The Double Effect of Pain Medication: Separating Myth from Reality

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ABSTRACT

The principle of double effect is used to justify the administration of medication to relieve pain even though it may lead to the unintended, although foreseen, consequence of hastening death by causing respiratory depression. Although a review of the medical literature reveals that the risk of respiratory depression from opioid analgesics is more myth than fact and that there is little evidence that the use of medication to control pain hastens death, the belief in the double effect of pain medication remains widespread. Applying the principle of double effect to end-of-life issues perpetuates this myth and results in the undertreatment of physical suffering at the end of life. The concept of double effect of opioids also has been used in support of legalization of physician-assisted suicide and euthanasia.

INTRODUCTION

In bioethics, the principle of double effect (PDE) is used to justify the administration of medication to relieve pain even though it may lead to the unintended, although foreseen, consequence of hastening death by causing respiratory depression. For example, the Encyclopedia of Bioethics presents as a standard illustration of the PDE the following scenario:

A physician seeks to alleviate a patient’s pain by administering the painkiller morphine but recognizes that the dosage is likely to shorten the patient’s life. The physician regrets this result but can avoid it only by so reducing the dosage that the chemical will not have sufficient pain-killing effect. . . . The physician expects to kill but does not intend to do so. . . .

The PDE provides that an action with both a good and a bad effect is ethically permissible if the following conditions are met:

1. The action itself must be morally good or at least indifferent.
2. Only the good effect must be intended (even though the bad or secondary effect is foreseen).
3. The good effect must not be achieved by way of the bad effect.
4. The good result must outweigh the bad result.

The PDE has its origins in Roman Catholic moral theology. In the paradigm case, although a physician is not allowed to directly abort a fetus (even to save the life of a woman), a physician is allowed to remove a diseased and life-threatening uterus containing a fetus. Although the physician expects the death of the fetus, he does not intend to kill it. Applying the PDE to the use of pain medication, the good effect (pain control) is intended, whereas the bad or secondary effect (hastening death) is foreseen but not intended.

The double effect of pain medication is a recurring theme in articles discussing end-of-life issues. According to many commentators, the
use of medication to treat pain and other symptoms in terminally ill patients may "hasten death," "potentially" hasten death, "actually speed up the process of dying," or "indirectly and unintentionally contribute to a patient's death." One commentator even stated that in some cases, the unintended hastening of death is the "unavoidable, known, and accepted consequence" of pain medication. Another stated that the "unavoidable and accepted consequence of [medication] may be to hasten death."8

Reading these articles, one would think that hastening death is an almost unavoidable consequence of treating pain. Even if one accepts the PDE as ethically correct, it is important to examine the medical reality behind it. Does the use of opioids at the end of life cause respiratory depression? Are patients dying sooner because their pain is treated?

If one accepts the application of the PDE in the administration of pain medication at the end of life, one might argue that it makes little difference whether the double effect of pain medication is real or not. However, the belief in double effect does in fact affect the care of patients and results in undertreatment of physical suffering at the end of life. The concept of double effect also has been used in support of legalization of physician-assisted suicide and euthanasia. Furthermore, using the PDE to justify using opioids to treat pain in dying patients contributes to the belief in the double effect of pain medication, which in turn leads to fear of hastening death and the undertreatment of pain.

**OPIOID-INDUCED RESPIRATORY DEPRESSION: FACTS AND MYTHS**

The double effect of pain medication is often discussed in the context of the terminal cancer patient. Two thirds of cancer patients with far-advanced disease have significant pain that requires the use of analgesics. The World Health Organization (WHO) has proposed the use of an "analgesic ladder" in treating cancer pain, using in sequence a non-narcotic, a weak opioid, and a strong opioid. The experience of the hospice movement has proved the efficacy of the use of opioids to treat pain in cancer patients, and professional organizations have published position papers recommending regular and adequate use of opioid analgesics for the pain of advanced cancer.

Because respiratory depression is potentially life threatening, it is considered the most serious opioid side effect and is of great concern to physicians and nurses. Opioids can depress both the rate and depth of respiration. Although respiratory arrest is possible, it occurs in combination with mental clouding and somnolence, allowing for a reduction or discontinuation of medication if these symptoms develop. Naloxone hydrochloride can be given to counteract the respiratory depressant effects of opioids, but it also reverses the analgesic effect and so should be titrated carefully.

An excessive dose can, of course, cause respiratory depression. The dose should be titrated to give the minimum dose necessary to achieve pain control. The risk of respiratory depression is greatest when opioids are first begun. Tolerance to the respiratory side effects develops rapidly, allowing "aggressive upward dose titration." Patients in pain also respond differently to opioids than do persons without pain. Pain acts as a natural antagonist to the respiratory depressant effect of opioids. As pain increases, the level of opioid necessary for relief goes up, but so does the tolerance to respiratory side effects. If tolerance to the analgesic effect of an opioid occurs, analgesia may be safely obtained by upward titration of the dose because there are "parallel curves for the development of tolerance to the analgesia and to respiratory depression." With careful titration, even very large doses may be safely administered.

Data on the clinical importance of opioid-induced respiratory depression come from three sources. One body of literature has addressed the effect of opioids in drug addicts, patients with acute postoperative pain, and volunteers without pain who received a single opioid dose. Although this literature has clearly established that opioid use can lead to respiratory depression, much of this data may not be relevant to dying patients receiving opioids for chronic pain relief.
ical studies evaluating oral and parenteral opioid use in cancer patients with chronic pain. In 1982, Twycross noted the results of a study by Walsh of seven cancer patients who were pain free on morphine and who did not have depressed respiratory rates or elevated arterial carbon dioxide pressure (Paco$_2$). A clinical study by Citron et al. published in 1984 examined the safety of 15 courses of continuous intravenous morphine in 13 patients. After changes in arterial oxygen pressure and arterial carbon dioxide pressure during the first 24 hours in a minority of patients, blood gas levels tended to remain at or return toward baseline values. Although continuous morphine infusion tended to decrease the respiratory rate, only bradypnea in the presence of marked somnolence (which occurred in one patient) was a cause for dose reduction. The authors concluded that "continuous intravenous morphine is a safe and effective means of relieving pain, even in patients with borderline pulmonary status."

Because he found reports of respiratory depression being uncommon in patients receiving oral morphine to be "surprising in view of the known effect of opiates on respiratory function," Walsh in 1984 conducted a prospective study of 20 patients who had been receiving morphine for at least 7 days. Finding an elevated Paco$_2$ in only one patient, he concluded that "chronic ventilatory failure appears to be neither common nor severe when oral morphine is used to treat chronic severe pain in advanced cancer—even in the presence of pre-existing respiratory tract disease."

Grond et al. studied the efficacy of the WHO cancer pain guidelines in 401 dying patients in Germany. They found the use of drugs according to WHO guidelines to be an "effective, safe, and simple method for relief of cancer pain until death." Of the 70% of the patients who needed opioids to control pain, none showed clinical signs of respiratory depression.

A third, and much larger source of information, comes from the extensive clinical experience reported by recognized experts in cancer pain, hospice, and palliative care. In 1982, writing about his experiences at Sir Michael Sobell House, a hospice in Great Britain, Twycross referred to the fear of respiratory depression as one of a number of myths that overemphasize the dangers of morphine. Even with large doses of morphine, respiratory depression "is rarely seen" because pain is a powerful antagonist to respiratory depression. Twycross found that "The use of morphine in the relief of cancer pain carries no greater risk than the use of aspirin when used correctly" [emphasis in the original]. Rather than hastening death, "the correct use of morphine is more likely to prolong a patient’s life . . . because he is more rested and pain-free."

Levy in 1985 stated that "Appropriately prescribed narcotics rarely cause clinically significant respiratory depression. The threshold for such depression is always above the sedative threshold which itself is above the analgesic threshold." K. M. Foley, chief of the Pain Service at Memorial Sloan-Kettering Cancer Center, stated that "respiratory depression is not a significant limiting factor in the management of patients with pain because with repeated doses, tolerance develops to this effect." Patients with pain can be treated "with escalating doses without respiratory compromise." Portenoy and Coyle, also from Memorial Sloan-Kettering Cancer Center, noted that respiratory depression is "extremely rare," and "the development of new respiratory symptoms is virtually never a primary drug effect in patients who have been receiving stable doses or who are undergoing dose increases following substantial prior opioid intake." Nevertheless, these investigators pointed out that respiratory depression is a "constant concern" of practitioners, who assume respiratory symptoms in cancer patients to be opioid induced. Cancer patients who develop respiratory symptoms usually have some other primary disease process. Even in those cases where improved respiratory function follows treatment with naloxone, the respiratory failure should not be assumed to be primarily drug related.

After treating some 2000 terminally ill patients, Storey reported that shortness of breath and pain "can be effectively palliated by administering narcotic analgesics," which can be safely used "if the dose is carefully titrated against the symptom." And in an article by Silverman and Croker, respiratory depression
is again referred to as one of several myths about opioids. Respiratory depression "is not clinically significant when patients are treated with regular doses of oral narcotics."\textsuperscript{25}

Hill noted that the fear of respiratory depression is "greatly exaggerated" and "rarely occurs in patients with severe pain." When respiratory depression occurs, it usually is in "opioid-naive patients after acute administration of an opioid" and is accompanied by sedation or mental confusion. Because tolerance to respiratory depression develops rapidly, opioids can be used for chronic pain "without significant risk."\textsuperscript{14}

Bonica found that with proper titration, "clinically significant respiratory depression does not occur because pain is a powerful respiratory stimulant and counteracts the narcotic-induced depression."\textsuperscript{26} According to Cain and Hammes, the "feared shortening of life with side effects is not likely."\textsuperscript{27} Interrisi and Hanks found that opioids can be used without "significant risk."\textsuperscript{15} Portenoy noted that for cancer patients treated with chronic opioid therapy, serious respiratory compromise is "exceedingly rare."\textsuperscript{28} And Cundiff reported that "with skillful management . . . no evidence exists that [opioids] shorten life."\textsuperscript{29}

Dahl, a pharmacologist, noted that "Respiratory depression is one of the most feared and misunderstood potential side effects of the opioids." Because pain is a stimulus to respiration, "clinically significant respiratory depression is rare."\textsuperscript{30} And, Berry, a pharmacist, found respiratory depression to be "an often stated but seldom observed side effect of opioid use." This is because pain is "nature's own antidote to respiratory depression."\textsuperscript{31}

### REPORTED CASES OF HASTENING DEATH

The literature contains little data to support the belief that appropriate use of opioids hastens death in patients dying from cancer and other chronic diseases. In their 1983 case report of a patient dying of lung cancer, Meier and Cassel reported that "Narcotic analgesics given in doses adequate to relieve pain suppressed her breathing, threatening respiratory arrest and death . . . . Her breathing slowed and became more shallow after each dose of narcotic."\textsuperscript{32} Nurses who were uncomfortable with the administration of sufficient narcotic were reassigned. Dosing adequate to relieve pain was continued, and the patient became unresponsive and died 3 days later. Although members of the health care team believed that adequate medication placed the patient at risk of an earlier death, it is not clear from the facts as described that the patient died sooner as a direct result of the narcotic analgesics. Moreover, in their discussion of the case, the investigators noted that "only in very rare cases does the administration of adequate pain medication pose a serious risk to life." More recently, one of these authors, Meier, along with Manfredi and Morrison, referred to the "myth that opioids, when used for the treatment of pain, are associated with a substantial risk of respiratory depression and death," and stated that "the clinical impression of those treating pain in the terminally ill with opioids is that the patient's death is related to the progression of the disease, not to the use of opioids, and that proper treatment of pain may actually prolong life rather than hasten death."\textsuperscript{33}

Cranford, a neurologist and ethicist, has described the death of his wife's mother from lung cancer.\textsuperscript{34} Although he was never the treating physician, he followed the case closely, and while a thousand miles away, suggested a "treatment plan" (a course of comfort medications) to the attending physician. Because radiation therapy was stopped and a switch to morphine to treat her pain resulted in sedation and was followed by death less than 12 hours later, Cranford was certain that they had hastened her death. But he acknowledges that death was probably due to pneumonia (discovered at autopsy), and it is not clear that the morphine she received hastened her death.

Even when physicians and nurses intend to hasten death, it is not clear that the medication given has this effect. Wilson et al. studied why and how sedatives and analgesics were ordered and administered during the withholding or withdrawal of life support.\textsuperscript{35} The patients in this study, the majority of whom were being removed from a ventilator, were expected to die within hours, and physicians
were more likely to err on the side of too much rather than too little medication. Though almost 40% of intensive care unit physicians and nurses listed hastening death as a reason (although never as the primary reason) for giving sedatives and analgesics, the researchers found “no evidence that death actually was hastened by the administration of drugs” and no evidence that “an apparent intent to hasten death actually did hasten it. . . .” Of course, this study did not prove that the administration of medication did not cause these patients to die sooner than they would have otherwise. It would be difficult to design a definitive study to determine whether opioid analgesics (or other central nervous system [CNS] depressant drugs) hasten death. A clinical trial that withheld medication from a control group would be unethical. However, the evidence from the body of literature reported above indicates that the double effect of pain medication used to treat pain in the dying patient is more myth than reality and that opioid analgesia can be effectively used without fear of hastening death.

It is important to emphasize that there is no debate among specialists in palliative care and pain control on this issue. There is a broad consensus that when used appropriately, respiratory depression from opioid analgesics is a rarely occurring side effect. The belief that palliative care hastens death is counter to the experience of physicians with the most experience in this area. No studies have shown that patients’ lives have been shortened through the administration of appropriate pain medication. A review of the literature yielded no evidence to support the notion that appropriate and effective treatment of cancer pain results in the earlier deaths of patients. Of course, it is possible that treatment by inexperienced physicians may lead to unintentional overdoses of medication, but this is neither inevitable nor unavoidable.

**UNDERTREATMENT OF PAIN DUE TO BELIEF IN THE DOUBLE EFFECT**

Misperceptions about opioids are a major cause of undertreatment of cancer pain. For example, Von Roenn et al. found that 65% of the respondents to a survey of physicians from the Eastern Cooperative Oncology Group acknowledged that concerns about managing side effects limited their use of analgesics. A study by Solomon et al. revealed that although 89% of physicians and nurses agreed that “Sometimes it is appropriate to give pain medication to relieve suffering, even if it may hasten a patient’s death,” 41% agreed that “Clinicians give inadequate pain medication most often out of fear of hastening a patient’s death.” Fried et al. also have studied physicians’ attitudes and practices regarding end-of-life decisions. One of five clinical scenarios presented in a survey was of a dying patient needing “larger and larger” doses of narcotics with a resultant concern that the patient would die of respiratory compromise; 86.3% of the respondents reported that they would give potentially lethal doses of pain medication to a dying patient in this situation.

Although a large majority of physicians in these last two surveyed groups claimed that they would administer pain medication that might result in an earlier death, that number is not 100%. Some physicians remain unwilling to administer appropriate comfort medication if they believe that it could result in the patient dying an earlier death. What is needed is not just an increased ethical awareness of the rights of patients to receive optimal palliative care, but an education on the medical facts: appropriate pain medication need not hasten death.

In a 1996 article in the *New England Journal of Medicine*, a primary care physician described the events of a “typical damn day,” which included a call from a nursing home concerning a new cancer patient he had just accepted but had not yet seen. The patient was dying, had deteriorating vital signs, and was racked with pain. The physician refused to order morphine because the family refused to consider naloxone and oxygen if the patient’s respiration was suppressed. “What do they want from me—the oncologist who unloaded this patient on me, the family who cannot bear the moans of their dying father? Give them Jack Kevorkian’s number, I mutter. No, I will not order the lethal injection. I don’t know this patient, or the family, or the disease.” The physician apparently failed to recognize the situation for the medical
emergency it was, and his mistaken belief that opioid use will directly cause the patient's death prevented him from fulfilling his duty to care for this patient.

Buchan and Tolle, reporting on the case of a dying patient who presented in an emergency room with severe pain, stated, "When emerging problems are poorly controlled, patients may die earlier than predicted when pain control is finally instituted." Although achieving pain control in such a situation may be difficult, even here the chance of pain medication hastening a patient's death is only a possibility, not a probability. What is disturbing is their advice that physicians who find it morally unacceptable to hasten death should refer the patient to another physician. It is well accepted that physicians (or nurses) should not be required to participate in activities they find morally repugnant, such as abortion or, if legalized, euthanasia. But it would be a tragedy for a physician to refuse to care for a patient based on the mistaken factual belief that the administration of pain medication will hasten the patient's death. A patient in extreme pain presents a medical emergency. Even in a situation where there is a risk that respiratory depression may occur, a physician is not justified in withholding analgesia. Every physician has a duty to provide relief to a patient dying in pain.

One article in the nursing literature actually seemed to caution against aggressive pain control. In an article entitled "Pain Control: Euthanasia or Criminal Act?," the author, both a nurse and an attorney (and director of risk management of an insurance company) advised nurses "to review their exposure to liability" relative to "the aggressive use of pain medication." Her fear is based on the false premise that medication adequate to relieve pain may hasten the patient's death and expose the nurse (standing right beside the physician) to liability for euthanasia. This nurse further advised other nurses that the underlying issue in pain management is the nurse's "intolerance of a patient's pain or suffering." This line of reasoning concluded with, "Just as a physician must learn that lack of a cure does not equate with failure, a nurse must learn that the presence of pain [in the dying patient] does not mean failure." One would hope that caregivers never become accepting of their patients' suffering!

Situations can arise in which the patient's family will resist any treatment that might hasten death. Disagreement between a physician and the family over other aspects of a patient's care may result in less than optimum analgesia to avoid even the appearance of hastening death. Even if a physician knows that the administration of an opioid is appropriate and will not hasten death, placating a family may take precedence over duty to the patient. Truog et al. described a case in which physicians were reluctant to suggest stronger sedation because doing so may have been perceived as a suggestion to hasten death.

**BIOETHICAL DISCUSSIONS OF THE DOUBLE EFFECT**

Relieving pain and providing comfort care is one of the primary duties of physicians and as such is a matter subject to ethical concern. Unfortunately, in ethical articles discussing end-of-life issues, any discussion of relieving pain is invariably followed, almost in the same breath, by a discussion of the double effect. Even when meant to encourage the use of opioids to relieve pain, these double effect discussions have the effect of reinforcing the misperception that cancer patients must die in pain unless medication that hastens death is administered. No data and little evidence can be found to support the notion that the use of medication to relieve pain is responsible for hastening the death of dying cancer patients. Yet, the ethical literature assumes it is a common occurrence. Few articles argue the point. It is just assumed to be true.

In their article, "The Physician's Responsibility Toward Hopelessly Ill Patients: A Second Look," Wanzer et al. urged the use of appropriate medication to better treat pain and stated that the "balance between minimizing pain and suffering and potentially hastening death should be struck clearly in favor of pain relief." Although these commentators made a very forceful argument for the need to increase the dosage of narcotics to whatever level is neces-
sary to provide adequate pain relief, they still extended the myth that palliative care is often fatal because such action is ethical "even though the medication may contribute to the depression of respiration or blood pressure, the dulling of consciousness, or even death . . ." [emphasis added].

It is often a nurse who must administer pain medication. In 1991, the American Nurses Association adopted a position statement on "Promotion of Comfort and Relief of Pain in Dying Patients":

Nurses should not hesitate to use full and effective doses of pain medication for the proper management of pain in the dying patient. The increasing titration of medication to achieve adequate symptom control, even at the expense of life, thus hastening death secondarily, is ethically justified.

In the Encyclopedia of Bioethics, Brock, discussing the risk of respiratory depression and earlier death from "larger and larger doses of morphine," stated that "when caring for dying patients, health professionals frequently take actions that may and sometimes do shorten the patient's life." Brock's statement is not untrue, but it is misleading. Without a doubt, health professionals "frequently" give pain medications to dying patients. And there may be "some" times when an apparently appropriate dose "may" shorten a patient's life, but as a review of the medical literature reveals, that "some" time is a very rare event.

In the widely cited "Decisions Near the End of Life," the American Medical Association's Council on Ethical and Judicial Affairs gave the following scenario as an example of the double effect: "gradually increasing the morphine dosage for a patient to relieve severe cancer pain, realizing that large enough doses of morphine may depress respiration and cause death." And under a heading that reads "Providing palliative treatments that may have fatal side effects," the council stated that "the level of analgesia necessary to relieve the patient's pain, however, may also have the effect of shortening the patient's life." The only reference given to support these statements is a 1988 report by the AMA's Council on Euthanasia.

Cavanaugh, in "The Ethics of Death-hastening or Death-causing Palliative Analgesic Administration to the Terminally Ill," stated that "Sometimes, the administration to a terminally ill patient of an opioid analgesic hastens or causes the patient's death insofar as it depresses respiration." He cited three references in support of this statement. The first citation was to a chapter in Advances in Pain Research and Therapy, "Opioid Analgesics for Cancer Pain," by Inturrisi. In this chapter, under the subheading "Respiratory Depression," Inturrisi stated that "respiratory depression is potentially the most serious adverse effect [of opioids]." But in the same paragraph, he goes on to say:

When respiratory depression occurs, it is usually in opioid-naive patients following acute administration of an opioid and is associated with other signs of CNS depression including sedation and mental clouding. Tolerance develops rapidly to this effect with repeated drug administration, allowing the opioid analgesics to be used in the management of chronic pain without significant risk of respiratory depression [emphasis added].

The second source cited by Cavanaugh was an ethics article by Latimer in which she discussed, among other things, the issue of the double effect of treating pain. She referred to the "... knowledge of potential risk for shortening life," but then included the following statement in parentheses: "in actual practice, the risk may be quite low." The third citation was an ethics article by Brescia, in which he referred to morphine as a therapeutic measure "that could shorten life." However, Brescia gave no citations in support of this statement, so this trail of citations runs out with no evidence that hastening death by the giving of opioid analgesics is any more than a mere possibility.

This mistaken view that treating pain in the dying patient hastens death is expressed in the popular press as well as in the biomedical literature. In an article entitled "End of Life Is-
sues” in the Catholic Herald, the publication of the Archdiocese of Milwaukee, Archbishop Weakland wrote about “the comfort expressed by a terminal cancer patient when he understood . . . that accepting pain killing medication, even if it shortened his life, was permitted.”49 And in an op-ed article in The New York Times, an opponent of legalized physician-assisted suicide stated, “Sometimes physicians perform acts that cause or hasten death . . . . They administer pain-relieving medications to patients with advanced terminal conditions after advising them that the risk of death will thereby be increased.”50 But a patient need not think that shortening his life is part of the bargain when he accepts pain medication.

Of course the commentators, with few exceptions, urge the use of sufficient medication to control pain. When they speak of the double effect, it is to reassure that use of opioids is ethical even at the risk of hastening death. However, it is one thing to say, as the pain specialists seem to, that opioids can be safely titrated upward without undue fear of hastening death, and it is quite another to say that use of opioids is permissible despite hastening death. Ethical or not, patients or their families may not want to hasten death, and physicians and nurses may wish to avoid even the appearance of doing so.

Even when meant to encourage the use of opioids to relieve pain, these double effect discussions have the effect of reinforcing the misperception that cancer patients must die in pain unless medication that hastens death is administered. As Grond et al. have noted, “Most doctors are much more aware of the side effects of opioids . . . than of the side effects of pain.”21

There has been some recognition in the ethical literature that the double effect of pain medications has been overemphasized. As early as 1982, Angell, in her article “The Quality of Mercy,” noted the “very low incidence of important side effects [in contrast with] the very high incidence of inadequate pain relief,” and then stated, “I can’t think of any other area in medicine in which such an extravagant concern for side effects so drastically limits treatment. We are used to a closer balance between risks and benefits.” However, while Angell found concerns about addiction to narcotics to be “irrelevant” in the patient with terminal cancer, she felt that concerns about respiratory depression should be “secondary.”51

Brody noted that the “persistent belief that adequate doses of narcotics will lead to . . . premature death” is a barrier to good palliative care.52 But Mitchell, who recognized that the fear that pain medication hastens death is a “common misunderstanding,” still felt the need to justify the giving of such medication under the PDE.53 Quill wrote of “exaggerated patient or physician fears about . . . indirectly hastening death,” but in the same article stated that care in difficult cases “may often involve the aggressive use of symptom relieving measures that might indirectly hasten death,” and that it is “accepted medical practice to give increasing amounts of analgesic medicine until the pain is relieved even if it inadvertently shortens life.”54 Quill, along with others, has criticized the use of the “rule of double effect” in end-of-life decision making for a variety of reasons, including the difficulty of determining intention.55,56 However, in the case of medication to relieve pain in the dying patient, the PDE should be rejected not on ethical grounds, but for a lack of medical reality.

It is not that respiratory complications can never occur. But there is a difference between noting the small possibility of respiratory depression and assuming that it will occur as a secondary effect of analgesia. When a patient goes into surgery, there is a very real, although small, risk of respiratory complications from anesthesia. However, we do not justify this risk in terms of the PDE. The decision to recommend surgery is a medical decision based on the perceived benefits from surgery outweighing the risks. The practice of medicine always involves weighing the benefits and burdens of treatment. Noting the slight possibility of a complication of treatment is different from expecting the complication to occur. An overdose of medication would be an accidental side effect, not a foreseen and expected occurrence. The risk of respiratory depression may be increased for some patients, for example, those for whom sedation is necessary or desired. A risk that may be unacceptable in a patient with acute pain who is expected to recover may be acceptable for a patient who is dying. But that
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is reflected in the weighing of burdens and benefits. Only if the use of opioids would lead to an expected and foreseen hastening of death would appeal to the PDE be useful.

Ashby and Stoffell recommended applying a risk-benefit analysis to curative, palliative, and terminal modes of intervention. In the terminal mode, we accept a risk of premature death, although as they noted, there is "no evidence that the skilled and appropriate delivery of palliative care measures (in particular the use of opioid analgesics and anxiolytic drugs) shorten life. . ."57

Bleich noted that the connection of respiratory depression with pain control is based more on myth than on medical fact, and argued that the PDE should not be applied to the risk of hastening death from pain medication. As he put it, the "assumption of prudent risk is synonymous with life. It is only when the bad or immoral effect of an action is foreseeable as a matter of certainty, near certainty or strong likelihood that a moral dilemma arises." And although the hastening of death in this situation is "within the realm of possibility, [it] does not rise to the level of the foreseeable."58

THE ROLE OF DOUBLE EFFECT IN THE PHYSICIAN-ASSISTED SUICIDE AND EUTHANASIA DEBATE

A troubling result of the mistaken belief in the double effect of pain medication is its effect on discussions of euthanasia and physician-assisted suicide. Giving pain medications is even referred to as "indirect euthanasia,"59 "double effect euthanasia,"60 or "accidental euthanasia."61 For example, in one article, the authors stated that "a common example of indirect euthanasia is the administration of large doses of narcotics to a terminally ill patient in unbearable pain."62 And although the AMA's Council on Ethical and Judicial Affairs, in its "Decisions Near the End of Life," rejected euthanasia and physician-assisted suicide and endorsed palliative care, the Council stated that the "ethical distinction between palliative care that may have fatal side effects and providing euthanasia is subtle. . ."11

In the past, the underlying theme of most discussions of the double effect of pain medication, even when referred to as indirect euthanasia, was that the administration of pain medications was ethical. Recently there has been renewed interest in "double effect euthanasia," equating it to, and using it to support, legalized physician-assisted suicide or euthanasia. The argument usually takes one of two forms or some combination of the two. First, because hastening death by drugs is already being done and is ethical, perhaps we should extend medical practice to allow physician-assisted suicide. The second argument is that because physicians are already hastening death, we should legalize it to provide safeguards.

Federal court cases

In 1997, the U.S. Supreme Court overturned decisions by the Second and Ninth Circuits of the Federal Appeals Court, which had held that state prohibitions against physician-assisted suicide in Washington and New York are unconstitutional.62,63

In Quill v. Vacco, the Court of Appeals for the Second Circuit had held that New York violated the Equal Protection Clause because it allowed the hastening of death through withdrawal of life support (which the court noted often requires the administration of "palliative drugs which may themselves contribute to death") while denying the right to physician-assisted suicide.64

In Compassion in Dying v. Washington, the Ninth Circuit had held that prohibiting physicians from prescribing life-ending medication for use by terminally ill, competent adults violates the Due Process Clause of the Fourteenth Amendment. This ruling was based in part on the double effect of pain medication. In a discussion of the state's interest in preventing suicide, Judge Reinhardt, writing for the court, stated:

Given current medical practices and current medical ethics, it is not possible to distinguish prohibited from permissible medical conduct on the basis of whether the medication provided by the doctor will cause the patient's death. As part of
In reversing these two Appeals Court cases, the Supreme Court held that state prohibitions against assisted suicide do not violate the Due Process Clause or the Equal Protection Clause and are therefore unconstitutional. However, the opinions in these companion cases reveal that the Supreme Court Justices assume the factual accuracy of the double effect of pain medication. For example, in Vacco v. Quill, the court noted in a footnote that a state may prohibit assisting suicide even though it may permit palliative care “which may have the foreseen but unintended ‘double effect’ of hastening the patient’s death.”

Most palliative care specialists would see little resemblance between the activity described above and the care they provide for their patients. Later in the decision, Reinhardt stated:

We see little, if any, difference for constitutional or ethical purposes between providing medication with a double effect and providing medication with a single effect, as long as one of the known effects in each case is to hasten the end of the patient’s life. . . . To the extent that a difference exists, we conclude that it is one of degree and not of kind.

If double effect medication is being given which will “indubitably” hasten death, then it is a case of active euthanasia and cannot be justified under the PDE. Foley pointed out the dangers of blurring these distinctions:

Physicians do struggle with doubts about their own intentions. The courts’ arguments [equating a lethal prescription with withdrawing life-sustaining treatment and aggressive treatment of pain] fuel their ambivalence about withdrawing life-sustaining treatments or using opioid or sedative infusions to treat intractable symptoms in dying patients. . . . Yet saying that physicians struggle with doubts about their intentions is not the same as saying that their intention is to kill. . . . Specialists in palliative care do not believe they practice physician-assisted suicide or euthanasia.

Double effect euthanasia

The supposedly well-known practice of double effect euthanasia is a recurring theme in arguments supporting physician aid-in-dying. Angell, who supports legalizing physician-assisted suicide, noted that both the United States and The Netherlands permit use of opioids that “might predictably shorten life, although we have no data as to how often this practice contributes to death.” According to Peter Goodwin, a leading supporter of the Oregon referendum that legalized physician-assisted suicide, “Dying patients are given larger and larger doses of morphine. We talk about the ‘double effect,’ and know jolly well we are sedating them into oblivion, providing permanent relief, and we don’t tell them.” Bert Keizer, a nursing home physician in The Netherlands and author of Dancing with Mister D, is quoted in Time magazine as saying, “Doctors all over the world shorten the lives of patients under the cover of pain reduction, and only we are stupid enough to talk about it.”

In Asch’s report of a survey on the experiences of critical care nurses with euthanasia, it is clear that some of the respondents, and to a lesser extent, the author, confuse the giving of pain medication with euthanasia. Nurses were asked if they had “ever administered a
Double Effect of Pain Medication

Medicine or performed some other act with the intent of causing or hastening that patient's death—other than the withdrawal of life-sustaining treatment?" Those answering yes to this question cited a range of activities. Some reported giving medications for the withdrawal of a ventilator or failing to decrease opiates when vital signs in an imminently dying patient deteriorated, activities that may not have hastened death. However, some activities described by the nurses would seem to constitute an abuse of medications and intentional killing. For example, one nurse described giving a higher dosage than prescribed and falsifying it as narcotic "waste." But even in this situation, because undertreatment of pain is so widespread, the administration of more than was prescribed may have only resulted in the giving of an adequate amount. What is troubling is that 19% of the respondents believe that they have intentionally hastened death, often without the request of the patient or family. Noting that "practice often leads policy," the investigator suggested that these results could be used to support euthanasia "because by making procedures explicit, one can provide the oversight essential for protecting both patients and health care professionals." But, as pointed out by Scanlon, commenting on this study, equating such activities to euthanasia "is inaccurate and may increase the already considerable confusion surrounding justified care at the end of life, particularly the use of opiates to manage pain."71

The concept of double effect euthanasia and arguments for legalizing physician-assisted suicide also appear in the popular press. In 1994, in one of a four-part series on euthanasia, the Milwaukee Journal daily newspaper used the following front page headline, "Morphine: When killing the pain kills the patient," and on an inside page, "Euthanasia/morphine has double effect."72 The following Sunday, a Journal editorial supported proposed aid-in-dying legislation that had recently been proposed by a Wisconsin state senator. Relying on the information in the previous articles, the editorial staff stated that "even the routine practice of administering increasingly heavy doses of morphine to pain-wracked cancer patients can hasten death, as physicians well know. Legalities aside, there is a very fine line between giving dying patients enough medicine to keep them pain-free and essentially overdosing them." The editorial went on to state that the proposed legislation "would provide the state with a better way of regulating a practice that already occurs."73

Death by morphine drip

In an op-ed article in The New York Times with the headline "Killing pain, ending life," Preston, a well known proponent of legalized euthanasia in Washington and one of the plaintiffs in the Compassion in Dying case discussed above, stated that "'morphine drip' is euthanasia by another name."74 Preston alleged that the practice of ending patients' lives with a morphine drip is routine and occurs tens of thousands of times a year. He explained that this practice, "society's wink to euthanasia," is known as the double effect, and is even accepted by the Catholic Church. He went on to say that he had "never found a colleague who thinks a morphine drip is wrong if the patient is dying." He argued that it is important to legalize euthanasia to bring this covert practice out into the open and regulate it. Rather than allow physicians to "secretly and silently" hasten death, he advocated allowing them to do so "openly and honestly."

Of course, an overdose of morphine or other drug can hasten death. But if given to hurry things up and end the patient's life, this would be direct euthanasia, not pain relief. If done without the patient's knowledge and permission, such activity would amount to nonvoluntary euthanasia. Commenting on Preston's article, Schwarz, an oncology pharmacist, stated, "In those rare instances when a practitioner . . . prescribes morphine or any other agent at dosages that may cause clinically unjustified harm, every health care professional has an obligation to deal with this suspected abuse," and act as an advocate for the patient.75

Whether or not physicians routinely rely on the "double effect of overdosing" to hurry up the death of their patients is a factual issue. There are at present no reliable data on whether death by "morphine drip" is a common occurrence or only another myth. Use of a morphine
drip to hasten death may reflect the unavailability of good palliative care. For example, in another op-end piece in The New York Times, with the highlighted quote, “Morphine eased my terminally ill husband’s pain, but hastened his death,” the author wrote of the deaths of three relatives, including her husband. A lack of palliative care left her to choose the dosage of morphine, “to drive the engine of death,” for her dying husband.76

Billings and Block have written a thoughtful article on death by morphine drip, which they refer to as “slow euthanasia.” They believe that hastening the death of a “lingering” patient may be common. “Medication is adjusted with the purpose of accelerating dying, not simply for providing comfort. . . .”77 Whether such a practice can ever be justified is beyond the scope of this article. But hastening death cannot be excused as a side effect of pain relief and increasing the dosage of medication beyond what is necessary for pain relief cannot be justified under the PDE.

Prescribing or administering appropriate pain medication does not hasten death. For this reason it is not indirect or any other type of euthanasia. It is important to place emphasis on this point because the supposed inability to adequately treat pain is an important part of the debate about euthanasia and physician-assisted suicide. Conflating the giving of pain medication with euthanasia only distorts discussions on this most difficult issue.

CONCLUSION

Clinical studies and decades of experience by experts in pain management and palliative care have shown that the double effect of pain medication has little basis in medical fact. Not only is it not necessary to rely on the PDE to justify giving adequate pain medication to dying patients, but such reliance on the PDE actually perpetuates the myth of the double effect of pain medication, directly contributing to the undertreatment of suffering at the end of life. It is ironic that an ethical principle that is used to justify adequate opioid analgesics contributes to the undertreatment of pain.

Pain is one of the most feared consequences of cancer, and as noted by Wanzer et al., patients have reason to “fear that needless suffering will be allowed to occur.”4 Often it is the inadequate management of pain or fear of future unrelieved pain that leads to suicide ideation or the request for euthanasia.78 And it is the fear of unrelieved pain that drives public support for assisted-suicide and euthanasia.42 But as noted by Foley, “treatment of pain is never a form of euthanasia.”49 In end-of-life discussions, focusing on the PDE and on a seldom occurring side-effect of pain medications diverts attention from the larger ethical issue of the undertreatment of pain and suffering in the dying patient. It is important that ethical analysis be grounded in medical reality.

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