PALLIATIVE SEDATION

Understanding the Territory
Disaster Prevention and Preparedness
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Vacco vs. Quill, 1997

“a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death.”
What we are NOT talking about...

• The dying patient who slips into an obtunded state due to metabolic changes of the dying process plus side effects of usual palliative treatments

• Sedation occurring as a side effect of high dose symptom-targeted medication (opioids for pain, anticonvulsants for seizures)
What we ARE talking about...

- An explicit decision to render a terminal patient deeply unconscious to prevent or respond to intractable suffering
- A highly prevalent practice nationwide, worldwide
• Peruselli et al, Italy: 6 month randomized prospective observational study of 401 patients admitted to 56 palliative care units in Italy. 25% were totally pharmacologically sedated in the last 12 hours of life.

• Use of sedation in the 13 centres which contributed more than ten patients to the study, ranged from 0% to 60%

• Palliat Med, 1999;13:233-241
Should we be talking about it?

No, because ...

• it’s simply one end of the continuum of usual palliative care

• there is no consensus on terms, definitions and procedures

• Why make things more complicated then they already are?
Should we be talking about it?

Yes, because …

• no other palliative intervention is designed to dim consciousness
• discussion develops consensus on terms and best practice
• “care at the end of life is full of ethically poignant and emotionally charged situations” (Ira Byock)
Should we be talking about it?

Yes, because …

• We’re doing a lot of it: Studies of prevalence in terminally ill patients range from 5-50%  

• Patients and families and sometimes Hospice staff ask for it
Does PS hasten death?


- 120 terminally ill patients with metastatic cancer assisted by a home care team. 52% of patients received PS.
- pain, dyspnea, delirium, and vomiting were the primary symptoms.
- The median survival was 25 days for patients receiving PS and 23 days for nonsedated patients.
Stone et al, UK: Retrospective review of charts of 115 patients noted 26% received PS (31% at the hospice, 21% at the hospital). No difference in total time of survival after admission between sedated and nonsedated patients was noted (18.6 vs 19.1 days, respectively), with survival after initiation of PS averaging 1.3 days.

Palliat Med. 1997;11:140-144
Should we be talking about it?

Yes, because …

• "It hath often been said that it is not death, but dying which is terrible."

  Henry Fielding

• We are ethically and morally obligated to do a better job at relieving suffering at the end of life
Should KP have policies?

NO, because ...

• There is no defined procedure, or even widely agreed upon names for it
• Patients and families might insist on it, rejecting usual palliative care
• Implementation across the continuum requires resources we don’t have
Should KP have policies?

YES because ...

• We need to define and standardize criteria and process especially when difficult issues are involved
• Best practice, clinician education
• More defensible legally
Do policies & procedures exist?

While there are individual institutions that have developed them, within the U.S., there is no system-wide, uniform set of policies and procedures that has been applied and validated across the continuum of care.
KP POLICIES AND PROCEDURES

- Kaiser Permanente NW Region
  internal.or.kp.org/cpg/content/PainPalliativeEdited.html

- Kaiser South Sacramento - Dr. Shelly Garone
And More Policies and Procedures

- Baylor University Medical Center - Robert Fine, MD
- Mary Washington Hospital - Rebecca Bigoney, MD
- Massachusetts General Hospital - J. Andrew Billings, MD
- Brigham and Women’s Hospital - Janet Abrahm, MD
International guidelines

• Japan: Morita, et al. - Created by a national multidisciplinary committee
  J. Pall Med, Vol 8, No. 4, 2005

• Netherlands: Royal Dutch Medical Association National Guidelines

• Multinational: De Graeff & Dean - Summary of a collaborative project of the European Association for Palliative Care
<table>
<thead>
<tr>
<th>TERMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sedation Therapy</td>
</tr>
<tr>
<td>• Palliative Sedation (PS)</td>
</tr>
<tr>
<td>• Terminal sedation (TS)</td>
</tr>
<tr>
<td>• Total sedation</td>
</tr>
<tr>
<td>• Palliative Sedation to Unconsciousness (PSU)</td>
</tr>
<tr>
<td>– Respite or Intermittent</td>
</tr>
<tr>
<td>– Continuous</td>
</tr>
</tbody>
</table>
DEFINITIONS

HPNA:

- Palliative Sedation is "the monitored use of medications intended to induce varying degrees of unconsciousness, but not death, for relief of refractory and unendurable symptoms in imminently dying patients."

Approved by the Board of Directors, January 2003
“palliative sedation” (PS):
The use of sedative medication at least in part to reduce patient awareness of distressing symptoms that are insufficiently controlled by symptom-specific therapies. The level of sedation is proportionate to the patient’s level of distress, and alertness is preserved as much as possible.

Approved by the Board of Directors
September 15, 2006
“Palliative Sedation to Unconsciousness” (PSU)

- The administration of sedatives to the point of unconsciousness, when less extreme sedation has not achieved sufficient relief of distressing symptoms. This practice is used only for the most severe, intractable suffering *at the very end of life.*
PS V. PSU

PS: Ramsay 1 sedated to 2
PSU: Ramsay 1 or 2 sedated to 3-6

RAMSA Y SEDATION SCALE

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Awake</td>
<td>Patient anxious and agitated or restless or both</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Patient cooperative, oriented and tranquil</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Patient responds to commands only</td>
</tr>
<tr>
<td>4</td>
<td>Asleep</td>
<td>A brisk response to a light glabellar tap or loud auditory stimulus</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>A sluggish response to a light glabellar tap or loud auditory stimulus</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>No response to a light glabellar tap or loud auditory stimulus</td>
</tr>
</tbody>
</table>
INTRACTABLE SUFFERING - Definitions and Indication for PS/PSU

• VA National Ethics Committee:
  – Severe pain or other clinical symptoms…not ameliorated by aggressive symptom specific interventions that are acceptable to the patient (or surrogate)
  – Specifically excludes existential suffering and patients not imminently dying
• **NHPCO**
  – Overwhelming physical, emotional or spiritual distress that is poorly relieved by other means (need not be imminently dying to use TS)

• **AAHPN**
  – Refractory and undurable symptoms in imminently dying patients

• **AAHPM**
  – Doesn’t define suffering. PS for “advanced disease”, PSU only “at the very end of life”.
ETHICS: The “neater” cases

• Hours to days prognosis, already not taking po, patient has clearly expressed desire be less conscious to avoid suffering even if death might be hastened
• Sudden catastrophic events: massive hemorrhage, rapid suffocation by tumor mass or hemorrhage
• Ventilator withdrawal
ETHICS: The “messy” cases

- Patients with weeks prognosis, still taking PO and interactive
- Patients without capacity – who’s to decide?
- Imperative to treating the family’s suffering or caregiver burnout
- Refusal to follow plan of care,
- Behavior that endangers self or others
- Purely existential or psychosocial suffering
Morita et al, Japan 2004:

Questionnaire sent to 105 physicians at all certified palliative care units in Japan. Of the 81 responses, 36% reported clinical experience in continuous deep sedation for psycho-existential suffering. The predicted survival in 94% of the 46 sedated patients was 3 weeks or less.

Ethics: Non-physical suffering

- Difficult to define as refractory, few therapeutic guidelines
- Often precedes by weeks or months the terminal phase of the dying process
- Sedation may actually be non-beneficial, depriving patients of the opportunity for growth and re-integration of the self
Ethics: Patient without Capacity

• For those who do not have ethical problems with PSU, denying these patients a beneficial palliative intervention would be inhumane

• For those who do, it may be sliding further down the “slippery slope” towards euthanasia
• Removing a patient’s consciousness is a type of social death
• The practice may appear to relieve symptoms but ...can be a form of abandonment
• It is not a target-specific therapy, it is a ...“bludgeon” for multiple symptoms

Letter from Davis & Ford, J. Pall Med, Vol 8 No.4 2005
Ethics: SLOW EUTHANASIA

- Morally equivalent when withholding AFN after the onset of PSU in patients who have not already ceased oral intake due to their disease process,
- There may become a societal "obligation to die" for those who no longer feel or are perceived to be valued
“Brave New Worlds” of PS?

Perkin and Resnik proposed using paralytics to stop breathing as an adjunct to PS/PSU at end of life, arguing that the patient may be suffering while undergoing agonal breathing in the last hours and the family certainly is suffering as they witness the process.

“Is the Last Gasp Really Necessary?

J Med Ethics 2002;28:164-169
<table>
<thead>
<tr>
<th>Variable</th>
<th>Clinical Specialists (n = 103), n (%)</th>
<th>General Practitioners (n = 53), n (%)</th>
<th>Nursing Home Physicians (n = 55), n (%)</th>
<th>All Physicians (n = 211), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without the intention of hastening death§</td>
<td>35 (34)</td>
<td>17 (32)</td>
<td>23 (42)</td>
<td>75 (36)</td>
</tr>
<tr>
<td>Partly with the intention of hastening death§</td>
<td>51 (50)</td>
<td>25 (47)</td>
<td>24 (44)</td>
<td>100 (47)</td>
</tr>
<tr>
<td>With the explicit intention of hastening death§</td>
<td>17 (17)</td>
<td>11 (21)</td>
<td>8 (15)</td>
<td>36 (17)</td>
</tr>
</tbody>
</table>
TS in the Netherlands

• Study illustrates what Quill calls “the ambiguity of clinical intentions”
• MD’s did not consistently honor the principle of autonomy and informed consent: discussed the decisions to use TS with patients/families in only 59% of cases, and to forego AFN in only 34%
Ethics: Rule of Double Effect

4 principles: addressing risk of hastening death with usual palliative care

Nature of the act: must be good, such as the relief of pain, or at least morally neutral

• Intention: good effect must be intended, the bad effect, though foreseen, is not intended
The Rule of Double Effect

• Means vs. Effect: The bad effect, such as death, must not be a means to the good effect, such as the relief of suffering.

• Proportionality: The good effect must outweigh the bad effect
Limitations of the RDE

The absolute prohibition against intentionally causing death collides with the principle of patient autonomy and may account for the reluctance of some physicians to honor their patients' requests to withdraw life-sustaining therapy.
The RDE and PSU

Relief of symptoms is the “good”, death or unconsciousness are the “bad” effects

• If hydration stops, death is inevitable and may be intended by patient or MD

• If AFN continues, the “bad” (unconsciousness) is still the means for producing the good (relief of suffering)
Beyond the RDE

Care at the end of life should be justified and guided by:

• the patient's right to self-determination and bodily integrity
• the provision of informed consent
• the absence of less harmful alternatives
• the severity of the patient's suffering

Quill, T NEJM, Volume 337:1768-1771 Number 24
“Without serious reasons, the dying person must not be deprived of consciousness. ... The dying person is deprived of the possibility of living his own life, by reducing him to a state of unconsciousness unworthy of a human being. This is why the administration of narcotics for the sole purpose of depriving the dying person of a conscious end is a truly deplorable practice.”

The Pontifical Council's 1994 Charter for Health Care Workers
It is a different matter when there is a serious clinical case for the administration of analgesics which suppress consciousness, as when there is violent and unbearable pain. In this case the anesthetic is said to be licit, provided certain conditions are fulfilled: that the dying person has fulfilled or could still fulfill his moral, family and religious obligations.

But there are nuances ...
"If the patient obstinately refuses and persists in asking for the narcosis, the doctor may agree to it without thereby becoming guilty of formal cooperation in the fault committed."

The Pontifical Council's 1994 Charter for Health Care Workers
• The administration of food and liquids, even artificially, is part of the normal treatment always due to the patient *when this is not burdensome for him*: their undue suspension could be real and properly so—called euthanasia.

The Pontifical Council's 1994 Charter for Health Care Workers
# Attitudes of German Bioethicists

## Table 3: Moral evaluation of different scenarios (details in valid percent, difference at 100% due to rounding)

<table>
<thead>
<tr>
<th>Dying patient</th>
<th>Acceptable</th>
<th>Not acceptable</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>øM</td>
<td>M</td>
</tr>
<tr>
<td>Physical suffering</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only sedation</td>
<td>98</td>
<td>97</td>
<td>1</td>
</tr>
<tr>
<td>Sedation + withdrawal of nutrition</td>
<td>86</td>
<td>89</td>
<td>12</td>
</tr>
<tr>
<td>Only withdrawal of nutrition</td>
<td>92</td>
<td>95</td>
<td>6</td>
</tr>
<tr>
<td>Physical suffering</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only sedation</td>
<td>61</td>
<td>52</td>
<td>23</td>
</tr>
<tr>
<td>Sedation + withdrawal of nutrition</td>
<td>55</td>
<td>44</td>
<td>29</td>
</tr>
<tr>
<td>Only withdrawal of nutrition</td>
<td>68</td>
<td>63</td>
<td>21</td>
</tr>
</tbody>
</table>

*M = respondents with a medical background; øM = respondents without a medical background*
<table>
<thead>
<tr>
<th>Patient with unfavourable prognosis</th>
<th>Acceptable</th>
<th>Not acceptable</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$M \quad \phi M$</td>
<td>$M \quad \phi M$</td>
<td>$M \quad \phi M$</td>
</tr>
<tr>
<td>Physical suffering</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only sedation</td>
<td>74</td>
<td>66</td>
<td>17</td>
</tr>
<tr>
<td>Sedation + withdrawal of nutrition</td>
<td>63</td>
<td>56</td>
<td>28</td>
</tr>
<tr>
<td>Only withdrawal of nutrition</td>
<td>78</td>
<td>71</td>
<td>17</td>
</tr>
<tr>
<td>Mental suffering</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only sedation</td>
<td>37</td>
<td>36</td>
<td>43</td>
</tr>
<tr>
<td>Sedation + withdrawal of nutrition</td>
<td>32</td>
<td>27</td>
<td>48</td>
</tr>
<tr>
<td>Only withdrawal of nutrition</td>
<td>52</td>
<td>50</td>
<td>34</td>
</tr>
</tbody>
</table>
Even the ethicists are all over the map.

The survey shows that acceptance of terminal sedation decreases when the patient is not yet dying, when sedation is used because of uncontrollable mental suffering, and when life-sustaining measures are terminated during sedation. Accordingly, terminal sedation in dying patients with physical suffering without withdrawal of treatment met with the highest acceptance, terminal sedation in patients with unfavourable prognosis with mental suffering and simultaneous withdrawal of treatment met with the highest disapproval.
Clinical Settings - Where and when the disaster might strike

- Intractable vomiting, bowel obstruction
- Escalating psychomotor agitation and/or combativeness in dementia patients, placing patient and/or caregivers at risk
Clinical Settings

- The patient who expresses profound distress caused by progressively severe disfigurement and breakdown of body integrity
- The patient in whom pain control has become unusually difficult because of significant intolerance to the side effects of opioids – such as myoclonus, delirium or hyperalgesia
Clinical Settings

- Patients and families who refuse to use the recommended opioids and other drugs for symptom control
- The patient who repeatedly verbalizes existential suffering: “I can’t take this anymore”, “I don’t want my family to go through this anymore”
PS for Non-physical distress

- Chater et al 24 surveyed 53 selected palliative care specialists from the United Kingdom, United States, Australia, Ireland, Italy, Canada, New Zealand. Psychological symptoms accounted for one third of the cases of PS.
- Only 50% of patients and 69% of family members were reported to have major involvement in the decision-making process for sedative therapy.
PAIN:

- Interventional approaches, XRT, bisphosphonates, radio-isotopes
- Complementary approaches, mind body
- Assess and treat hyperalgesia - opioid rotation, ketamine
- Call a colleague
DISASTER PREVENTION

VOMITING:

- Bowel obstruction: venting G tube, anti-secretory meds, sub q hydration, GI stenting
- Compounded PLO formulations for transdermal use, low dose barbiturates
Fainsinger et al argued for a thorough evaluation of cognitive impairment and agitation in terminally ill patients and reduced the use of PS to 3% of inpatients on their palliative care unit secondary to disciplined assessments for causes of cognitive deterioration, treatment of reversible causes, and the use of hydration and opioid rotation.

Fainsinger also did a retrospective review of 117 and 162 patient charts before and after implementing protocol for assessment and management of cognitive impairment, demonstrated a decline in the prevalence of agitated and impaired mental status from 26% to 10%, with an associated reduction in frequency and dose of neuroleptic and benzodiazepine medication use.
SPIRITUAL/EXISTENTIAL DISTRESS

• Don’t underuse our chaplains - they need to get involved from the beginning
• Recognize the overlap with the physical, assess for undisclosed symptoms
• Music and art therapy
When the idea isn’t yours ...

• “Doc, put me to sleep at the end so I won’t suffer”.

• “I’m moving to Oregon, Doc”
THE PATIENT WHO REQUESTS PAS

DIGNITY CONSERVING THERAPY

Prospective intervention trial, Canada & Australia, n=100

• Brief individualized psychotherapeutic intervention that created a legacy document

• Pre and post assessment of dignity, depression, suffering, hopelessness, sense of purpose, sense of meaning, desire for death, will to live, and suicidality

• Post intervention decreases were significant in suffering and depressive symptoms

• Those satisfied with the intervention reported increased will to live

You may not have much warning.

The issue of palliative sedation can arise suddenly.

Our experience living in earthquake country tells us we need to formulate a disaster plan and know where our supplies are kept.
Our experience living in palliative care country tells us we should have a plan for the patient and family whom we can anticipate may get hit by “the big one”.
What’s in your disaster kit?
KP.org Clinical Library - enter “palliative sedation” in search field:

• Resource guide developed by TPMG Hospice Medical Directors workgroup,
  http://cl.kp.org/pkc/ncal/clib/guidelines/palliative/palliative_sedation.htm

• Full text sources on Docushare
  http://dms.kp.org/docushare/dsweb/View/Collection-117411
<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Palliative care</td>
<td>Must be available, in place, and unable to adequately relieve current suffering</td>
</tr>
<tr>
<td>Usual patient characteristics</td>
<td>Severe, immediate, or otherwise unrelievable symptoms (for example, pain, shortness of breath, nausea, vomiting, seizures, delirium) or to prevent severe suffering (for example, suffocation sensation when mechanical ventilation is discontinued)</td>
</tr>
<tr>
<td>Terminal prognosis</td>
<td>Usually days to weeks</td>
</tr>
<tr>
<td>Patient informed consent</td>
<td>Patient should be competent and fully informed or noncompetent with severe, otherwise irreversible suffering (clinician should use advance directive or consensus about patient wishes and best interests)</td>
</tr>
</tbody>
</table>

*Source: Annals of Internal Medicine • Volume 132 • Number 5*
Family participation in decision
Incompetent patient
Second opinion(s)
Medical staff participation in decision

Clinician should strongly encourage input from and consensus of immediate family members. Can be used for severe, persistent suffering with the informed consent of the patient’s designated proxy and family members. If no surrogate is available, team members and consultants should agree that no other acceptable palliative responses are available.
Should be obtained from an expert in palliative care and a mental health expert (if uncertainty exists about patient’s mental capacity).
Input from staff involved in immediate patient care activities is encouraged; physician and staff consent are required for their own participation.

Source: Quill, Byock

"Annals of Internal Medicine • Volume 132 • Number 5"
More general guidelines: Paul Rosseau

Presence of a terminal illness with refractory symptom(s)
A current do-not-resuscitate (DNR) order
Exhaustion of all palliative treatments\(^a\)
Consideration of ethical, psychiatric, and spiritual consultations and assessments
Consideration of a second opinion from an independent physician
Obtaining written informed consent\(^a\)

\(^a\)Palliative sedation may occasionally be performed without exhausting all palliative measures and obtaining written informed consent in emergent situations, such as massive terminal hemoptysis or compression of the trachea by a tumor mass causing severe dyspnea or suffocation.
Rousseau, continued

Discussion regarding continuation of artificial nutrition and/or hydration in patients receiving such treatments

Consideration of a trial of time-limited respite sedation, particularly in cases with existential suffering.

Palliative Sedation and the Fear of Legal Ramifications
<table>
<thead>
<tr>
<th>Medication</th>
<th>Type</th>
<th>Usual Starting Dosage</th>
<th>Usual Maintenance Dosage</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midazolam</td>
<td>Rapid, short-acting benzodiazepine</td>
<td>0.5–1.5 mg/h after bolus of 0.5 mg</td>
<td>30–100 mg/d</td>
<td>Intravenous or subcutaneous</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>Benzodiazepine</td>
<td>1–4 mg every 4–6 h orally or dissolved buccally; infusion of 0.5–1.0 mg/h intravenously</td>
<td>4–40 mg/d</td>
<td>Oral, buccal, subcutaneous, or intravenous</td>
</tr>
<tr>
<td>Propofol</td>
<td>General anesthetic; ultrarapid onset and elimination</td>
<td>5–10 mg/h; bolus doses of 20–50 mg may be administered for urgent sedation, but continuous infusion is required</td>
<td>10–200 mg/h</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Thiopental</td>
<td>Ultrashort-acting barbiturate</td>
<td>5–7 mg/kg of body weight to induce unconsciousness</td>
<td>Initial rate may range from 20 to 80 mg/h; average maintenance rates range between 70 and 180 mg/h</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Pentobarbital</td>
<td>Long-acting barbiturate</td>
<td>2–3 mg/kg, slow infusion, to induce unconsciousness</td>
<td>1 mg/h, increasing as needed to maintain sedation</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>Long-acting barbiturate</td>
<td>200 mg loading dose, repeated every 10–15 minutes until patient is comfortable</td>
<td>Approximately 50 mg/h</td>
<td>Intravenous or subcutaneous</td>
</tr>
</tbody>
</table>

Source: Quill, Byock,
General Dosing Guidelines

- Increase dose by approximately 30% hourly until desired level of sedation is achieved
- If symptoms return, increase again in 30% hourly increments
- Previous doses of opioids and other symptom targeted medications should be continued
Palliative Sedation

JAMA, October 12, 2005—Vol 294, No. 14
Case #1: PSU in the ICU

- TK, 48 yo Japanese buddhist nun with Stage III ovarian cancer
Case #2: Drinking to death

• SA, 71 yo Mexican American man with progressive alcoholic liver disease and dilated cardiomyopathy