Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated?

**Deactivating Permanent Pacemaker in Patients With Terminal Illness**

Patient Autonomy Is Paramount

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Cardiovascular implantable electronic devices (CIEDs) are common in the United States as treatment for cardiac rhythm problems. These devices can be life-sustaining. As patients age and suffer from worsening cardiac-related disorders and other terminal illnesses, the electrophysiology community can expect increased requests for device deactivation from patients and their surrogates, creating tension between competing ethical obligations to respect patient autonomy, on the one hand, and to promote patient well being (“beneficence”) and avoid harm (“nonmaleficence”), on the other.

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The ethical propriety of withdrawal of other similar life-sustaining treatments, such as ventilator support and implantable cardioverter-defibrillator (ICD) shock therapy, is now well established.1–3 Despite this, withdrawal of pacemaker therapy remains controversial. This report examines the sources of this controversy and supports the conclusion that there is no ethically significant difference between pacemaker therapy and other life-extending treatments and that requests for its withdrawal from competent informed patients or their surrogates should be honored. Because pacemaker therapy is discussed here in the context of life-sustaining therapy, the concepts apply mostly to pacemaker-dependent patients. Discussions regarding CIED therapy withdrawal should occur early in the patient’s care and should not be distinguished from other forms of life-saving treatment. In each case, the discussion should involve a determination of the patient’s goals and preferences, which are entitled to respect.

Discussion

In 2008, the American College of Cardiology, American Heart Association, and Heart Rhythm Society issued Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Guidelines).3 The Guidelines state that caregivers “generally make a distinction between deactivating a pacemaker and deactivating an ICD or CRT device.”1 Physicians are understandably uncomfortable when faced with a request for deactivation of pacing therapy provided to pacemaker-dependent patients whose death will likely ensue from their underlying disease. Allowing death to occur, even at the end...
of life, runs against the grain of physician training to heal patients and often is perceived as a form of failure.2

The Guidelines do not imply that deactivation is unethical but state that ICDs and pacemaker deactivation may be requested by the patient and that honoring this request “should not be regarded as either physician-assisted suicide or euthanasia.”1 Like the Guidelines, the Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (ECM), also issued in 2008, emphasizes patient autonomy and states: “withholding or withdrawing [life-sustaining] treatment on the patient’s instruction is not equivalent to aided suicide or euthanasia.”1 The Guidelines reflect the evidence-based opinions of experts and are not mandates. The circumstances of individual patients may differ, requiring the judgment of the health care provider. The Guidelines and the ECM do recognize a clinician’s right to withdraw from the treatment of a patient based on a conscientious objection and to refer the patient to another physician.1,3

Core Ethical Principles
The established ethical principles that govern deactivation of CIEDs and other treatments include autonomy, beneficence, and nonmaleficence.1–7 Of these, autonomy is paramount for competent adults because of their politically sanctioned right to live by their values.5,8 Based on personal preferences and goals, an informed patient, with the requisite mental capacity for decision-making, can refuse treatment, including life-sustaining interventions.3,4,6 No ethical or legal distinction exists between withholding and withdrawing treatment.1,9 The seminal Quinlan case follows this principle, finding that life-sustaining treatment can be withdrawn without imposing liability.10 The Guidelines reflect this: “The withholding and withdrawing of life-sustaining treatments … from terminally ill patients, who do not want the treatments, is ethical and legal.”1

The concepts of beneficence and nonmaleficence delineate the physician’s part of the ethical axis. Beneficence, or promotion of the patient’s well-being, is fundamental in medicine. A complementary relationship exists between it and autonomy. Physicians define the medically acceptable treatment options that will promote patient well-being. However, because of autonomy, competent well-informed patients may identify a particular treatment option as best for them or refuse treatment altogether. Thus, patients define “beneficence” for themselves in light of their own values.8

Nonmaleficence complements beneficence; it prohibits acts or omissions that harm the patient. In ethics, the concept of harm refers primarily to moral harm and not merely to the occurrence of an adverse outcome.2,11 Thus, withdrawal of care is nonmaleficent if done in accordance with the wishes of a competent patient, even when an existing pathology runs its course and results in the patient’s death.2,9,11 Under this circumstance, the withdrawal does not cause moral harm to the patient.2,11

According to the American Medical Association, with respect to end-of-life care, the physician’s obligation is explicit and essentially unconditional: “Whether the intervention be less complex (such as antibiotics or artificial nutrition and hydration) or complex and more invasive (such as dialysis or mechanical respiration) and whether the situation involves imminent or more distant dying, patients’ preferences regarding withholding or withdrawing intervention should be honored in accordance with the legally and ethically established rights of patients.”12

Approaches to Ethical Deactivation
Several approaches to the ethical issues concerning device deactivation have been offered in the literature. All share the same ethical tipping point. Specifically, preexisting disease progression, absent device therapy, is the ethical and legal bright line differentiating the patient’s natural death from illicit killing and physician-assisted suicide.2

The concept of treatment benefits or burdens is discussed by Pellegrino11 and Rhymes,3 who address the case of a pacemaker-dependent patient with progressive dementia whose surrogate had requested deactivation of the implanted pacemaker. Under Pellegrino’s analysis, futility of the treatment (pacing therapy) results when the “effectiveness” of the treatment (capacity of the treatment to alter the natural history of the disease) is weighed against the benefits and its direct and indirect burdens, as perceived by the patient. Although the pacemaker prolongs life, it does not cure the existing cardiac pathology or halt the progressive effects of dementia. Given this fact, withdrawal of pacing therapy results in no moral harm.11

Rhymes uses a similar benefit/burden analysis. If, in the patient’s eyes, the burden of the pacemaker, even if small, outweighs the benefit of a prolonged life, the pacemaker may be deactivated.9 Rhymes states that when a physician “deactivates a pacemaker in a patient who may die of cardiac arrest, the physician is not introducing a new pathology as the cause of death. Rather … an existing disease pathology is allowed to complete its natural history, no longer interrupted by medical intervention.”9 The withdrawal of technology only changes the time of death and the physician is not deemed to kill the patient.

In a recent article, Sulmasy13 offers another alternative analytic framework for consideration and discusses the philosophical relationship between “self” and internal interventions such as an ICD. Sulmasy considers whether the device replaces an organ or body part (and in that sense becomes an organic part of the patient) or substitutes for or supports an impaired function. If the former, its withdrawal could be an act of unethical killing. If the latter, neither killing nor assisted suicide takes place and withdrawal can be morally permissible. Sulmasy concludes that an ICD is a substitutive device and therefore may be ethically deactivated at the patient’s
request. Though Sulmasy does not discuss cessation of pacemaker therapy, it would be incorrect to conclude that a pacemaker, unlike a defibrillator, is a “replacement” and its deactivation is therefore unethical. Why?

According to Sulmasy, a replacement provides a function that has been pathologically lost. “Replacement therapies become part of the restored physiology of the patient, part of … an intact individual organism.” As examples, he refers to heart, kidney, and islet cell transplants. Substitutive interventions also provide a lost function and may assist in stabilizing the patient, but they do not become an organic part of the body.

Sulmasy lists 6 criteria as a basis for determining whether an intervention is a replacement or substitutive. When these criteria are applied critically, there is no substantive difference between pacemakers and defibrillators:

1. Response to changes in host organism. Although both devices respond to changes in the heart’s electrophysiology, those responses are distinctly different from the organic interaction with the body, as is the case with a transplanted heart or kidney.
2. Growth and self-repair. Neither device grows or repairs itself or is self-sustaining. A malfunction requires expert repair or replacement.
3. Independence from external energy and supplies. Both devices rely on batteries, which deplete and then require replacement at periodic intervals. Neither is independent from external energy sources.
4. Independence from external expert control. Pacemakers and ICDs are subject to periodic device checks. Although many pacemakers function independently, they can and often are under expert control from outside the body.
5. Immuno compatibility. The devices are compatible with the body in the sense that they are inorganic and not subject to immunologic rejection. However, the nature of compatibility differs from examples of a replacement (eg, a transplanted heart), where tissue and antibodies must be compatible.
6. Integration into the body. Both are foreign to the body but are placed in it, consisting of an energy source and leads to the heart.

Using Sulmasy’s criteria, if an ICD is substitutive, with its continuous sensing capacity, so too is a pacemaker.

Some might argue that the pacemaker is integrated into the body because it is implanted, but this untenable. The first pacemakers were external to the body but performed the same function as internal pacers. Implanting the device under the skin does not change the nature of the device, only its location. Like pacemakers, left ventricular assist devices are likely to become internalized. The location of the device, Sulmasy says, is of no moral significance.

These electronic devices, paraphrasing Sulmasy, assist the heart to perform its normal physiological function in an abnormal way. They remediate but do not replace or restore the impaired natural electric conductivity of the heart. In both cases, the heart’s organic function remains abnormal. As the body deteriorates at the end of life or in the course of illness (due to profound acidosis, hypoxemia, and so forth), pacemakers and ICDs gradually become less effective as the heart fails to respond to artificial conductivity provided by the devices. At best, the devices produce a temporary condition of medical stability from bradycardia.

The continuous operation of an internal device and its life-sustaining function do not substantively distinguish it from external interventions that perform the same function. A ventilator, outside the body, supports an impaired respiratory function. Likewise, an ICD and pacemaker support a damaged or defective heart. Both devices and the ventilator may extend life; all 3 embody sophisticated technology; all can be withdrawn or turned off by a switch. There is no ethically meaningful difference because one intervention is located outside the body and the other is implanted in it. The outcome of turning off or withdrawal is the same, allowing death to occur at some point as the result of the patient’s illness. If one accepts that turning off a ventilator is ethical under appropriate circumstances, then one must also accept that turning off a pacemaker is as well.

An analogy can also be drawn with the treatment of diabetes. An implanted pump used to provide insulin to a diabetic does not eliminate diabetes or restore pancreas function. Similarly, the pacemaker provides needed electric impulses to the heart. Periodically, the insulin pump needs a supply of insulin from outside the body, just as a pacemaker requires new batteries. The pump keeps glucose levels within normal range and alleviates the eroding impact of diabetes. In contrast, implanted islet cells become an indistinguishable part of the body and restore the function of the pancreas. It is an overstatement to claim that an internal pump or pacemaker constitutes a “replacement” for an impaired pancreas or heart.

To define withdrawal of pacemaker therapy as “killing” the patient or “physician-assisted suicide” not only violates accepted usage of these terms, it would also force patients to suffer unwanted continued medical interventions just as much as intermittent ICD shocks prolong an unwanted extension of life. It means, having implanted the device under one set of circumstances, the patient is condemned by his physician to its use despite changed conditions and patient desires. For these patients, the device is obsolescent and has outlived its useful life. Forced treatment of competent adults is contrary to the beneficent and nonmaleficent practice of medicine.

For some time, clinicians resisted cessation of ICD therapy and were reluctant or unwilling to discuss ICD deactivation even at the end of life. Today, the comfort aspects of ICD...
withdrawal are recognized.4–6 As a result, ICDs are often deactivated at the end of life under appropriate circumstances and with valid authorization. Nonetheless, there are physicians who remain uneasy about pacemaker deactivation. This is partly because of the difference between withdrawing ICD shocks and pacing therapy in a pacemaker-dependent patient whose death may occur rapidly after withdrawal. Such discomfort often involves a misplaced sense of responsibility for death associated with the withdrawal of treatment as opposed to withholding it. It also reflects a commendable unwillingness of physicians to easily accept the death of a patient.2,16 Resisting death on behalf of patients is a virtue, but it becomes a vice when done at the expense of the patient’s right to decline treatment.

At the end of life, an ICD can cause discomfort to patients, and clinical considerations might dictate its deactivation. Pacemaker therapy is different from ICD therapy; one provides therapy for rapid arrhythmias and the other provides painless therapy until death is near. This distinction also makes physician compliance with the request more difficult. It is easier to withdraw painful shocks than it is to withdraw painless impulses that temporarily support life. Pacemaker deactivation will vary by device model but may be accomplished by programming the mode or programming the output to subthreshold levels. Caring physicians might counsel against termination of pacemaker therapy imperceptible to the patient on the grounds of comfort to avert symptomatic bradycardia, worsening heart failure, and syncope.5 Additionally, patients and families may feel that the device will continue to keep the heart beating and prolong life. In this regard, patients, surrogates, and families should be counseled that, at end of life, acidosis and hypoxia will prevent capture and thus the pacemaker itself is not artificially prolonging life. Although leaving the pacemaker active may be a comfort measure, deactivation would not be the moral cause of death.11 If, after counseling and explaining the consequences of deactivation, the patient persists in the request for deactivation, it is ethical and proper to do so even though the caregiver disagrees and death from the underlying cardiac or noncardiac illness may ensue.

Conclusion
We recognize that some in the electrophysiology community might decline to deactivate a pacemaker, based on a conscientious objection. Such objections, however strongly held, are not a legitimate basis for caregivers to impose their personal moral values on patients or to characterize other clinicians, who would deactivate the device, as favoring or engaging in euthanasia. No physician should perform deactivation of a pacemaker if she or he conscientiously objects. In this case, a physician has the obligation to transfer the care of his or her patient to a physician who is willing and able to carry out the well-informed decision of the patient.

Mainstream biomedical ethics and professional practice standards recognize the propriety of withdrawal of life-sustaining treatments. Whether the life-sustaining treatment is medication, food, water, or ICD or pacemaker therapy is itself not morally relevant; nor is whether the device is internal or external. For competent adults, patient autonomy or control over one’s body is the overriding principle associated with medical therapy. Thus, an informed patient or surrogate, with capacity to make medical decisions, has a right to refuse any and all medical treatment, including continued pacemaker therapy.

Disclosures
Dr Lewis receives speaker honoraria from and is a consultant for Medtronic.

References
In keeping with the principle of autonomy, patients have the right to request withdrawal of medically futile treatments. Why, then, do physicians feel uncomfortable about deactivating a pacemaker in a pacemaker-dependent person, but not when deactivating an implantable cardioverter-defibrillator? For pacemaker-dependent patients, the progression of their underlying disease will eventually result in failure of pacing stimuli to capture the heart, and death will occur naturally. In contrast, to intentionally interrupt pacing in such a patient probably will result in their nearly instantaneous death, regardless of their underlying medical illnesses (if any). To stop pacing in such a patient is a deliberate act that is intended to hasten death. As such, the ethical “bright line differentiating the patient’s natural death from illicit killing and physician assisted suicide” would indeed seem to have been crossed. Among the considerations proposed by Sulmasy for differentiating substitutive from replacement therapies, pacemakers are responsive to changes in the host organism by tracking sinus node function, independent of external energy supplies, independent of external controls for normal operation; immunologically compatible; and well integrated into the body. We maintain that withdrawal of pacing from a pacemaker-dependent patient is a decision to terminate a life-sustaining replacement therapy that has become an integrated part of the person and is distinctly different from deactivating antitachycardia therapies of an implantable cardioverter-defibrillator (a substitutive treatment). For those who are not opposed to physician-assisted suicide, this distinction may not be morally relevant, but for those opposed to this practice, the distinction is glaring.

Response to Zellner et al

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