

**COMMUNITY ETHICS COMMITTEE REPORT to the
HARVARD ETHICS LEADERSHIP GROUP**

RE: **Palliative Sedation – Continuous Deep Sedation as Comfort Care until Death**

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INTRODUCTION

The Community Ethics Committee (CEC) is a group of sixteen members living in the Boston metropolitan area who are representative of the diverse population served by the Harvard-affiliated teaching hospitals. The need for such a consultative group has been evident for a long time since the few community members on hospital ethics committees are not able to be representative of multiple, diverse communities. Solicitation for membership on the Committee has been cast widely through community, business, and religious groups, with a specific application process to ensure selection of a diverse and effective working group.

The CEC's members are diverse as to socio-economic status, religious affiliations, cultural and language groups, and educational backgrounds. Ten of the members are women and six are men; they range in age from teens to seventies. Some have advanced degrees and some only have high school diplomas. Among the members are a high school administrator, a high school teacher and a high school student; a rabbi and a minister of a large downtown Boston church; individuals with disabilities and parents with disabled children. Two are retired, one from a large Boston law firm. The members are students and writers and small business owners. They volunteer at a local rape crisis center, on an Institutional Review Board, in health care facilities. They belong to eight different religious traditions, including atheism, and they are fluent in seven different languages. Most of the members were able to attend the Harvard Bioethics Course in June of 2007, where the CECE first met and began the conversation as the Community Ethics Committee.

PROCESS

The Committee met throughout the Winter of 2009 into the Autumn of 2010 to educate itself about the issue of "Palliative Sedation". We came to the topic with no preconceived notions of its rightness or wrongness. As individuals, we came to the topic without a clear understanding of the words "palliative" and "sedation" and without a sense of how difficult the task would be that lay before us.

In December of 2009, the Committee met with Dr. Craig Blinderman, who was with Massachusetts General Hospital's Palliative Care Service and Co-Director of the MGH Cancer Pain Clinic, and Dr. Rosemary Ryan, who is the Associate Medical Director of VNA Hospice Care as well as a member the Medical Mission Sisters religious

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order. We solicited the opinions of many additional palliative care specialists in the Boston area. These physicians, nurses, medical personnel and bioethicists presented their concerns, stating that somehow this treatment option “felt different” from other palliative measures made available to patients. The doctors also presented their questions, asking how the community felt about this treatment option, recognizing it could be seen as approaching the threshold into illegal euthanasia and physician assisted suicide. We learned about the broader medical community’s differing views and comfort levels surrounding a therapy that does not cause but surely ends in a patient’s death.

In addition to our monthly meetings, the Committee members corresponded by e-mail and shared articles we had found and information we had gathered and, as part of our process, the Committee reviewed existing hospital and hospice policies which deal with this subject. Perhaps most importantly, the CEC members spoke about these issues with family, friends and colleagues – the community. Monthly meetings were at the Harvard Medical School and, although scheduled to run for three hours, discussions often continued much longer (more than once members were standing in the parking garage until late in the night doggedly trying to sort out these issues). More than any other topic the Committee has addressed to date, the issues raised by Palliative Sedation brought out more vividly the differences of our varying religious, ethnic and cultural backgrounds and of our diverse perspectives on existential pain, the purpose of suffering, and the preservation of dignity at end of life.

In addition to the uniquely individual views of end-of-life suffering, one of our primary dilemmas was the confusion caused by the vocabulary used in connection with this topic. Neither of the words in the term “Palliative Sedation” is immediately accessible or transparent to the general public and neither is adequate to define what the Committee was really examining. The phrase “Palliative Sedation” was itself distancing – making sterile and unexplainable a highly charged topic. The lack of a consistent and clear vocabulary made the concepts we were wrestling with even more troubling and hard to clarify. We concluded that clarity in the words we chose to describe this treatment option was crucial not only to the ultimate usefulness of this Report but to ensuring the medical community adequately communicates these complex issues to patients, their families and friends, as well as to the general public.

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Based on our group discussions and in order to obtain everyone's viewpoints, our Committee leadership developed a survey that elicited individual Committee members' views on the questions initially presented by Dr. Blinderman and Dr. Ryan. Lastly, we met in April, May, September, November and December to review the survey responses and to focus our thoughts regarding "Palliative Sedation". Some of the comments from that survey are included as Comments in this Report.

RESOURCES and SURVEY

A Bibliography of articles and resources distributed to the CEC is attached as Attachment 1; the Survey that was circulated to the CEC members via "Survey Monkey" is Attachment 2.

RESPONSES and COMMENTS

The Committee focused on three questions which arose in connection with its review of Palliative Sedation. In brief, those questions were:

1. What is the language that should be used to frame this particular treatment option?
2. For which patients would Palliative Sedation be an appropriate treatment option? Should the option of Palliative Sedation be discussed with every terminally ill patient, their surrogate and family?
3. Was there a point at which some members of the Committee felt a line was crossed into the illegal realm of euthanasia or physician-assisted suicide? Or another way of stating the question - what are the fact situations in which the Committee members felt greater levels of personal discomfort at offering Palliative Sedation as a treatment option or felt higher levels of independent professional scrutiny would be required?

The responses set forth below are necessarily condensed and cannot completely reflect the richness of the Committee's discussions or the care with which we wrestled with these issues.

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1. What is the language that should be used to frame this particular treatment option?

The CEC was particularly sensitive to the fact that the language used in its Report might frame the underlying rationale for accepting or rejecting whether Palliative Sedation should be presented to terminally ill patients and their families and surrogates as a viable treatment option.

The term “palliative” is not readily accessible to the general public. In fact, the specialty that has developed around Palliative Care and the creation of Palliative Care units in hospitals are relatively new to the health care community. To the general public, at one end of the spectrum “palliative” is a meaningless term while at the other end of the spectrum “palliative” is synonymous with “giving up”, “end of the road”, and even, in some disability advocate circles, “death making.”

The term “sedation” is similarly opaque. The Committee spoke about the fact that a glass of wine at the end of a busy day is sedating, as may be a dose of an antihistamine to alleviate allergies. In the context of Palliative Sedation, we are talking about a treatment option that renders a patient unconscious so that the unremitting, untreatable pain is no longer terrorizing the patient.

The Committee spent hours wrestling with these terms, concepts and modifiers, and in the end, we surrendered to using the terminology already established in the medical literature. But, even so, we could not “call it a day”. We were convinced that if we could not adequately define and articulate what we were talking about, then we could not adequately or honestly answer the questions asked of us. We knew the stakes were high - terminally ill patients suffering from untreatable pain need us to be able to say what we are thinking.

The complicating factors in this discussion turned out to be the modifiers, the nuances to the general and broad category of Palliative Sedation. During the process of framing our thoughts, we were forced to further define the terms we used and focused on the following subcategories within the general category of Palliative Care:

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- a. Imminently Terminal – in defining the time until expected death, “imminently terminal” meant a prognosis by the attending physician (ideally a palliative care specialist) of days to weeks until death, hence the sedation administered would be permanent, with the expectation it would be continuously administered until the patient’s death;
- b. Pain – in wrestling with what kind of pain would justify unconsciousness, we concluded that both physical or psychological/existential pain alone could prove to be such an overwhelming burden as to significantly and adversely affect an individual’s quality of life, sufficient to justify a comfort care treatment option of unconsciousness;
- c. Untreatable – in describing the level of pain which would justify unconsciousness, “untreatable pain” could also be described as intractable, refractory, unremitting, or ceaseless pain – pain which had not been diminished by any other available treatment modality whether that be traditional or alternative forms of medical care administered in an attempt to alleviate physical, psychological and spiritual pain;
- d. Palliative – in focusing on palliative or comfort care, we highlighted the primary therapeutic objective of rendering a patient unconscious thereby providing comfort by relieving the sensation of pain in the only way remaining to medical science - unconsciousness;
- e. Unconsciousness – in using the term “sedation” in “Palliative Sedation”, we meant a sedation to the point of unconsciousness, but with the goal of attaining a point of unconsciousness proportional to the pain sought to be overcome, meaning a “deep sedation” until death (as contrasted with remedial sedation sometimes available to patients to provide them a respite from their pain, with the expectation that the sedation will be reversible and temporary);
- f. Patient – in being clear about who we were talking about, we noted the fact that a patient was a minor or never competent did not disqualify them from considering Palliative Sedation a possible treatment option;
- g. Artificial nutrition and hydration – in articulating the Committee’s expectations about when Palliative Sedation might be offered, the decision about whether a patient receiving artificial nutrition and hydration should continue with that support should be made independent of the decision to use Palliative Sedation; and we concluded there might be unusual circumstances when artificial nutrition and hydration might be continued while Palliative Sedation is also administered (i.e. when religious or cultural views would require it);

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- h. Physician-administered – in addressing what is done and how, we understood that the sedative was to be administered by qualified and trusted medical staff, ideally with a palliative care physician present, in either a hospital, residential hospice or home hospice setting; and
- i. Physician intent – in finding Palliative Sedation ethically justified, we did not rely solely on physician intent (and the corresponding reliance upon the ethical concept of “double effect”) as much as we relied on the fact that the sedative dosage was the minimal dosage required to render the patient unconscious, providing the desired comfort-level. The Committee members emphasized that the underlying therapeutic goal was truly comfort care and not death (thus distinguishing it from euthanasia and physician-assisted suicide).

Based upon the above, the Committee is most comfortable using the phrase “Palliative Sedation” with the explicit understanding that the CEC’s Report addresses a small subset of that term which we identified as “Continuous Deep Sedation as Comfort Care until Death”.

2. For which patients would Palliative Sedation be an appropriate treatment option? Should the option of Palliative Sedation be discussed with every terminally ill patient, their surrogate and family?

The Committee was unanimous in concluding that Palliative Sedation, and more explicitly Continuous Deep Sedation as Comfort Care until Death, is an appropriate treatment option when the patient is imminently terminal and suffering from untreatable pain.

Notwithstanding this conclusion, however, certain qualifiers are required for purposes of this Report. “Imminently terminal” means a prognosis of death occurring within a few weeks. “Untreatable pain” means either physical or psychological/existential pain that has not yielded to any other available treatment – nothing else has been found to abate or diminish the patient’s pain. In those cases, however, the Committee felt strongly that the option of providing Continuous Deep Sedation as Comfort Care until Death was ethically justified and even recommended.

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Committee members were struck by the extraordinarily personal differences found in dying patients' end-of-life experiences and choices as presented in both media reports and personal encounters which members shared. Because each dying person's journey is uniquely their own, the challenges that physicians and medical staff face in navigating through the shoals – guiding patients and their loved ones to a dignified and pain-managed end – are formidable. We recognized the understandable difficulty of initiating a discussion about the hard realities of medical staff failing to alleviate pain and patients being imminently terminal. Although difficult, the CEC concluded the option of providing a comfort care treatment of Continuous Deep Sedation as Comfort Care until Death must be presented. Discussions about these issues were difficult and sometimes heated and yielded much unsettling uncertainty. The difficulty of the task does not warrant its avoidance. Even for those patients who may not want to recognize the proximity of their death or who may value the existential benefit of suffering, the exercise of control over one's body and self provided by the option of Continuous Deep Sedation as Comfort Care until Death may provide a significant and needed benefit. For that reason, the Committee concluded that offering the option of Continuous Deep Sedation as Comfort Care until Death when pain cannot be borne any longer can it itself provide sufficient comfort and relief such that the offer should be made available made to every terminal patient. Not that such a treatment option would be appropriate or available immediately upon its mention, but that Continuous Deep Sedation as Comfort Care until Death would be presented as a possible treatment option if and when appropriate.

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- 3. Was there a point at which some members of the Committee felt a line was crossed into the illegal realm of euthanasia or physician-assisted suicide? Or another way of stating the question - what are the fact situations in which the Committee members felt greater levels of personal discomfort at offering Palliative Sedation as a treatment option or felt higher levels of independent professional scrutiny would be required?**

By establishing the various subcategories set forth in answer to the first question, the Committee was able to target those areas of discussion and those fact situations where discomfort arose. The members' uneasiness with Continuous Deep Sedation as Comfort Care until Death as a treatment option increased when a patient was not clearly close to death, was not professionally treated for psychological depression, or had not exhausted all reasonably available treatment options for physical pain. Additional concerns were presented when family members or surrogates were making the decision, especially in situations where the patient was a child or never competent. The Committee returned repeatedly to the fact that the treatment option of Continuous Deep Sedation as Comfort Care until Death must be only for the benefit of the imminently dying patient, to relieve otherwise untreatable pain. Its primary goal cannot ever be to ease the family's experience of a loved one's death by removing all manifestations of a patient's agitation or discomfort.

Perhaps the most difficult situation for the Committee to contemplate in the context of Continuous Deep Sedation until Death as a comfort care measure was the concurrent withdrawal of artificial nutrition and hydration. The Committee came to two related conclusions in this regard: first, artificial nutrition and hydration must be a medically indicated benefit for it to continue, and second, it was thought to be a rare situation in which the continued administration of artificial nutrition and hydration would be medically indicated when a patient was imminently terminal and in untreatable pain. We recognized, however, that certain situations might arise where the continued administration of artificial nutrition and hydration was of such a therapeutic value (not necessarily to accomplish a physiological benefit but to satisfy patient and family religious, cultural or emotional needs to provide sustenance to a loved one) that it must continue. We recognized the strong mandate under these circumstances to nurture a loved one with food and water. The Committee understood there could be a situation where family members might not be persuaded to stop artificial nutrition and hydration even though it might be medically useless and perhaps contraindicated, but those family members still might consent to the comfort care provided by Continuous Deep Sedation until Death. In such a case, the Committee felt strongly that Continuous Deep Sedation as Comfort Care until Death could and should be provided even though artificial nutrition and hydration continues.

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Areas of Special Concern to the CEC

Existential Suffering

In contradistinction to physical pain and suffering, Existential Suffering specifically among those who are imminently dying, may involve a singular or cluster of manifestations loosely labeled as psychosocial, religious or spiritual. Those manifestations may include: fear of death or dying, anxiety over separation from loved ones, loss of relationships, absence of meaning or further purpose in life, indignity, dependence and lack of control of self, disability, weariness with the protracted struggle to live, with concern for burdening family or society, isolation, and loneliness, abandonment by God, faith, and guilt,

These symptoms may be accompanied by and closely related to physical pain or may occur without undue physical discomfort. They may be present in patients long before death is imminent. Finally Existential Suffering may wax and wane over a period of time with or without specific intervention.

There is no clear consensus in the medical community regarding definitions of Existential Suffering, no clear understanding of its dynamics, and no objective measurements available. Nevertheless, most in the medical community agree that such suffering should be addressed by physicians, psychiatrists and other mental health workers, chaplains and palliative care specialists with the same attention and compassion that is paid to physical suffering, employing appropriate medications, spiritual counseling and psychosocial supports.

In those rare instances in which Existential Suffering is refractory to other interventions and death is imminent, the Committee, after lengthy discussions, agreed that Continuous Deep Sedation as Comfort Care until Death should be offered and made available as a treatment option. Nevertheless, the Committee also concluded this treatment option should be made available only when the utmost caution is exercised and only following multiple discussions with medical and family stakeholders as well as the patient, when possible.

Importance of Acknowledging How We Die

The Committee was struck by some physicians' claims that: (i) Palliative Sedation is rarely used in their practices, even though they practice medicine primarily in end-of-life care settings, and (ii) Palliative Sedation is not an issue that raises pressing ethical concerns for them because it is not part of their therapeutic practice. This led the Committee to be concerned about the integrity of the terminology used in this area and the possible misunderstanding among patients, their families and medical practitioners about Palliative Sedation as a viable treatment option to ameliorate intractable pain.

Because the term Palliative Sedation is so broad, it is ambiguous and that ambiguity could lead to a large range of physician practice choices. Physicians may conclude that administering medications that render a patient unconscious is therapeutic without calling it "Palliative Sedation." It can be argued that such a state of unconsciousness robs an individual of their humanity and such a therapy is administered as a way to reduce the suffering of family and staff in attending a difficult death. The Committee was concerned that physician fatigue and nurses' understandable distress at caring for an individual suffering intractable pain would lead to choosing a therapeutic treatment option which would in every respect be "Palliative Sedation" but would not be identified as such. Those CEC members who have been present when an individual dies and those in their communities who have attended deaths, acknowledge and recognize that many, if not most, deaths are preceded by the administration of sedatives or opioids. Clarity of language when speaking about Palliative Sedation and explicit definitions are absolutely necessary to provide the protections that are necessary so that decisions about therapies are transparent and the patient's ultimate interest in a dignified death is preserved and protected. The decision must be part of a joint and considered evaluative process after significant efforts have been made to address the patient's pain and suffering.

Importance of Acknowledging When We Die

The Committee was struck by the literature indicating that physicians' predictions of the timeframe in which a patient is imminently dying are woefully optimistic. What that meant to the Committee was that patients who could benefit from palliative and hospice care services were often ill-advised to wait. The term "imminently dying" as a qualifier for the use of Palliative Sedation then became problematic for the Committee. If the indicator for even discussing the use of Continuous Deep Sedation as Comfort Care until Death is the patient must be "imminently dying" and if that indicator is poorly ascertained, then patients could suffer needlessly.

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This fuzziness in determining which patients are “imminently dying” was raised as a concern when the Committee focused its discussions on those “outlier” situations when there is intractable pain but the patient is not, in fact, “terminal” or “imminently dying.” We considered the rare cases where patients with long-term chronic diseases had found no relief for their suffering. Those individuals would likely die because their bodily systems were shutting down due to the unremitting pain, but they were not yet technically “imminently dying”. The Committee concluded that, even though rare, the treatment option of Palliative Sedation should still be offered. As one member said, it is ethically the right thing to do.

Another aspect of “imminently dying” with which the Committee wrestled was whether the sedation administered in Palliative Sedation needed to be “permanent”. Situations were presented when the patient might be willing to be brought out of an unconscious state, for instance, in order to say goodbye to a particular family member or to meet a newborn baby. The balancing of the benefits and burdens of such an approach to Palliative Sedation was left to the patient and family members, but the Committee concluded that the burden of bringing a patient out of a state of “deep sedation” in order to enjoy some significant social benefit was ethically supportable.

Euthanasia and Physician-Assisted Suicide Distinguished from Palliative Sedation

The Committee members were specifically asked about their reaction to Palliative Sedation as a treatment option that could be perceived as being “close to the line” of illegal euthanasia and controversial physician-assisted suicide. Most of the members’ first reactions to the whole concept of Palliative Sedation involved confusion as to whether that line was, in fact, being crossed. After our extensive and lengthy self-education about the subject, however, we concluded that Palliative Sedation is NOT close to the line of illegal or controversial medical procedures associated with dying and, instead, we felt strongly that Palliative Sedation is an important treatment option that should be made available to patients in the appropriate circumstances. Both euthanasia, where the physician is the agent administering a lethal substance, and physician-assisted suicide, where the patient is the agent administering a lethal substance, have as their chief end the death of the patient. The primary goal in either circumstance is not to relieve intractable pain but, rather, it is to end life. The CEC felt strongly that the primary goal of Palliative Sedation is to relieve intractable pain and, as a result, it falls into an ethically supportable and potentially advisable treatment option.

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Related to our conclusion that Palliative Sedation is a supportable treatment option was the Committee members' reluctance to rely exclusively on the ethical "rationale" of double effect, which focuses on the intent of the prescribing physician. Two aspects of sedated patients' deaths were of importance to the Committee in this regard – (1) studies which indicated that some sedated patients lived longer than un-sedated patients and (2) the assurance that sedated patients died from the progression of their disease and not from the sedation alone. In our research, we found studies showing that some patients who had been suffering from intractable pain and who had received relief through Continuous Deep Sedation as Comfort Care until Death actually lived longer than those whose pain was not alleviated. In those cases, the deep sedation did not shorten patients' lives – instead, they died from the underlying disease. In the end, the Committee felt strongly that Continuous Deep Sedation as Comfort Care until Death in cases of intractable pain is a treatment option that should be made available to an imminently dying patient suffering from intractable pain and is an ethically acceptable part of a physician's armamentarium.

Protections Needed

Although the CEC acknowledges that discussion of Palliative Sedation as a treatment option is a difficult one to broach, the Committee is convinced that it is a treatment option that should be available in the appropriate circumstance. In that regard, the Committee wrestled with two concerns – when should such a treatment option be presented and whether the requirement of extensive pseudo-legal protections would "chill" the use of Palliative Sedation when it would otherwise be appropriate.

The obligation to inform as many patients and families as possible about Palliative Sedation in as unobtrusive a way as possible became paramount to the CEC members. The CEC suggests that an informative brochure be made available to patients and families that would be part of the materials presented upon a consult with a pain management team or palliative care team. In this way, patients and their families could have access to the information in a non-threatening and individualized way, not tied directly to the medical care their loved one receives. It was the Committee members' hope that eventually the option of Palliative Sedation would be included in such documents as Advance Directives and become a natural part of patient-physician discussions when a terminal diagnosis is made. In addition, early dissemination of such a treatment option was encouraged because it could provide the patient with hope – there are those who have said they are not afraid of dying, they are afraid of the pain that could accompany dying. As pain management and palliative care expertise increases, Palliative Sedation may become a treatment option that is less and less necessary. To the

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extent a patient's intractable pain at the end of life remains, however, the option of Palliative Sedation should be available and even encouraged.

Which leads to the next concern the Committee raised. While procedures such as requiring an institutional Ethics Committee review or a formalized second opinion might seem protective of the patient's interests, the Committee wanted to be sure there were no procedural impediments to the use of Palliative Sedation when it was appropriate. Members repeatedly brought the discussion back to the primary goal at hand – a patient who is suffering otherwise untreatable pain and who is imminently dying – should anything stand in the way of providing relief to such a patient?

The Committee's assumption was that, during the time period when all reasonable pain-relieving treatment modalities were being explored, discussions about Palliative Sedation should occur and safeguards such as an institutional Ethics Committee review or a formalized second opinion should be explored. At the point when the medical care team reaches the conclusion that the patient suffers from intractable pain, extensive discussions will have already occurred with the patient, if possible, and with the family about the patient's goals of care. If Palliative Sedation is deemed an appropriate treatment option, then the patient's pain should be treated by administering Continuous Deep Sedation as Comfort Care until Death without further formal procedural review.

One last observation which the Committee felt important to make has to do with encouraging institutions to develop a strong palliative care specialty service. The literature that the Committee reviewed repeatedly made the point that the care of patients at the end of life is immeasurably enhanced by the involvement of medical care teams who are trained in palliative care – both in their particular skill in conducting constructive dialogs with patients and families about end-of-life issues and in their expertise in pain management. It is probably fair to say the goal of everyone is a “good death” – one in which the dignity of the person is maintained, when pain is well-managed and familial and community supports are in place. To the extent palliative care specialists can be made available to provide such specialized care, the patients and their families benefit and that is a good thing.