REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 5-A-08

Subject: Sedation to Unconsciousness in End-of-Life Care

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Referred to: Reference Committee on Amendments to Constitution and Bylaws (Raymond G. Christensen, MD, Chair)

INTRODUCTION

The duty to relieve pain and suffering is central to the physician's role as healer and is an obligation physicians have to their patients. Palliative care is universally accepted as a multidisciplinary approach to prevent and relieve suffering of patients with life-limiting illnesses. In this setting, palliative sedation is an important technique for combating extreme suffering; however, there is much debate over the use of palliative sedation to unconsciousness because of its potential to be misconstrued as active euthanasia. Even when done properly, it may still provoke moral objection due to the mistaken perception of a risk of hastening death.

The Council on Ethical and Judicial Affairs (CEJA) held open discussion on this topic at the 2006 Interim Meeting CEJA Open Forum and concluded that ethical guidelines should be drafted for inclusion in the AMA's *Code of Medical Ethics*. The practice of palliative sedation can be used therapeutically at several levels. These range from mild sedation in which the patient remains awake but with a lowered level of consciousness, to intermediate sedation in which the patient is asleep but may be woken up to communicate briefly, to sedation to unconsciousness. Patients should receive the appropriate level of sedation justified by the severity of their symptoms. The palliative use of sedation to unconsciousness should only be implemented in the rarest of circumstances when symptoms are not relieved by lesser amounts of sedative.[1] Sedation in palliative care is referred to in a variety of ways in the literature including sedation, terminal sedation, end-of-life sedation, and total sedation. For the most part, the use of sedation in palliative care is not ethically controversial. However, many remain concerned about sedating a terminally ill patient to the level of unconsciousness as an intervention of last resort.

This report examines the ethics of the palliative use of sedation to unconsciousness as an intervention of last resort for a terminally ill patient to reduce severe, refractory pain or other distressing clinical symptoms that have not been relieved by aggressive symptom-specific palliation. This report will not dwell on the specific ethics of withholding or withdrawing life-

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sustaining medical treatment, euthanasia, or physician assisted suicide, all of which are addressed in the AMA's *Code of Medical Ethics*, but may differentiate palliative sedation to unconsciousness from such interventions for the purposes of clarification.

BACKGROUND

The AMA currently has a number of ethics and House policies that pertain to palliative care and sedation. Though no Opinion in the *Code of Medical Ethics* speaks directly to the issue of palliative sedation, there are several Opinions which cover the concept of palliative care and other treatment decisions at the end of life. Opinion E-2.20, "Withholding and Withdrawing Life-Sustaining Treatment," states that "the social commitment of the physician is to sustain life and relieve suffering" and "[w]here the performance of one duty conflicts with the other, the preferences of the patient should prevail."[2] Additionally, E-2.20 states that "there is no ethical distinction between withdrawing and withholding life sustaining treatment" and "[a] competent adult patient may, in advance, formulate and provide a valid consent to the withholding or withdrawal of life-support systems in the event that injury or illness renders that individual incompetent to make such a decision." [2] Furthermore, the Opinion outlines the capacity of a surrogate decision-maker to choose to withhold or withdraw life-sustaining treatment and additionally states that the obligation of a physician includes "providing effective palliative treatment even though it may foreseeably hasten death."[2]

The *Code* also has Opinions regarding both euthanasia and physician-assisted suicide. Opinion E-2.21, "Euthanasia," defines euthanasia as "the administration of a lethal agent by another person to a patient for the purpose of relieving the patient's intolerable and incurable suffering."[3] Opinion E-2.211, "Physician-Assisted Suicide," defines physician-assisted suicide as a practice that "occurs when a physician facilitates a patient's death by providing the necessary means and/or information to enable the patient to perform the life-ending act."[4] The *Code* finds both of these practices "fundamentally incompatible with the physician's role as healer," "difficult or impossible to control," and possessing serious societal risks.[3,4] However, the Opinions emphasize the following:

> . . . physicians must aggressively respond to the needs of patients at the end of life. Patients should not be abandoned once it is determined that cure is impossible. Multidisciplinary interventions should be sought including specialty consultation, hospice care, pastoral support, family counseling, and other modalities. Patients near the end of life must continue to receive emotional support, comfort care, adequate pain control, respect for patient autonomy, and good communication.[3,4]

A number of policies of the House of Delegates also pertain directly to the subject of palliative care. Policy H-85.958, "Palliative Care and End-of-Life Care," "recognizes the importance of providing interdisciplinary palliative care for patients with disabling chronic or life-limiting illness to prevent and relieve suffering and to support the best possible quality of life for these patients and their families."[5] The policy additionally encourages research in the field of palliative medicine and encourages physicians to familiarize themselves with patient eligibility criteria for hospice benefits.[5] House Policy H-85.999, "Symptomatic and Supportive Care for Patients with Cancer,"

supports "clinical research in evaluation of rehabilitative and palliative care procedures for the cancer patient, this to include such areas as pain control, relief of nausea and vomiting, management of complications of surgery, radiation and chemotherapy, appropriate chemotherapy, nutritional support, emotional support, rehabilitation, and the hospice concept."[6]

Several specialty societies, whose members play a role in palliative care, support the appropriate use of palliative sedation to unconsciousness. The American Academy of Hospice and Palliative Medicine (AAHPM) *Position Statement on Palliative Sedation* supports the use of palliative sedation to the level of unconsciousness to relieve otherwise intractable suffering. The statement affirms that "patients need and deserve assurance that suffering will be effectively addressed, as both the fear of severe suffering and the suffering itself add to the burden of terminal illness."[7] In the position statement *Quality Care at the End of Life*, the American Academy of Pain Medicine (AAPM) states that "in rare circumstances, when pain and suffering are resistant to treatment, sedation may be therapeutic and medically appropriate to obtain relief if consistent with the express wishes of the patient."[8]

Federal and state courts have also weighed in on the matter of palliative sedation to unconsciousness, differentiating the practice from physician-assisted suicide and removing criminal liability for physicians who provide this manner of care to terminally ill patients. A 1997 Supreme Court decision that ruled against physician-assisted suicide supported the concept of palliative sedation to unconsciousness and states "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."[9] In response to the Supreme Court opinions regarding physician-assisted suicide, several states have amended their criminal code and clarified that actions of palliative care are ethically and legally distinct from assisted suicide and manslaughter.[10,11]

Palliative care is an integral part of the treatment regimen of terminally ill patients. However even with the highest standards of care and attempts at palliation, it is estimated that between 5% and 35% of patients receiving palliative care in hospice programs experience severe pain and other intractable symptoms in the last week of life.[12]

Studies have examined physicians' views on palliative sedation to unconsciousness. A query of palliative care experts composed of physicians and nurse specialists from eight countries found that 89% believed that this practice was sometimes necessary in the management of terminally ill patients.[13] In 2004 a survey was conducted in order to gauge the frequency of support for this practice among American internists. This study of Connecticut members of the American College of Physicians found that more than three-fourths of respondents *believed* that if a terminally ill patient has intractable pain despite aggressive analgesic efforts, it is then ethically appropriative to provide sedation to unconsciousness. The majority of the physicians who supported this practice of sedation to unconsciousness did not support physician-assisted suicide.[15]

CLINICAL ISSUES

Palliative sedation to unconsciousness is only appropriate for terminally ill patients "as an intervention of last resort to reduce severe, refractory pain or other distressing clinical symptoms that have not been relieved by aggressive symptom-specific palliation." Specifically, such clinical symptoms include pain, nausea and vomiting, shortness of breath, agitated delirium, and dyspnea. Additionally, palliative sedation to unconsciousness has been indicated for patients who exhibit urinary retention due to clot formation, gastrointestinal pain, uncontrolled bleeding, and myoclonus.[16] Severe psychological distress may also warrant palliative sedation to unconsciousness when potentially treatable mental health conditions have been excluded.[16] Purely existential suffering may be defined as the experience of agony and distress that results from living in an unbearable state of existence including, for example, death anxiety, isolation, and loss of control. Some have proposed that such suffering in and of itself should also be recognized as an appropriate indication for palliative sedation to unconsciousness, but this remains controversial.[1] However, the Council concurs with those who argue that existential suffering, distinct from previously listed clinical symptoms, is not an appropriate indication for treatment with palliative sedation to unconsciousness, because the causes of this type of suffering are better addressed by other interventions.[18] For example, palliative sedation to unconsciousness is not the way to address suffering created by social isolation and loneliness; rather such suffering should be addressed by providing the patient with needed social support. For patients whose suffering is existential, it is necessary to show compassion and enlist the support of the patient's broader social and spiritual network in order to address issues which are beyond the scope of clinical care.[17]

ETHICAL CONSIDERATIONS

As described above, a wide spectrum of actions can be taken to relieve the various forms of suffering a terminally ill patient may experience at the end of life. When the usual armamentarium of medical interventions has been exhausted, choices still remain; these range from letting the terminal illness take its course without further intervention to unacceptable choices, such as euthanasia. Actions that are solely intended to hasten the death of patients, such as physician-assisted suicide or euthanasia, are ethically and medically unacceptable (both are "fundamentally incompatible with the physician's role as healer"[3]). In contrast, the withholding and withdrawing life-sustaining treatment, when done based on the patient's autonomous refusal of unwanted care, and allowing the natural course of disease to take place, are ethically and medically appropriate. Palliative sedation to unconsciousness is intended to relieve patient suffering, and, like withholding or withdrawing life support, may also allow the natural process of terminal disease to take place. A recent review of studies of opiate and sedative use in palliative care concluded that there is no evidence to support shortened survival of terminally ill patients who were sedated.[13,14]

Though evidence suggests that opiate and sedative use in the palliative care setting rarely if ever hastens patient death, ethical issues of "intention" and "proportionality" remain of concern. When exploring the ethics of palliative sedation and differentiating it from those of physician-assisted suicide and euthanasia, it is paramount to consider the primary intention of the measure being utilized. Although intended to relieve suffering, physician-assisted suicide and euthanasia achieve

this by bringing about death, where palliative sedation is intended to relieve suffering by providing proportionate sedation. Death due to the course of a terminal illness is anticipated in a patient who receives palliative sedation to unconsciousness. However, bringing about the patient's death is not the intent of the sedation.[19] Although intent cannot be observed directly, it can be gauged in part by examining the medical record. Repeated doses or continuous infusions are indicators of proportionate palliative sedation, whereas one large dose or rapidly accelerating doses out of proportion to the level of immediate patient suffering may signify lack of knowledge or an inappropriate intention to hasten death.[1] These questions about intent demonstrate the importance of careful documentation in the medical record of purpose and strategy for patients receiving any palliative care including palliative sedation to unconsciousness.

The doctrine of double effect illuminates how intent makes some forms of end-of-life care morally permissible and others unacceptable. The principle of double effect is applied to situations where it is impossible to avoid all harmful actions. It requires that the good effect (relieving severe suffering) must outweigh the bad effect (potential to unintentionally hasten death), and that the bad effect (ending the patient's life) cannot be the means of achieving the good effect (relieving suffering).[21] Proportionality is also a central tenant of the principle of double effect; the level of sedation sought (and the associated risk of hastening death) must be in direct relationship with, and justified by,[22,23] the level of unacceptable suffering the patient is experiencing. The greater the patient's pain or suffering, the more a physician must be willing to sedate a patient in order to reduce and hopefully eliminate the unacceptable symptoms. The combination and amount of sedative must be just sufficient, but not more so, to relieve distressing clinical symptoms.[1] Furthermore, the concepts of proportionality and justification help to differentiate palliative sedation from physician-assisted suicide and euthanasia since in the case of palliative sedation the physician aims only to sedate to a level of unconsciousness and no further.[20]

It is also important to consider palliative sedation to unconsciousness from the perspectives of autonomy, beneficence, and non-maleficence. Similar to the ethical argument made for withholding or withdrawing life-sustaining medical treatment where the principle of patient autonomy requires that physicians respect the decision of a patient who possesses decision-making capacity to forgo life-sustaining treatment, autonomous decision-making dictates that a fully informed patient should also be able to choose palliative sedation. A designated surrogate decision-maker would also be able to choose palliative sedation for a patient who lacks decision-making capacity and meets the criteria for receiving sedation at the end of life. Requests for palliative sedation to unconsciousness (by patients or their surrogates) that do not fit within acceptable clinical parameters identified by the definition of palliative sedation are inappropriate. The principle of beneficence dictates taking necessary steps to relieve pain and suffering. When discussing the possibility of palliative sedation, it is necessary to fully inform the patient or surrogate about the various levels of sedation and whether intermittent sedation or continuous sedation to unconsciousness is an appropriate option. Patients and their surrogate decision-makers, with guidance from their physicians, should separately decide whether they will continue to receive any life-sustaining treatments and whether they want to maintain, withhold or withdraw life-sustaining interventions (including nutrition and hydration.)

CONCLUSION

Palliative sedation to unconsciousness is an important tool in the armamentarium of palliative medicine. For patients whose illnesses are terminal and end stage, palliative sedation to unconsciousness can ameliorate such intractable symptoms as delirium, pain, dyspnea, nausea, and vomiting. It is medically and ethically acceptable under specific, relatively rare circumstances. Because palliative sedation to unconsciousness is intended to be maintained until the patient's death, it should be used only as a therapy of last resort for relief of severe, unrelenting clinical symptoms after the failure of other aggressive interventions, including psycho-social support.[7] It is important to ensure that patients are indeed at the end stage of a terminal illness and that other forms of symptom-specific treatment are not effective. It is most appropriate as part of a multi-disciplinary mode of palliative care that addresses the whole patient in the context of that patient's family system, spiritual beliefs and values. It is not appropriate for suffering that is mainly existential.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and that the remainder of this report be filed.

The duty to relieve pain and suffering is central to the physician's role as healer and is an obligation physicians have to their patients. 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. It is an accepted and appropriate component of end-of-life care under specific, relatively rare circumstances. When symptoms cannot be diminished through all other means of palliation, including symptom-specific treatments, it is the ethical obligation of a physician to offer palliative sedation to unconsciousness as an option for the relief of intractable symptoms. When considering the use of palliative sedation, the following ethical guidelines are recommended:

(1) Patients may be offered palliative sedation when they are in the final stages of terminal illness. The rationale for all palliative care measures should be documented in the medical record.

(2) Palliative sedation to unconsciousness may be considered for those terminally ill patients whose clinical symptoms have been unresponsive to aggressive, symptom-specific treatments.

(3) Physicians should ensure that the patient and/or the patient's surrogate have given informed consent for palliative sedation to unconsciousness.

(4) Physicians should consult with a multidisciplinary team, including an expert in the field of palliative care, to ensure that symptom-specific treatments have been sufficiently employed

and that palliative sedation to unconsciousness is now the most appropriate course of treatment.

(5) Physicians should discuss with their patients considering palliative sedation the care plan relative to degree and length (intermittent or constant) of sedation, and the specific expectations for continuing, withdrawing or withholding future life-sustaining treatments.

(6) Once palliative sedation is begun, a process must be implemented to monitor for appropriate care.

(7) Palliative sedation is not an appropriate response to suffering that is primarily existential, defined as the experience of agony and distress that may arise from such issues as death anxiety, isolation and loss of control. Existential suffering is better addressed by other interventions. For example, palliative sedation is not the way to address suffering created by social isolation and loneliness; such suffering should be addressed by providing the patient with needed social support.

(8) Palliative sedation must never be used to intentionally cause a patient's death.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement

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