Palliative Sedation: 
*Medical, Ethical, and Legal Issues*

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Disclosure Slide

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Questions

• Is there a need for palliative sedation therapy (PST)?
• When is it indicated?
• What is an “intolerable”, “intractable”, “refractory” symptom?
• Who defines the “intolerability”?
• What is “existential suffering”?
• What is “imminently dying” or “terminal illness”?
• Is PST a form of “physician-assisted suicide” or “euthanasia”? 
NO Consensus about definitions, indications, and treatment decision-making

...there are some trends...

- Schildmann E and Schildmann, J. Palliative sedation therapy: A systematic literature review and critical appraisal of available guidance on indication and decision making. Journal of Palliative Medicine. 2014 May;17(5);601-611
  (9 studies included in qualitative analysis: Japanese guideline, Dutch guideline, international guideline, EAPC framework, NHPCO statement, Canadian framework)


Definitions are essential for understanding Palliative Sedation Therapy (PST)
<table>
<thead>
<tr>
<th>Table of Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFINITION:</td>
</tr>
<tr>
<td>terminology</td>
</tr>
<tr>
<td>definitions</td>
</tr>
<tr>
<td>distinctions: PAS, euthanasia</td>
</tr>
<tr>
<td>INCIDENCE</td>
</tr>
<tr>
<td>INDICATIONS:</td>
</tr>
<tr>
<td>refractory (intractable) symptoms:</td>
</tr>
<tr>
<td>- physical</td>
</tr>
<tr>
<td>- psychological (existential)</td>
</tr>
<tr>
<td>PHARMACOTHERAPY FOR SEDATION</td>
</tr>
<tr>
<td>ETHICAL ISSUES</td>
</tr>
<tr>
<td>LEGAL ISSUES</td>
</tr>
<tr>
<td>PROPOSED CRITERIA</td>
</tr>
<tr>
<td>LITERATURE REVIEW</td>
</tr>
<tr>
<td>COMPARATIVE GUIDELINES</td>
</tr>
</tbody>
</table>
Sedation: Terminology

- induced sedation
- prolonged sedation
- intermittent sedation
- “slow euthanasia” (Billings)
- complete sedation
- “artificial sleep” (sommeil artificiel)
- terminal sedation
- palliative sedation to unconsciousness
- controlled sedation
- proportionate palliative sedation (Quill)

Palliative Sedation Therapy (PST)
Palliative Sedation: Definition

Action of deliberately inducing and maintaining deep sleep, but *not deliberately causing death*, for the relief of one or more intractable symptoms, (often called “refractory symptoms”) when all other possible interventions have failed, and the patient is perceived to be terminally ill.

Cherny, N. and Portenoy R. Sedation in the management of refractory symptoms. J Palliat Care. 1994 Summer; 10(2);31-8
Palliative Sedation Therapy (PST)

Use of specific **sedative medications**:

- to relieve **intolerable suffering**
- from **refractory symptoms**
- by a **reduction in patient consciousness**
- using **appropriate drugs**
- carefully titrated to the **cessation of symptoms**

Palliative Sedation: Definition

Palliative sedation to **unconsciousness** is the administration of **sedative medication** to the point of unconsciousness in a **terminally ill** patient.

It is an intervention of **last resort** to reduce severe, **refractory** pain or other distressing clinical symptoms that do not respond to aggressive symptom-specific palliation.

*American Medical Association (AMA), 2008*
Palliative Sedation: Definition

Lowering of patient consciousness using medications for the expressed purpose of limiting patient awareness of suffering that is intractable and intolerable for the limited number of imminently dying patients who have pain and suffering that is:

a) unresponsive to other palliative interventions less suppressive of consciousness and

b) intolerable to the patient

National Hospice and Palliative Care Organization (NHPCO), 2010
Palliative Sedation: Definition

Monitored use of nonopioid medications intended to lower the patient’s level of consciousness to the extent necessary, for relief of awareness of refractory and unendurable symptoms.

Hospice and Palliative Nurses Association, 2011
Palliative Sedation: Definition

Intentional lowering of awareness towards, and including, unconsciousness for patients with severe and refractory symptoms…

1. After careful interdisciplinary evaluation and treatment of the patient

2. When palliative treatments that are not intended to affect consciousness have failed or, in the judgment of the clinician, are very likely to fail

3. Where its use is not expected to shorten the patient’s time to death

4. Only for the actual or expected duration of symptoms

American Academy of Hospice and Palliative Medicine (AAHPM), 2014
Palliative Sedation: Distinctions

**Physician-assisted suicide (PAS) or assisted suicide**

- Also called PAD: physician assisted in dying
- Physician facilitates a patient’s death by providing the necessary means and/or information to enable the patient to perform the life-ending act\(^1\)
  - Agent: patient
  - Intent: death of person
  - Reflected in the dosing of medication

**US:** Legal in Oregon, Washington, Vermont, New Mexico. Status disputed in Montana; many states have introduced bills to allow PAD.

**WORLD:** Switzerland, Germany, Japan, Albania, Netherlands

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Palliative Sedation: Distinctions

Euthanasia

Administration of a lethal agent by another person to a patient for the purpose of relieving the patient’s intolerable and incurable suffering (…compassionate reasons…)²

Agent: third party

Intent: death of person

Reflected in the dosing of medication

US: illegal

World legal: Netherlands, Belgium, Columbia, Luxembourg

Palliative Sedation and Hastening Death

• Not the intention: symptom relief
• Dose of medication is adjust accordingly
• Does not hastened death

(references/see review of literature)

- Sykes N, Thorns A. Sedative use in the last week of life and the implications for end-of-life decision making. Arch Inter Med. 2003 Feb 10;163(3):341-4
Palliative Sedation

Incidence:

- Variable according to definition and country
  - US: 10% of MDs (1156) (making patient unconscious until death)\(^1\)
  - Europe: 22%-45% MDs\(^1\)
  - Britain: 20\(^1\)
  - Belgium: 14.5\(^2\)
  - Italy: 13.2\(^3\)

\(^1\)Putman MS, Yoon JD, Rasinki KA, Curlin FA. Intentional sedation to unconsciousness at the end of life: Findings from a national physician survey. J of Pain and Symptom Manage (2013) 46;3; 326-334


Palliative Sedation: Definition

Palliative sedation ≠ Morphine drip
Palliative Sedation

REFRACTORY SYMPTOM:

“Symptom that cannot be adequately controlled despite aggressive efforts to identify a tolerable therapy that does not compromise consciousness.”

In that case, the intervention is:

- incapable of providing acceptable relief
- associated with excessive and intolerable acute and chronic morbidity
- unlikely to provide relief within a tolerable time frame

Also suggested by HPNA
Palliative Sedation

Intractable symptoms/suffering

• …is suffering that has not adequately responded to all trialed interventions and for which additional interventions are either unavailable or impractical…¹

• …not adequately controlled despite aggressive efforts to identify tolerable therapy that does not compromise consciousness…²


Palliative Sedation

Intolerable symptoms/suffering

• Unbearable. Only the patient can identify when suffering has become intolerable.”

NHPCO
Palliative Sedation

Terminal illness

• No definition - AMA

• Refer to a life expectancy of 6 months or less - NHPCO

• No legal definition
Palliative Sedation

Imminent death

- No legal definition
- Death that is expected to occur within hours to days - HPNA
- Prognosis of death within 14 days: “days to weeks” - NHPCO

- Question: Proximity of time vs. intensity of symptom distress
Palliative Sedation

Others

• “whose clinical symptoms have been unresponsive to aggressive symptom-specific treatments…” - AMA
Palliative Sedation: Indications

Physical symptoms

• Usually well-accepted if intractable

• Most common:
  – pain
  – dyspnea
  – delirium
Palliative Sedation: Indications

Existential suffering

- No widely accepted definition
- Broadly accepted as “not physical as etiology”
- Suffering that arises from a loss or interruption of meaning, purpose, or hope in life"¹
- “There is no consensus around the ability to define, assess, and gauge existential suffering, to measure the efficacy of treatments for existential distress…” AAHPM
- “…experience of agony and distress that may arise from such issues as death anxiety, isolation, and loss of control” AMA


Definition adopted by NHPCO
Palliative Sedation: Indications

Existential suffering

• “Exceptional” by eight guidelines
• Controversial
• Positions statements:
  • AAHPM: “…There is no consensus if PS is in the realm of medicine to palliate (existential suffering). Patients with existential suffering should be thoroughly assessed and treated through vigorous multidisciplinary efforts which may include involving professionals who are not usual members of the PC care team. If PS is used for truly refractory existential suffering, it should not shorten survival.”
Palliative Sedation: Indications

Existential suffering (cont’d)

• “NHPCO believes that hospice and palliative care professionals have an ethical obligation to respond to existential suffering using knowledge, tools, and expertise of the interdisciplinary team. Having carefully reviewed the data and arguments for and against using palliative sedation for existential suffering, the Ethics Committee is unable to reach an agreement on a recommendation.”…

• AMA: “PS is not an appropriate response to suffering that is primarily existential…”
Palliative Sedation: Ethical Issues

- Major ethical principles:
  - Beneficence (Do good)
  - Autonomy (Do not violate individual freedom)…informed consent

- Secondary ethical principles:
  - Truth Telling (tell the truth)…informed consent (integrity, sincerity in intention)
  - Principle of proportionality: risk-benefit ratio (how much harm can be justifiably risked to effect good)
  - Principle of Double Effect
Palliative Sedation: Ethical Issues

PRINCIPLE OF DOUBLE EFFECT

- Refers to situations where a desirable effect (good) is linked to an undesirable effect (bad).

- The good effect is direct and wanted. The undesirable effect is indirect, might be foreseen but not wanted.
Ethical Issues: Principle of Double-Effect

**CONDITIONS** of Application:

1. The treatment proposed must be beneficial or at least neutral (relief of intolerable suffering)

2. Only the good effect (relieving pain or symptoms) should be intended, although some untoward effects might be foreseen (loss of consciousness)

3. The good effect must be achieved directly by the action and not by way of the bad effect

4. The good result (relief of suffering) must outweigh the untoward outcome (hastening death)
Palliative Sedation: Legal Issues

• Accepted legally

• Criteria for legal evaluation of action: GOOD MEDICAL PRACTICE STANDARD

• Courts support for sedation concept:
  • Acknowledges a right to pain control / relief of suffering
  • Courts recognize improper pain management as a breach of good medical practice and as an unacceptable practice
    U.S. SUPREME COURT (Vacco vs. Quill)

• Patients Bill of Rights: promoting good medical practice
Good Medical Practice Criteria

• According to Medical Associations (Guidelines, position statements), scholars, practice, literature..

• The following associations have recognized PST as acceptable practice under conditions:
  • American Medical Association: AMA
  • American Academy of hospice and Palliative Medicine: AAHPM
  • National Hospice and Palliative Care Organization: NHPCO
  • Hospice and Palliative Care Nurse Association: HPNA
  • European Association for Palliative Care: EAPC
  • International Guideline: de Graeff
Palliative Sedation: Pharmacotherapy

Multiple regimens

Ideal medication:
- Rapid onset of action
- Short duration of action
- Induce sedation
- Minimal side effects

Medications used:
- Opioids
- Benzodiazepines
- Neuroleptics
- Barbiturates
- General anesthetics (propofol)
Palliative Sedation: Pharmacotherapy

**Opioids**
- Not reliable sleep inducing agents
- May produce counter-productive side effects
- Should be continued if pain or dyspnea an issue

**Benzos**
- May have paradoxical effects
- Commonly used

**Barbiturates**
- Reliably induced unconsciousness

**Neuroleptics**
- None of these alone can induce sedation
- May be used in combination

**Anesthetic agents**
- Propofol can be an excellent agent
- Restrictions
Palliative Sedation: Proposed Criteria

- Clarify Medical Situation
- Education of Patient and Family/Staff
- Implementation
- Documentation
- Informed Consent
Palliative Sedation: Implementation

- Monitor the patient
- Respond to family and needs
- Reassess frequently
Palliative Sedation: Literature Review

• Better references/guidelines
• Questions remain on many aspects
• Agreement on:
  • Terminal illness/imminent death (various times)
  • Physical symptoms intractable/refractory
  • Intention is symptom relief
  • Plan made explicit in informed consent
  • Informed consent obtained from patient/decision maker
  • Discussion amongst interdisciplinary team (ideal PC)
  • Solid documentation
  • Justification by principle of double effect and proportionality


Palliative Sedation: Literature Review

• Inconsistencies:
  • **Prevalence:** variable/controversial (linked to definition)
  • Level of sedation (proportionate/total unconsciousness)
  • Timing: “2 Weeks”, “hours to days”, “very end of life”, “final stages”, “days to weeks”
  • Symptom indications: existential suffering??
  • Medications selection; anecdotal, multiple agents
  • Coadministration of life-sustaining treatments

Schildmann, E. Schildmann, J. Palliative sedation therapy: A systematic literature review and critical appraisal of available guidance on indication and decision making. J Palliat Med (2014)17:5;601-611 (811 references were reviewed/ 9 studies included in qualitative analysis)

## Literature Review

<table>
<thead>
<tr>
<th>Studies</th>
<th>Symptoms</th>
<th>Medication</th>
<th>Incidence/Surv.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tatsuya JPSM (1996)12/1</td>
<td>dyspnea, pain, general malaise, agitation, nausea</td>
<td>midazolam 55%, morphine 55%, haloperidol 33%, diazepam 15%, scopolamine 13%, bromazepam 6%, chlorpromazine 4%, barbiturate 4%</td>
<td>48.3% (143) 3.9 days</td>
</tr>
<tr>
<td>Ventafridda, VJPallCare (1990) 6/3</td>
<td>dyspnea (33/63), pain (31/63), delirium (11/63)</td>
<td>increase opioids, psychotropic drugs</td>
<td>52% (120) 2 days</td>
</tr>
<tr>
<td>Faisinger, RJPallCare (1991)7/1</td>
<td>delirium, pain</td>
<td></td>
<td>16% (100)</td>
</tr>
</tbody>
</table>
## Literature Review

<table>
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<th>Medication</th>
<th>Incidence/Surv.</th>
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<tbody>
<tr>
<td>Chater, S Knoll et al. trait. douleur Vol. 10/1, fev. ’97</td>
<td>Pain 31% distress (angoisse) 22% agitation/delirium 18% dyspnea 17% nervosity 17% emotional distress 16% anxiety 15%</td>
<td>midazolam (15-120mg/24hr) methotrimethazine chlormethiazole phenobarbital benzo(lora/clona/dia) chlorpromazine haloperidol</td>
<td>*panel of 51 experts 78% in favor</td>
</tr>
<tr>
<td>Lichter et al. JPallCare (1990) 6/4</td>
<td>Pain 51% dyspnea 22% confusion 9% nausea vomiting 14% agitation/restlessness 42%</td>
<td>increase opioids benzo haloperidol chlorpromazine</td>
<td>36% (200) last 48 hrs</td>
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</table>
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<th>Studies</th>
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<th>Medication</th>
<th>Incidence/Surv.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greene, WR South Med.J. (1991) 84/3</td>
<td>pain, vomiting, seizures, restlessness</td>
<td>amobarbital IV 20-215 mg/hr thiopental IV: 20-80 mg/hr multiple drugs</td>
<td>2-4 days 23 days</td>
</tr>
<tr>
<td>McIver, B JPSM (1994) 9/5</td>
<td>dyspnea, restlessness</td>
<td>chlorpromazine: Pr 25mg q4-12h IV 12.5mg q4-12h (mean: 50mg/day) PR as effective as IV</td>
<td>Mean: 1 day</td>
</tr>
<tr>
<td>Burke, A MedJAustr (1991) 155 oct.</td>
<td>restlessness, anxiety, myoclonus/twitching/seizures</td>
<td>midazolam S.C. (2.5-10mg q2h) mean: 20-60 mg/day</td>
<td>86 patients</td>
</tr>
</tbody>
</table>
## Literature Review

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<th>Medication</th>
<th>Incidence/Surv.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottomley, DM</td>
<td>agitation, restlessness</td>
<td>Midazolam S.C. (syringe driver): 0.4-0.8 mg/hr</td>
<td>4 days</td>
</tr>
<tr>
<td>JPSM (1990) 5/4</td>
<td></td>
<td>Mean: 2.9 mg/h, 69.6 mg/day early tolerance: add</td>
<td>6-11 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>dizepam (26%)</td>
<td></td>
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<tr>
<td>Truog, R.D.</td>
<td>physical, nonphysical</td>
<td>Deep sedation: thiopental (5-7mg/kg: mean: 70-]</td>
<td></td>
</tr>
<tr>
<td>NEJM (1992)</td>
<td></td>
<td>180mg/hr) pentobarbital (1-3mg/kg)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td><strong>Mild/Moderate:</strong> Benzo Opioids Phenothiazine</td>
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<thead>
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<th>Medication</th>
<th>Incidence/ Surv.</th>
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<tbody>
<tr>
<td>Mercadante, S JPSM (1995)</td>
<td>delirium</td>
<td>propofol 50-70mg/hr</td>
<td>8 hrs</td>
</tr>
<tr>
<td>Moyle J JPSM (1995)</td>
<td>delirium</td>
<td>propofol 50-200mg/hr recommended: 5-70mg/hr</td>
<td>9 days</td>
</tr>
<tr>
<td>Stone P Pall Med 11:140-144</td>
<td>delirium (30 pts) mental anguish, pain dyspnea</td>
<td>Midazolam, benzo Methotrimeprazine, haloperidol Chlorpro / Pheno</td>
<td>1.3 days</td>
</tr>
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## Comparative Guidelines

|------------|-----------------------------------------------|---------------------------------|---------------------------------|-----------------------------------------|
| Use of specific sedatives | - relieve intolerable suffering  
- refractory symptoms  
- reduction of consciousness | Monitored meds to induce state of decreased / absent awareness to relieve intractable suffering in ethically acceptable manner | Lower patient awareness by meds for intractable /intolerable suffering | Use of meds to reduce consciousness for intolerable and refractory symptoms in patient with advanced progressive illness |

### Population

| Progressive/terminal disease  
Life expectancy: days to weeks  
Deep sedation: Death in hours/days | Palliative care patients with intolerable distress  
Deep sedation: Death hours to days | Terminally ill patients  
Death imminent  
Prognosis death: < 14 days | Advanced progressive illness  
Prognosis death: 1 – 2 weeks |

### Indications

| Refractory symptoms  
Existential distress: exceptional circumstances | Intolerable/refractory physical symptoms  
Severe nonphysical symptoms occasionally, end of life | Symptoms refractory to treatment  
Intolerable suffering (pain, dyspnea, delirium, restlessness)  
Existential suffering: Great caution  
Multiple discussions  
Trial of respite-sedation | Refractory, intolerable suffering  
Existential: Rare cases  
After expert consultation |

### Comparative Guidelines

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<td></td>
<td>PC specialist Consensus in palliative care team Active involvement of patient or surrogate/proxy</td>
<td>Clinician with expertise in palliative care Interdisciplinary evaluation when possible Input from teams, family Involvement of PMD (primary physician)</td>
<td>MD with palliative care expertise Interdisciplinary conferences Responsibility of team to assess level of suffering Patient is the only one who can identify intolerability</td>
<td>Experienced palliative care MD or 2nd opinion from MD with experience in palliative sedation All relevant team members Involvement of patient/family Disagreement: Consult Ethics Committee</td>
</tr>
<tr>
<td>Information Consent</td>
<td>Informed consent from patient or representative Detailed recommendations on content of informed consent</td>
<td>Discussion with patient (noncritical situation) Reference to surrogate decision-maker (lack capacity) Detailed recommendations on content of consent</td>
<td>No specific information</td>
<td>Reference to substitute decision-making Detailed recommendations on content of informed consent</td>
</tr>
<tr>
<td>Decision About Life-Sustaining Treatment</td>
<td>Separate discussion</td>
<td>Separate discussion</td>
<td>DNR in effect Separate decision</td>
<td>Separate decision</td>
</tr>
</tbody>
</table>

Palliative Sedation is a therapy of last resort.
Case Study

• BD is a 36 y.o. man with Stage IV melanoma involving the mediastinum and neck with secondary pain, dyspnea, and anxiety. He is ambulatory and has a limited appetite. PPS is 40%. He has a past history of drug abuse. He is aware of his diagnosis and guarded prognosis. He is currently in an inpatient hospice for symptom control.

• While hospitalized, patient was started on a PCA of Dilaudid with titration for his pain and Lorazepam 1mg q8h for anxiety/dyspnea.

• Both were titrated for maximum results. Despite the adjustments, the patient remained with pain, dyspnea, and became more and more anxious.

• The neck mass was increasing, and so was his dyspnea (decreased breath sounds).
Case Study (Cont’d)

Despite multiple interventions, the patient’s symptoms were not satisfactorily controlled, and he had some side effects. The medical team had multiple discussions with the patient, who remained alert.

At one point, the patient said, “I cannot take this anymore, do something.”

What was the response of the team?

How do you qualify this intervention?
Case Study 2

KD is a 62 y.o. woman dying at home from metastatic lung cancer. Her pain has been treated with high dose long-acting opioids. Her dyspnea has been treated with a combination of oxygen, opioids, and intermittent nebulizer treatments.

KD tells her physician that her pain and dyspnea are well-controlled, but she is distressed at the constant thought of her impending death. She says, “I know I am going to die; I just cannot tolerate lying here thinking about it day after day.” KD asks her physician to sedate her to unconsciousness until she dies.

Putman MS, Yoon JD, Rasinki KA, Curlin FA. Intentional sedation to unconsciousness at the end of life: Findings from a national physician survey. J Pain and Symptom Manage (2013) 46;3; 326-34.
Case Study 2

Question:
How appropriate to sedate KD to unconsciousness?
Case Study 2

Answer:

• Amongst 1156 MD (various specialty), 62% responded
  – Very appropriate 8%
  – Somewhat appropriate 19%
  – Not very appropriate 35%
  – Not appropriate at all 37%

Putman MS, Yoon JD, Rasinki KA, Curlin FA. Intentional sedation to unconsciousness at the end of life: Findings from a national physician survey. J Pain and Symptom Manage (2013) 46;3; 326-34.
Bibliography


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Bibliography


  - [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4099031/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4099031/)
Palliative Sedation: Medical, Ethical, and Legal Issues

Q/A