JOURNAL OF PALLIATIVE MEDICINE
Volume 8, Number 3, 2005
© Mary Ann Liebert, Inc.

Implementing Institutional Change: An Institutional Case Study of Palliative Sedation

ZEV D. SCHUMAN[1], MAUREEN LYNCH, M.S., A.P.R.N., B.C., P.C.M., A.O.C.N.,[2] and JANET L. ABRAHM, M.D., F.A.C.P.

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

ABSTRACT

Palliative sedation is used in the rare patient who has intractable distress at the end of life. Implementation of palliative sedation, however, may meet resistance from various clinicians and other hospital staff. To ensure that our patients had access to this important treatment modality, we found it necessary to engage in a process of institutional change that resulted in acceptance of the use of palliative sedation in the non-ICU setting.* In this paper, we will review the processes we found to be successful in hopes that they will also be efficacious for others wishing to produce similar change within their institutions. We first will review the theoretical foundations described in organizational development and change management literature. Next we describe our implementation strategies (including education, multidisciplinary alliances, and the development and approval of a practice guideline). Finally, we discuss in detail the role of interpersonal interactions. Three clinical cases are used to demonstrate the change in attitudes, processes, and outcomes.

INTRODUCTION

Case 1: The appearance of resistance often foreshadows the coming of change

A 70 year-old-man with bone pain from metastatic prostate cancer was admitted to a standard hospital floor, accompanied by his wife. His pain was not well controlled with a PCA pump and he began begging for pain relief, while asserting, "sleepy is fine." Despite adjuvants and a continuous opioid infusion, his pain control was inadequate, his sedation increased, and he developed myoclonus. He was semiawake, arousable, and responded to verbal communication during which he reiterated that becoming sleepier would be acceptable. His wife also wanted relief of his pain and accepted that he would need to be sedated and might never return to full consciousness. The palliative care NP and the anesthesia pain service fellow discussed the possibility of using what was then termed terminal sedation. The anesthesia pain fellow stated that he was not familiar with this intervention and was not comfortable participating in it, and he then left to attend to other patients. The NP discussed with staff nurses the possibility of sedation to relieve the patient's

[1]Tufts University School of Medicine, Boston, MA.
[2]Dana–Farber Cancer Institute, Boston, MA.
*The institution referred to in this paper refers to the the Dana–Farber Cancer Institute/Partners CancerCare partnership and the Brigham and Women's Hospital.

distress. One staff nurse responded, "If you want to kill your patient, you'll have to do it on another floor." The floor's nurse manager called an ethics consult. The ethics consult supported the need to provide relief even if sedation occurred. The patient was evaluated by the MICU attending who concurred. The patient was transferred to the MICU, started on a propofol drip, and died peacefully about 36 hours later.

Palliative sedation is the use of sedating medication to relieve a dying patient's severe physical, psychological, or existential distress that cannot be controlled despite other aggressive measures.[1] The goal of palliative sedation is to relieve intractable distress, not to hasten death. The U.S. Supreme Court in its 1997 decision regarding physician-assisted suicide affirmed the importance of intent, supporting the ethical principle of double effect.[2] The use of continuous infusions of sedating agents is common in intensive care units, but these agents are rarely used for this purpose outside that setting. In our facility in prior years, therefore, patients who needed palliative sedation were transferred to the ICU in their final hours. Neither the families nor the unit staff members who had to transfer the patient were satisfied with this solution. When we formed our institution's first palliative care team, we worked to help create an environment in which all staff would understand the ethical underpinnings of palliative sedation and, supported by the expertise of the palliative care team, would feel competent in providing palliative sedation to the rare patient who required it in a non-ICU settings.

Other authors have reviewed several working definitions of palliative sedation[3] or have described the development of a practice guideline for palliative sedation in a Canadian comprehensive, integrated health system.[4] In this paper, however, we will review all the processes we found to be successful in a tertiary care teaching hospital in creating the institutional change that enabled adoption and implementation of a Guideline for Palliative Sedation Outside the ICU (see Appendix A for a copy of the guideline). We will first review the theoretical foundations described in organizational development and change management literature. Next we describe our implementation strategies (including education, multidisciplinary alliances, and development and approval of a practice guideline). (See Table 1). Finally, we discuss in detail the role of interpersonal interactions in promoting change.

STRATEGIES FOR IMPLEMENTING POLICY CHANGE

Theoretical foundation

The organizational development and change management literature often refers to Lewin's pioneering social psychology theories. Lewin introduced the well-known three-phase change process of "unfreezing" the present state, "moving" toward a new level of performance, and then "freezing" at the new state, as a model of group development.[5] Lippitt further clarified the role of the change agent and the dynamics of the development process. He did this by expanding on Lewin's phases and developing the following useful concepts: identifying "a need for change" or "a problem awareness," establishing the "change relationship," and recognizing "resistance forces."[6] Curtis and White more recently outlined strategies for recognizing and overcoming resistance to change.[7] In our institution, then, what were the *need for change*, the *components* of change, the *barriers* to change, the *stakeholders* in the change, and the *allies* in change; and what were the crucial internal psychological issues that caused resistance to change?

The *need for change* with respect to delivering palliative sedation outside the ICU setting began with recognition that some patients do have intractable distress at the end of life and that we have a commitment to alleviate their suffering to

Table 1. Strategies for Implementing Policy Change

Theoretical foundation
Identification: identify the need for change, the components of change, the barriers, the stakeholders, and the allies
Transition and recognizing resistance to change
Implementation strategies (purpose: overcoming resistance)
Education
Multidisciplinary alliances
Establish guidelines
Interpersonal interactions
Consensus-building relationships
Trust building: proving commitment, showing proper intention, honoring life
One-on-one teaching during implementation

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

the best of our abilities. In addition, we were responding to the nurses and other unit staff who were torn by their desire to continue to care for their patients and their ethical, moral, and technical concerns about providing palliative sedation on their units. In turn, the ICU staff members who were accepting these patients for their last hours felt they could not provide optimal support to families whom they barely knew and were concerned that their expertise was really best used in trying to save patients who needed the level of care provided in their unit. The impetus for a planned institutional change, therefore, came from the conflicts, as well as the family and staff distress, that arose when a patient required sedation at the end of life outside the ICU setting.

At our institution, the major *component of the change* was the establishment of a team who were expert in pain and palliative care and in psychosocial oncology.

As case 1 demonstrated, staff nurses proved to be one of the major *barriers to change*. The staff nurses were present more of the time with the suffering patients than were the physicians, which intensified their concerns about doing the right thing. As case 1 illustrates, many of the nurses feared that interventions such as palliative sedation were akin to euthanasia.

The *stakeholders* involved were numerous, including management, the staff nurses and nurse managers, the pain and palliative care team, psychosocial oncology team, ICU staff, pharmacists, doctors, ethics consultation service, social workers and chaplains, and, last but not least, the patients and families, who were suffering.

The *allies* included members of the ethics consultation team, patients and families, nursing management, nursing education, and nurses and nursing assistants.

After identifying the factors involved in the change, it is essential to ally with the individuals who would be involved in carrying out policies. Helping others manage the internal psychological process of change, the *transition*,[8] and directing them toward a *resolution* requires first expecting the development of uneasiness, and then recognizing and addressing the *causes of resistance*. The recent paper by Curtis and White[7] describes common causes of resistance and offers strategies for reducing resistance (Table 2).

IMPLEMENTATION STRATEGIES

Implementation strategies were developed to overcome resistance among the various stakeholders.

Table 2. Resistance: Causes and Solutions

Causes
Increased stress: Any change requires readjustment and thus constitutes a stressor.
Denial: Denial of the need for change can occur when material is first presented.
Lack of understanding, trust, and ownership: People can distrust the intentions of the change.
Uncertainty: Lack of information about future events, linked to loss of control.
Motivation: The drive to fulfill our needs, including safety, belonging, and esteem.
Different perceptions: If there is a difference in assessment between the recipient of change and the implementer, it causes *cognitive dissonance* (conflict between one's own beliefs and the tasks with which one is confronted).
Personality: An individual may have an inherent personality trait that renders him or her less open to change.
Solutions
Introduce change slowly: Allow people to adjust to change and to seek out information.
Participation: Allow stakeholders to take an active part in change; having an opportunity to express their ideas and fears will reduce uncertainty and their self-interest will be less threatened.
Psychological ownership: This refers to being psychologically tied to a policy and having a feeling of possessiveness for that policy.
Education and facilitation: Educate about the need to change. Help recipients to understand implementer's assessments.
Development of trust: Requires open and honest communication. Allow opportunities for clarification, seek understanding of their reservations, and engage in constructive confrontation of the divisive issues.
Additional support: Providing additional support during the change implementation reduces anxiety and fear of the change. Practice active listening to problems and suggestions. Encourage social support that acts as a buffer against stress.
Change agent: Use of an external change agent who can help facilitate introduction of the change.

Adapted from Curtis and White (2002).[7]

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

Education

The pain and palliative care team developed a plan to educate the nurse managers and staff nurses, since they were the major stakeholders who would implement palliative sedation. As one nurse said, "The doctor writes the order and then walks away. We are the ones who have to push the drug and carry the guilt that we are doing something wrong, that we are killing someone." The pain and palliative care team physician, nurse practitioner, and pharmacist conducted in-services on floors that might be asked to participate in palliative sedation. The in-services included a definition of palliative sedation, legal and professional statements about the duty to relieve suffering, the distinction among palliative sedation–euthanasia–physician-assisted suicide–"slow euthanasia." Case examples included options that were available short of palliative sedation to relieve patient distress (e.g., consults from the pain service, social work, chaplaincy, and the palliative care service). During the in-services, nurses expressed concern with their inability to relieve the suffering of some of their dying patients; palliative sedation quickly became seen as a solution and many nurses appeared to develop psychological ownership of the procedure.

Following these in-services, the palliative care team presented material similar to that contained in the in-services at nursing grand rounds and at a hospital-wide ethics forum. This comprehensive educational effort, which lasted several years, was successful in reducing resistance by relieving uncertainty about what palliative sedation represented, explaining what the nursing role would be in the procedure, establishing trust, increasing psychological ownership, and providing ethical underpinnings for the procedure.

Multidisciplinary Alliances

The multidisciplinary alliance present in the palliative care team helped to engage the stakeholders and promote collaboration for institutional change. The pain and palliative care team included physicians, NPs, a palliative care specialty pharmacist, two fellows, and a psychiatrist from the psycho–oncology group. We had already established alliances with the anesthesia pain service, social work, chaplaincy, and the ethics committee. These alliances and the expertise within our multidisciplinary pain and palliative care team enhanced our reputation as a resource for relieving patient suffering and for helping their families.

Case 2

> After the educational effort began, a staff nurse called the pain and palliative care consultation team, requesting them "to come and do that thing you do." The patient was a 58-year-old man with relapsed AML in the hospital for his second bone marrow transplant. He developed GVHD and hepatic fungal infection. His course was further complicated by intracranial bleeds that precipitated seizure activity that could not be controlled by anticonvulsants, steroids, and benzodiazepines. His wife and mother, who were at the bedside, acknowledged the poor prognosis and asked that something be done to stop the seizure activity that was now constant.
>
> The pain and palliative care consultation team consulted with the oncology team and neurology, who affirmed the poor prognosis and the intractability of the seizures. After intensive discussion with the family and the treating teams, palliative sedation was considered. But the nursing staff were unfamiliar with the medications recommended. There were no written guidelines for giving the agents outside of the ICU setting describing how the patient should be monitored and delineating what parameters should be used to adjust the medications. The pain and palliative care team, the neurology team, and the nursing staff developed an ad hoc protocol that supported the concerns of the nursing staff. They agreed to implement the procedure and the sedation was almost immediately effective in controlling the patient's seizures.

Guidelines. Case 2 illustrates the need for formal guidelines on palliative sedation regarding a range of issues related to ethics, eligibility, and procedures. The team drafted a guideline with assistance from stakeholders previously identified.

The guideline at our institution was adapted with permission from the then unpublished paper "Sedation for Intractable Distress of a Dying Patient," a policy developed by Eric Krakauer and colleagues at Massachusetts General Hospi-

tal, who work with this population of patients.[9] In addition, we used concepts from papers by Wein[10] and Cherney and Portenoy.[11] Prerequisites for initiation of the intervention and a detailed outline of the physician and RN responsibilities are included in the guidelines (Appendix). The members of the ethics committee were active participants in modifying our initial draft guideline and thereby became a powerful ally for change. They provided support in obtaining approval from hospital executive committees whose consent was required for final approval. Issues that committee members raised during the process of guideline development included possible abuses and premature use of palliative sedation, the necessity of palliative care consultation, involvement of the primary care and inpatient attending physicians, and delineation of the informed consent and assent process.

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

Interpersonal Interactions

Consensus-Building Relationships. To bring about change and introduce new procedures that alter behaviors and challenge old ways of doing things, the members of the pain and palliative care team worked to establish healthy relationships with stakeholders. The team focused on building consensus in these relationships. Since different people have different perceptions of the same intervention, it was important to discover their initial concerns. Statements like "Tell me what you understand about this procedure" served as invitations for clinicians to share their apprehensions. Respectfully listening to their goals and their discomforts allowed the pain and palliative care team members to be sensitive to stakeholders' needs and to align their actions with these needs. By proceeding slowly to allow for consensus, the team fostered acceptance and nurtured stakeholders through their feelings of uncertainty, while allowing a feeling of psychological ownership to arise.

The palliative care team built consensus top down by presenting their recommendations first to the nurse managers. Once the nurse managers had a chance to air their concerns and develop a plan with the team, the manager would introduce the team and their recommendation to the staff nurses with a plan for implementation. This method of communication helped to decrease stress for staff nurses and provided additional social support during implementation.

Trust Building. Staff must trust that the clinicians who are initiating palliative sedation consider this a serious decision and an intervention that carries profound weight and possible consequences. Staff must believe that the clinicians will provide this intervention with great care, respect, and attention to the response of the patient and family and the concerns of staff.

Trust building was possibly the most crucial element in bringing about acceptance of palliative sedation in our institution. The staff nurses needed to believe that they were doing the right thing for their patient. In the hospital, nurses may doubt that doctors care as much about their patient's suffering as they do. Doctors may write the orders and then leave the nurse to negotiate the difficult situation. Being present with the nurse as witnesses to suffering and helping with implementation of new and ethically complex interventions was essential to establishing trust.

Our pain and palliative care team demonstrated to nurses its commitment by being present until the distress was relieved and shouldering a portion of the responsibility. Gaining a team reputation for respecting and honoring life and for providing relief of suffering in cases that did not require palliative sedation during months of consultations were also crucial to nurses' willingness to trust our judgment that a given patient's distress could be relieved only by palliative sedation.

If stakeholders are to participate in palliative sedation, they must also trust that the palliative care clinician's intentions are to provide comfort without intentionally hastening death. The doctrine of double effect legitimizes palliative sedation because, although death is a foreseeable consequence, it is not the intention of the action.[12] For this reason, a lethal dose of sedation is not administered and a hastened death is not desired. A resolution of refractory symptoms is the desired goal. To emphasize that we were recommending palliative sedation, not euthanasia, we monitored patient's response to medications, carefully titrated the doses to effect, and gave the patient (who was present although unconscious) ongoing respect and care.

One-on-one Implementation. Palliative sedation should be done in collaboration with the patient's nursing staff. According to our guidelines, the inpatient attending or implementing clinician (such as the palliative care team attending physician)

should endeavor to ensure that all involved staff understand the purpose of the procedure and its ethical, professional, and legal bases. This opportunity for one-on-one teaching has been invaluable. In addition, a member of the palliative care team is either present or is consulted by phone by the on-site physician when the patient's condition requires a change in the infusion protocol. The team monitors the patient closely and provides frequent supportive visits with the nurse and family.

CONCLUSIONS

Case 3

In 2003 a 65-year-old man with colon cancer metastatic to the peritoneum and abdominal viscera was admitted to our institution for pain control. His wife accompanied him. The pain and palliative care team and the anesthesia pain team collaborated to treat his pain with adjuvants and systemic opioids, epidural, and then intrathecal medications, including an opioid. For a brief period, the epidural medications relieved his discomfort with so few side effects that he was able to complete the work that was important to him and to say his good-byes. However, he and his family desired a transition to an intrathecal catheter to simplify his care once he went home.

Unfortunately, the intrathecal medications were not successful and he required increasing doses of systemic opioids. He developed severe nighttime delirium and continuous and increasingly severe myoclonus. The added medications for the myoclonus and delirium did not fully control his symptoms and produced unacceptable sedation. He declined opioid rotation because he felt he could not tolerate this suffering any longer. After extensive discussion with the patient, his wife, and the other clinicians involved, the palliative care team recommended palliative sedation using pentobarbital because he had paradoxical agitation from benzodiazepines. The team's attending physician obtained the consent of the primary oncology team caring for this patient.

Because this would be the first use of palliative sedation on this nursing unit, to build a consensus, the team met with the nurse manager and the charge nurse and discussed with them what was then the draft Guidelines for Palliative Sedation Outside the ICU. The nurse manager then accompanied the team to discuss the guidelines with the staff nurses. With the help of the pain and palliative care team pharmacist, the pentobarbital was prepared and delivered by the staff nurse with the team in attendance. His other palliative medications were continued. His myoclonus stopped, he did not appear to be in discomfort, and his wife felt he was at peace in his sedation. He died that evening after 12 hours of palliative sedation. The next week the patient's family doctor called the pain and palliative care team, recalling the patient's wife's appreciation and thanking the team for the "uniquely compassionate care."

Palliative sedation is an essential procedure that can relieve the otherwise intractable distress of dying patients. Our commitment to alleviate patients' suffering to the best of our abilities requires us to ensure that our institution allow its clinicians to provide this relief, while educating and supporting its staff as they participate in implementing the sedation in accord with accepted ethical and professional standards. With an understanding of some of the relevant elements of organizational development and change theory, of key implementation strategies (education, multidisciplinary alliances, and a practice guideline), and of the role of interpersonal interactions, we hope clinicians in other institutions will share our success in bringing about the changes needed to provide optimal care to patients at the end of life and their families.

REFERENCES

1. Lynch M: Palliative sedation. Clin J Oncol Nurs 2004;7:653–667.
2. Rousseau P: The ethical validity and clinical experience of palliative sedation. Mayo Clin Proc 2000;75: 1064–1069.
3. Chater S, Viola R, Paterson J, Jarvis V: Sedation for intractable distress in the dying—A survey of experts. Palliat Med 1998;12:255–269.
4. Braun TC, Hagen NA, Clark T: Development of a clinical practice guideline for palliative sedation. J Palliat Med 2003;6:345–354.

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

5. Lewin K. *Field Theory in Social Science: Selected Theoretical Papers*. New York: Harper Torchbooks, 1951.
6. Lippitt R, Watson J, Westley B. *The Dynamics of Planned Change*. New York: Harcourt, Brace and World, 1958.
7. Curtis E, White W: Resistance to change: causes and solutions. Nurs Manage (Harrow) 2002;8:15–20.
8. Bridges W. *Managing transitions: Making the most of change*. Reading, MA: Addison-Wesley, 1991.
9. Krakauer EL, Penson RT, Truog RD, King LA, Chabner BA, Lynch TJ: Sedation for intractable distress of a dying patient: acute palliative care and the principle of double effect. Oncologist 2000;5:53–62.
10. Wein S: Sedation in the imminently dying patient. Oncology 2000;14:585–592.
11. Cherny NI, Portenoy RK: Sedation in the management of refractory symptoms: Guidelines for evaluation and treatment. J Palliat Care 1994;10:31–38.
12. Quill TE, Lo B, Brock DW: Palliative options of last resort. A comparison of voluntarily stopping eating and drinking, terminal sedation, physician-assisted suicide, and voluntary active euthanasia. JAMA 1997;278:2099–2104.

Address reprint requests to:
Janet Abrahm, M.D., F.A.C.P.
44 Binney Street
Shields-Warren 420
Boston, MA 02115

E-mail: jabrahm@partners.org

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

APPENDIX

GUIDELINES FOR THE USE OF PALLIATIVE SEDATION IN THE NON-ICU SETTING*

In the United States, there is legal and professional support for palliative sedation. The United States Supreme Court (in *Vacco* v. *Quill* 521U.S.793, 1997) recognized the right of patients to receive palliative sedation if that is what is required to relieve their suffering at the end of life. The codes of ethics of the national professional societies of medicine, nursing, and pharmacy all have determined that the provision of pallative sedation is consistent with ethical practice.

A. Definition

Palliative sedation for purposes of these guidelines means the use of medication to induce sedation to relieve an imminently dying patient's severe distress that cannot be controlled despite other aggressive measures. The goal of palliative sedation is to relieve intractable distress, not to hasten death. Palliative sedation is not physician-assisted suicide or euthanasia.

The BWH policy on Ethical Decision Making for Dying Patients (VIII-18) provides additional pertinent information.

B. Prerequisites for Initiation of Palliative Sedation

1. The patient must be dying imminently from a severe, irreversible, life-threatening illness such as advanced incurable cancer, end-stage major organ failure, advanced AIDS, advanced neuromuscular disease, or advanced dementia.
2. The patient must be distressed by one or more target symptoms, such as pain, dyspnea, intractable cough, myoclonus or agitation, that are refractory to standard palliative medications such as opioids, benzodiazepines, and neuroleptics.
3. An active order must exist to withhold at least the following life-sustaining treatments: chest compressions, defibrillation, endotracheal intubation, mechanical ventilation, use of pressors. If the patient has an implanted defibrillator, it must be inactivated.

*©2004 Brigham and Women's Hospital. All rights reserved. No part of these guidelines may be reproduced, stored, or transmitted in any form or by any means without prior permission from the Brigham and Women's Hospital.

4. In most circumstances, measurement of routine vital signs, use of cardiac monitors, oxygen monitors, and other monitors should be stopped when palliative sedation is initiated.
5. The inpatient attending physician must have initiated or be in agreement with the plan to provide palliative sedation. When possible, the primary physician will be contacted for input. The implementing physician (i.e., either the inpatient attending physician, an attending physician experienced in performing palliative sedation, or the palliative care attending physician) will endeavor to ensure that all involved staff understand the purpose of the procedure and its ethical, professional, and legal bases.
6. The inpatient attending physician shall consult with the Pain and Palliative Care Service (632-6464) to ensure that all other options for symptom control and relief of suffering have been addressed. In-house consultation for palliative sedation is available 24 hours a day, 7 days a week.
7. Informed decision making: The implementing physician must document the discussion of risks and benefits of palliative sedation with the patient or, if the patient does not have capacity to make medical decisions, with a surrogate decision maker. The discussion should include the option of being awakened from the sedation at a future time, if possible, to see if the patient desires to be conscious and/or whether the patient's symptoms can be controlled. However, the patient and/or surrogate should be informed that the effort to awaken the patient may not be successful.

C. Protocols for Administration of Palliative Sedation

Drug Selection

1. The desired endpoint of therapy is loss of consciousness to relieve otherwise intractable symptoms. This is distinct from sedation that may occur as a foreseen and tolerated but unintended effect of certain symptom-relieving medications, such as opioids to relieve pain, cough, or dyspnea; lorazepam for anxiety; or chlorpromazine for delirium. This guideline applies to situations in which sedation is the intended means to relieve an otherwise intractable symptom in an imminently dying patient. It is the *intention* to induce sedation as the means of controlling an intractable symptom in an imminently dying patient, not the particular medication(s) used, that defines the circumstances of palliative sedation.
2. Palliative sedation may be required in imminently dying patients who experience refractory neurotoxicity (i.e., myoclonus, seizures, hyperalgesia, or delirium) from opioid therapy, or in delirious patients who either are refractory to parenteral antipsychotics, or who require more immediate symptom control than will be achieved with antipsychotics. In these situations, sedatives such as midazolam or pentobarbital may be used while therapy directed toward controlling the target symptom is continued (e.g., opioids, antipsychotics).
3. Either midazolam or pentobarbital, therefore, may be used for any refractory symptom. The choice of agent is based on specific properties of the drug, desired outcomes, and known drug sensitivities.
   a. Choose midazolam if potential reversal of sedation is desired (i.e., to assess efficacy of other interventions such as relief of myoclonus through opioid rotation, or response of delirium to appropriate therapy).
   b. Choose pentobarbital if there is a contraindication to benzodiazepines, if immediate sedation is required for symptom relief, or if reversal of sedation is not contemplated.

General Guidelines Using Continuous Midazolam Infusion

1. A loading dose of 0.01 to 0.05 mg/kg should be given by an attending physician via slow IV push (over 2 minutes). May repeat to achieve desired effect. Subcutaneous continuous-infusion midazolam can be used in place of intravenous midazolam for the purpose of palliative sedation.

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

2. During loading dosing, an attending physician must be present at the bedside and remain there for 15 minutes or until the desired level of sedation is achieved.
3. Infusion should be started at the time of the loading dose (infusion rate: 0.02 to 0.1 mg/kg/hr or 25% of the loading dose). The infusion rate should be titrated to the desired level of sedation. A bolus equal to the hourly rate may be given up to every 2 hours. These boluses should be considered when making adjustments to the patient's hourly rate.
4. The patient's comfort should be assessed frequently and the infusion rate adjusted if necessary. Adverse effects to be monitored include tachycardia, agitation, and involuntary movements.
5. Dose adjustments are to be made based on evidence of pain or other distressing symptoms.
6. Patients with pain requiring an opioid should continue to receive the opioid and dose adjustments should be made for increased pain. Antipsychotics and other symptom-directed therapies should also be continued and monitored or adjusted.
7. Midazolam infusions are stable for 24 hours after dilution in NS or D5W. Standard concentration is 0.5 mg/mL. Compatibility data are limited.

General Guidelines Using Continuous Pentobarbital Infusion

1. A loading dose of 1 to 2 mg/kg should be given by an attending physician via slow IV push or hung as an IV bolus (no faster than 25 mg/min).
2. During loading dosing, an attending physician must be present at the bedside and remain there for 15 minutes or until the desired level of sedation is achieved.
3. Infusion should be started at 1 to 2 mg/kg/hr at the time of the loading dose and titrated to the desired level of sedation. A bolus equal to the hourly rate may be given up to every 2 hours. These boluses should be considered when making adjustments to the patient's hourly rate.
4. The patient's comfort should be assessed frequently and the infusion rate adjusted if necessary. Adverse effects to be monitored include agitation.
5. Dose adjustments are to be made based on evidence of pain or other distressing symptoms.
6. Patients with pain requiring an opioid should continue to receive the opioid and dose adjustments should be made for increased pain. Antipsychotics and other symptom-directed therapies should also be continued and monitored or adjusted.
7. Pentobarbital infusions are stable for 12 hours after dilution. Standard concentration is 1 mg/mL. Concentration may be increased for fluid conservation up to 5 mg/mL. Compatibility data are limited.

D. Physician Responsibility

1. A note must be entered in the medical record by the implementing attending or the pain and palliative care physician initiating the sedation. This note must state that (1) the clinical indication for palliative sedation is to relieve the target symptom, (2) the goal is not to hasten death, (3) all prerequisites have been met, and (4) the symptom has been refractory to other measures taken to relieve it. The note must also document the risk–benefit discussion with the patient or surrogate decision maker.
2. The physician's orders must specify the:
   - Indication
   - Loading dose
   - Initial infusion rate
   - Infusion rate range (mg/hr) and time interval for boluses and infusion rate adjustments
3. The initiating physician should either administer the loading dose of midazolam or be present at the bedside when the loading dose of pentobarbital is hung and remain on the unit, reassessing the patient for at least 15 minutes or until the patient is no longer in apparent distress.

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

4. The inpatient attending physician must assess and document in the medical record the efficacy of this therapy at least daily.
5. After an initial dose range is found that maintains the desired level of sedation, any change in the range requires physician documentation of the reason for the adjustment (intention).

E. RN Responsibility

1. The RN should participate in and understand the decision to provide palliative sedation and its ethical, legal, and professional bases.
2. Medication administration
   a. Drug solution should be inspected visually for evidence of precipitation prior to administration. If precipitation is present, the solution should not be used.
   b. Continuous infusion must always be administered by infusion pump. The pump must be clearly identified as administering a continuous infusion, including selected drug.
   c. Once the desired level of symptom control is achieved, the infusion should be maintained at the lowest rate that supports this desired level of symptom control.
   d. Continuous infusion should be interrupted or discontinued only upon a physician's order.
   e. The pharmacy should be notified 2 hours before the next infusion is needed to permit drug preparation and to avoid interruption of the infusion. Consultation with pharmacy regarding drug compatibility is required prior to drug preparation.
3. Patient assessment
   a. In some instances (e.g., at the patient's or family's request), a patient receiving palliative sedation will continue to have vital signs and oxygen saturation monitored. If the patient exhibits lowered blood pressure, respiratory rate, or O_2 saturation, these signs should not lead to reduction of the infusion rate.
   b. The infusion rate should be increased as ordered should the patient exhibit evidence of ongoing distress (e.g., pain or other target symptoms). The dose adjustment and the reasons for it and the level of comfort before and after adjustment of the range should be documented in the nursing progress notes.
   c. Effects of therapy should be evaluated at least every 15 minutes for the first hour, then at least every 30 minutes for the second hour, then at least hourly for the duration of therapy. Parameters to be evaluated include pain, stridor, tachypnea, and effect on target symptom(s).

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.

REFERENCES

Beauchamp, T.L., & Childress, J.F. (2001): *Principles of Biomedical Ethics*, (5th ed.). New York: Oxford University Press.

Beel, A., McClement, S.E., & Harlos, M. (2002). Palliative sedation therapy: a review and definition of terms. *International Journal of Palliative Nursing*, 8(4), 190–199.

Cherney, N.I. (2000). The use of sedation in the management of refractory pain. *Principles & Practice of Support Oncology Updates*, 3(4), 1–11.

Cherney, N.I., & Portenoy, R.K. (1994). Sedation in the management of refractory symptoms: Guidelines for evaluation and treatment. *Journal of Palliative Care*, 10(2), 31–38.

Cowan, J.D., & Palmer, T.W. (2002). Practical guide to palliative sedation. *Current Oncology Reports*, 4, 242–249.

Cowan, J.D., & Walsh, D. (2001). Terminal sedation in palliative medicine—definition and review of the literature. *Supportive Care in Cancer*, 9, 403–407.

Fine, P.G. (2001). Total sedation in end of life care: Clinical considerations. *Journal of Hospice and Palliative Nursing*, 3(3), 81–87.

Krakauer E. Policy and procedure entitled "Sedation for Intractable Distress of a Dying Patient (SIDD Pat) using continuous pentobarbital infusion." Unpublished manuscript.

Krakauer, E.L., Penson, R.T., Truog, R.D., King, L.A., Chabner, B.A., & Lynch, T.J. (2000). Sedation for intractable distress of a dying patient: Acute palliative care and the principle of double effect. *Oncologist*, 5, 53–62.

Quill, T.E., Dresser, R., & Brock, D.W. (1997). The rule of double effect—A critique of its role in end of life decision making. *New England Journal of Medicine*, 337(24), 1768–1771.

Quill, T.E., Lo, B., & Brock, D.W. (1997). Palliative options of last resort: A comparison of voluntary stopping eating and drinking, terminal sedation, physician assisted suicide and voluntary active euthanasia. *Journal of the American Medical Association*, 278(23), 2099–2104.

Rousseau, P. (2000). The ethical validity and clinical experience of palliative sedation. *Mayo Clinic Proceedings*, 75(10), 1064–1069.

Rousseau, P. (2001). Existential suffering and palliative sedation: A brief commentary with a proposal for clinical guidelines. *American Journal of Hospice and Palliative Care*, 18(5), 299–301.

Rousseau, P.C. (2002). Palliative sedation. *American Journal of Hospice and Palliative Care*, 19(5), 295–297.

Wein, S. (2000). Sedation in the imminently dying. *Oncology*, 14(4), 585–592.

Downloaded by Janet Abrahm from www.liebertpub.com at 07/12/23. For personal use only.