POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

I. POLICY:

It is the policy of Yukon Kuskokwim Health Corporation (YKHC) to perform safe and effective pain relief for painful or unpleasant procedures.

II. PURPOSE:

The following policy establishes a general approach to the management of the sedated patient as well as minimum criteria for those performing Procedural Sedation and Analgesia (PSA). The policy outlines a specific protocol to ensure the safe performance of procedural sedation and defines the requirements by which a Licensed Independent Provider(LIP)may obtain PSA credentials at YKHC.

III. PROCEDURE:

A. Definitions:
Procedural Sedation and Analgesia (PSA) is the administration of sedative, analgesic, and/or dissociative medications to more comfortably allow the performance of a procedure while simultaneously preserving the patients respiratory and protective airway reflexes. Previously, similar techniques have been termed conscious sedation, however, the terminology procedural sedation and analgesia more accurately describes the intended outcome and has replaced the older nomenclature. Graduated terms to describe the "depth" of sedation based upon the level of responsiveness of the patient: whether light, moderate, deep or general anesthesia, have also been used. This methodology however, undermines the realization that PSA is a dynamic spectrum through which a patient may rapidly progress. Still, these terms provide a means through which one can rapidly describe the level of response expected from the patient.

1. Light sedation represents anxiolysis resulting in a patient capable of normal verbal communication although coordination may be affected.
2. Moderate sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal or light tactile stimulation while maintaining protective airway reflexes.
3. Deep sedation/analgesia is a drug-induced depression of consciousness during which patients are not easily aroused, and may need airway and/or ventilatory assistance, but may respond purposefully to repeated or painful stimulation.

4. General anesthesia, in contrast, is a state of drug-induced loss of consciousness in which patients are not arousable and often have impaired cardio respiratory function needing support.
5. Dissociative sedation, as that which occurs with ketamine, is not adequately described in any of these older classifications schemes. Dissociation represents a trance-like state where the patient has a markedly decreased ability to respond, accompanied by profound analgesia and amnesia while maintaining normal respiratory and cardiovascular function.

B. Inclusion:
This policy applies to all patients who receive a narcotic in combination with a benzodiazepine; or ketamine, propofol, etomidate or other similar agent for the purpose of performing a procedure or a diagnostic exam.

C. Exclusion:
Excluded from this policy are intubated patients or patients undergoing Rapid Sequence Intubation. Patients who are receiving narcotics for pure analgesia purposes or patients receiving benzodiazepines for either muscle relaxation or anxiolysis are also excluded. This policy also does not apply to patients receiving general anesthesia or monitored anesthesia care in the operating room.

D. Provider qualification:
A Licensed Independent Practitioner who is administering procedural sedation must be credentialed through YKHC as defined in this protocol. More broadly that provider must feel comfortable with the management of the patient at the expected level of sedation and the potential for inadvertent progression into the next deeper level of sedation. The provider must be skilled in basic and advanced life support appropriate for the patient's age with an emphasis on airway management including intubation. Additionally, the provider must have a comprehensive understanding of the medications being used including their expected responses and potential complications.

E. Initial Credentialing Criteria
1. Providers must have formal training in procedural sedation, whether during residency, prior practice or proctoring by another provider at YKHC.
2. Providers should have performed a minimum of 10 sedations in the prior 5 years.
3. Providers should be certified in BLS, ACLS or PALS/APLS as age appropriate, or be boarded in Emergency Medicine, Critical Care, or Anesthesiology.

4. Providers must complete the PSA quiz and score 85% or higher.
5. Upon completion of these criteria PSA credentials will be granted through the Medical Staff Executive Board and Governing Board per usual procedure.

F. Maintenance of Credentials

A provider's performance of PSA will be reviewed as needed by the Emergency Department Director or Anesthesia/OR Director. It is recommended that a provider perform a minimum of 5 sedations per year although less may be deemed appropriate by the respective department director.

G. Patient selection.

For routine sedations (non-emergent) patients should be ASA class I, II or III. Children who are ASA III need to be thoroughly assessed for the need of sedation in relation to the relative risk of the procedure. A pre-sedation evaluation and History and Physical exam needs to be documented by the provider. This evaluation should include at minimum: significant past medical history; current medications; allergies; alcohol, tobacco and illicit drug use; pregnancy status if applicable; airway assessment (Mallampatti score etc); cardiovascular assessment; pulmonary assessment; complete set of vital signs including heart rate, BP, respiratory rate and oxygen saturation; a baseline pain score or FLACC score. All pediatric patients must have a weight as well. The standard Emergency Department physicians chart adequately meets this qualification.

When selecting patients for PSA, alternative approaches should also be considered and discussed with the patient or caregiver as appropriate. Such alternatives include: distraction/relaxation, simple analgesia, local anesthesia, regional anesthesia, a combination of these techniques or general anesthesia in the OR.

H. Fasting status.

Currently the topic of fasting status or NPO is controversial. The American Society of Anesthesiologists has recommendations for elective operative procedures. They further state that the risk of aspiration should be considered in the setting of urgent or emergent procedures when deciding the target level of sedation, timing of the procedure or the use of prophylactic endotracheal intubation. The American College of Emergency Physicians has stated that there is no data to show that preprocedural fasting alters outcomes. They have however, presented a guideline that takes into account the urgency of the procedure as well as the risk status of the patient. These guidelines will be accepted and utilized here. Please see the attached table.

POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

I. Consent:
Written informed consent from the patient or their caregiver should be obtained unless the patient's condition will not tolerate delay. Documentation should be done utilizing the YKHC Procedural Sedation consent form. If the patient is incapacitated and thus unable to perform the consent and no surrogate is available then, two independent Licensed Practioners may sign the consent.

J. Process
1. An RN with training in PSA is required to assist in the PSA procedure and will be required to maintain timely records of vital signs and medications administered via the PSA Spread Sheet. The provider and nurse will work in conjunction to optimize the safety of the patient at all times. Safety measures will include the following:
    i. Appropriately sized equipment for the patient to include: oxygen delivery devices and functional oxygen availability, BVM, suction equipment, availability of oral and nasal airways, close proximity to crash cart and any appropriate reversal agents.
    ii. A pre-procedural "time out" to verify the patient, the procedure, and the intended plan of sedation.
    iii. All patients will be placed on a cardiac monitor with SpO_2 monitor. End tidal CO_2 monitoring will be considered if available.
    iv. An IV will be in place for all agents except IM ketamine
    v. Vital signs will be recorded every 5 minutes.
2. The provider will stay at the bedside until reasonable probability of respiratory or hemodynamic complications have ceased. The RN will remain at the bedside until the patient has recovered to baseline mental status.
3. The nurse will continue to monitor the patient until the Aldrete score is 9 or more at which time the patient maybe discharged.
4. Patients must be discharged into the care of a reliable, sober adult. Patients will be given discharge instructions to include post sedation care. This should include warnings to refrain from driving or performing activities that require coordination. The "Discharge Navigator" program in the Emergency Department will fill this requirement. Patients should also not be left alone for minimum of 12 hours after PSA. Patients should refrain from drinking alcohol for at least 24 hours.

K. Performance Improvement
1. All procedural sedations will be logged in the ED sedation log book or the OR log book.

2. The following adverse events occurring during or immediately following a sedation shall initiate a performance review.
    i. Cardiac arrest
    ii. Respiratory arrest requiring BMV or intubation
    iii. anaphylaxis
    iv. Administration of a reversal agent
    v. Persistent hypotension requiring more than a single fluid bolus of crystalloid (1 L in an adult or 20 ml/kg in a child)
    vi. Medication administration error
    vii. Hypoxia demonstrated by SpO2 < 89% for greater than 60 seconds
    viii. Aspiration event
3. It is the responsibility of the provider and the nurse performing the sedation to report the adverse event to the appropriate supervisor.
4. Cases of sedation performed in the Emergency Department that require review will be reviewed by the ED director or his/her designate.
5. Cases of sedation performed in OR that require review will be reviewed by the OR director or his/her designate
6. Adverse events will be reviewed by the appropriate supervisor for any necessary intervention or further reporting to the PI committee.

POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

Appendix A: ASA classification

ASA 1: A patient with localized pathology related to the procedure being performed, without systemic manifestations

ASA 2: A patient with mild systemic manifestations of disease, which may or may not be caused by the pathology related to the procedure, which is well-controlled and which causes minimal limitation in life style or physical activity (e.g., asthma at baseline with basically normal peak flow rate, with or without medication; restrictive ASD or VSD without any evidence of congestive heart failure or pulmonary hypertension and on no medication)

ASA 3: A patient with systemic disease which results in a significant impairment in physical activity or life style (e.g., poorly controlled asthma with significantly reduced peak flow rate; static encephalopathy with seizures and tube feeding without reflux; congenital cardiac disease with controlled congestive heart failure or desaturation; acute lymphoblastic leukemia in remission on maintenance chemotherapy; chronic renal failure with routine dialysis and normal electrolytes and hypertension moderately controlled with medication; insulin-dependent diabetes)

ASA 4: A patient with severe disease, which is a threat to life (e.g., a patient on inotropic therapy, requiring ventilatory assistance, with a recent head injury and alteration of consciousness, septic shock, severe dehydration and hypovolemic shock)

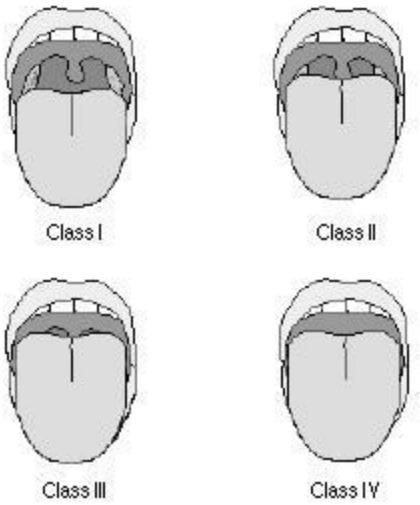
ASA 5: A moribund patient who may die with or without the procedure

ASA 6: A brain-death patient with cardiopulmonary function maintained for organ donation

E modifier: Emergency status with need for procedure without sufficient time for adequate treatment of physiologic risk factors including insufficient fasting time

POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

Appendix B: Mallampatti Score



POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

Appendix C: American College of Emergency Physicians' Fasting and Emergency Department Procedural Sedation and Analgesia Guidelines

Standard-risk patient[a]

Oral intake in the prior 3 hours	Procedural Urgency[b]			
	Emergent Procedure	*Urgent Procedure*	*Semi-Urgent*	*Non-Urgent*
Nothing	All levels of sedation	All levels of sedation	All levels of sedation	All levels of sedation
Clear liquids only	All levels of sedation	All levels of sedation	Up to and including brief deep sedation	Up to and including extended moderate sedation
Light snack	All levels of sedation	Up to and including brief deep sedation	Up to and including dissociative sedation; non-extended moderate sedation	Minimal sedation only
Heavier snack or meal	All levels of sedation	Up to and including extended moderate sedation	Minimal sedation only	Minimal sedation only

Higher-risk patient[a]

Oral intake in the prior 3 hours	Procedural Urgency[b]			
	Emergent Procedure	*Urgent Procedure*	*Semi-Urgent*	*Non-Urgent*
Nothing	All levels of sedation	All levels of sedation	All levels of sedation	All levels of sedation
Clear liquids only	All levels of sedation	Up to and including brief deep sedation	Up to and including extended moderate sedation	Minimal sedation only
Light snack	All levels of sedation	Up to and including dissociative sedation; non-extended moderate sedation	Minimal sedation only	Minimal sedation only
Heavier snack or meal	All levels of sedation	Up to and including dissociative sedation; non-extended moderate sedation	Minimal sedation only	Minimal sedation only

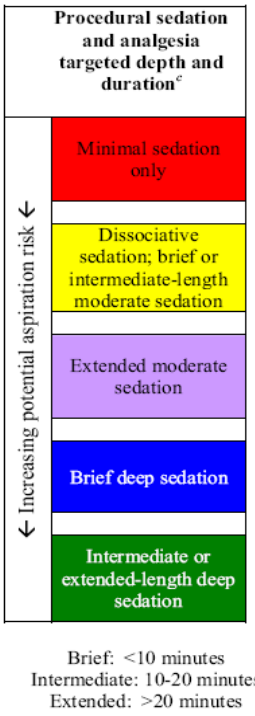


Figure. Prudent limits of targeted depth and length of ED procedural sedation and analgesia according to presedation assessment of aspiration risk

from *Ann of EM, Vol 49, No 4 April, 2007. pp454-61*

Examples of Urgency:

1. Emergency: cardioversion for life-threatening dysrhythmia, reduction of markedly angulated fracture or dislocation with soft-tissue or vascular compromise, intractable pain or suffering
2. Urgent: care of dirty wounds and lacerations, animal and human bites, abscess incision and drainage, fracture reduction, hip reduction, lumbar puncture for suspected meningitis, arthrocentesis, neuroimaging for trauma
3. Semi-urgent: care of clean wounds and lacerations, shoulder reduction, neuroimaging for new-onset seizure, foreign body removal, sexual assault examination
4. Non-urgent or elective: non-vegetable foreign body in external auditory canal, chronic embedded soft tissue foreign body, ingrown toenail

POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

Appendix D: Aldrete discharge scores:

Activity	
Able to move 4 extremities voluntarily or on command	2
Able to move 2 extremities voluntarily or on command	1
Able to move 0 extremities voluntarily or on command	0
Respirations	
Able to cough and deep breathe	2
Dyspnea or limited breathing	1
Apnea	0
Circulation	
Systemic BP +/- 20 mmHG of pre-PSA level	2
Systemic BP +/- 20-49 mmHG of pre-PSA level	1
Systemic BP +/- 50 mmHG of pre-PSA level	0
Consciousness	
Fully awake	2
Arousal by calling	1
Not responding	0
Oxygen Saturation	
Able to maintain SpO2 >92% on room air	2
Need supplemental oxygen to maintain SpO2 > 92%	1
SpO2 < 90% with supplemental oxygen	0

A cumulative score of 9 or greater is criteria for discharge

POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

Appendix E: Agents and Analgesic options currently available at YKHC

benzodiazepenes
- midazolam
- lorazepam
- diazepam

opiates
- morphine
- fentanyl
- (hydromophone is available if the patient is allergic to morphine and fentanyl)

ketamine
etomidate
propofol

Currently there are no barbiturates available.

Reversal agents
- Flumazanil
- Narcan

Alternatives
- Dextrose "sweet ease"
- Topicals
  - EMLA
  - LET
  - benzocaine
- Locals
  - Lidocaine
  - Bupivicaine (Marcaine)

POLICY: Procedural Sedation and Analgesia	POLICY NUMBER: PF_016_PC
CATEGORY: Patient Functions	EFFECTIVE DATE: 7/20/2011
CHAPTER: Provision of Care, Treatment and Services	SUPERSEDES: 3/1/09, 6/2006

Procedural Sedation and Analgesia Quiz

1. Which of the following is false regarding morphine.

    a. hypotension is a possible side effect
    b. histamine release is a potential side effect
    c. rapid administration can cause rigid chest syndrome
    d. 0.1 mg/kg is an acceptable pediatric dose

2. Which of the following is false regarding benzodiazepines:

    a. midazolam used orally for anxyolysis is procedural sedation
    b. midazolam has more amnestic properties than lorazepam
    c. diazepam should not be used with patients who have a history of seizures
    d. midazolam mab be administered IV, IM, PO, and intransally

3. Midazolam has the all of the following properties except:

    a. anxiolysis
    b. analgesia
    c. antiepileptic
    d. amnestic

4. Which of the following do not increase the risk of airway difficulties during a sedation procedure:

    a. increased ASA class
    b. Down's syndrome
    c. Mallampatti class I
    d. Recent URI in patient receiving Ketamine

5. Ketamine is classified as a:

    a. benzodiazepine
    b. narcotic
    c. induction agent
    d. dissociative sedative

6. Propofol should be avoided in the following patients

    a. patients with allergies to shellfish
    b. patients with allergies to nuts
    c. patients with allergies to eggs
    d. patients with allergies to corn

7. The procedural sedation protocol would pertain to the care of which one of the following patients:

    a. 12 yo male with a foreign body in his foot whom you treat with oral oxycodone and local lidocaine
    b. reduction of a dislocated shoulder utilizing intrarticular injection of lidocaine
    c. fentanyl and versed are used to assist in the intubation of a 2 day old infant with respiratory failure
    d. attempt to reduce an incarcerated inguinal hernia in 45 yo male utilizing etomidate

8. Goals of sedation include:

    a. minimize pain
    b. controlling behavior to allow performance of a procedure
    c. guard the patient's safety and welfare
    d. all of the above.

9. Which of the following agents provide analgesia?

    a. fentanyl
    b. diazepam
    c. chloral hydrate
    d. propofol
    e. none of the above

10. Flumazenil may be used to reverse the effects of _____.

    a. midazolam
    b. lidocaine
    c. ketamine
    d. chloral hydrate
    e. a and b

11. Key elements required to provide safe sedation/analgesia include:

    a. skilled personnel
    b. appropriate equipment
    c. monitoring
    d. all of the above

12. Chest wall rigidity is an adverse effect most commonly associated with:

a. nitrous oxide
b. fentanyl
c. morphine
d. meperidine
e. propofol

13. The combined use of narcotics and benzodiazepines increases the risk of:

a. cholestatic jaundice
b. methemoglobinemia
c. respiratory depression
d. arrhythmias

14. Which of the following should be conducted prior to performing a procedure that requires sedation?

a. obtain informed consent
b. review the patients' drug history
c. examine the patients' airway
d. determine the patients' ASA classification
e. all of the above

15. The following equipment should be readily available when sedating a child:

a. equipment for iv access
b. oral airway
c. suction apparatus
d. oxygen delivery system
e. all of the above

16. Risks associated with procedural sedation include:

a. apnea
b. aspiration
c. respiratory depression
d. cardiovascular compromise
e. all of the above

17. The following drugs have the correct effects listed except:

    a. fentanyl – may cause chest wall rigidity, respiratory depression
    b. ketamine – emergence reaction with hallucinations, increases intracranial pressure
    c. etomidate - myoclonus
    d. benzodiazepines – respiratory depression and hypotension
    e. propofol – redman syndrome

18. Ketamine should not be used in patients with URI's because there is an increased risk of _____.

    a. bronchoconstriction
    b. laryngospasm
    c. nystagmus
    d. emergence hallucinations

19. A patient who is scheduled for an EGD presents with wheezing and has been using an albuterol inhaler every four hours. This patient would be classified as a _____ on the American Society of Anesthesiology classification.

    a. Class 1
    b. Class 2
    c. Class 3
    d. Class 4
    e. Class 5

20. Which of the following drug-reaction pair is incorrect?

    a. flumazenil – seizures
    b. morphine – histamine release
    c. propofol – hypotension
    d. etomidate - hypertension

POLICY: Procedural Sedation and Analgesia	**POLICY NUMBER: PF_016_PC**
CATEGORY: Patient Functions	**EFFECTIVE DATE: 7/20/2011**
CHAPTER: Provision of Care, Treatment and Services	**SUPERSEDES: 3/1/09, 6/2006**

Committee Approval:

TJC STANDARD REFERENCE: **PC.13.20, PC.13.30, PC.13.40, PI.2.20**

Department Director Signature: _____ Date: _____

MSEC President's Signature:_____ Date: _____

Governing Body Chair Signature: _____ Date: _____

P&P Committee Signature:_____ Date: _____

Vice President Signature: _____ Date: _____

If policy crosses divisions additional signatures needed.

Vice President Signature: _____ Date: _____

Vice President Signature: _____ Date: _____

Vice President Signature: _____ Date: _____

Vice President Signature: _____ Date: _____

President/CEO Signature:_____ Date: _____