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Interprofessional Webinar Series

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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”?

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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)
- Gurschick L, Mayer DK, Hanson LC. Palliative Sedation: An Analysis of International Guidelines and Position Statements. Am J Hosp Palliat Care. 2014 May 7, p. 1-12 (including: ACP-ASIM, HPNA, AAHPM, AMA,EAPC, NHPCO, NCCM)
- Abarshi E, Rietjens J, Caraceni A, Payne S, Deliens L, Van der Block L. Towards a standardized approach for evaluating guidelines and guidance documents on palliative sedation: study protocol. BMC Palliat Care. 2014 Jul 7;13:34

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Definitions are essential for understanding Palliative Sedation Therapy (PST)

UJA Federation of New York

Table of Contents

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)

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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

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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

De Graeff A. and Dean, M. Palliative sedation therapy in the last weeks of life: A literature review and recommendations for standards. J. Palliat Med. 2007 Feb;10(1):67-85

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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

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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

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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

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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

[1]Council on Ethical and Judicial Affairs. American Medical Association. Decisions near the end of life. JAMA. 1992 Apr 22-29;267(16): 2229-33

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

[2]Council on Ethical and Judicial Affairs. American Medical Association. Decisions near the end of life. JAMA. 1992 Apr 22-29;267(16): 2229-33. Updated June 1996

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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)

- Claessens P, Menten J, Schotsmans P, Broeckaert B. Palliative sedation: A review of the research literature. J Pain Symptom Manage. 2008 Sep;36(3):310-33
- Rietjens JA, et al. Palliative sedation in a specialized unit for acute palliative care in a cancer hospital: Comparing patients dying with and without palliative sedation. J Pain Symptom Manage. 2008 Sep;36(3):228-34
- 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
- Kohara H, Ueoka H, Takeyama H, Murakmi T, Morita T. Sedation for terminally ill patients with cancer with uncontrollable physical distress. J Palliat Med. 2005 Feb;8(1):20-5

Palliative Sedation

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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

[2]Chambaere K, Bilsen J, Cohen J, et al. Continuous deep sedation until death in Belgium: A nation-wide survey. Arch intern Med 2010;170:490-493

[3]Mercadante S, Porzio G, Valle A, et al. Palliative sedation in advanced cancer patients followed at home: A retrospective analysis. J Pain Symptom Manage 2012;43:1126-1130

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Palliative Sedation: Definition

Palliative sedation /= Morphine drip

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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

Cherny, N., and Portenoy R. Sedation in the management of refractory symptoms. J Pall Care 10:2(1994):31-38
Also suggested by HPNA

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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]

1. Kirk TW and Mahon MM. Palliative Sedation Task Force of the National Hospice and Palliative Care Organization Ethics Committee. National Hospice and Palliative Care Organization position statement and commentary on the use of palliative sedation in imminently dying terminally ill patients. J of Pain and Symptom Manage 2010 May;39(5):914-23

2. Cherny NI and Portenoy RK. Sedation in the management of refractory symptoms: Guidelines for evaluation and treatment. J Pall Care 10:2(1994):31-38

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Intolerable symptoms/suffering

- Unbearable. Only the patient can identify when suffering has become intolerable."

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Palliative Sedation

Terminal illness

- No definition - AMA
- Refer to a life expectancy of 6 months or less - NHPCO
- No legal definition

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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

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Palliative Sedation

Others

- …“whose clinical symptoms have been unresponsive to aggressive symptom-specific treatments…” - AMA

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Palliative Sedation: Indications

Physical symptoms

- Usually well-accepted if intractable
- Most common:
  - pain
  - dyspnea
  - delirium

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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

[1]Cherny N, Coyle N, Foley K. Suffering in the advanced cancer patient: A definition and taxonomy. J Pall Care 1994;10:57-70

Definition adopted by NHPCO

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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."

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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…"

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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

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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.

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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)

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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)

    Washington vs. Glucksberg 521 US 702 (1997)

- Patients Bill of Rights: promoting good medical practice

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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

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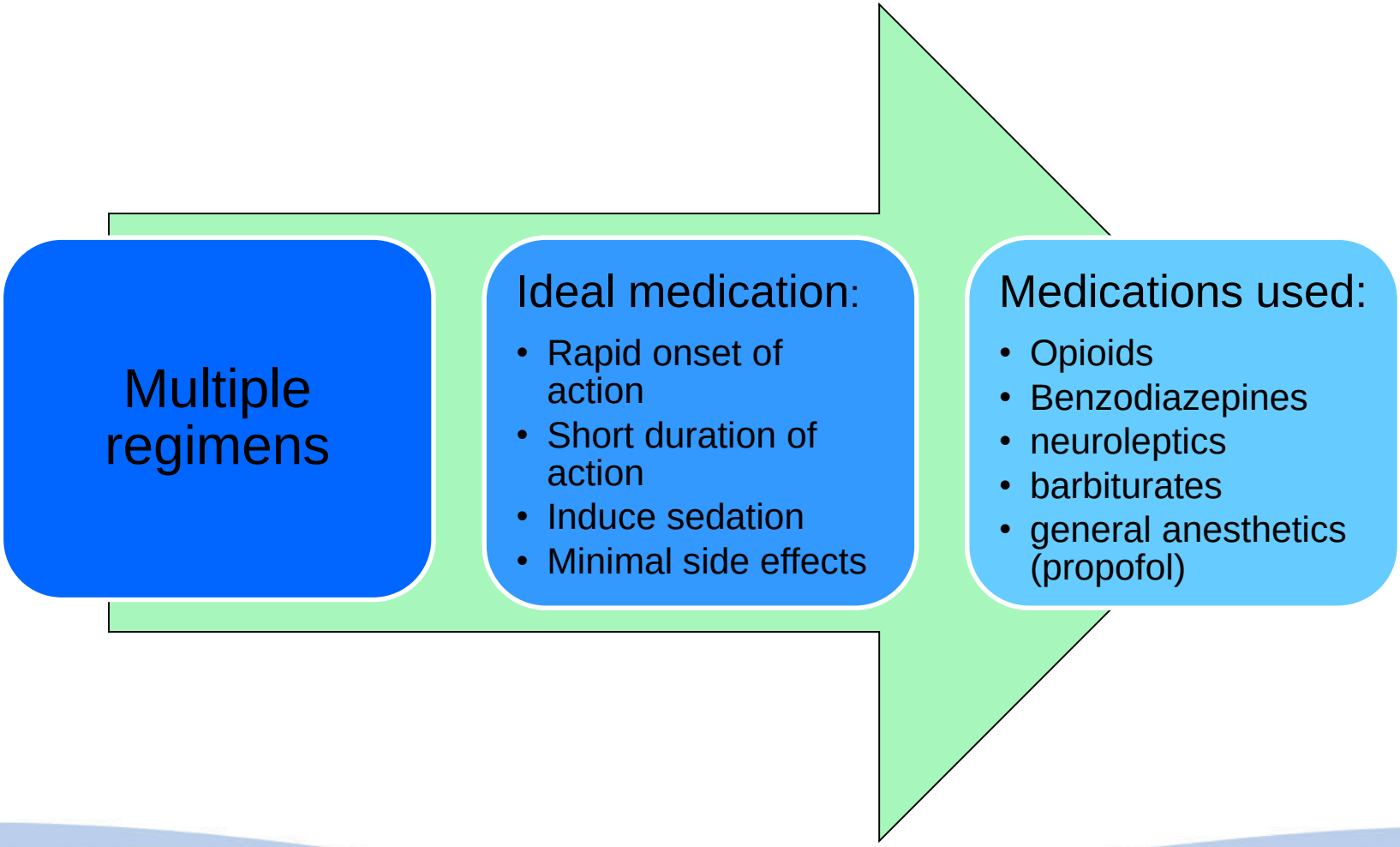
Palliative Sedation: Pharmacotherapy



Palliative Sedation: Pharmacotherapy

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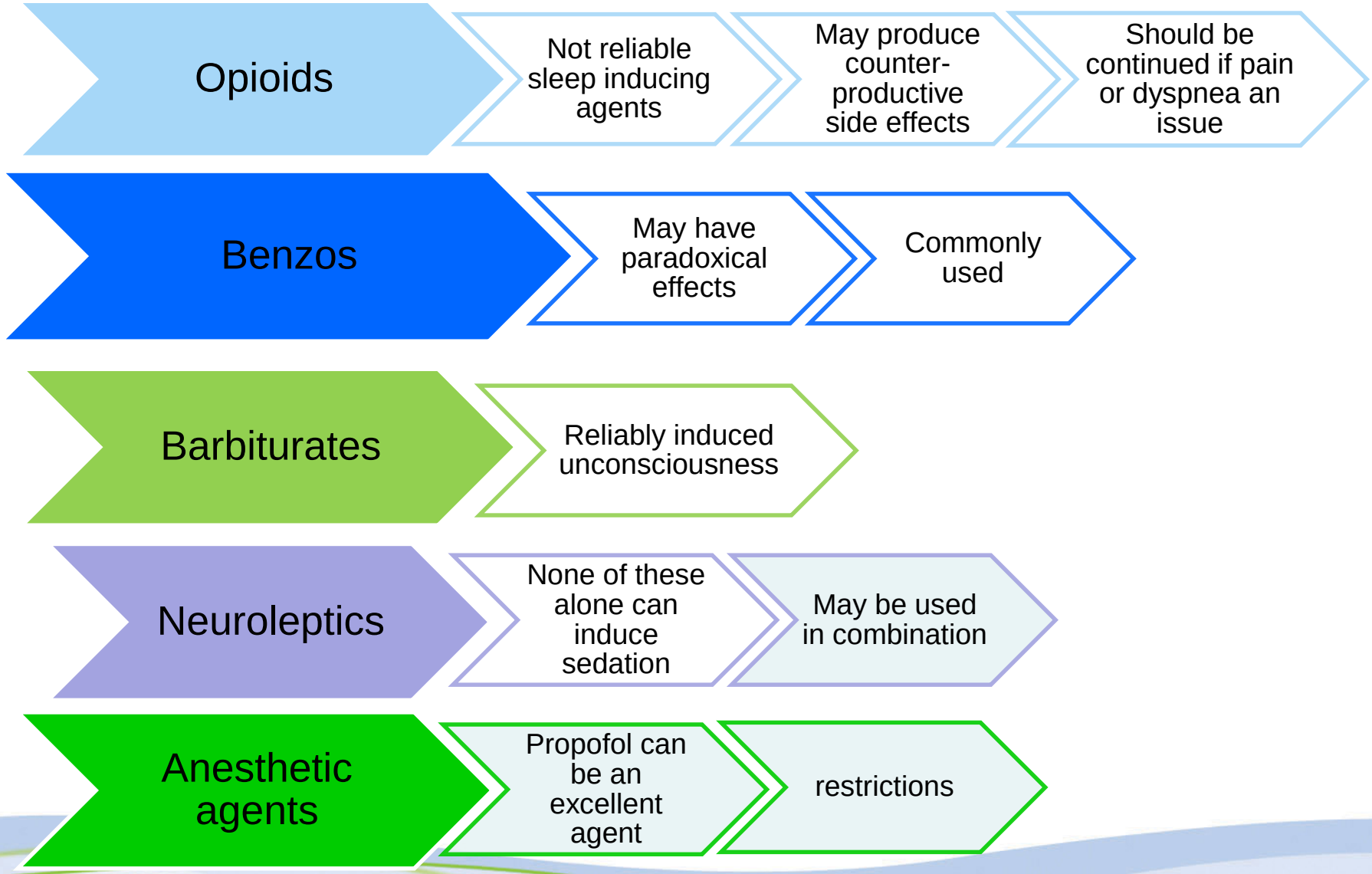

Palliative Sedation: Proposed Criteria

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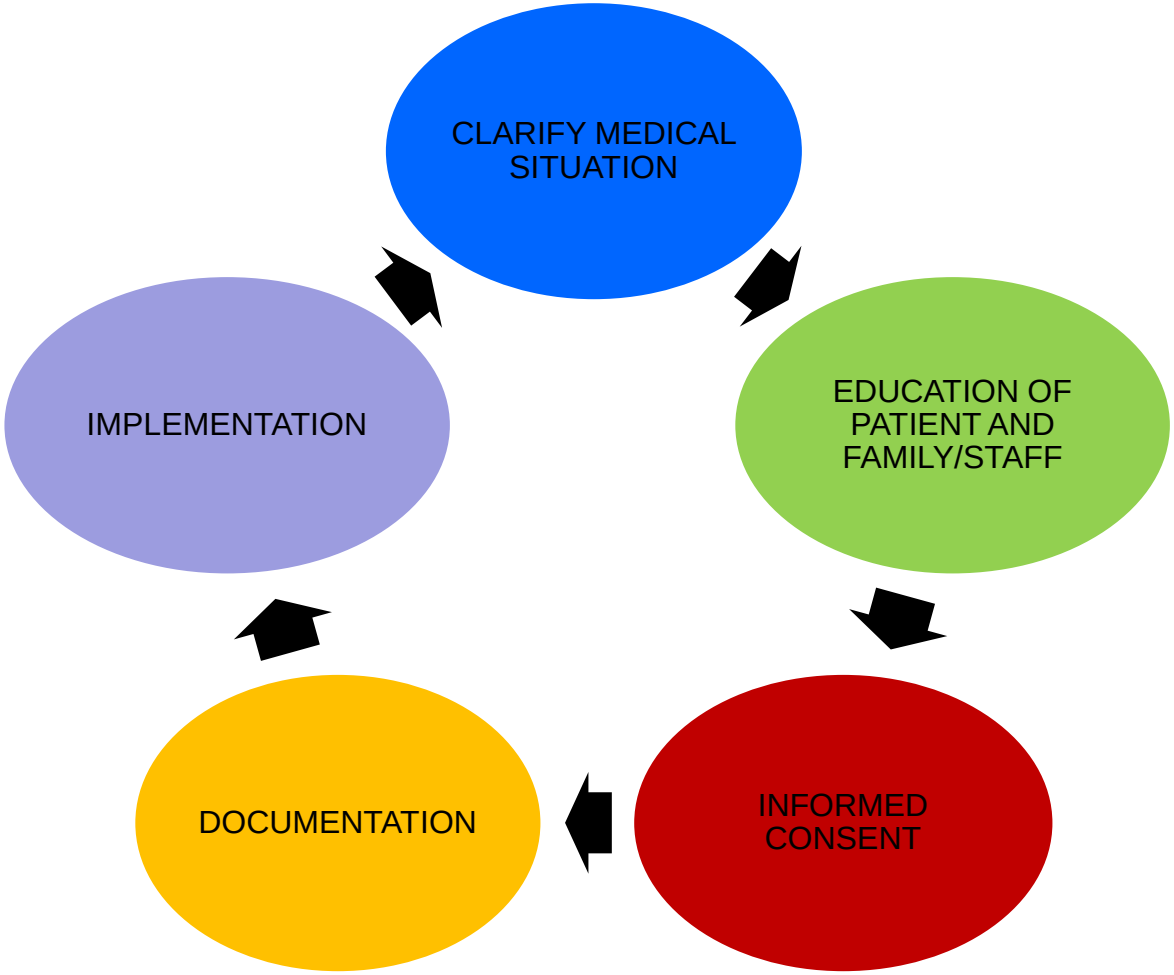

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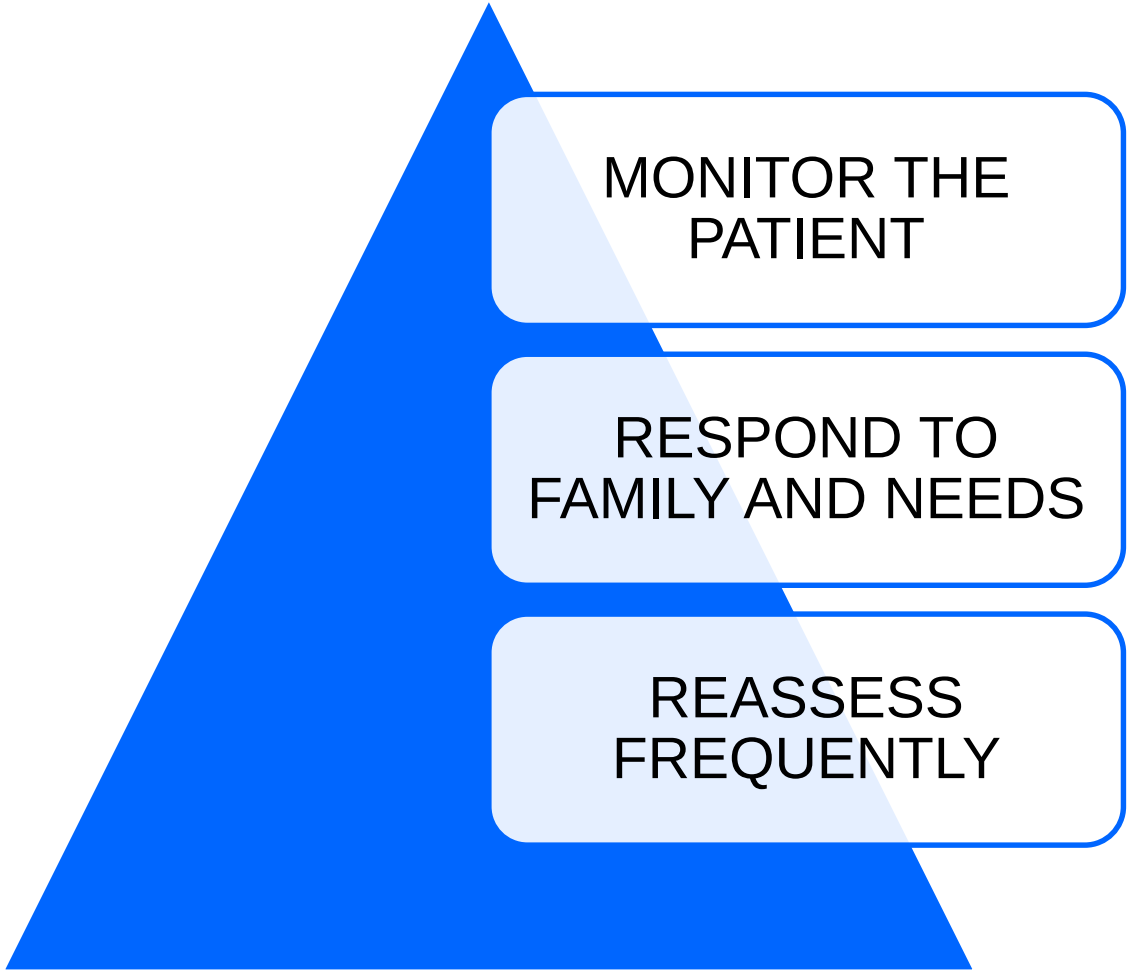
Palliative Sedation: Implementation



Palliative Sedation: Literature Review

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- **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

Schildmann, E., and 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;601-11. (9 studies included in qualitative analysis)

Palliative Sedation: An Analysis of International Guidelines and Position Statements. Am J Hosp Palliat Care 2014, May 7, p. 1-12.

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)

Palliative Sedation: An Analysis of International Guidelines and Position Statements. Am J Hosp Palliat Care 2014, May 7th p. 1-12

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Literature Review

Studies	Symptoms	Medication	Incidence/ Surv.
Tatsuya JPSM (1996)12/1	dyspnea pain general malaise agitation nausea	midazolam 55% morphine 55% haloperidol 33% diazepam 15% scopolamine 13% bromazepam 6% chlorpromazine 4% barbiturate 4%	48.3% (143) 3.9 days
Ventafridda,V JPallCare (1990) 6/3	dyspnea (33/63) pain (31/63) delirium (11/63)	increase opioids psychotropic drugs	52% (120) 2 days
Faisinger,R JPallCare (1991)7/1	delirium pain		16% (100)

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Literature Review

Studies	Symptoms	Medication	Incidence/ Surv.
Chater, S Knoll et al. trait. douleur Vol. 10/1, fev. '97	Pain 31% distress (angoisse) 22% agitation/delirium 18% dyspnea 17% nervosity 17% emotional distress 16% anxiety 15%	midazolam (15-120mg/24hr) methotrimeprazine chlormethiazole phenobarbital benzo(lora/clona/dia) chlorpromazine haloperidol	***panel of 51 experts 78% in favor**
Lichter et al. JPallCare (1990) 6/4	Pain 51% dyspnea 22% confusion 9% nausea vomiting 14% agitation/restlessness 42%	increase opioids benzo haloperidol chlorpromazine	36% (200) last 48 hrs

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Literature Review

Studies	Symptoms	Medication	Incidence/ Surv.
Greene, WR South Med.J. (1991) 84/3	pain vomiting seizures restlessness	amobarbital IV 20-215 mg/hr thiopental IV: 20-80 mg/hr multiple drugs	2-4 days 23 days
McIver,B JPSM (1994)9/5	dyspnea restlessness	chlorpromazine: Pr 25mg q4-12h IV 12.5mg q4-12h (mean: 50mg/day) PR as effective as IV	Mean: 1 day
Burke, A MedJAustr (1991) 155 oct.	restlessness anxiety myoclonus /twitching/ seizures	midazolam S.C. (2.5-10mg q2h) mean: 20-60 mg/day	86 patients

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Literature Review

Studies	Symptoms	Medication	Incidence/ Surv.
Bottomley, DM JPSM (1990) 5/4	agitation restlessness	Midazolam S.C. (syringe driver): 0.4-0.8 mg/hr Mean: 2.9 mg/h, 69.6 mg/day early tolerance: add dizepam (26%)	4 days 6-11 days
Truog,R.D. NEJM (1992)	physical nonphysical	**Deep sedation:** thiopental (5-7mg/kg: mean: 70-180mg/hr) pentobarbital (1-3mg/kg) **Mild/Moderate:** Benzo Opioids Phenothiazine	

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Literature Review

Studies	Symptoms	Medication	Incidence/ Surv.
Mercadante, S JPSM (1995) 10:639-642	delirium	propofol 50-70mg/hr	8 hrs
Moyle J JPSM (1995) 10:643-646	delirium	propofol 50-200mg/hr recommended: 5-70mg/hr	9 days
Stone P Pall Med 11:140-144	delirium (30 pts) mental anguish, pain dyspnea	Midazolam, benzo Methotrimeprazine, haloperidol Chlorpro / Pheno	1.3 days

Comparative Guidelines

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	International Guidelines De Graff et. al. (2007)	EAPC Framework Cherny et al. (2009)	NHPCO Statement Kirk et al. (2010)	Canadian Framework Dean et al. (2012)
Definition	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

Adapted from: Schildmann, E., Schildman, J. Palliative sedation therapy: A systematic literature review and critical appraisal of available guidance on indication and decision making. J Palliat Med. 2014 May; 17(5):601-611.

Comparative Guidelines

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	International Guidelines De Graff et. al. (2007)	EAPC Framework Cherny et al. (2009)	NHPCO Statement Kirk et al. (2010)	Canadian Framework Dean et al. (2012)
Decision-Maker	PC specialist Consensus in palliative care team Active involvement of patient or surrogate/proxy	Clinician with expertise in palliative care Interdisciplinary evaluation when possible Input from teams, family Involvement of PMD (primary physician)	MD with palliative care expertise Interdisciplinary conferences Responsibility of team to assess level of suffering Patient is the only one who can identify intolerability	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
Information Consent	Informed consent from patient or representative Detailed recommendations on content of informed consent	Discussion with patient (noncritical situation) Reference to surrogate decision-maker (lack capacity) Detailed recommendations on content of consent	No specific information	Reference to substitute decision-making Detailed recommendations on content of informed consent
Decision About Life-Sustaining Treatment	Separate discussion	Separate discussion	DNR in effect Separate decision	Separate decision

Adapted from: Schildmann, E., Schildman, J. Palliative sedation therapy: A systematic literature review and critical appraisal of available guidance on indication and decision making. J Palliat Med. 2014 May; 17(5):601-611.

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Palliative Sedation is a therapy of last resort

Case Study

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- 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).

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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?

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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.

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Case Study 2

Question:
How appropriate to sedate KD to unconsciousness?

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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.

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