patient response to these medications and the synergistic effect they have when used together.** Synergism is not only found with sedation but also, with the exception of ketamine, with decreases in heart rate, blood pressure, and respiration. It is also important to point out the practitioner performing the procedure should not also be tasked with delivering the sedation/analgesic medications. (Cohen et al., 2007)

It is recommended that the person who delivers the medications and monitors the patient have no other responsibilities. Regardless of the choice of medications they should be carefully titrated with adequate time to exert their maximal effect. (ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, 2002)

Pharmacodynamics - Pharmacodynamic properties of propofol are dependent upon the therapeutic blood propofol concentrations. Steady-state propofol blood concentrations are generally proportional to infusion rates. Undesirable side effects, such as cardiorespiratory depression, are likely to occur at higher blood concentrations which result from bolus dosing or rapid increases in infusion rates. An adequate interval (3 to 5 minutes) must be allowed between dose adjustments in order to assess clinical effects.

The hemodynamic effects of DIPRIVAN Injectable Emulsion during induction of anesthesia vary. If spontaneous ventilation is maintained, the major cardiovascular effect is arterial hypotension (sometimes greater than a 30% decrease) with little or no change in heart rate and no appreciable decrease in cardiac output. If ventilation is assisted or controlled (positive pressure ventilation), there is an increase in the incidence and the degree of depression of cardiac output. Addition of an opioid, used as a premedicant, further decreases cardiac output and respiratory drive.

If anesthesia is continued by infusion of DIPRIVAN Injectable Emulsion, the stimulation of endotracheal intubation and surgery may return arterial pressure towards normal. However, cardiac output may remain depressed. Comparative clinical studies have shown that the hemodynamic effects of DIPRIVAN Injectable Emulsion during induction of anesthesia are generally more pronounced than with other intravenous (IV) induction agents.

Induction of anesthesia with DIPRIVAN Injectable Emulsion is frequently associated with apnea in both adults and pediatric patients. In adult patients who received DIPRIVAN Injectable Emulsion (2 to 2.5 mg/kg), apnea lasted less than 30 seconds in 7% of patients, 30 to 60 seconds in 24% of patients, and more than 60 seconds in 12% of patients. In pediatric patients from birth through 16 years of age assessable for apnea who received bolus doses of DIPRIVAN Injectable Emulsion (1 to 3.6 mg/kg), apnea lasted less than 30 seconds in 12% of patients, 30 to 60 seconds in 10% of patients, and more than 60 seconds in 5% of patients.

During maintenance of general anesthesia, DIPRIVAN Injectable Emulsion causes a decrease in spontaneous minute ventilation usually associated with an increase in carbon dioxide tension which may be marked depending upon the rate of administration and concurrent use of other medications (e.g., opioids, sedatives, etc.).

During monitored anesthesia care deep sedation, attention must be given to the cardiorespiratory effects of DIPRIVAN Injectable Emulsion. Hypotension, oxyhemoglobin desaturation, apnea, and airway obstruction can occur, especially following a rapid bolus of DIPRIVAN Injectable Emulsion. During initiation of deep sedation, slow infusion or slow injection techniques are preferable over rapid bolus administration. During maintenance of deep sedation, a variable rate infusion is preferable over intermittent bolus administration in order to minimize undesirable cardiorespiratory effects. In the elderly, debilitated, or ASA-PS III or IV, aortic stenosis or cardiomyopathy patients, rapid (single or repeated) bolus dose administration should not be used for deep sedation.

For general anesthesia or monitored anesthesia care deep sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. Sedated patients should be continuously monitored, and facilities for maintenance of a patent airway, providing artificial ventilation, administering supplemental oxygen, and instituting cardiovascular resuscitation must be immediately available. Patients should be continuously monitored for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation. These cardiorespiratory effects are more likely to occur following rapid bolus administration, especially in the elderly, debilitated, or ASA-PS III or IV patients.

Contraindications - DIPRIVAN Injectable Emulsion is contraindicated in patients with a known hypersensitivity to DIPRIVAN Injectable Emulsion or any of its components.

DIPRIVAN Injectable Emulsion is contraindicated in patients with allergies to eggs, egg products, soybeans or soy products.

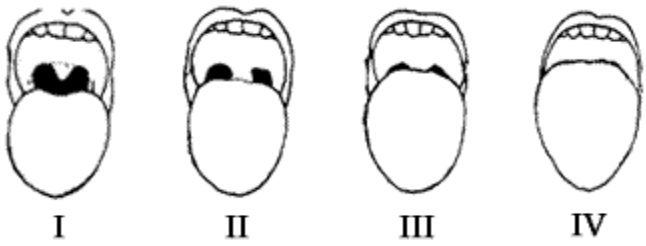
Sedative/Hypnotic	**Dose**
Propofol (Diprivan)	Initial Dose: 10-40 mg Additional Dose: 25-75 mcg/kg/min or 10-20 mg Onset: 1 min Peak Effect: 1-2 min Duration: 4-8 min

Monitoring and Evaluation - Appropriate patient selection criteria are an important factor in deep sedation. The ASA has devised a patient categorization system based upon patient co-morbidities and risk of adverse events.

ASA Physical Status	**Meaning**
Class I	A normal healthy patient
Class II	A patient with mild systemic disease (eg, controlled reactive airway disease)
Class III	A patient with severe systemic disease (eg, a child who is actively wheezing)
Class IV	A patient with severe systemic disease that is a constant threat to life. (eg, a child with status asthmaticus)
Class V	A moribund patient who is not expected to survive with the operation (eg, a patient with severe cardiomyopathy requiring heart transplantation)
Class VI	A declared brain-dead patient for organ donation
E (suffix)	Physical status classification appended with an "E" connotes a procedure undertaken as an emergency (e.g., an otherwise healthy patient presenting for fracture reduction is classified as ASA physical status I E)

Special attention must be given to the patient's airway. In a closed claims review, respiratory compromise accounted for the single largest class of adverse outcomes (Cheney, Posner, and Caplan, 1991). There is no one evaluation that will determine whether a patient will have a difficult airway. Any of the following conditions may be considered a potential difficult airway: obesity, malocclusion of the jaw, congenital abnormalities, trisomy 21, cervical vertebrae disease, and past facial trauma. Patients who have difficulty extending their neck may have < 3 finger breadths of distance between upper and lower incisors or < 3 finger breadths distance between their hyoid bone and mental process may all be potential difficult airways. The Mallampati airway classification system in evaluating is also an important tool the patient's airway (Wilson and Benumof, 1998).

Mallampati Airway Classification System



- Faucial pillars, soft palate and uvula visualized
- Faucial pillars and soft palate visualized, uvula partially masked by base of tongue
- Only soft palate visualized
- Soft palate not visualized

NPO Guidelines

Aspiration pneumonia is a risk anytime a patient is to undergo a procedure with deep sedation. As the patient is sedated he or she may lose the reflexes that protect their airway allowing gastric contents to flow up the esophagus and down into the lungs. This can lead to aspiration pneumonitits, respiratory failure, and even death. The incidence pulmonary aspiration in recent literature is 1.4-4.7 per 10,000 anesthetics. It has been shown that pulmonary aspiration occurs equally in those who received chemoprophylaxis versus those who did not. Factors that have been shown to increase risk of aspiration are increasing ASA physical status, emergency procedures, parturients, obesity, and those with gastric esophageal reflux disease. Patients should be questioned during the preprocedural evaluation as to the time of their last oral intake and the contents of that intake. The procedure should be postponed until the proper amount of time has elapsed from their last oral intake. Any patient undergoing moderate sedation in an emergency is at increased risk of pulmonary aspiration and the risks versus benefits of the procedure should be reviewed (Stoelting, 1995).

Summary of Fasting Recommendations

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
Regular meal	8 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 complete gastric emptying. The fasting periods noted above apply to patients of all ages. Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

Because 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. Additional fasting time (*e.g.*, 8 h or more) may be needed in these cases. Both the amount and type of food ingested must be considered when determining an appropriate fasting period.

During deep sedation it is possible for the patient to move from deep sedation into a state of general anesthesia. If this happens, the patient may lose his protective airway reflexes or spontaneous ventilation. It is important the provider and staff be advanced cardiopulmonary resuscitation certified in order to rescue the patient from general anesthesia. The ability to manage an airway in this circumstance should not be overlooked and emergency airway equipment such as an oral airway and bag valve mask should be immediately available anytime deep sedation is being performed. Oxygen, suction, intubation equipment, and crash cart should also be available (ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, 2002).

One of the most valuable recent developments in the monitoring of patients undergoing deep sedation is the addition of end tidal carbon dioxide (ETCO2) monitor or capnography. Most of these monitors detect the concentration of CO2 in the patient's exhaled breath by drawing a sample of the breath into the monitor and using an infra red beam or gas chromatography to measure the concentration. The results are then displayed as either a numerical value (capnometry) or more usefully as a graph potted against time (capnography). Careful monitoring of this waveform can lead to the detection of respiratory insufficiency, apnea, or airway obstruction often before desaturation is detected in pulse oximetry. Disadvantages of this technology are the cost of the monitor and possible distorted readings when using oxygen at high flows. Nasal cannulas and

masks with ETCO2 sampling ports are now commercially available. (Srinivasa and Kodali, 2008) According to Vargo, Zuccaro, Dumont, Conwell, Morrow, and Shay, (2002), the use of ETCO2 monitoring was more successful in detecting apnea andhypoventilation more than both pulse oximetry and visual observation during procedural sedation. Miner, JR., Heegaard and Plummer, (2002), found that ETCO2 monitoring during procedural sedation in the emergency room may add to the safety of the sedation by detecting episodes of hypoventilation. The ASA recommends ETCO2 monitoring for any patient undergoing deep sedation (ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, 2002).

Vital signs should be recorded at a minimum of every five minutes or sooner. A non-invasive blood pressure cuff and standard electrocardiogram monitoring should be used. The person monitoring patient status, administering medications, and recording vital signs should not be the same person performing the procedure. This persons only duties are to administer medications and monitor the patient.

Consciousness is another important monitoring parameter. Patients undergoing deep sedation should maintain the ability to provide a purposeful response to repeated or painful stimulation. Withdrawal to painful stimuli is not a purposeful response. If the patient fails to respond appropriately the patient has moved into general anesthesia criteria and should be “rescued” back into deep sedation (ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, 2002).

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Drug	*Dosage*	*Clinical Effect*	*Special Considerations*	*Antidote*
PROPOFOL	***Adult:*** ***IV:*** 1mg/kg push followed by 0.5mg/kg q3-5 minutes PRN. **Pediatric:** **IV:** 1mg/kg push followed by 0.5mg/kg q3-5 minutes PRN.	Immediate 5 minutes	*-Hypotension* *-Anaphylaxis* *-Peds: use with Fentanyl may cause serious bradycardia* *-Support airway* *-Discard syringe within 12 hours*	***No reversal agent***

SAN ANTONIO REGIONAL HOSPITAL

DEEP SEDATION EXAMINATION

1) On pre-procedure evaluation, it is noted that a patient can only open her mouth 1 cm because of temporomandibular joint disease. Which of the following is most likely?

A. The patient will have difficulty breathing while awake
B. It may be difficult to rescue the patient if she stops breathing
C. The patient is likely to become hypoxic during minimal sedation (anxiolysis)
D. The patient will require a greater than expected dose of sedative medications

2) During sedation with propofol, a patient stops breathing and become unresponsive to verbal or tactile stimulation. The pulse oximeter reads 86%. Which of the following is most likely to improve the patient's oxygenation?

A. Positive pressure ventilation
B. Supplemental nasal oxygen
C. Intravenous flumazenil
D. Intravenous naloxone

3) The use of supplemental oxygen during sedation

A. Increases the likelihood of hypoxia
B. Delays the detection of apnea by pulse oximetry
C. Should be avoided during moderate("conscious") sedation
D. Decreases the likelihood of airway obstruction

4) A patient has a history of controlled HTN, insulin dependent diabetes and has recently developed angina limiting his exercise tolerance. The most appropriate ASA classification for this patient would be:

A. Class 1
B. Class 2
C. Class 3
D. Class 4

5) What are some ways to decrease the risk of aspiration during a deep sedation procedure?

A. Ensure adequate NPO status
B. Administer Reglan prior to the procedure
C. Consider intubating patients with high frequency of active GERD
D. All of the above

6) The reversal agent for propofol is?

A. Romazicon
B. Versed
C. Narcan
D. None of the above. There is no antidote.

7) Relative contraindications to propofol administration are:

A. Hypovolemia
B. Aortic Stenosis
C. Full Stomach
D. All of the above.

_____	_____	_____
Physician Printed Name	**Physician Signature**	**Date**

(For Medical Staff Office Use Only) _____ # OF MISSED QUESTIONS □ Pass □ Fail

(May only miss one (1) for a passing score)