

Principle of Double Effect and End-of-Life Pain Management: Additional Myths and a Limited Role

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IN HER MANUSCRIPT analyzing the relationship between the principle of double effect and effective pain management, Fohr critically explores the assumption that opioids, when used according to established pain management guidelines, pose a substantial risk of hastening death. She persuasively argues, and supports with a large body of clinical data, that good pain management is more likely to prolong life than shorten it, that it certainly improves the patient's quality of life, and that the risks of sedation and respiratory depression are greatly overstated in the literature. Clinical studies demonstrate that tolerance to the sedating and respiratory depression effects of opioids develops relatively quickly when compared with their analgesic effects. Therefore, the risk of encountering these symptoms as side effects is highest early in treatment, and they can be easily managed with dose adjustments and low-dose naloxone if needed. The risk of hastening death in these circumstances is remote and clearly unintended, and not dissimilar to the risk of death during routine surgery or the risk of prescribing other medications with rare, but potentially lethal side effects.

The fear of hastening death, or of being perceived to hasten death, is one of many barriers to effective pain management. Therefore, studies demonstrating the safety and effectiveness of good pain management need to be more widely publicized, and the link so reflexively cited between the principle of double effect and the prescription of opioids for the treatment of

chronic pain in the terminally ill needs to be broken. As Fohr suggests, the principle of double effect is no more relevant to usual pain management than it is to many standard medical practices.

Unfortunately, other myths with regard to pain and symptom management with the terminally ill where the principle of double effect may have more relevance are glossed over and even perpetuated in the article. I share the general belief that sophisticated pain relief techniques, along with the support of multidisciplinary programs of care such as hospice, can provide pain relief acceptable to the patient in "virtually all" patients throughout the dying process.¹⁻⁶ However, when defining "virtually all," the percentage cited by palliative care and pain relief specialists usually ranges from 95% to 98% of patients. This is very reassuring, unless you are unfortunate to be one of the 2% to 5% for whom pain becomes uncontrollable. In my clinical experience, most patients in this 2% to 5% have had good pain and symptom management for the majority of time in their terminal illness, but they unfortunately develop increasingly difficult problems as death approaches.

A more realistic look at the best case scenario of pain management in the terminally ill comes from studies of pain and symptom management of dying patients in hospice and palliative care programs. When such patients have been surveyed about their symptoms one week prior to death, 2% to 35% described their pain as "severe" or "intolerable."⁷⁻¹⁰ In one study,

an additional 25% described their shortness of breath as "unbearable."⁹ Studies about the patterns of analgesic use just prior to death show that some dying patients experience a "crescendo" of pain just prior to dying, requiring rapidly escalating doses of analgesics, although the exact percentages vary considerably between centers.⁷⁻¹⁰ As with pain, patients with mild to moderate shortness of breath can be symptomatically helped with small doses of around-the-clock opioids without significant risk of hastening death. However, a small percentage develop extremes of shortness of breath prior to death that require medically more aggressive and ethically more complex treatment.

The problems of accelerating pain or extreme shortness of breath just prior to death constitute medical emergencies¹¹ where the principle of double effect warrants consideration because the risk of hastening death, albeit by a relatively small amount of time, is clearly relevant. Of course, the goal of treatment in these circumstances is to relieve the patient's suffering, and patients may have strong views about what kind of intervention is acceptable. For example, some patients whose pain is unbearable prior to death may be refusing any opioids for personal reasons, despite being informed and encouraged to take advantage of them by the health care team. Other patients may choose to limit the dose of opioids to avoid sedation, so they can remain as alert as possible for their final days. If pain or other symptoms increase substantially prior to death, some patients may reach a point where they will accept being sedated to escape the agony. To achieve that goal, the dose of opioids and sedatives must sometimes be increased to the point where the patient loses conscious awareness of their suffering. Here the risk of hastening death is very real, either by causing respiratory depression, or by impairing the patient's ability to eat, drink, or handle secretions. In fact, a hastened death may be explicitly what the patient is requesting in order to escape suffering.¹²

The principle of double effect is important to some patients, families, and clinicians as they face these medical emergencies where the patient is highly symptomatic in the face of ex-

cellent palliative care and on the verge of death with no realistic prospect of recovery or improvement. The principle may be especially helpful to those who believe that hastening death is absolutely wrong no matter how egregious the patient's suffering and how ready the patient is to die. For the aggressive management of pain or shortness of breath with accelerating doses of morphine, death can be viewed as a foreseeable outcome of treatment, but not its purpose. The principle requires that the patient's suffering is proportionately severe to warrant the risk of hastening death. Although the principle of double effect is important to many clinicians depending on their religious and ethical training and may allow them to respond to such critical situations without violating fundamental moral tenants, it is not necessary for all to share or accept this rule.¹³ For example, some patients in the same circumstances may be prepared for death and want to hasten death by any means possible, the sooner the better. Because the moral prohibition against intentionally hastening death is at the core of the rule of double effect, the patient's open expression of intention may make some clinicians more reluctant about acting. On the other hand, other clinicians may view sedating these patients to unconsciousness to escape from their pain, and then not giving them food or fluids, as a form of "slow euthanasia," which is clearly outside the boundaries of the principle of double effect.¹⁴ This may or may not preclude them from participation, depending on how they view the possibility of intentionally hastening death as a last resort in these difficult cases. Because there is some ambiguity inherent in these actions,¹⁵ we need to learn more about how bedside clinicians think and feel about them,¹⁶ rather than prejudge how they should be thought about according to abstract ethical or religious principles.¹⁴

Now back to the original question: Does the principle of double effect, with its reliance on the subjective realm of intention that cannot be reliably measured, evaluated, or verified, have relevance to pain management and end-of-life care? The answer, in my opinion, is a qualified yes. As argued by Fohr, the principle is simply irrelevant to the vast majority of pain manage-

ment cases because the risk of hastening death is so remote, and clearly unintentional if it were to occur as a rare side effect. Its application to usual pain management activities may create irrelevant ambiguity and hesitation that is unnecessary, and not warranted by available data.

The principle of double effect should be used when it is important to patients, families, and health care providers who believe in an absolute prohibition against intentionally hastening death as they respond to accelerating terminal pain or suffocation at the very end of life. The principle is not absolutely necessary, however, to respond to these challenging clinical problems, and is less fundamental than the following domains¹⁷:

1. Is the patient's suffering proportionately severe to warrant the risks of the intervention?
2. Has the patient been fully informed about all likely outcomes of the intervention, both intended and foreseen, and is he or she aware of all reasonable alternatives? (If the patient is not capable of consent, then the family or surrogate decision maker must consent on the patient's behalf using the principle of substituted judgment.)
3. Is the intervention the least harmful one available, given the patient's clinical circumstances and personal values?

These considerations have relevance, whether or not one uses the principle of double effect, to any last resort intervention where there is considerable likelihood that death will be hastened, including accelerating doses of opioids to treat terminal pain or shortness of breath, terminal sedation to treat other severe symptoms, withdrawal of life-sustaining therapy, voluntarily stopping eating and drinking, or physician-assisted suicide.¹⁷

People of goodwill and considerable clinical and ethical experience may view and use the principle of double effect very differently as they evaluate end-of-life practices. To the extent that the principle allows patients, families, and clinicians to respond in an ethically and clinically responsible way to palliative care emergencies without violating the fundamental values of any of the participants, it should

be used and protected. To the extent that it overstates the risks of usual pain management, reinforces uncritical thinking about inherently complex actions, allows clinicians to avoid responsibility for reasonably foreseeable outcomes, and encourages the expression of multilayered intentions in a nongenuine, "politically correct" fashion, the principle of double effect should be abandoned as a guide to end-of-life treatment.

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