Hospice & Palliative Care
Federation of Massachusetts

Palliative Sedation Protocol

A report of
the Standards and Best Practices Committee
Hospice & Palliative Care Federation of MA
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Palliative Sedation Subcommittee:

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Disclaimer: *The medications that are included in this protocol are to be used as a guide only. Clinical decisions must be made on a case-by-case basis*.

PALLIATIVE SEDATION PROTOCOL

Purpose and Definitions

Palliative Sedation is the monitored use of medications (sedatives, barbiturates, neuroleptics, hypnotics, benzodiazepines or anesthetic medication) to relieve refractory and unendurable physical, spiritual, and/or psychosocial distress for patients with a terminal diagnosis, by inducing varied degrees of unconsciousness. The purpose of the medication(s) is to provide comfort and relieve suffering and not to hasten death.

Refractory Symptoms that justify the use of **Palliative Sedation** are symptoms that cannot be adequately controlled despite aggressive efforts by the interdisciplinary team to provide timely, tolerable therapies that do not compromise consciousness.

Ethical Issues/Justification

The justification for Palliative Sedation is based on the principles of beneficence, non-maleficence, autonomy, and fidelity. The **intent** of Palliative Sedation is the relief of suffering and not to end the patient's life. Congruent to this intent, the **outcome** is that the patient is made unaware of un-endurable suffering through sedation. According to the principle of autonomy an individual has the right to decide care for themselves according to their values, beliefs, or life plan. Informed consent is required in order to make autonomous decisions based on the risks and benefits of any intervention. When a patient no longer has capacity to make decisions for himself/herself, the principle of fidelity, which includes the promise not to abandon another, allows a designated health care proxy or patient representative who knows the patient's wishes, to make informed decisions regarding the patient's care.

Assumptions regarding appropriateness of palliative sedation.

1. Palliative Sedation is used only when there are refractory symptoms
2. Generally the patient's prognosis is hours to days. The intent of palliative sedation is control of suffering, not to hasten death
3. An interdisciplinary team is involved in completing a comprehensive assessment and determining the plan of care
4. The patient, or if lacking capacity, the patient's representative, family, physician, and the interdisciplinary team collaborate regarding the appropriate utilization of Palliative Sedation.
5. Pain management is maintained
6. Informed consent is obtained from the patient if possible or from the patient's health care proxy or designated representative
7. For existential suffering "respite" sedation can be considered for a limited amount of time. Patients requiring respite sedation may not have a prognosis of hours to days.
8. The patient has a DNR order

9. Palliative sedation in a setting other than a hospice inpatient unit or hospital will require the presence of continuous care licensed nurses for a minimum of the first twenty four hours of care. A competent hospice team member must document daily confirmation of effectiveness of the treatment.
10. Staff competency must be demonstrated in the provision of palliative sedation
11. Hospice providers will discuss the provision of hydration and nutrition as a separate intervention with the patient and family

Procedures:

1. Whenever a patient experiences refractory symptoms, palliative sedation may be considered as an intervention to control unendurable suffering.
2. A decision to initiate palliative sedation must be preceded by a comprehensive interdisciplinary assessment of the patient and a discussion of treatment expectations and options
3. Informed consent is required of the patient, or in cases where the patient lacks decision-making capacity, by their health care proxy or designated representative. A discussion of the risks and benefits of palliative sedation will be part of the informed consent process. The written consent for Palliative Sedation will be obtained
4. The patient's primary physician will be involved in the decision to initiate palliative sedation. The patient's physician and the hospice medical director must agree on the decision to implement palliative sedation.
5. Palliative sedation may be implemented in an inpatient setting or at home. For patients who remain at home a continuous care nurse must be provided <u>at least</u> twenty-four hours.
6. If conflicts or disagreements arise relative to initiation of palliative sedation a consultation with the hospice ethics committee is recommended
7. The patient's primary physician or hospice medical director will write the order for palliative sedation (see attached medication guidelines)
8. Once the patient is sedated, medications are not increased unless there is evidence of renewed distress. A lowering of the dose of the sedatives may be attempted at the discretion of the physician, or at the request of the patient's representative. "First stage anesthesia" is the goal of sedation. First stage anesthesia is defined as the onset of disorientation to loss of consciousness. The eyelash reflex is used to assess level of sedation. A soft tactile stroke over a closed eyelid should cause a reduced flicker/reflex in a first state anesthesia. A lack of flicker (reflex) indicates deep sedation and a need to cut back on the dose.
9. Decrease in sedatives will be initiated if the patient experiences, heavy snoring, and abrupt onset of apnea. **Gradual** deterioration of respiration is expected in terminal patients and should not alone constitute a reason to decrease sedation

10. A registered nurse will assess the patient continuously during initiation of therapy and every one-hour until the dose is adjusted to a stable dose. The nurse will monitor the patient for any adverse effect.
11. Sedation will not be attempted by increasing opioid dosages, however opioids will be continued at the previous level in order to ensure pain management and to prevent opioid withdrawal.

Consent Form

See attached

PALLIATIVE SEDATION FOR REFRACTORY SUFFERING CONSENT FORM

Patient name_____

Documentation of refractory suffering:_____
_____
_____
_____

Palliative measures previously attempted:_____
_____
_____
_____
_____

Outcomes of previously attempted palliative measures:_____
_____
_____

Patient _____ Health Care Proxy/Patient representative _____ (check one)

( ) Able to respond intelligibly to queries

( ) Able to take a part rationally in decision-making

( ) Able to articulate the decision

Information presented:

( ) Nature and progress of stage of terminal illness (prognosis)

( ) Nature and possible impact of proposed controlled sedation

( ) Limitation, side effects, and risks of the proposed controlled sedation.

( ) Issues related to hydration and nutrition during sedation

( ) I am aware that Dr._____ (primary physician) agrees with the plan to initiate palliative sedation.
With knowledge of the risks discussed by the physician(s), I consent to controlled sedation for refractory suffering.

Date_____ _____ _____
Patient or authorized representative signature **relationship**

Physician Signature_____ **Date**_____

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DRUG PROTOCOL FOR PALLIATIVE SEDATION

Drug Name/ Class	**Suggested starting dose**	**Usual maintenance dose**	**Drug interactions**	**Side effects or adverse reaction**	**Incremental dose for titration**	**Issues to consider/ Incompatibilities**	**Cost (these are estimates)**
Midazolam (Versed)/ benzodiazepine	Infusion IV or SQ at 0.5 to 1.5 mg/hour after a loading dose of 1-5 mg	30-100 mg/day	CNS depressant so use cautiously with opiates or other CNS depressants Diltiazem and verapamil increase midazolam levels	Hiccups, decreased respiratory rate, nausea and vomiting, variations in blood pressure and pulse rates, paradoxical behavior or excitement	***Hourly maintenance dose should be 25-33% of the required induction dose** *Bolus is equal to the hourly rate every two hours *Adjust the maintenance dose every 2 hours based on numbers of rescue doses needed	Drug of choice for "respite sedation" or whenever reversal of sedation is desired. Drug has a short half-life Drug may be mixed with morphine, Demerol, atropine or scopolamine IV drug is diluted with D5W or normal saline Drug has minimal cardiovascular effects at sedating doses	10mg/5 ml in a 120 ml bottle= $148.00, inj 5mg/ml @$41/ vial
Lorazepam (Ativan)/ benzodiazepine	Start infusion at 0.5- 1 mg/hr 1-4 mg po or buccal q 2-6 hours	4-40mg/day Start at 1mg for drug naïve patient	CNS depressants, May increase digoxin levels and risk of toxicity	Paradoxical agitation Hypotension, Abdominal discomfort, nausea	Titrate dose in increments of 0.5-1mg q 15 minutes times three SQ or IV push, titrate by 1 mg q 2 hours	For bolus dosing, dilute with equal volume of sterile water for injection, normal saline for injection, or D5W. Give slowly at no more than 2 mg/minute	100 tabs @$66, 2mg/ml inj. @ $47
Pentobarbital (Nembutal)/Long acting barbiturate	60-200 mg PR q4h 1-3mg/kg IV loading dose followed by 1 mg//hr	50-150mg	CNS depression potentiated by narcotics	N/V, respiratory depression, rash, Stevens-Johnson syndrome, angioedema, hypotension, syncope, bradycardia laryngospasm, Paradoxical excitement in the elderly	Increase in 1 mg/kg increments per hour to maintain sedation	*Difficult to obtain from community pharmacies Drug has a long half life and sedation reversal is difficult DO NOT mix with other drugs in syringe or IV. Diluted solution is stable for twelve hours only Parenteral solution is alkaline which can cause local tissue reactions and injection site pain with extravasation	12 supp. of 100mg @ $66

Drug Name/ Class	Suggested starting dose	Usual maintenance dose	Drug Interactions	Side effects or adverse reactions	Incremental dose for titration	Issues to consider/ Drug incompatibilities	Cost
Phenobarbital/Long acting barbiturate	60-120 mg PR, PO, SQ Loading dose is 200 mg bolus 1-3 mg/kg SQ or IV bolus dose, followed by starting infusion of 0.5 mg/kg/hr	Approx. 50 mg/hour	CNS depression potentiated by narcotics, Valproic acid can increase Phenobarbital levels	Paradoxical excitement in the elderly, Hypotension, nausea and vomiting, Steven's Johnson Syndrome, angioedema, rash Agranulocytosis, thrombocytopenia	Increase in increments of 30 mg Increase in 1 mg/kg/hr increments to maintain Sedation	Drug has long half life and reversal of sedation is difficult Drug has no analgesic effect; minimal effect on salivation; respiratory and cardiac depressant effects are dose dependent Don't mix parenteral drug with any acidic solution Dilute drug with half-normal saline, normal saline, D5W, lactated Ringer's or Ringer's solution	0.10 per tab, $1.25 per PR dose, 130mg/ml vial @ $8.00
Chlorpromazine (Thorazine) phenothiazine	25-100 mg q 4-12 hours PR 12.5 mg q 4-12 hours or 3-5 mg/hour IV	12.5-50mg every 4-12 hrs	Anticonvulsants can lower seizure threshold Barbiturates may decrease phenothiazine effect	May cause hypotension and Extrapyramidal reactions, neuroleptic malignant syndrome, urinary retention.	Good choice for patient with mild dementia Additional 25-50 mg in one hour as needed	Drug has no analgesic effect; minimal respiratory effect; Dose dependent vasodilation with resultant reduction in blood pressure. For IV solutions mix drug with D5W, Ringer's injection, lactated Ringer's injection or normal saline for injection	100 mg PR @ $2.00 each, 25mg/ml for a 10 ml vial @ $70

Drug name/ Class	Suggested Starting Dose	Usual Maintenance Dose	Drug Interactions	Side effects or adverse reactions	Incremental dose for titration	Issues to consider/ IV incompatibilities	Cost
Haloperidol (Haldol)/ :butyrophene	1.0-2.0 mg PO 0.5-1 mg SQ or IV --For continuous infusion: 1.0mg initial dose followed by infusion of 0.5mg to 1.0mg/hr	5 to 15 mg per day	Increased CNS depression when used with other CNS depressants, Anticholergenics are potentiated when combined with Haldol causing increased anticholigernic effect	May cause extrapyramidal reactions, seizures, neuroleptic malignant syndrome, urinary retention, dyaphoresis, N/V	Generally do not exceed 20mg/day to minimize the risk of neuroleptic malignant syndrome Increase infusion rate by 0.5 mg/hr	Drug is beneficial for patients with dementia	$0.12 per 2 mg tab 50mg/ ml/ 1 ml vial @ $34

Note: Dose ranges are highly variable, determined by patient weight, renal and hepatic function, state of hydration, concurrent medication use and other variables. Start low and titrate the dose to the desired clinical end point. Doses should be increased by approximately 30% every hour until sedation is achieved. Once the desired sedation is achieved the dose is usually maintained at that level as long as the patient seems comfortable. Previous doses of opioids and other symptom relieving medications should be continued

10/30/03

Palliative Care Clinical Competency

Palliative Sedation

PURPOSE:

The purpose of this clinical competency is to provide the learner with the knowledge and skills to assess, initiate and evaluate palliative sedation as an appropriate procedure for patients with intractable physical and non-physical suffering.

OBJECTIVES:

After completing this competency and related learning activities, the learner will be able to:

1. Define palliative sedation and differentiate it from routine and aggressive symptom control including management of terminal restlessness.
2. Discuss the ethical, legal and clinical issues in the assessment and initiation of palliative sedation.
3. Outline the steps of an effective palliative sedation process.
4. List the responsibilities of the interdisciplinary team before, during and after the palliative sedation procedure.

PRECEPTOR:

Patient Care Manager
Agency Medical Director

Clinical Competency - Palliative Sedation

Provide the learner with the knowledge and skills to assess, initiate and evaluate palliative sedation as an appropriate procedure for patients with intractable physical and non-physical pain.

LEARNER OBJECTIVES	LEARNER ACTIVITIES	DATES COM-PLETED
Define palliative sedation and differentiate it from routine and aggressive symptom control	Read: 1. NHPCO publication: Total Sedation: A Hospice and Palliative Care Resource Guide. (This document must be ordered from NHPCO) 2. Hospice and Palliative Care Federation Palliative Sedation Protocol **Discuss with preceptor:** 1. Definition of palliative sedation 2. How palliative sedation differs from the management of terminal restlessness	
Discuss the ethical, legal and clinical issues in the assessment and initiation of palliative sedation	**Rea**d: Palliative Sedation by Maureen Lynch from Clinical Journal of Oncology Nursing 7(6), p 653-657. **Discuss with preceptor:** - the incidence of palliative sedation - at least four intractable symptoms for the appropriate use of palliative sedation - the clinical guidelines for palliative sedation - the ethical issues of palliative sedation including: 1 the principle of beneficence 2 the intent of palliative sedation 3 circumstances where the initiation of palliative sedation would be unethical 4 agency's palliative sedation policy 5 use of consent form	

LEARNER OBJECTIVES	LEARNER ACTIVITIES	DATES COM-PLETED
Outline the steps for an effective palliative sedation process	Review with preceptor 1. the basic non-drug care needs of the patient and family choosing palliative sedation including - use of non-drug therapies - use of the interdisciplinary team - education 2. at least four drug classifications used for palliative sedation and their recommended dose ranges 3. the clinical signs used to assess the level of sedation 4. clinical symptoms that would determine dosage reduction 5. Review the enclosed case study 6. Discuss with preceptor the steps you would take to provide the palliative care protocol to this patient	
The responsibilities of the interdisciplinary team before, during and after the procedure	Discuss with the preceptor the role of the following team members in providing palliative sedation - the medical director - agency pharmacist - primary care nurse - interdisciplinary team - patient and family	

Preceptor's Signature: _____ Date_____

Learner's Signature: _____ Date_____

Clinical Competency
Palliative Sedation
Post-Test

1. What is the definition of palliative sedation?

2. When is palliative sedation an appropriate treatment intervention for patients and their families?

3. Define the ethical principles that are relevant to the use of palliative sedation.

4. What clinical sign is used to determine the appropriate level of palliative sedation?

5. What is the role of the patient and family before, during and after the initiation of palliative sedation?

Case Study

Mr. Z. is a 48-year-old white, married male who lives at home with his wife, 10 year old son and 14-year-old daughter. He was diagnosed with stage IV colon cancer one year ago and despite surgery, chemotherapy and radiation therapy his disease has progressed. He has a large palpable tumor in the left lower quadrant of his abdomen, metastasis to the liver, and to the retroperitoneal area. Kidney function is impaired. His condition is deteriorating rapidly. His symptoms include severe pain, occasional diarrhea, nausea and vomiting. Mrs. Z. must work out of the home every day in order to maintain health insurance for the family. She is scheduled to begin a two-week vacation from work. Mr. Z. is very close to his children and they are distressed with their father's rapid deterioration.

During the last two weeks Mr. Z's pain has been rapidly escalating. The interdisciplinary team has tried various opioids, corticosteroids and other adjuvants. Currently the pain regimen includes the use of a PCA with continuous morphine SQ as well as neurontin at the maximum dose for treating shooting pain in the rectal area. He uses an anti-emetic as needed with fair control of nausea and vomiting. Medications have needed to be adjusted every twenty-four to forty-eight hours in response to increases in pain. He has been evaluated for a nerve block and an epidural infusion but is a poor candidate. He describes his "pain and his life as un-endurable suffering and that he cannot bear to be such a burden to his family". He has stated on several occasions that he does not want his children to remember him this way. His po intake at this point is minimal. He is restless and asks hospice to "do something" to end his suffering.