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Palliative sedation: welcome guidance on a controversial issue

Katherine Hauser and Declan Walsh *The Harry R. Horvitz Center for Palliative Medicine, Cleveland Clinic, Cleveland, OH, USA*

Palliative sedation (PS) is the use of medications to reduce consciousness for the relief of *intolerable* and *refractory* symptoms, in patients with limited life expectancy. The ethical justification of palliative sedation is based upon the principles of double effect, autonomy and proportionality.[1] Double effect is predicated upon the primary intent being to relieve suffering, despite potential foreseeable, but unintended, adverse effects. Proportionality is based upon the use of PS in the face of intolerable distress as a 'therapy of last resort', when all other potentially less harmful options have been expended or are inappropriate.[1] PS is neither slow euthanasia nor physician-assisted suicide. Both of these practices involve the specific intent to end life, the deliberate use of lethal doses of sedation drugs, or non-therapeutic escalation of doses disproportionate to symptom distress. PS does not shorten life overall (when implemented in specialist palliative care units), despite the expected risk of individual complications (e.g. respiratory or hemodynamic compromise, aspiration, or venous thromboembolism).[2]

Sedative drugs first appeared in modern medicine in the 19th century, with bromide and chloral hydrate. Barbiturates were introduced in 1903, and benzodiazepines in 1959. The first descriptions of sedation for symptom control in advanced disease were published in 1990–1991.[2] The early literature described a wide range in prevalence, indications and clinical practices. The prevalence in these reports ranged from 16% to over 50%.[2] Indications included agitation and restlessness, pain, delirium, respiratory distress, myoclonus, and psychological symptoms. Drugs used for sedation included benzodiazepines, antipsychotics and barbiturates. Despite a number of prospective studies and published guidelines, evidence upon which to base practice has remained limited and controversial issues persist. These include almost every aspect of PS; the definition and terminology (palliative versus terminal), the types of sedation included under this term (intermittent versus continuous, light versus deep), the indications (physical or existential distress), the use of artificial hydration and nutrition, and the ethical basis and differentiation from euthanasia.

Decisions about palliative sedation are complex and can have significant implications for the patient and lasting impact on family and staff. Staff need to develop awareness of their own preferences about care of the dying, and the potential role of frustration, sense of failure and burnout in decision making. Individual physician personal and professional factors may influence the practice of PS, including prevalence, determination of refractoriness, level of sedation used, and drugs employed. Families and staff need extensive support to understand the decision-making process, and be clear about the goals and expected outcomes. Identifying a family spokesperson (preferably one chosen by the patient) may help communication, especially for large, geographically scattered or conflicted families. Without effective communication families may be left with feelings of profound confusion, guilt or remorse, which complicate their subsequent bereavement. For these reasons evaluation and decision making by a multidisciplinary team skilled in palliative care is essential prior to initiating PS.

Initiating PS without palliative medicine involvement is potentially hazardous. Palliative medicine consultation has been demonstrated to elicit previously undocumented diagnoses (especially delirium), and suggest multiple management strategies in advanced cancer, even within tertiary cancer centers.[3] A dilemma in decision making arises where there is a lack of access to, or awareness of, specialized interventions including palliative medicine, psychiatry, interventional pain management, and spiritual care. Non-palliative medicine physicians need to have insight into their own therapeutic limitations, whilst palliative medicine physicians should be available to provide support via telephone or videoconference to isolated clinicians.

Corresponding author:
Dr Declan Walsh, Professor and Director, The Harry R. Horvitz Center for Palliative Medicine, Cleveland Clinic, 9500 Euclid Avenue, M76, Cleveland, OH 44195, USA.
Email: WALSHT@ccf.org

The controversial issues and complexity of clinical decision making about PS highlight the need for international standards or guidelines upon which to base clinical practice and evaluate future research. The European Association for Palliative Care (EAPC) framework for use of sedation in palliative care represents a consensus from many international experts, built upon an extensive literature review and consideration of previous guidelines (this issue, page xx).[4] This is a framework, rather than a guideline. It can be used as a basis for guideline or protocol development at a national or institutional level, to reflect the local cultural, medical, and legal climate. The framework describes in detail both inappropriate and substandard use of sedation. It then sets out a series of considerations for evaluation, communication, decision making, documentation, and support in circumstances where palliative sedation is considered and initiated.

The proposed framework identifies pharmaceuticals indicated for PS and includes recommended doses. These will vary according to local availability, cost, and experience. The route of administration and location also have an impact on drug delivery, as infusion pumps may not be available in all settings. Use of general anesthetic drugs, e.g. propofol, may be restricted in many institutions by local regulatory or pharmaceutical regulations. We consider chlorpromazine the drug of first choice in PS for the relief of refractory distress. It can be given orally, parenterally, or rectally, is affordable and effective.[5] It also has beneficial effects for delirium, dyspnea, nausea and vomiting, and pain. In contrast haloperidol is not recommended, as it is less sedating than other antipsychotics.

Once initiated PS must be monitored regularly and objectively. Appendices to the framework detail instruments for monitoring distress and sedation. It is important to note that sedation is not universally effective. A Japanese multi-center study found inadequate symptom relief in 17%, and persistent severe delirium in 4%.[6] Rescue doses of sedatives should be available, similar to routine opioid prescribing, for breakthrough distress. Monitoring and titration of sedation to objective signs of distress, including down titration if appropriate, distinguishes this practice from euthanasia. In certain circumstances (e.g. planned continuous deep sedation) down titration may be inappropriate and distressing to the patient, family, and staff. It also raises troubling practical and ethical dilemmas.

Perhaps the most controversial indication for sedation is unresolved psychosocial or existential distress. As palliative care physicians we must reflect on whether the role of medicine is to relieve all human suffering. Suffering is an essential part of the human experience and may have meaning for patients and their families.[1] One key recommendation in this framework for existential distress is that refractoriness should be determined only after *repeated* evaluation by a *skilled* clinician who has a *relationship* with the patient. This implies that a single psychiatry consultation to rule out depression or anxiety is insufficient. Involvement of a social worker, chaplain, and ethicist, including evaluation of the family and social circumstances, may also be needed before decisions are made. Existential distress is perhaps the most important place for intermittent or respite sedation: time for rest and reorganization may resolve some of the distress.

Organizations that use this framework to develop locally relevant guidelines must be aware of certain caveats. Guidelines may have unintended consequences, especially when applied out of context. The population and practitioners to whom the guideline refers must be defined clearly. Considerations include the following:

- Which practitioners should be responsible for PS?
- Should the practice of PS be restricted to licensed palliative medicine specialists?

Clearly this will be influenced by the local level of palliative care services. However, in institutions with a palliative care service, consultation should, in our view, be automatic beforehand. One risk of widespread acceptance of the practice is the use of PS as a veiled method of euthanasia. Physician titration of drugs with the intent to shorten life is well documented in many countries.[7] Safeguards will be needed to ensure this EAPC framework is not inappropriately used to support this practice. This is especially true in countries or states with legalized euthanasia or physician-assisted suicide, where PS could be used with the intent to bypass the legal prerequisites. We are concerned that unlike previous guidelines this framework does not propose the prerequisite of a written 'do not resuscitate order' (DNR) before PS. In particular, in the case of continuous deep sedation near death this would seem imperative. For sedation due to existential distress where life expectancy may be longer, DNR orders may need to be individualized.

Every institution with a palliative care service should have a protocol for the implementation of PS. This protocol should include requirements for consent (written or verbal) by the patient or surrogate, documentation, and evaluation. Protocols may also consider pre-consent for sedation, e.g. during conversations and decisions about advance directives and resuscitation. Guidance and expectations must be included about the appropriate continuation of all other comfort measures, e.g. oxygen, nursing care, mouth care, etc., within an overall plan of care. This is especially relevant in the home setting where full-time nursing care may

unavailable or intermittent. Documentation should always be in the medical record and any other documents accessed by the whole team, e.g. home nursing notes. Once protocols are implemented clinical practice should then be audited regularly to ensure ethical implementation and quality standards.

In the future, we hope this framework will encourage research based upon prospective multi-center international studies. Studies should use a universal definition and objective outcomes (including sedation and distress scales, complications, and family outcomes in bereavement). Perhaps the large discrepancies apparent in the literature in prevalence and indications will be minimized by future research. This document represents a groundbreaking effort on behalf of the EAPC and international palliative care community to agree upon a structured approach to a controversial and sensitive issue. The authors are to be congratulated on a significant clinical and academic achievement.

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