Philosophical Oncology: Calling on the Principle of Double Effect

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Abstract
Reasonable human behavior is based on doing something for a consequence that is perceived as good. Ethical medical decision-making is based on prioritizing values after understanding the relevant facts. There is an ethical obligation to do no harm. This is especially true in relieving the pain and suffering of dying patients; in these cases, treatment has the risk of contributing to a patient's death. The principle of double effect has been helpful as a moral guide in troubling cases to discern what actions are acceptable, even though the action could lead to an end that would seem as immoral as if the effect were directly intended. This principle, though, is not without problems and critics, and some have pointed out its shortcomings as an ethical guide. (JNCCN 2003;1:429-434)

“Palliative Care: It Relieves Symptoms, Even If It Kills You” — A medical student’s definition of palliative care

Human behavior and conduct is never easy to understand. The actions of the human drama are complicated and are driven by a multitude of factors such as individual character, neurobiology, feelings, emotions, timing, values, and motives, including anger (murder), depression (suicide), greed (fraud), jealousy (lies), love (self-sacrifice), and compassion (care). Under the influence of community and social ethics, reasonable human action is based on doing something for a consequence that offers a perceived improvement over the current state. In the clinical situation, physicians are presented with a specific problem to solve and, using their medical skills and the “baggage of accumulated knowledge,” make a decision.

Most practicing clinicians are not moral philosophers, nor do they have formal training in bioethics. Many of these moral concepts, principles, and rules are slowly absorbed over many years of medical training and patient experience. It is not surprising that physicians often turn to bioethicists for help in their search for rules on which to base difficult decisions. Principles and rules, however, may be inadequate to justify some particular action, that is, they may have too many inclusions or exclusions to be useful for a specific patient. Furthermore, discussions of moral philosophy can be too detached for the practical day-to-day clinician.

The ethical question requires asking if some particular action should take place. Ethics is the branch of philosophy that formally studies the nature of the ideal human character, as well as the reasons that validate human behavior as right or wrong. It provides a mechanism whereby individuals, once they are given a set of facts, conditions, or circumstances choose from among a variety of alternatives. Medical ethics offers clinicians and others involved in patient care a framework for clarifying complex, often troubling dilemmas that arise. Furthermore, it defines which choices are obligatory, permissible, or frankly wrong. Ethical questions simply ask: “How should one act with what is known?” Ethical medical decision-making is based on a prioritization of values (personal, religious, professional, legal, moral) that are outside the scope of pure medical knowledge. Therefore, in any clinical situation, the therapeutic option depends on clarifying the specific matter at hand, understanding the relevant facts, articulating one's personal values, and, finally, choosing the potential consequences from among the given alternatives.

Illness is, ultimately, the source of meaning for a physician's conduct and therapeutic action. It is an ontological break on personhood and establishes the moral encounter between healer and the sick. "Medical morality,
therefore, is grounded in a philosophical conception of the healing transaction.” In an ethical framework, the guiding principle is centered on doing what is best for the patient. This concept of beneficence dictates that the health care providers must strive to benefit the patient, and to do so, must weigh the benefits and burdens. The overall ends of medicine are to heal and to comfort persons who are sick: to help them avoid untimely death, prolong life, reduce pain, diminish disability, and, most importantly, avoid unnecessary suffering. What is “best” for each patient will be different for each patient.

The Western concept of personhood demands three things: equality, self-determination (agency), and individuality. Many patients with serious medical illnesses are robbed of their personhood and autonomy because the illness undermines individual goals and self-respect. Patient autonomy (self-rule) and informed consent, in the United States, are grounded firmly in common law and constitutional rights of privacy. Soundness of therapy is determined by medical appropriateness, but the patient determines what is in his or her best interest as he or she sees it, whether the clinical team agrees or disagrees with the patient’s choice.

At times, decisions are different than expected (such as refusal of life-saving treatment), and conflict can arise from what the patient and clinician individually determine as “best.” The authenticity of patient decisions at times can be questioned when patients make unexpected choices, even when the patient’s mental capacity appears not to be in question. Is the real person speaking? Mental capacity is examined to determine whether or not a patient is able to decide. Clinicians are forced to deal with the limitations of a patient’s mental and emotional ability to make choices because of illness, fear, pain, disfigurement, denial, guilt, anger, avoidance, ambivalence, and economic stress.

Furthermore, physicians have an ethical obligation to do no harm. This well recognized medical axion—primum non nocere—is the other side of the coin of beneficence, non-malificence. It is the clinician’s balancing act of negotiating the equation of gains over loses or benefits over burdens (proportionality). This is especially important to consider when a specific treatment procedure is known to cause a potentially harmful effect. Although seemingly simple to the lay public, just “not harming someone” may be difficult in medical practice. Medical oncology is a medical discipline especially filled with the experiences of people facing fear, uncertainty, and loss. Even when experienced physicians give their presence at the bedside, these clinical situations of caring for terminally ill produce unnerving feelings, induced by a sense of conflicting roles, goals, legal liability, and concern to not make things worse.

The aggressiveness of a given therapy as well as the need to continue some form of treatment is often based on a patient’s prognosis. Giving a prognosis is the oncologist’s professional responsibility of predicting a patient’s outcome. Confirming the diagnosis, reviewing the extent of disease, analyzing the natural history of disease and the tempo of progression, assessing the patient’s symptoms and performance status, and the trajectory toward death all help to clarify the possible outcome and the best course of treatment. This exercise is fundamental, because the clinician must distinguish between the effectiveness of an action that will remedy something and what is a real benefit to a patient, ultimately, defined only by the patient.

The therapy chosen is not based on what the clinical team would like to happen, but what they foresee probably will happen. It is also useful for the oncology team to remember that bad outcomes do not mean bad treatment decisions were made. Success in managing the multiple, diverse, and troubling signs and symptoms of advanced malignancy often becomes the overriding imperative, especially for patients facing death. For a typical cancer patient, the clinical experience in oncology points to discrete decision phases: diagnosis, surveillance to exclude recurrence (disease-free survival), recurrence or progression, second or third line treatment, experimental therapy (phase I studies), salvage treatment, hospice care, and, finally, the last days and hours of life. Most oncologists understand the distinction between treatment designed to offer cure and that which seeks a meaningful tumor response. However, the real challenge is determining whether active measures directed against the disease should be abandoned and only comfort measures given.

Oncologists have certain obligations; they too are physicians with a unique role and purpose. Some of these duties, rightly, are owed to society (research, prevention) and others to the profession of medicine itself (ethical behavior, competency); most obligations are due to the patient. These include but are not limited to duties of confidentiality, trust, compassion,
forthitude, integrity, and respect for autonomy. However, foremost is the obligation of clinicians to preserve and extend life and, whenever possible, to relieve pain and physical suffering. The clinician also is accountable to define the manner of care in a patient’s last days. The contemporary physician, unfortunately, no longer may be expected to have the virtue of benevolence, but is required by law to act according to the principles of beneficence and non-maleficence. During the final hours of life, the resignation of finality and limits demands a different spectrum of clinical goals, to only enhance comfort. Once there is clear recognition that the cancer therapy cannot change irreversible vital organ pathology and the dying process is seen as both difficult and expected, the moral distinction between allowing a patient to die and shortening life should appear less clear. Patients who are understood to be dying have few, if any, meaningful medical options. They represent the troubling cases talked about in philosophy and medical ethics classes.

The obvious mandate to comfort the dying while avoiding the potential of causing adverse events and, perhaps, even hastening death, is a common dilemma facing oncologists. Certainly, clinicians do not need to seek death for these patients, because it will arrive soon enough in cases in which there is obvious widespread disease. The urgency to promote adequate patient comfort escalates during the final days, but the physician must act within the expected boundaries of his or her defined role. Indeed, the challenge of diminishing symptom distress, anxiety, dyspnea, and agitation does not stem from a sense of treatment failure, but from a physician’s compassionate duty of non-abandonment to relieve human misery. All come to understand that the cancer can be beyond the means at the oncologist's disposal.

Despite medicine’s mandate to comfort and the recent public attention to bring patients a “good death,” the current practice of medicine, unfortunately, is “more a hope than standard” for most patients. Forty percent of patients will die with unrelieved distress. Pain remains inadequately treated, with a reported incidence ranging from 20% to 70%. A “good death” may be defined, simply, as a death that any of us would want for ourselves, if we were able to choose. Often, the final days are managed by clinicians who are ignorant of analgesic pharmacology, negligent in appropriate assessment, unable or unwilling to commit to enough time, deliver poor continuity of care, offer poor communication, and most disturbing, are apathetic or not troubled by another’s troubles. There is the added nervousness among many caregivers that their actions will enhance the medical problem or hasten the dying process. For example, administering opioids can suppress the respiratory drive. When questioned, almost 90% of physicians and nurses agreed that it is morally permissible to administer medication to relieve pain, even if it contributes to a patient’s death. In these situations, the principle of double effect can provide guidance.

The rule of double effect stems from a Roman Catholic moral theological principle dating back as far as the Middle Ages. According to Christian thinking, evil is neither inevitable nor an illusion, but emanates out of man’s rebellion in the garden of Eden (Genesis 3:4) to “know good and evil.” In this tradition, humans live in a world where good and evil are mixed, ambiguous, and at times, difficult to distinguish, and we are called to be “cunning as serpents, yet harmless as doves” (Matthew 10:16). The principle requires that four conditions be satisfied for an action to be permissible: 1) First, the nature of the act itself must be good or neutral (e.g., giving opioids). 2) The intention of the agent (a physician) is to achieve the beneficial effects of the action (relief of pain and suffering). 3) The bad effect must not be intended, but only foreseen and tolerated. The good effect must not be produced by the bad effect (relief of suffering must not be directly caused by death). Therefore, in relieving the suffering, you get rid of the sufferer; the bad effect must not be a means to the good effect. 4) The good consequence of the action must outweigh the bad effect. There must be proportionality between the good and bad effects (therefore, relief of suffering can only be achieved at high risk of death). This is not a legalistic formula, but serves as a moral guide for physicians to discern what is acceptable, even though the action could lead to an end that would be seen as immoral if the effect were directly intended.

Obvious pairs of actions with identical ends and consequences might be morally different because of differences in the initial intentions of the agent. Intention is crucially important in moral reasoning. Indeed, most criminal law is founded on a notion of motivation; common sense suggests that this is true. “Harms done intentionally are both bad and wrong … harms done unintentionally may be bad, but except for special situations such as negligence, are not con-
sidered wrong.” If the clinician orders a bolus dose of intravenous potassium to a seriously ill patient (assuming physician competency), the motives of the clinician appear very clear and knowable; the goal of relieving suffering is admirable, but the means chosen are not (intentional killing).

One could argue that a person’s intentions are private and unknowable. Hypothetically, a physician may have a serious conflict of interest (evil motives) toward a dying patient (business partner, ex-wife, mother-in-law), and he or she may intend harm while relieving that patient’s pain. More commonly, it may be difficult for clinicians to separate their intentions in situations that call for relief of suffering with potentially lethal drugs. For example, for a terminal patient with a protracted terminal illness, the patient’s circumstances—inability to move (cervical cord compression), severe dyspnea and strider (pulmonary and local recurrence obstructing the trachea), intractable pain, and severe anxiety—all may lead a physician to conclude that both intentions (comforting and hastening death) are not such “bad” consequences. These intentions may arise from real sense of compassion; they may not remain private and unknowable.

In such troubling cases, it may be impossible for the physician to articulate any real difference in intent. Thirty-nine percent of physicians who had sedated patients while ceasing mechanical ventilation reported they intended to hasten death. Lo concludes, “the doctrine of double effect leads to the implausible conclusion that physicians are more justified in administering large doses of narcotics if they can put out of mind the possibility that death may be hastened.”

If one believes that hastening death is always an absolute moral wrong, a clinician would have difficulty in calling on the rule of double effect for guidance as a valid argument for action. This rule, obviously, does not authorize euthanasia or assisted suicide, because they do not meet the four conditions. Beauchamp and Childress prefer a model of intentionality based on will versus wishes, that is, the physician “can desire not to do what he intends to do, in the same way that we can be willing to do something, but, at the same time, be reluctant or even detest doing it.” Furthermore, nothing in the principle of double effect helps the clinician to conclude that death in these difficult cases is “bad.” Critics justly point out that the principle accepts a consequentialist approach; it permits and tolerates a patient dying ever so slowly with titrating opioid doses rather than approving an action that relieves pain and suffering quickly with a lethal dose of opioids.

Often, the oncologist is torn in totally opposing directions because of conflicting moral obligations, clearly defined by the nature of the professional commitments: the duty to comfort versus the duty not to kill (principle of conflicting duties). The President’s Commission for the study of Ethical Problems in Medicine concluded, however, that individuals are equally responsible for all the possible foreseeable effects of their actions. Therefore, it is not necessary to separate “means” from “foreseen consequences.” The Commission further states that clinicians are not immune from blame, because they are in breach of responsibility from their professional obligations and standards, along with their inability to totally fulfill them. Despite this obvious moral paradox that physicians find themselves in, philosophers offer no opinion on what clinicians should do in these predicaments to avoid blame. Philosophers seem to assume a conservative viewpoint in voicing what actions clinicians may legitimately commit in the care of the dying.

The rule of double effect goes to the core of a person’s behavior, which arises from “proper motivational structure” and good character. “[The] intention to kill another person may be less relevant morally than the motive in doing so.” The principle removes culpability because the moral rules have not been violated. In the real world, especially in medicine, it is impossible to live, work, and function and never foresee the possibility of causing harmful consequences from some action. Indeed, the rule of double effect was born out of the ambiguity and difficulty in knowing good and evil. The position that one can act only if a good is accomplished without any harms or burdens is a position of moral purism, and it creates the potential for paralysis of action. It makes doing anything worthwhile impossible. This refusal to act for the comfort of the dying is an abandonment of the physician’s fundamental responsibility and obligation to comfort.

Current United States law has supported the moral guidance of the double effect rule and has prohibited the lethal injection by any agent, with the explicit purpose of causing a person’s death. In the English case of R v Adams (1957), Justice Devin wrote, “... he [the doctor] is entitled to do all that is proper and necessary to relieve pain and suffering, even if the measures he takes may incidentally shorten life.”
This approach was further endorsed in the Supreme Court of the United States, which rejected a constitutional right to assisted suicide, but supported sedation to comfort refractory symptoms during a patient’s last days. Because the law includes language of proportionality, clinicians continue to give potentially lethal medication to relieve a terminally ill person’s suffering.

Some criticize the principle for having “shortcomings as an ethical guide” for the following reasons: 1) the rule began in a specific narrow religious tradition; 2) current society calls on multiple traditions for end-of-life care; 3) the rule prohibits intentional killing, even if a competent dying patients ask for it; 4) individual intentions are hard to validate; and 5) the rule has prohibited some confused physicians from giving pain relief for fear of blame. Cherny believes the justification of the use of sedation in the management of refractory pain is best served by “goal-appropriateness” and proportionality rather than the principle of double effect. “It has become a meaningless mantra recited by cynical surreptitious practitioners of euthanasia cloaked as palliative care practitioners.”

The principle of double effect is designed exclusively for cases in which an action has both good and bad effects. One also may wonder if the principle applies at all if the premise we have taken as fact, that opioids hasten death in treating terminal patients’ pain and suffering, is indeed false. In a large study assessing survival and opioid usage in the last days of life of 1,103 terminal patients, no correlation was found between dose of opioids and hastening death. Nearly 75% of these dying patients had a stable dosing pattern, with only 4.2% needing an increased dose. It may be that the risk factors considered clinically important to determine potential survival and impending death are not relevant in a study population only days away from death. Bruera, in an uncontrolled study, suggested that subcutaneous morphine could decrease the subjective discomfort of dyspnea without statistically modifying oxygen saturation, respiratory rate, or end tidal Paco2. He later showed that intermittent injections of morphine were safe and effective for the management of shortness of breath in terminal cancer patients.

There is always a moral imperative for medical care that comforts. Unfortunately, established standards for due care for the dying are insufficiently developed by physicians, and moral theories from theologians and philosophers appear inadequate and unsatisfactory. Physicians seem not to understand the “end of medicine” and philosophers are having trouble articulating the “end of man.” Ironically, the rule of double effect appears to have both “desirable (good) and undesirable (bad) consequences on clinical conduct. It has given moral guidance to clinicians who commonly prescribe high-dose opioids for pain in the terminally ill, while prohibiting direct, intentional killing of patients despite their suffering, competency, or willingness to die.

However, the reality that some physicians do not provide pain relief to patients apparently in need because of fear of shortening a patient’s life is disturbing. Clinicians must clarify their goals for the management of dying patients with neither a goal to prolong life nor a goal to seek death. Nonabandonment is the medical philosophy that goes beyond the usual standards of legal negligence. Clinical presence is the physician’s gift of nonabandonment with all the necessary elements of care: comfort, compassion, communication, calmness, continuity, and closure. In the end, physicians must recognize the human capacity to have mercy for another living person in need to relieve the indignity that such illness causes. In the final analysis, it is mercy, humanity, and compassion that should win over any rules.

References


