

The Doctrine of Double Effect

A Review for the Bedside Nurse Providing End-of-Life Care

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Nurses on the front lines of palliative care are frequently presented with ethically challenging situations involving the use of palliative sedation and increasing opioids at the end of life. The doctrine of double effect is an ethical principle dating back to the 13th century that explains how the bad consequences of an action can be considered ethically justified if the original intent was for good intention. This article examines the doctrine of double effect through case examples and presents supporting and opposing opinions about its relevance to clinical practice. Implications for nursing care are discussed.

KEY WORDS

doctrine of double effect, ethics, palliative care, palliative sedation

urses are on the front lines of patient care. As such, they are frequently presented with ethically challenging situations. Nowhere do these ethical questions arise more poignantly than in the care of patients at end of life. Feelings of moral distress can result when nurses feel conflicted about the care that they provide. Hence, an understanding of moral principles underlying care is an integral step in maintaining a sustainable professional perspective when one is faced with the experience and consequences of intense suffering and the associated decisions about life and death.

The doctrine of double effect (DDE) is an ethical concept frequently offered as justification for challenging decisions in care. Over the past several decades, heated debate has revolved around this ethical construct, with varying levels of abstraction presented.^{2,3} This article

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aims to address how the DDE applies to the daily practice of the hospice and palliative nurse.

The DDE is a moral principle taken from the teachings of the 13th century Catholic theologian Saint Thomas Aquinas. The basic idea of the principle is the focus on the *intention* of the care provider: if the intention of an act is good, the foreseeable negative effects can be justified.⁴ Aquinas introduced a precursor of today's DDE to justify killing in self-defense: a good person's intent was on the immobilization of an attacker, and with this intent, the action is not considered evil if it unintentionally causes death of the assailant.⁵

Over centuries, the DDE has been used in the consideration and discussion of a range of ethically complex scenarios, including euthanasia, abortion to save maternal life, and morally justified warfare. The doctrine has continued to be mired in controversy, because ethicists, legal scholars, theologians, and philosophers debate the abstract concepts of moral reasoning, intention, foresight, and other underlying moral theories. And the consideration of the consideratio

In this article, the moral principle of DDE will be examined specifically in its clinical application to the process of ethical decision-making in the care of persons at end of life. This application of DDE has been frequently examined in light of 2 common clinical scenarios: (1) the administration of increasing opioid doses for symptom management at end of life and (2) the use of sedation to unconsciousness (palliative sedation) for the treatment of intractable symptoms at the end of life. While referencing the many and varied abstract debates, ^{3,7,8} this article attempts to remain clinically focused and to apply the concepts to concrete clinical scenarios encountered by nurses every day, examining the question, "How does DDE remain relevant to the nurse at the bedside?"

DEFINITION

The DDE emanates from the fact that some actions seem to have both a good and a bad effect. It has also been described as the "principle" (to dissociate it from a religious origin or the "rule" of double effect. The DDE aims to describe the best practice when a clinician must distinguish the positive benefits of an intervention against the known foreseeable but unintended risks and burdens of such therapy. It has figured extensively not only in discussions of

end-of-life decisions that seem to have a good effect (ie, comfort) but also in the likelihood or possibility of a bad effect (ie, shortening life). The principle states that the risk of a negative known (foreseen), unintended consequence, or adverse effect of treatment can be justified if it was not the original and main intent of the action. Theologian Mangan originally articulated the most quoted definition of DDE in 1949. He described how the DDE provides moral justification for an action if 4 basic criteria are met. These criteria are listed, with comment, in Figure 1. 8,11-13

CLINICAL SCENARIOS

Consider the following case:

Ms SK was a 77-year-old woman followed by oncology for her widely metastatic lung cancer. Her disease was refractory to treatment and progressed; she grew weaker. She chose comfort-focused care and refused further cytotoxic therapy. Extensive osseous involvement began to cause her excruciating bone pain at multiple sites, and the pain progressed despite several courses of palliative radiation therapy, bisphosphonates, and increasing doses of opioids and coanalgesic medications. She was dyspneic and anxious, with both symptoms aggravated by her severe pain. She was admitted to a local hospital for general decline, dehydration, and severe pain. Increasing doses of intermittent intravenous morphine were administered with suboptimal effect, and 2 days after admission, a continuous morphine infusion with prn clinician-administered boluses was ordered. After aggressive dose titration, at last, the patient seemed to achieve an acceptable level of comfort and calm. She remained intermittently awake and interacted with family at her bedside, but some of the staff was uncomfortable administering increasingly high doses of opioid, fearing that they would hasten the patient's death.

Are these nurses ethically justified in giving very high doses of opioids for pain at the end of life? If one applies Mangan's¹¹ 4 conditions of the DDE, the principle applies in the following manner:

- The action of administering opioids to relieve suffering is, in itself, good.
- The intent of administering opioids is for the good effect of pain relief, not the bad effect/intention of hastening her death.
- 3. The pain relief (good effect) is not achieved by shortening her life (bad effect).
- 1 The action in itself, by reason of its very object, be good or at least indifferent
- 2. The good effect and not the evil effect be intended
- (*The clinician's intention is solely to produce the good effect*)

 3. The good effect not be produced by means of the evil effect
- 4. There be a proportionately grave reason for permitting the evil effect (The good effect must outweigh the bad effect)

FIGURE 1. Four conditions of the doctrine of double effect (*Italics added by author*). Adapted from $^{8,11-13}$

4. The good effect of adequate pain relief and alleviation of suffering outweighs the possibility of shortened life. One can now consider this case with a different outcome.

The described 77-year-old woman was admitted to the inpatient unit with severe excruciating pain that did not respond to increasing doses of intravenous opioids. The patient and family pleaded with the clinician to end her suffering, and a dose of a lethal drug was ordered for her to take on her own (as would be ordered in the case of physician-assisted death) or administered to end her life so she no longer suffered (as in the case of euthanasia).

Examination of this scenario within the DDE framework reveals violation of numbers 1 and 3 of the conditions of DDE:

- 1. The action of ending life is, in itself, a bad effect. Although some may argue that death in this scenario is not evil but a release from pain, the third condition is still applicable and is violated:
 - 3. The pain relief (good effect) was achieved by the bad effect (ending the patient's life).

Hence, because the DDE forbids the achievement of good ends by wrong means, it is generally accepted that the DDE does not provide moral justification for euthanasia or physician-assisted death, as described in this case. Presented here is another case involving sedation at the

end of life:

Mr TS was a 56-year-old man with advanced hypopharyngeal squamous cell carcinoma, extensive locally advanced disease, and lung and bone metastases. He had been on the hospice unit for the past 2 months; during this time, the cancer progressed, causing edema, partial blindness and deafness, severe pain, excessive secretions, dyspnea, anxiety, and constant oozing of blood in the oral cavity. The patient also suffered from nausea unrelieved by pharmacological or nonpharmacological interventions. He eventually refused enteral tube feeding, understanding the implications that this might shorten his life span. It became difficult to treat this patient's pain and anxiety without oversedation. Finally, the patient requested increased pain medicine and benzodiazepines; because despite a variety of interventions, he continued to suffer from multiple severe symptoms and requested that he wanted to "just be comfortable and sleep." A combination of around-theclock-alternating morphine and lorazepam lead to sedation. The patient was monitored closely, and medications titrated for comfort and sedation. The patient died quietly and in apparent comfort the next day.

This case demonstrates one variant of palliative sedation, the use of sedation to take away consciousness as the only available way to reduce otherwise terrible suffering. Gurschick and colleagues, ¹⁴ in their state-of-the-science paper, report that there remains considerable heterogeneity in the definitions and guidelines for palliative sedation. According to Gurschick et al, ¹⁴ the ambiguous use of various



terms (palliative sedation to unconsciousness, continuous deep sedation, and proportionate palliative sedation) are leading to the use of "palliative sedation" to mean all of these. However, one should note the difference between deep sedation as seen in this case, as compared with the earlier description of Ms SK. Palliative sedation to unconsciousness and continuous deep sedation both aim for an unconscious state. The previous patient, Ms SK was intermittently sedated, but she was able to awaken, interact, and potentially take food and fluids. However, in the case of Mr TS, his intractable symptoms and level of suffering indicated the use of deeper sedation to unconsciousness, to lower his awareness of suffering. According to the American Association of Hospice and Palliative Medicine, clinicians should not assume that palliative sedation is irreversible. Sedation should be proportionate to the patient's level of distress and used only for the duration of the symptoms. 15 Unfortunately, at times, intractable symptoms last until the time of death.

Language and terminology are important, and it is important to note that current professionals consider the term "terminal" sedation to be inappropriate because it implies that the practice is designed to shorten life; thus, the more appropriate terminology is the term "palliative sedation," with defining additional terms, such as superficial, deep, intermittent, or continuous.

In considering the DDE in this case of deep sedation to unconsciousness that is continued until death, the moral justification is all about intent. As described in the recently updated *Position Statement on Palliative Sedation*, the Hospice and Palliative Nursing Association declares

"The principle of double effect provides justification in which the process is based on the intended outcome of pain and symptom relief and the proportionality of benefit and harm. The intent of palliative sedation is to relieve suffering in dying patients but not to deliberately hasten death. This is very distinct from euthanasia, assisted suicide, or any intervention such as inappropriate escalation of analgesic or sedative doses where the intent is solely to hasten the patient's death."

Examining palliative sedation within the framework of the 4 conditions for DDE, one sees that it can be an appropriate intervention and fulfills the 4 conditions of the principle of double effect.

- 1. The sedation, in itself, is for a good effect: alleviation of symptoms such as pain, dyspnea, and agitation. Like all sedation that controls pain or is used for surgical anesthesia, it can carry the risk of an unintended bad effect, death, but the action itself is good.
- 2. The intention of administering the sedation is for the good effect, not the intention of hastening death.

- 3. The good effect (decreased suffering) is not obtained by means of the bad effect (death).
- 4. There is a proportionately grave reason (intractable symptoms) for permitting the bad effect.

SUPPORT FOR THE DDE

The DDE has been supported by numerous professional and legal organizations. The use of medication to promote comfort and relieve pain in dying patients is supported by the American Nurses Association, which writes "Achieving adequate symptom control, even at the expense of life ... is ethically justified." ¹⁷

The American Medical Association describes and supports continuous deep sedation as a therapeutic approach generated only by control of symptoms, the explicit intention only to control symptoms, never to expedite death.¹⁸

The DDE has a long history of use in American case law, ⁷ and it has been used to defend the practice of palliative sedation and prohibit assisted suicide. Court decisions, such as those in the 1997 US Supreme Court decisions put forth in Vacco v. Quill and Washington v. Glucksberg, stated that a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication to alleviate that suffering, even to the point of unintentionally causing unconsciousness and hastening death. ¹² Rulings on these cases provided clear support for the legality of sedation and clarified the distinction between intentionally hastening death and the appropriate use of sedation to treat symptoms, even if death is hastened. ¹⁹ Case law in support of this principle has also been clearly supported in British courts. ²⁰

Finally, the premier reference for professional nursing ethics, *The ANA Code of Ethics*, states that "The nurse should provide interventions to relieve pain and other symptoms in the dying patient consistent with palliative care practice standards and may not act with the sole intent to end life." ^{21p3}

THE DDE APPLIED IN OTHER CLINICAL SCENARIOS

Although the DDE is most frequently discussed in the context of the aforementioned care scenarios (opioids and sedation at the end of life), the hospice and palliative care nurse may encounter other challenging decisions where this principle may apply. Healthcare teams facing issues such as those listed in Figure 2 may also benefit from discussion and analysis from the perspective of the double effect principle.

DEBATE AND CONTROVERSY

Controversy has long revolved around this ethical principle; ethics theorists and bedside clinicians alike have debated its use and relevance. Some feel that the DDE

- Use of QT prolonging or arrhythmogenic medications which may lead to earlier cardiac death (i.e. use of certain anti-psychotics with intractable delirium)
- Administration of chemotherapy in medically frail patients, in which the intended effect is elimination of malignant cells, but this benefit must be balanced again the unintended but predictable risk of death from neutropenic sepsis. ¹⁰
- The withdrawal of IV hydration in last days/weeks of life to decrease burden of symptoms such as pulmonary congestion and painful edema; such intervention may lead to decreased symptoms, but could also increase mental clouding and hasten death.
- * The author acknowledges that the consequences listed in these possible scenarios have not been systematically studied and are hypothetical in nature to encourage consideration of the underlying ethical principle.

FIGURE 2. Other potential cases in which doctrine of double effect may be applied*.

is a general axiom, a principle on which rests all medical care. Eminent palliative care specialist Robert Twycross⁹ proposes that although the principle has usually been discussed in the most extreme cases, in actuality, all interventions and treatments carry some inherent risk of foreseeable negative outcomes.

Some critics argue against the relevance of the DDE in clinical care at end of life. Some of the main arguments critiquing the use of the DDE as justification for medical decisions include the following:

1. The DDE is not clinically relevant because evidence has accrued that the appropriate use of opioids and sedation do not shorten life. 16,22 Palliative care specialists challenge the notion that opioids do actually hasten death, in fact, arguing that there is evidence that in some instances higher doses of opioids and sedatives actually prolong survival in patients after extubation in the intensive care unit. 23 A variety of studies purport to demonstrate that survival is no different between patients receiving palliative sedation and similar patients.²⁴ However, there are limitations to these studies, given the inability to conduct randomized controlled trials concerning these types of endof-life decisions. 8 Critics point out that these studies have not been methodically strong, with the bulk being retrospective reviews and none using randomization into 2 arms. 10,25

Despite the limitations in this evidence, professional organizations generally support the premise that the DDE is not needed in good palliative care practice. For example, the Association for Palliative Medicine of Great Britain and Ireland²² in their *Position Statement on the Double Effect* states that "The APM believes that DE is unnecessary to justify the use or dosing regimens necessary to manage pain or distress in all but the most exceptional circumstances. Professionals who are concerned that they are shortening life by using these medications should contact their local specialist palliative care services."

2. Several ethicists believe that the principle involves too much ambiguity, and it is not conceptually clear enough for clinical utility. Lindblad et al² maintains that the DDE fails to provide the morally relevant distinction between intended effects and foreseen effects that can account for the alleged moral difference between issues such as sedation therapy and euthanasia: "The core of this criticism has been that the distinction between intended and foreseen effects cannot be made conceptually clear enough." Clinicians may have more than one intention when carrying out an action. Ethical scholars insist that proponents of DDE need to provide further clarification and justification of the moral difference between intended and foreseen effects.

The DDE remains controversial because critics claim that although intentions do count in moral evaluation "the distinction on which DDE rests is hopelessly obscure because human intention is multilayered, ambiguous, subjective, and often contradictory." ^{5p3} These ambiguities seem to be the reason why existing guidelines concerning palliative sedation recommend the use of this practice only as a "last resort."

3. A final argument against the need for the DDE arises when clinicians and ethicists ask "Is death even considered a negative adverse effect?" Some argue that the DDE is not relevant in end-of-life care because death is not really a negative or bad outcome, merely the expected outcome.

"The DDE is irrelevant because it requires there to be a bad effect that needs justification. This is not the case in end-of-life care for patients diagnosed as dying. Here, bringing about a satisfactory dying process for a patient is a good effect, not a bad one. DDE becomes irrelevant when the patient's dying is no longer viewed as an evil or bad outcome to be avoided.... A diagnosis of dying allows clinicians to focus on good dying and not to worry about whether their intervention affects the time of death."

NURSING IMPLICATIONS

Despite the persistent debate over its relevance and usage, bedside clinicians continue to rely on the DDE to provide rationale for complex and sometimes disturbing clinical challenges. What are the implications of this for the practicing nurse? Several areas warrant consideration. These nursing implications are outlined in Figure 3 and detailed here in after.

Informed Consent

Like all medical treatments and interventions, one expects the patients and surrogate decision makers to be fully informed about the benefits and potential adverse effects of therapy at the end of life. The use of high-dose opioids and palliative sedation should also adhere to this ethical practice. Berger⁴ writes that the ethical principle of autonomy requires that the patient or surrogate decision maker would need to be informed of the risks and give valid consent to justify use of this rule.



- Informed consent
- Safeguards
- Considering Nutrition and Hydration
- Proportionate use of medications
- Ethical review
- Personal reflection

FIGURE 3. Nursing implications when considering the doctrine of double effect.

It is standard practice to obtain informed consent and document in the medical record specifically before initiating palliative sedation. Ideally, informed consent should be obtained from the patient before it becomes necessary, preferably along with the family or surrogate. In this manner, the patient's wishes can be more accurately honored, even if the patient is no longer able to speak when palliative sedation is indicated.²⁷ Advance directives could include such decisions as well.

Because nurses often have close rapport with patients and families, they should ideally be present during the process of informed consent to ensure full understanding of the options, to assist and empower families to express their viewpoints clearly, and to provide a calm comforting presence and support. Vigilant attention to patient comfort and dignity and family support are key nursing interventions.

Safeguards

The interdisciplinary team should confirm that safeguards are in place to ensure that the use of high-dose opioids or palliative sedation is appropriate. Have all reversible causes for the severe symptoms been explored? Have all other treatment possibilities been tried or examined? Have all other resources been considered? Has informed consent taken place and documentation of such entered into the medical record?²⁵ An interdisciplinary team approach ensures that all options are considered.

The Issue of Food and Fluids in Palliative Sedation

The act of providing deep palliative sedation often prohibits the ability to eat or drink, which can be considered as an unintentional but foreseeable effect. The patients do have the right to refuse any treatment, including food and fluids, but when patients are sedated continuously and food and fluids are also withheld, death is inevitable. Some believe that in this case the DDE justification is "dubious" because the bad effect could have been avoided by providing nutrition and hydration, and death can be viewed as a result of clinician-induced dehydration rather than the underlying disease. ²⁵

As mentioned earlier, reviews of the literature reveal that palliative sedation itself does not necessarily hasten death. ^{26,28} Yet frequently, the initiation of palliative sedation is accompanied by the decision to forego or withdraw medications, artificial feeding, and hydration, a decision that may hasten death.

Decisions about sedation and decisions about artificial nutrition and hydration and continuing medical treatment should be made as 2 separate issues.²⁴ If there are indications to withhold food and fluids (for example, if they are exacerbating symptoms or if patient has previously refused them), it is appropriate that this decision be upheld. On the other hand, there may be situations where food and fluids were indicated before the sedation was initiated, and artificial nutrition and hydration may be continued, with the expectation that sedation may eventually be lightened.¹

PROPORTIONATE USE OF MEDICATIONS

A basic assumption of the DDE involves the concept of proportionate use of medications; the dose of the opioids or sedatives should be the lowest dose needed to achieve the goal of symptom relief. Supporters of proportional palliative care promote clinically appropriate, symptom-guided, and closely monitored sedation. He following recommendations can facilitate this well-considered intervention.

- 1. Form an explicit plan for symptom management, which may include opioids or sedation.
- 2. Include in the plan the decision about the potential for lightening of sedation and reassessment of need for the intervention.
- 3. Use consistent and validated symptom assessment tools (ie, nonverbal pain scales) for objective evaluation and use in determining criteria for dose escalation.
- 4. Address concomitant family suffering with education and emotional and spiritual support.
- 5. An institutionally approved, established procedure or protocol can facilitate optimal end-of-life symptom management. A variety of healthcare institutions and international professional organizations have published position statements and guidelines on palliative sedation for patients with intractable suffering. ^{14,29}

Ethics Review

Nurses and other care providers come to these complex situations with their own individual cultural beliefs and person values. Challenged with ethical dilemmas, nurses need to be able to reflect and explore any moral conflicts that may arise. Occasionally, there is a need for a clinician to opt out of care with the ability to refer care to an appropriate and knowledgeable alternate clinician. Professional and administrative support is integral in

these difficult scenarios. It is imperative that a mechanism exists where questioning clinicians can explore their ethical concerns. Nurses should be familiar with their institutional ethics review committees, policies, and resources.

Personal Reflection

Continuous personal reflection and mindfulness about ongoing ethical issues can lead to a more healthy response to the moral distress, which can result from exposure to extreme suffering and the clinical response to such. A spiritual-support person, a professional colleague, or a loved one can all be the means of helpful philosophical discourse on ethical issues such as the DDE and its usage in clinical decision-making. The complexities of the debates on such abstract ideas of intent and foresight should not discourage nurses from examining these complicated but intriguing concepts. The desire for ethical and compassionate caregiving should be the overarching motivation of all nurses, and perhaps considering the questions in a basic and simple framework is best. In fact, ethicist Daniel P. Sulmasy proposed a simple check about intention when considering the issues of aggressive symptom management versus potentially hastening death. He suggests asking oneself, "If the patient were not to die after these actions, would I feel that I had failed to accomplish what I had set out to do?"30 This simple question can cut through the abstract debate to clarify the underlying intent of one's intervention.

CONCLUSION

The DDE continues to be a source of controversy and lively debate. This is because of the basic ambiguity involving the fact that although an earlier death may not be intended it may also be considered a good outcome if suffering is present. Care providers may have mixed feelings about the patient's death. Despite these ambiguities, the DDE remains an ethical and legal touchstone around treatment of the terminally ill.⁴

Caring for those suffering at the end of life is, without doubt, a stressful endeavor. Rather than avoiding ethical discussions out of fear, ethical uncertainty, or legal ramifications, clinicians should remind themselves that it is their underlying compassion and conscience that mandates such inspection. As Berger⁴ writes, "DDE applies, not primarily in contexts in which one is looking to allocate praise or blame regarding past actions, but in contexts in which good people are struggling with what they ought to do in difficult cases."

Nurses should embrace these ethical discussions. By sharing and considering all perspectives and openly acknowledging complexity, we can continue to find intellectual and spiritual meaning and fulfillment in our frequently hectic and emotionally demanding practice.

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