The Use and Abuse of the Principle of Double Effect

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The principle of double effect (PDE) is an important principle of medical ethics. Yet it is often poorly understood, abused, and criticized. In this article, the author explains the purpose of the PDE. It is further explained that the PDE requires (1) that there be two effects that follow from the doctor's actions; (2) that one effect be intended and the other unintended; (3) that the unintended bad effect cannot be the cause of the intended good effect; and (4) that the good effect must outweigh the bad effect. The differences between intentions, beliefs, desires, and motives are explained. Screening questions about clinical intentions are proposed, and guidelines for morphine dosing that would be consistent with an intention to relieve pain and not to cause death are offered. The PDE does not relieve physicians of responsibility for their actions, but only sets conditions under which they may not be held morally culpable for the unintended side effects of actions they undertake responsibly. As an example, the use of morphine is distinguished from the use of pancuronium to treat the gasping of a patient for whom ventilator treatment is being discontinued. The PDE would permit the use of morphine, but the PDE would not permit the use of pancuronium in such a case.

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The principle of double effect is a much maligned, much abused, and much misunderstood principle of medical ethics. Yet, if properly applied, it is a critically important moral principle for any physician who believes that morality does not depend solely on the consequences of a given intervention.

Some physicians *do* believe that acts are morally justified solely on the basis of the consequences. For them, no rule or duty is absolute. They do not need a principle of double effect. The right thing to do in any given situation always depends on the consequences.

But many clinicians have moral beliefs that present them with a series of principles and rules that they are told never to violate. The Ten Commandments is an example of such a set of moral rules. The Hippocratic Oath is another. Many physicians believe that they have a number of moral duties, including a duty to help patients to be cured of their illnesses and to be relieved of their symptoms, a duty to be honest with patients, a duty to preserve life, a duty to respect patients' dignity and autonomy, and others.

Those who follow moral systems with rules and duties can have a harder time in clinical practice than physicians who believe that the right thing to do depends solely on the consequences. Duties may be in conflict. There is a duty to promote the good of the patient—e.g.—to relieve pain. On the other hand, there is a also a rule against killing patients, at least according to those who follow the Hippocratic precept that one must "never administer a poison to anybody when asked to do so." (1) Giving morphine to a patient who is dying because of respiratory failure is likely to hasten that death. Would this not mean that the doctor would be killing the patient by giving morphine? Would this knowledge, therefore, force a physician to abandon the duty to help the dying patient with pain relief? How does one resolve such a dilemma? The principle of double effect offers one way for helping to do so.

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THE PRINCIPLE OF DOUBLE EFFECT

The principle of double effect (PDE) states that one may, in conflict situations, violate one moral rule in order not to violate another. But one cannot do so willy-nilly. The PDE sets five mandatory conditions (2):

1. There must be two effects that follow from one's action, one good and one bad.
2. The action cannot be evil in itself.
3. One must sincerely intend the good effect, not the bad effect.
4. The bad effect cannot be the cause of the good effect under one's plan.
5. The good that one foresees must be proportionately much greater than the bad that one foresees, but does not intend.

Although it sounds complex, physicians engage in this sort of reasoning intuitively all the time. For example, a physician may contemplate giving morphine to a patient who is dying because of respiratory failure. Such a physician generally fulfills all five conditions of the PDE. First, the physician clearly knows that there are two likely physiologic effects that follow from this action—pain relief and respiratory depression. The physician might even believe that these effects are mediated by different subtypes of μ receptors. Second, it would be odd for a physician to think that there would be anything intrinsically evil about injecting morphine. Third, assuming that this physician subscribes to the Hippocratic moral code, which states that physicians should not kill their patients but yet have a duty to help them (1), the physician might very sincerely intend only the pain relief, but not the death of the patient. Fourth, although it is true that death by morphine intoxication would end the suffering of the patient, this cannot be the physician's plan according to the PDE. The physician must plan to relieve pain by the direct analgesic effects of morphine. The physician cannot plan to relieve pain by way of the death caused by a rapid intravenous infusion of a lethal dose. Competent clinicians readily recognize the difference between these two plans and know how to carry out one and not the other. Fifth and finally, clinicians must judge that the direct benefits of their acts, namely the pain relief caused by the analgesic effects of morphine, constitute a proportionately much greater good in these circumstances than the bad of hastening the inevitable death of the patient. A good clinician would judge this to be the case. If so, then, according to the PDE, the physician may proceed with a clear conscience. The physician's dilemma has been resolved: the morphine can be administered and the duty to relieve suffering fulfilled without violating the duty not to kill a patient.

INTENTION: NOT BELIEF OR DESIRE

Clinicians sometimes worry that this is all specious and that anything one foresees as coming about because of one's clinical actions, or any outcome one foresees and desires, is actually intended. But the notion that intention is the same as belief or desire is overly simplistic (3).

For example, consider the fact that many clinicians every day intend to do things that they do not desire (e.g., answering pages at 2 AM). Clinicians also intend to do things that they do not believe will happen (e.g., trying against all odds to resuscitate a previously healthy 21-year-old victim of a motor vehicle accident who ends up in the emergency department pulseless and breathless with multiple traumatic injuries). Having an intention requires that one must *commit* oneself to bringing something about. This is not a belief or a desire. So, for example, consider the case of Karen Ann Quinlan. One may suppose that everyone *believed* that she would die after disconnecting her respirator. It is likely that most parties involved, motivated by a concern that her long-suffering state should end, *desired* that she should die after disconnecting the respirator. But this does not mean that they *intended* that she should die by the means of disconnecting her from the ventilator. One can easily suppose that the disconnection itself, not the death, fulfilled the intention of their action. If asked what the aim was, one could suppose that the family would readily have responded that their goal was the removal of the ventilator, which they believed to be an obstacle to death. It would seem that the intention of the act (what they were committed to bringing about by way of their act) was to have Karen off the ventilator, not to have Karen dead. As is well known, despite any beliefs or desires to the contrary, Karen Ann Quinlan began to breathe on her own after being disconnected. She survived for 10 more years.

Clinicians who want to explore their intentions in such situations ought to ask themselves the following two screening questions. These questions are far from perfectly sensitive or specific, but they can serve as a useful starting point for an honest exploration of intentions.

If, hypothetically, the outcome that you claim to foresee but not intend were to fail to come about

- How would you feel?
- What would you do?

Suppose, for example, that you were caring for a morphine-naive patient who was suffering from lung cancer. Suppose you were to consider injecting 20 milligrams of intravenous morphine sulfate over 15 minutes of careful titration and elicitation of feedback from the patient. Suppose that if you had done so, the patient were to express relief from pain but to have become somewhat somnolent with a respiratory rate slowed to 10 breaths per minute. How would you feel? Would you feel that you had failed? Would you be frustrated that the patient was still alive and still suffering from existential angst despite relief of pain? What do you think you would do? Would you next draw up a syringe filled with 50 milligrams more morphine sulfate with a plan to inject it over 1 minute? If you were sincerely to answer, "No," to these questions, this is consistent with an intention to relieve pain and not to kill. If you were sincerely to believe that you would not plan to take further measures to try to bring about the patient's death (the result that you claimed not to intend), this is also perfectly consistent with an intention to relieve pain and not to cause death. If you were sincere about your answers to these questions and sincere in the intention to relieve pain and not to kill, then even if it were to turn out that the respiratory rate were to have dropped to 6 and not to 10 after a slow and careful injection of 20 milligrams of intravenous morphine, and if the patient were to have died 30 minutes later, you would have satisfied

all the conditions of the PDE, and you would be able to proceed with a clear conscience.

INTENTIONS ARE NOT MOTIVES

Sometimes physicians confuse intentions with motives. For example, a physician who gives a dying patient who has no previous narcotic exposure 20 milligrams of intravenous morphine and a physician who gives that same patient 1000 milligrams of intravenous morphine may both have the same motives, but they clearly have different intentions. Both are likely to be motivated by mercy and a desire to relieve suffering. But, one intends to relieve suffering by causing analgesia and the other intends to relieve suffering by causing death. Motives *start* intentions but are not the same as intentions (4). An intention is a commitment to bring about an event in a certain way. Motives help to explain why one has an intention, but a motive is not an intention.

DOSAGE, INTENTION, AND ACTION

Physicians sometimes worry about basing morality on intentions, in part because intentions are so difficult to know (5). They ask, could not a doctor administer massive doses of morphine, claiming to be intending only the analgesic effects but merely foreseeing the lethal respiratory depressant effects?

It is true that intentions can be difficult to know. But the fact that there are some gray areas does not mean that the distinction between what is intended and what is unintended is meaningless. As philosopher Elizabeth Anscombe once observed, "The fact of twilight does not mean that you cannot tell day from night." (6)

These worries may be most intense in the case of a drug such as morphine. Therefore, I would like to offer a few rough-and-ready clinical criteria for distinguishing between killing and foreseeing death as a side effect when using morphine under the auspices of the PDE. Little is known about how much morphine constitutes a lethal dose, because until recently physicians were more preoccupied with the safety than with the lethality of morphine, and no one has conducted controlled clinical trials to determine how much would be required to kill a human being. Most of the data available are, therefore, based on retrospective analyses of accidental overdoses. And further, there is a great deal of variation among individuals, and tolerance to various effects of the drug develops in individuals who have been treated with long-term morphine therapy. Nonetheless, based on what is presently known about morphine dosing (7–12), I would propose the following rules of thumb for clinicians:

1. For morphine-naive individuals not being treated with other sedatives or suffering from underlying respiratory embarrassment, initial doses in excess of 250 milligrams orally or 60 milligrams intravenously; *rapid* intravenous administration of morphine (i.e., delivering a bolus in much less than 5 minutes); and rapid repetition of escalating doses (e.g., increasing doses at 5-minute intervals) are all more consistent with an intention to kill than to relieve pain.

2. For individuals treated with long-term morphine therapy at a given level of drug tolerance, a dose that would have been sufficient to cause the death of the patient in the absence of the underlying terminal condition, and at that level of tolerance, would be proscribed as independently lethal. To administer such a dose would certainly indicate an intention to cause death. Rapid intravenous administration of single boluses greater than or equal to the baseline maintenance dose or rapidly repetitive boluses at doses escalating by more than double the baseline dose are also more consistent with an intention to kill than to relieve pain.

3. Doses less than these independently lethal doses that nonetheless hasten the death of the patient because of the combined effects of the drug and the underlying terminal condition may plausibly be consistent with intending pain relief and not death under the PDE. As the dose approaches the independently lethal dose, the claim that one intended only pain relief and not death becomes less plausible.

4. Increasing doses given to individuals who are already comatose and not apparently capable of experiencing pain are inconsistent with an intention to relieve pain but not cause death.

The justification for using a massive dose could only be that analgesic doses have not been effective in relieving all suffering and that what is intended is to relieve suffering by death. One should note, for example, that only a minority of Dutch patients who seek euthanasia or assisted suicide report that the suffering they experience is due to unrelieved pain (13). It would not be possible for a physician credibly to claim to have intended only pain relief in administering 1000 milligrams of morphine by rapid intravenous infusion to a patient who had no previous exposure to morphine and no tolerance to the drug. Because the massive doses of morphine in such cases would be used to bring about the bad outcome (death) in order to achieve the intended good outcome (relief from suffering), the fourth condition of the PDE would be violated.

RESPONSIBILITY AND DOUBLE EFFECT

Some commentators have expressed worries that justifying physicians' actions by the PDE might imply that physicians bear no responsibility for the effects of their actions that they claim were not intended (14).

This, however, is a misinterpretation of the PDE. Although space considerations prohibit a full explanation of the philosophy of intentional action, it may suffice to discuss the difference between intended consequences and side effects (3,4). If I undertake an action intentionally, I am responsible for the act and for all of the consequences that I could and should have foreseen. But I am not always judged to have acted immorally if some foreseen but unintended consequences occur. This is what is meant by a side effect. To say that something is a side effect has moral meaning. I am responsible for the side effects that I foresee and cause. I can only risk bad side effects for an important reason. But if a side effect is foreseen, yet unintended, and the action is nonetheless undertaken for a good reason, I am not always judged to be guilty of having acted wrongly. The PDE is a means of assuring that such decisions are made responsibly.

The concept of a side effect is ubiquitous in clinical practice. This is how the PDE plays its important role. If I operate on a patient knowing that a scar is likely, I do so *intentionally* and accept responsibility for the scar as a side effect of the operation. But *the in-*

tention of my action is only the removal of the diseased appendix, not the scar that I can foresee as a likely side effect. I can also give morphine *intentionally*, knowing that it might hasten death, but *the intention* of my action would be pain relief and not the death of the patient.

I can apply the screening questions to test my sincerity. I would not feel frustrated if the patient were to experience pain relief but were still breathing. I would not seek alternate ways to try to cause the death of the patient. Under these circumstances, I would not be held blameworthy for giving the morphine, but I would still be responsible for making a careful decision. I should not give morphine and risk an accelerated respiratory death to treat a minor pain that could be relieved by acetaminophen.

The PDE is a means of assuring that such decisions are made responsibly. To be morally acceptable, the act must fulfill the conditions of the PDE. The third condition of the PDE requires that death not be *the intention* of the physician's action. The fourth condition requires that death must not be the cause of the good for which the physician aims, that is, the relief of pain. And the fifth condition requires that the reason to proceed despite the side effect must be proportionate. In this case, it is. If the patient is dying anyway, pain control would become paramount. Therefore, the use of morphine would be justified according to the PDE.

A surgeon is not judged to have behaved in a morally wrong fashion because he caused a scar in performing an appendectomy. Certainly, a surgeon could be blamed for trying to cause a scar, or for causing a scar but not performing the operation. But in most cases one can presume that it is not the surgeon's *intention* to cause a scar; it is not something the surgeon is committed to achieving. One who uses the PDE to make a decision is responsible for the decision and responsible for all the effects of that decision. The PDE only states that if its conditions are met, one cannot be blamed for the bad side effects that one could foresee but did not intend.

ONE PRINCIPLE AMONG MANY

Another objection to the PDE is that it sometimes seems that the right thing to do would be to bring about a bad event in order to cause a good event (i.e., doing evil in order to achieve good) (15). The fourth clause of the PDE would seem to prohibit this. Consider, for example, the amputation of a gangrenous limb. Losing a limb is bad. Yet, one could not claim that the amputation was not the cause of the good intended—the saving of the patient's life. So, it would seem as if an act so common as amputation could not be justified by the PDE.

This assessment is correct as far as the application of the PDE is concerned. The amputation could not be justified by the PDE. But this is not an objection to the PDE. The PDE is not the sole principle of medical ethics. In traditional Roman Catholic medical ethics, for example, no one would think to try to justify amputation by appeal to the PDE. These cases are covered by another principle, the principle of totality, that suggests that one may legitimately remove parts of a human being's body in order to preserve the life of that human being (15). Similarly, there are a number of other principles of this system of ethics that are relevant to medical ethics. There is a principle of cooperation governing interactions with persons who are engaged in acts that one considers immoral. There is also a distinction between ordinary and extraordinary means. Each of these applies to a different set of circumstances, and that is why it is not legitimate to criticize the PDE on the grounds that it does not cover all of these circumstances. It was never meant to do so.

AN INTERESTING EXAMPLE OF THE ABUSE OF DOUBLE EFFECT

A case was recently discussed in which an intensivist argued that the PDE justified the use of benzodiazepine sedation and pancuronium neuromuscular blockade before discontinuation of ventilator support for a conscious 78-year-old woman who was dying of complications of viral pneumonia (16). The authors were justifiably suspicious of this reasoning, but it is instructive to see precisely why this is an abuse of the PDE.

Most people would feel a bit uneasy about giving this patient pancuronium but would not feel similarly uneasy about giving morphine. The PDE can help to explain this intuitive discomfort.

The intensivist might want to claim that there were two effects of the pancuronium. There would be a good effect of preventing the patient from gasping, both for her sake and for her family's. But there would also be a bad effect—her death via respiratory arrest. Could the physician who used pancuronium rationally claim to intend only the prevention of gasping and not the acceleration of the patient's death?

I think not. This claim is no more rational than a claim that one intended only to swallow food and not to eat it. Pancuronium causes the patient not to gasp by causing her not to breathe. Causing her not to breathe is killing her. To legitimately apply the PDE, the bad that one foresees but allegedly does not intend cannot be the cause of the good that one intends. Neuromuscular blockade prevents gasping by preventing breathing. To prevent someone from breathing is killing. Therefore, one cannot claim to intend only to prevent gasping while not intending to cause death.

By contrast, consider the use of a therapeutic dose of morphine in this same situation. Morphine would ease her gasping. Yet it would do so not by causing complete respiratory arrest but by easing her pain and sense of respiratory distress. All of these pharmacodynamic effects of morphine would be occurring through different subtypes of opiate receptors at different locations in the central nervous system and with different dose-response curves and different kinetics. Clearly, some respiratory depressant effect is likely to occur. However, it is not necessary that complete respiratory arrest should occur in order for the patient to experience relief from the symptoms of respiratory distress. Hence, one *can* legitimately claim to intend one event and not the other and can apply the PDE correctly in this situation. Given that the patient is dependent on a respirator, that it is burdensome for her to continue this treatment, that the likelihood of recovery is negligible, and that the family has stated that they think the patient would deem the burdens of treatment disproportionate to the benefits, it would be legitimate to declare the treatment extraordinary and to withdraw respirator support. Once one had decided to withdraw support, one

could apply the PDE to examine the use of morphine. Each of the conditions of the PDE would be fulfilled. Morphine is not intrinsically evil. One can rationally intend to relieve respiratory distress without intending respiratory arrest. Relief from respiratory distress would not be caused by respiratory arrest. And in the situation of imminent death, the anticipated good of symptom relief would seem proportionately greater than the bad of hastening that death by the side effect of respiratory depression. The PDE would, therefore, allow the use of morphine in this setting, but not the use of pancuronium.

SUMMARY

The PDE can play an important role in clinical bioethics, but it must be used carefully. One will require a moral principle like the PDE if one believes that intentions play a critical role in ethics and that deciding whether an act is right or wrong does *not* depend solely on the consequences. Such physicians, facing conflict situations, must often choose to tolerate unintended side effects in order to achieve good. Considered in this light, the PDE is ubiquitous in the justification of medical practices.

The PDE has been criticized on the grounds that there is nothing special about intention. Some argue that every outcome that a physician desires or believes will result from a particular act is intended. However, this represents a very superficial understanding of the notion of intention. Intention is not the same as desire or belief. It is not the same as motive. Intention involves a commitment to bring about an event, even if one does not desire it and even if one believes that it is well-nigh impossible, no matter what the motive is.

The PDE has also been criticized because it is said illegitimately to relieve physicians of moral responsibility for the consequences of their acts. But this is a caricature of the PDE. The PDE does not relieve physicians of their responsibility for the consequences of their acts. Rather, it states under what conditions they might not be held culpable or blameworthy for the bad consequences that they foresee, but do not intend, in making a decision for which they are fully responsible.

Further, the PDE has been criticized as blocking *all* cases in which one causes some harm or loss in an effort to do something good. This criticism reflects a naive understanding of the role and the limits of the PDE. The PDE is not the *only* principle of medical morality. One needs to understand when and where to apply the PDE and how to use it properly.

Finally, the PDE has been criticized for allowing physicians to justify almost anything simply by redirecting their intentions. But intention redirection is an abuse of the PDE, not a legitimate use of the PDE. Physicians must be honest with themselves. Physicians cannot claim to intend a consequence that depends on the event that they foresee but claim not to intend.

The PDE is a principle of moral realism that is very appropriate for medical practitioners to understand. Side effects are the rule, not the exception in medical practice. Used correctly, the PDE helps physicians to navigate in a real world where it is often impossible to do any good at all for patients without risking harm. The PDE also helps to put appropriate moral limits on the effort to do good for patients. Not just *anything* can be justified as long as it all works out for the best. To those practitioners who believe that the end does not always justify the means, the PDE is an essential moral tool.

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