Published in final edited form as:

Prog Cardiovasc Dis. 2012 ; 55(3): 290–299. doi:10.1016/j.pcad.2012.09.003.

Deactivation of Pacemakers and Implantable Cardioverter-Defibrillators

Daniel B. Kramer, MD^{*,#,*}, Susan L. Mitchell, MD, MPH^{*,#}, and Dan W. Brock, PhD[#]

^{*}Hebrew SeniorLife Institute for Aging Research

^{*}Beth Israel Deaconess Medical Center

[#]Harvard Medical School

Abstract

Cardiac implantable electrical devices (CIEDs), including pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs), are the most effective treatment for life-threatening arrhythmias. Patients or their surrogates may request device deactivation to avoid prolongation of the dying process or in other settings, such as after device-related complications or with changes in their health care goals. Despite published guidelines outlining theoretical and practical aspects of this common clinical scenario, significant uncertainty remains for both patients and health care providers regarding the ethical and legal status of CIED deactivation. This review outlines the ethical and legal principles supporting CIED deactivation at patients' request, centered upon patient autonomy and authority over their own medical treatment. The empirical literature describing stakeholder views and experiences surrounding CIED deactivation is described, along with lessons for future research and practice guidance surrounding the care of patients with CIEDs.

Introduction

“Or shall I go out as a light does, not first blown out by the wind, but grown tired and weary of itself - a burnt out light? Or finally, shall I blow myself out, so as not to burn out?”

- Nietzsche, *The Gay Science*¹

Cardiac implantable electrical devices (CIEDs), including pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs), are the most effective treatment for life-threatening arrhythmias. Millions of patients are living with these permanently-implanted devices, and tens of thousands more receive them each month.² An aging population in the United States (US) and increasing penetrance in emerging markets, coupled with broadening clinical indications for device implantation, will support continued growth in CIED implantation.

All of these patients will eventually pass away, either from progression of their underlying heart disease or from nonarrhythmic problems such as malignancies, dementia, lung disease,

© 2012 Elsevier Inc. All rights reserved.

Address for Correspondence: Daniel B. Kramer, MD, 1200 Centre Street, Boston, MA, danielkramer@hsl.harvard.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

or infections. Studies have found 5-20% annual mortality rates for device recipients, meaning that tens of thousands of deaths occur annually among these patients.⁵⁻⁸ In that context, patients or their surrogates may request device deactivation to avoid prolongation of the dying process or to avoid device-specific problems such as ICD shocks. Patients may consider deactivation in other settings, such as after device-related complications or with changes in their health care goals. In response to clinical ambiguity surrounding CIED deactivation, professional societies in the US and Europe published guidelines outlining theoretical and practical aspects of this common clinical scenario. Despite this guidance and a number of qualitative studies evaluating stakeholder beliefs and perspectives, significant uncertainty remains for both patients and health care providers regarding the ethical and legal status of CIED deactivation.¹¹

The goals of this review are to provide an overview of: (a) the ethical and legal status of CIED deactivation; (b) published empirical data regarding practices, knowledge, and preferences surrounding CIED deactivation; and (c) major themes and lessons for future research and practice emerging from the existing literature.

Ethical and Legal Status of CIED Deactivation

It is not surprising that patients and clinicians remain confused about patient rights over their own medical therapy. Indeed, at least one critically lauded film ended with a patient “trapped” by ongoing ventilator support in defiance of her expressed wishes following a severe (but not lethal) spinal cord injury.¹² The award-winning movie ends with the patient being euthanized by her friend and mentor, an extreme response to a problem with a comparatively simple and legal (if less dramatic) solution. The outrage (both real and manufactured) over the Terry Schiavo case also imposed ambiguity on a case that was legally and morally straightforward.

Patient autonomy underlies both ethical and legal principles surrounding CIED deactivation. Fundamentally, respect for autonomy and individual personhood support a patient’s right to dictate decisions about one’s own treatment. This includes informed consent but also a general right of refusal, or a “right to be left alone” that legally extends from the constitutional right to privacy and personal liberty. Legally, patients in the US may refuse therapies, even those that are life-prolonging, and even if the patient has previously consented to that same therapy.¹⁵⁻¹⁸ Patients need not be terminally ill to make these requests. The empirical data noted below suggests that many stakeholders view CIEDs as distinct from other life-sustaining therapies, and PMs as different from ICDs. However, there is no legal or ethical basis for these positions.

Considering the legal arguments first, US courts have determined that patients have the right to make decisions regarding medical treatments, including treatment refusals such as those involving cases of feeding tubes (*Bouvia*)¹⁹ and ventilator support (*Quinlan* and *Cruzan*). These decisions highlight the priority of a patient’s right to refuse ongoing therapy, and extends them (with some restrictions noted below) to surrogate decision-makers in cases in which patients lack decision-making capacity. The Supreme Court’s decision not to review the Schiavo case may be viewed a sign that the legal authority of patients and surrogates to accept and refuse treatment is considered settled, though no US case has specifically addressed CIEDs.¹⁴ Neither the *Bouvia*, *Quinlan*, or *Cruzan* decisions drew significant distinctions between different types of life-sustaining therapy, and thus there is no reason to believe that PMs or ICDs would be treated differently from other therapies, even (as in the case of PMs in patients without an underlying rhythm) if death were immediate following deactivation of the device. Similarly, considerations such as a patient’s underlying illness or prognosis, or the immediate consequences of deactivation, are legally irrelevant.

Surrogate decision-makers are theoretically afforded the same authority as the patients for whom they speak. However, the US Supreme Court has upheld (in *Cruzan*) the ability of states to establish standards for decisions to withdraw specific therapies. For example, in *Cruzan*, the majority opinion noted that Missouri could hold a “clear and convincing” standard for establishing a patient’s wishes via a surrogate due to the highly personal nature of end-of-life decisions and the grave risks of error. Thus in Missouri as well as other states certain thresholds of evidence must be met to withdraw treatment, though curiously this is not true to decline initiation of that same treatment.

States also vary in the way in which surrogates are appointed (spouse, children, etc.) if one is not specifically designated by the patient as their “durable power of attorney for health care”. This is distinct from other elements of advance care planning, which might include a “living will,” which is a written expression of a patient’s health care-related values and goals as they relate to health care as well as preferences for treatment under specific circumstances. As noted below, limited research suggests that patients with CIEDs tend not discuss their device-specific views with their surrogates.²⁵

There are few reasons to question the legal support for deactivation of CIEDs. In many ways the ethics are similarly straightforward: patient autonomy is paramount, and no patient is committed to any therapy he or she no longer wishes to receive. Surrogates have the same moral authority (if not always the exact same legal authority) to speak for patients lacking decision-making capacity. Despite many firm views to the contrary, there are no meaningful ethical or legal differences between PMs or ICDs from the standpoint of deactivation. Some might object that PMs deserve distinction, due to factors such as being permanently implanted and continuously functioning, and in that sense more like an organ transplant or new heart valve. But these and other objections do not hold up to scrutiny, as (for example) other continuous therapies such as mechanical ventilation can be withheld or withdrawn, and replacement kidneys or heart valves cannot be “turned off” in any coherent way.²³ In any case, it strains the relevant principles to understand why characteristics of the *device* would override a *patient’s* right to decline it.

Indeed, a physician who would refuse to deactivate a PM should be asked if they would allow a patient with heart block or any other indication for a PM to decline implantation. Failure to respect a patient’s wishes regarding implantation if it is refused is, legally, assault, and it would be hard to imagine caregivers compelling a competent patient to undergo an unwanted surgical procedure. It is then difficult to understand by what principles these same objectors would decline to deactivate a device, as doing so similarly commits a patient to a therapy that is unwanted. Though it is common to appeal to distinctions between withholding versus withdrawing therapy in this context, it is well-established that this distinction is, from a moral point of view, meaningless.²⁶ Most simply, in either case a patient dies from the underlying disease (complete heart block, for example, or progressive heart failure), and the intention of caregivers is to avoid an intervention viewed as burdensome from the patient’s perspective and not from an applied intervention.²⁷

Two additional important ethical considerations deserve comment. The first is the experience of CIED deactivation, and the other is the closely-related problem of conscientious objection. The “lived experience” of deactivating CIEDs under specific situations carries some moral weight for health care providers, though not enough to override the wishes of a patient. As one participant in a nursing focus group noted, “In turning off the pacemaker, it feels like I have just turned your heart off.”²⁸ While patients have every right to request such an act, we should also be cognizant of the impact that participating in terminal palliative care may place on providers. Respect for autonomy

demands recognition of the personhood not just of the patient but of their providers, who must reconcile their actions with their personal and professional values.

Not all health care providers are trained in the provision of palliative sedation, assurance of symptom control at the end-of-life, or in the clinical and logistical details of treatment withdrawals. CIED deactivation may be even more intimidating insofar as special training is required to use a device programmer to actually turn off a device. And those with the most specific training of all – industry employed allied professionals (IEAPs) – are well-versed in the devices' technology but are not at all equipped professionally to provide end-of-life care. Some manufacturers actually forbid pacemaker deactivation by IEAPs, though ICD deactivation is allowed under a physician's direction. Though provider discomfort itself is not a reason to forgo deactivation, neither may it be completely ignored or overridden if an alternative provider can be found. In principle, this is equally true for cessation of therapies such as mechanical ventilation, which may also lead to immediate or at least unpredictable death. Despite our own legal and ethical certainty, some health care providers will continue to object to device deactivation. In these cases, we agree with the Heart Rhythm Society guidelines' stipulation that physicians in this position have an obligation to arrange for alternative provisions of care in cases of conscientious objection that cannot be resolved by (for example) ethics or clerical consultation.⁹

Two consensus statements have been written outlining the principles and best practices surrounding CIED deactivation. These broadly follow the same ethical principles outlined here, and provide logistical considerations for actually performing device deactivations. The US guidelines were developed by the Heart Rhythm Society in collaboration with the American College of Cardiology, American Geriatric Society, American Academy of Hospice and Palliative Medicine, American Heart Association, and Hospice and Palliative Nurses Association, with representatives from the European Heart Rhythm Association.⁹ The European Heart Rhythm Association published its own guidelines several months later, but with an important distinction arising from the diversity of national laws in Europe: "... [T]here are countries where the deactivation of antibradycardia pacing in a pacemaker-dependent patient is prohibited by law. It is therefore crucial to be aware of the legal situation in the jurisdiction in which you are practicing."¹⁰ Aside from this difference, the guidelines are largely harmonious and argue for CIED deactivation as an extension of patients' self-determination regarding their own treatment. Both documents add the important point that potential religious objections to device deactivation do not hold up to theological scrutiny, as major traditions support both patient autonomy as well as physicians' ability to withdraw or withhold care considered to be futile or otherwise inappropriate.

Published Data on CIED Deactivation

Published research surrounding CIED deactivation has expanded over the past decade. These studies included some limited investigations of actual clinical practice of deactivation on a backdrop of multiple qualitative studies using surveys or focus groups to evaluate the experiences and perspectives of different stakeholders. To review this literature, we identified articles presenting empirical research regarding CIED deactivation in Pubmed using "ICD deactivation", "ICD end-of-life", "pacemaker deactivation", and "CIED deactivation" as search terms, supplemented by manual review of bibliographies and consultation with experts in the field. This strategy reproduced and extended the search methodology and findings previously presented in a review by Russo in 2011.¹¹ Each of these articles is briefly described, with a focus on the major findings emerging from each study. The TABLE describes the study design and principal findings of each of the 19 identified studies, which are grouped for discussion by their predominant theme and context.

Clinical experiences of CIED deactivation

Goldstein led two efforts describing ICD deactivation practices. One included family interviews for 100 patients with ICDs who died.²⁹ They found that 27 of the 100 contacts recalled the patient receiving a shock in the last month of life, including 8 who were shocked in the final minutes of life. A third of those shocked and 27% overall had discussions about deactivation, and 21% overall were deactivated. A second study surveyed 414 hospice facilities to evaluate their policies and preparedness for ICD deactivation.³⁰ Though 97% of facilities admitted patients with ICDs, only 10% had a policy addressing deactivations, compared with over half reporting that patients had been shocked in their facility within the past year.

Two other retrospective studies commented on the experience of dying with an ICD. Kobza and Erne reported on 36 patients who died with ICDs, including 8 patients with ICDs and terminal cancer.³¹ They found that though 6 of these 8 patients had discussed deactivation with their care providers, none elected to have deactivation performed, despite experiencing extensive appropriate shocks and even electrical storm (5 of 8). Lewis et al performed a chart review of 63 patients who died with ICDs, including 20 whose devices were deactivated and 40 whose were not.³² Shocks were more common in the latter group, of whom 21% received a shock within 30 days of death (compared with 15% in group whose devices were subsequently deactivated). No pacing therapies were deactivated as per institutional policy, though subgroup analysis of pacemaker-dependence (N = 6) suggested that this variable did not affect time to death after ICD deactivation.

Two surveys focused on ambulatory heart failure patients. Stewart et al surveyed 105 ambulatory heart failure patients (65% with an ICD) regarding their expectations for survival and benefits conferred by an ICD.³³ Overall, patients optimistically forecast their own longevity as well as the expected survival advantage conferred by ICDs: over 50% of respondents estimated that primary prevention ICDs could save 50 lives per 100 patients treated over a 5 year period, nearly 10 times the best estimate from one representative clinical trial.³⁴ With regard to end-of-life treatment, more patients with than without ICDs understood the ease with which a device could be deactivated, and substantial numbers of patients indicated they would *not* want their device deactivated even in circumstances such as daily shocks (55%), terminal cancer (70%), or constant dyspnea (100%).

Raphael et al surveyed 54 patients with heart failure with a focus on knowledge and preferences regarding ICD deactivation.³⁵ They reported that only 3% of patients recalled discussion of possible deactivation during the informed consent process, though more than a third learned of this later in their clinical course. One quarter of patients who had been shocked had also considered ICD deactivation at some point, though overall prognosis and preferences for a “quick death” weighed more heavily than shock experiences as factors influencing decisions to deactivate an ICD. A smaller sample of patients were also interviewed about a theoretical “variable therapy” option for their device, in which shock therapy could be turned off for specific periods (such as at night). This was viewed favorably in a qualitative way but not explored in more detail in this study, and is not a current feature of any device.

Patient and provider comparisons

Several groups of studies assessed patients and health care providers regarding deactivation. Goldstein et al interviewed physicians (N = 12)³⁶ and held focus groups for patients (N = 15)³⁷ evaluating their views on deactivation of ICDs. Physicians reported that advance care planning discussions rarely included comment on ICD deactivation, and perceptions of ICDs as different from other life-sustaining therapies. Patients noted that none had actually

discussed ICD deactivation with their physicians, or indeed even knew that doing so was an option.

Kramer et al surveyed both physicians³⁸ (N = 185) and patients with hypertrophic cardiomyopathy²⁵ (N = 546) regarding ethical and legal views on PM and ICD deactivation. The physicians self-identified as generally comfortable with discussing end-of-life care, but were much less comfortable discussing PM or ICD deactivation than other life-sustaining therapies such as dialysis. There was considerable uncertainty about the legal status of physician-assisted suicide and euthanasia, and notably 19% of physicians viewed deactivation of a PM in a PM-dependent patient to be physician-assisted suicide and 9% viewed it as euthanasia. Patients were similarly uncertain regarding the ethical and legal status of CIED deactivation, and viewed it as distinct from cessation of other life-sustaining therapies such as mechanical ventilation or renal dialysis. Patients with ICDs only rarely included discussion of their device in advance care planning. Kramer et al also held focus groups of cardiovascular nurses (N = 14) probing similar questions around decision-making for PM and ICD deactivation.²⁸ Themes that emerged included a narrow emphasis on procedural details during informed consent for ICD implantation, and incomplete or infrequent advance care planning discussions. Nurses in general maintained distinctions between withholding and withdrawing therapy and also were less comfortable with PM versus ICD deactivation.

Kapa et al presented several case scenarios and legal questions regarding PM and ICD deactivation to 336 “medical professionals” (physicians, nurses, and industry personnel), 236 patients, and 70 legal professionals.³⁹ They found that the majority in all 3 groups (98%, 85%, and 90%, respectively) supported ICD deactivation when requested by a terminally ill person. Support for deactivating an ICD to avoid shocks (i.e., not due to terminal illness) was not as strong, as only 53% of patients and 45% of legal professionals considered this to be legal (though 85% of medical professionals correctly deemed it so). With regard to PMs, the striking finding in this study was that 37% of medical professionals and 34% of patients thought deactivation in a PM-dependent patient would be physician-assisted suicide or euthanasia, though only 15% of legal professional thought this to be the case.

Stand-alone provider surveys

Mueller et al surveyed Heart Rhythm Society members (N = 787) to evaluate practices and attitudes related to ICD and PM deactivation.⁴⁰ Most (86%) had been involved in ICD deactivation, and 77% had received requests for PM deactivation, though respondents were more comfortable with the former. IEAPs performed approximately half of all deactivations for both devices types. Mueller et al also held focus groups of IEAPs (N = 17) to explore their role in CIED deactivation.⁴¹ Participants noted confusion amongst patients about the role of IEAPs compared with physicians, though IEAPs commonly fielded requests to deactivate ICDs and frequently did so, without much moral distress. In contrast to the survey results, PM deactivations were describes as uncommonly requested, and several IEAPs noted that they would refuse to do so if asked (and are forbidden to do so by company policy).

Goldstein et al published a research letter in which 147 physicians from different specialties were asked about barriers to conversations regarding ICD deactivation.⁴² They found that non-cardiologists were less likely to agree that their patients understood why they had an ICD at all, and less likely to agree that patients know that deactivation was an option.

Kelley et al surveyed 585 physicians from different specialties using vignettes and Likert-scale questions.⁴³ They found that physicians were more likely to favor discussing advance

directives and do not resuscitate status than ICD deactivation specifically, and that clinical experience with ICD deactivation discussions predicted future willingness to do so. In general, vignettes with sicker patients engendered greater support for ICD deactivation discussions. Respondents commonly (85%) viewed deactivation of PMs and ICDs as different from each other. A substudy from this same survey noted that geriatricians and internists felt inadequately informed to initiate discussions about ICD deactivation.⁴⁴

Marinskis and Erven presented a survey to 47 centers in Europe regarding opinions and practices for ICD deactivation, receiving responses mostly from electrophysiologists (82%) with the remainder general cardiologists (no N given).⁴⁵ Respondents reported commonly considering ICD deactivation for terminally ill patients, particularly those receiving multiple shocks, though only 4% routinely discussed this possibility at the time of implant. Two thirds rejected the possibility of performing ICD deactivation remotely, were that function to become possible.

Hauptman et al surveyed 734 physicians (divided between cardiology, geriatrics, and general internists) from the American Medical Association Database regarding end-stage heart failure decision-making.⁴⁶ Respondents commonly (>90%) noted similarities between end-stage heart failure and other terminal conditions such as lung cancer, but were uncomfortable predicting short-term mortality (< 6 months). Discussions with patients about ICD deactivation were uncommon for non-cardiologists (60% of geriatricians and 75% of internists never having done so), though interestingly about 75% of all 3 specialty groups considered their own to be in the best position to initiate these conversations with patients.

Sherazi et al surveyed 87 physicians in upstate New York regarding knowledge and preferences regarding ICD deactivation.⁴⁷ They found that nearly half of respondents were uncertain about the legality of ICD deactivation, though nearly 75% had cared for patients with ICDs and terminal illnesses. Despite this uncertainty about the legal status of doing so, more than 75% were “somewhat” or “very” comfortable with actually deactivating a device in theory.

Major Themes from Empirical Studies

Though not meant to be an exhaustive discussion of each of these studies – several of which include very long and complex survey instruments – a number of important themes emerge from these data, with lessons we have derived from these for the community of providers caring for patients with ICDs.

Specialties differ in their experience and comfort with ICD deactivation

Multiple authors noted marked discrepancies between cardiologists and non-cardiologists (and between electrophysiologists and other cardiologists) with respect to experience and knowledge surrounding device deactivation. This included uncertainty about the legal and ethical status of PM or ICD deactivation, the procedure for doing so, and views on which specialty should be responsible for initiating this discussion with patients.

Lesson—At a bare minimum, all specialists involved in the care of patients with ICDs should be aware that these can be deactivated, and that doing so when requested by a patient or surrogate is ethical, legal, and logistically simple (i.e. does not require surgery). Given the multidisciplinary care of patients with ICDs, it is essential that the responsibility for advance care planning (including discussions regarding ICD deactivation) are delegated to *someone*, though who that might be could reasonably vary for different patients according to their specific patterns of care. Given their familiarity with the devices and frequent (often twice a year or more) direct contact with patients, the cardiologist following a patient’s ICD

longitudinally should be responsible for ensuring that someone has taken this role, and perhaps to play an educational role if a primary care physician (for example) seems to be the right person to have this discussion with a specific patient but may lack the necessary knowledge to do so.

Pacemakers and ICDs are viewed as different from other life-sustaining therapies

This was a finding in surveys of patients and providers, and may in part extend from lack of familiarity with PM and ICD deactivation in practice. In general, the public is more likely to be aware of “pulling the plug” on mechanical ventilation (which may be nearly as immediately lethal as deactivating a pacemaker). Cessation of more subtle or gradual therapies such as dialysis or chemotherapy also seems to be both more familiar and less confounded by technical knowledge, as many physicians and patients are under-informed regarding the process by which devices are deactivated. At a more theoretical level, there may remain for many substantial confusion or uncertainty about the ethical and legal status of ceasing life-sustaining therapy in general, and that is unsurprisingly more pressing for these less-familiar devices.

Lesson—Some physicians involved in end-of-life care continue to need better education about the basic ethical and legal principles supporting patient autonomy and self-determination. At the very least, ready access to expert consultants (ethics support services or palliative care consultation) would fill this gap, though this may not help with real-time discussions at the bedside or in advance care planning discussions. As newer life-sustaining devices such as ventricular assist devices become more common, understanding the applicability of ethical and legal precedents to new therapeutics will become increasingly important. Theoretical analyses of the ethics surrounding ventricular assist devices suggests that they should not be treated differently than other life-sustaining therapies,⁵² but how this plays out in practice is not known.

Pacemakers and ICDs are viewed as different from each other

The previous theme and lesson extend to the firm, fixed view by many patients and providers that PMs and ICDs have different moral and legal standing. (In some countries in Europe, that may actually be true from a legal standpoint, but it is not the case in the US.) One worries, however, that those who object to deactivating PMs in PM-dependent patients would also object to discontinuing ventricular assist device therapy, which is similar insofar as it is continuous, implanted, and “painless” (e.g. patients do not feel the device working, though it may prolong a dying process). More research is needed, however, to understand exactly what features of PMs and PM deactivation give rise to these beliefs, and how immutable they are in the face of educational initiatives. At the same time, these data suggest that actual PM deactivation is uncommon in practice, and it is not clear if there are patients whose dying processes are needlessly extended by failure to recognize PM deactivation as an option.

Lesson—PM deactivation remains less accepted than ICD deactivation, but both the reasons for this and its impact in clinical care are unknown.

Advance care planning needs improvement

The knowledge deficits described above likely contribute to the disappointing advance care planning for patients with PMs and ICDs. Understanding that these devices can be turned off is an obvious prerequisite to including them in living wills or discussions with health care proxies or providers.

Lesson—This reinforces the concept that an individual on a patient's care team needs to be responsible for advance care planning, and that providers with electrophysiologic expertise should ensure that those involved in decision-making are adequately informed about the possible treatment options. Starting this process at device implantation, would as a matter of standardized practice at least guarantee that patients are aware of the possibility of device deactivation.

Patient preferences are hard to predict

Lastly, the few studies evaluating patient preferences under specific circumstances show somewhat surprising findings, including a preference *not* to have one's ICD deactivated even under circumstances many physicians would consider futile.

Lesson—Both in practice and in public policy and educational efforts, it should not be assumed that patients will actually elect for PM or ICD deactivation, or – even when educated to the contrary – view it as consistent with either their ethical or religious principles or health care goals generally. However, the goal is not to promote device deactivation, but to support patients' self-determination and control over their own medical treatment.

Conclusion

If philosophy begins with wonder (as Socrates put it), cardiac electrophysiology might start with similar amazement in arrhythmia pathophysiology and the extraordinary devices designed to extend and improve patients' lives. Discussions of deactivating CIEDs inevitably seem to obscure the remarkable progress over the past decades in treating bradyarrhythmias and sudden cardiac death. Though occasional recalls of PM or ICD components often spur critics of device-based therapy in general, in some ways it is remarkable that these devices work as well as they do, for as long as is experienced by typical patients.⁵⁴ Indeed, it is because so often patients reach their end before their devices that the clinical, ethical, and legal challenges presented here come to be considered at all. We have argued here that any physician involved in the care of patients with PMs and ICDs are obligated to understand fundamental technical features of these devices, and the applicability of basic principles of patient autonomy and life-sustaining treatment to CIED management at the end-of-life or at patients' request. As one philosopher wrote, just years before his own undignified passing and a century before modern ICDs:

Death freely chosen, death at the right time, brightly and cheerfully accomplished amid children and witnesses: then a real farewell is still possible, as the one who is taking leave is still there; also a real estimate of what one has achieved and what one has wished, drawing the sum of one's life.

- Nietzsche, *Twilight of the Idols*⁵⁵

Acknowledgments

Funding: Dr. Kramer is supported by an award from the John A. Hartford Foundation. Dr. Mitchell is supported by NIH-NIA K24AG033640.

References

1. Nietzsche, FW.; Kaufmann, WA. The gay science; with a prelude in rhymes and an appendix of songs. 1. New York: Vintage Books; 1974.

2. Hammill SC, Kremers MS, Stevenson LW, et al. Review of the registry's fourth year, incorporating lead data and pediatric ICD procedures, and use as a national performance measure. *Heart Rhythm*. Sep; 2010 7(9):1340–1345. [PubMed: 20647056]
3. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. *Circulation*. May 27; 2008 117(21):e350–408. [PubMed: 18483207]
4. Hlatky MA, Sanders GD, Owens DK. Evidence-based medicine and policy: the case of the implantable cardioverter defibrillator. *Health Aff (Millwood)*. Jan-Feb;2005 24(1):42–51. [PubMed: 15647214]
5. Lamas GA, Lee KL, Sweeney MO, et al. Ventricular pacing or dual-chamber pacing for sinus-node dysfunction. *N Engl J Med*. Jun 13; 2002 346(24):1854–1862. [PubMed: 12063369]
6. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. Mar 21; 2002 346(12):877–883. [PubMed: 11907286]
7. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med*. May 20; 2004 350(21):2140–2150. [PubMed: 15152059]
8. Cleland JG, Daubert JC, Erdmann E, et al. The effect of cardiac resynchronization on morbidity and mortality in heart failure. *N Engl J Med*. Apr 14; 2005 352(15):1539–1549. [PubMed: 15753115]
9. Lampert R, Hayes DL, Annas GJ, et al. HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy This document was developed in collaboration with the American College of Cardiology (ACC), the American Geriatrics Society (AGS), the American Academy of Hospice and Palliative Medicine (AAHPM); the American Heart Association (AHA), and the European Heart Rhythm Association (EHRA). *Heart Rhythm*. May 13.2010
10. Padeletti L, Arnar DO, Boncinelli L, et al. EHRA Expert Consensus Statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy. *Europace*. Oct; 2010 12(10):1480–1489. [PubMed: 20675674]
11. Russo JE. Original research: deactivation of ICDs at the end of life: a systematic review of clinical practices and provider and patient attitudes. *Am J Nurs*. Oct; 2011 111(10):26–35. [PubMed: 21926561]
12. Winter RO, Birnberg BA. Million dollar baby: murder or mercy. *Fam Med*. Mar; 2009 41(3):164–166. [PubMed: 19259837]
13. Quill TE. Terri Schiavo--a tragedy compounded. *N Engl J Med*. Apr 21; 2005 352(16):1630–1633. [PubMed: 15784658]
14. Annas GJ. "Culture of life" politics at the bedside--the case of Terri Schiavo. *N Engl J Med*. Apr 21; 2005 352(16):1710–1715. [PubMed: 15784657]
15. Annas GJ, Densberger JE. Competence to refuse medical treatment: autonomy vs. paternalism. *Univ Toledo Law Rev*. Winter;1984 15(2):561–596. [PubMed: 11649779]
16. Pellegrino ED. Decisions to withdraw life-sustaining treatment: a moral algorithm. *JAMA*. Feb 23; 2000 283(8):1065–1067. [PubMed: 10697071]
17. Quill TE, Barold SS, Sussman BL. Discontinuing an implantable cardioverter defibrillator as a life-sustaining treatment. *Am J Cardiol*. Jul 15; 1994 74(2):205–207. [PubMed: 7726890]
18. Rhymes JA, McCullough LB, Luchi RJ, Teasdale TA, Wilson N. Withdrawing very low-burden interventions in chronically ill patients. *JAMA*. Feb 23; 2000 283(8):1061–1063. [PubMed: 10697070]
19. *Bouvia v. Superior Court (Glenchur)*. 179 Cal App 3d 1127. 1986 225 Cal. Rptr. 297.
20. *Cruzan v. Director, Missouri Department of Health*. 497 U S 261 (1990). Supreme Court of the United States; 1990. 497 U S 261 88–1503

21. In re Quinlan. 70 N J 10, 355 A.2d 647 (1976). New Jersey Supreme Court; 1976. 70 N.J. 10, 355 A.2d 647
22. Hook CC, Mueller PS. The Terri Schiavo saga: the making of a tragedy and lessons learned. *Mayo Clin Proc.* Nov; 2005 80(11):1449–1460. [PubMed: 16295025]
23. Sulmasy DP. Within you/without you: biotechnology, ontology, and ethics. *J Gen Intern Med.* Jan; 2008 23(Suppl 1):69–72. [PubMed: 18095048]
24. Zellner RA, Aulisio MP, Lewis WR. 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. *Circ Arrhythm Electrophysiol.* Jun; 2009 2(3):340–344. discussion 340. [PubMed: 19808485]
25. Kramer DB, Kesselheim AS, Salberg L, Brock DW, Maisel WH. Ethical and legal views regarding deactivation of cardiac implantable electrical devices in patients with hypertrophic cardiomyopathy. *Am J Cardiol.* Apr 1; 2011 107(7):1071–1075. e1075. [PubMed: 21296323]
26. Olsen ML, Swetz KM, Mueller PS. Ethical decision making with end-of-life care: palliative sedation and withholding or withdrawing life-sustaining treatments. *Mayo Clin Proc.* Oct; 2010 85(10):949–954. [PubMed: 20805544]
27. Quill TE, Dresser R, Brock DW. The rule of double effect--a critique of its role in end-of-life decision making. *N Engl J Med.* Dec 11; 1997 337(24):1768–1771. [PubMed: 9392707]
28. Kramer DB, Ottenberg AL, Gerhardson S, et al. “Just Because We Can Doesn’t Mean We Should”: views of nurses on deactivation of pacemakers and implantable cardioverter-defibrillators. *J Interv Card Electrophysiol.* Dec; 2011 32(3):243–252. [PubMed: 21805140]
29. Goldstein NE, Lampert R, Bradley E, Lynn J, Krumholz HM. Management of implantable cardioverter defibrillators in end-of-life care. *Ann Intern Med.* Dec 7; 2004 141(11):835–838. [PubMed: 15583224]
30. Goldstein N, Carlson M, Livote E, Kutner JS. Brief communication: Management of implantable cardioverter-defibrillators in hospice: A nationwide survey. *Ann Intern Med.* Mar 2; 2010 152(5):296–299. [PubMed: 20194235]
31. Kobza R, Erne P. End-of-life decisions in ICD patients with malignant tumors. *Pacing Clin Electrophysiol.* Jul; 2007 30(7):845–849. [PubMed: 17584265]
32. Lewis WR, Luebke DL, Johnson NJ, Harrington MD, Costantini O, Aulisio MP. Withdrawing implantable defibrillator shock therapy in terminally ill patients. *Am J Med.* Oct; 2006 119(10):892–896. [PubMed: 17000222]
33. Stewart GC, Weintraub JR, Pratibhu PP, et al. Patient expectations from implantable defibrillators to prevent death in heart failure. *J Card Fail.* Feb; 2010 16(2):106–113. [PubMed: 20142021]
34. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med.* Jan 20; 2005 352(3):225–237. [PubMed: 15659722]
35. Raphael CE, Koa-Wing M, Stain N, Wright I, Francis DP, Kanagaratnam P. Implantable cardioverter-defibrillator recipient attitudes towards device deactivation: how much do patients want to know? *Pacing Clin Electrophysiol.* Dec; 2011 34(12):1628–1633. [PubMed: 21955046]
36. Goldstein NE, Mehta D, Teitelbaum E, Bradley EH, Morrison RS. “It’s like crossing a bridge” complexities preventing physicians from discussing deactivation of implantable defibrillators at the end of life. *J Gen Intern Med.* Jan; 2008 23(Suppl 1):2–6. [PubMed: 18095036]
37. Goldstein NE, Mehta D, Siddiqui S, et al. “That’s like an act of suicide” patients’ attitudes toward deactivation of implantable defibrillators. *J Gen Intern Med.* Jan; 2008 23(Suppl 1):7–12. [PubMed: 18095037]
38. Kramer DB, Kesselheim AS, Brock DW, Maisel WH. Ethical and legal views of physicians regarding deactivation of cardiac implantable electrical devices: a quantitative assessment. *Heart Rhythm.* Nov; 2010 7(11):1537–1542. [PubMed: 20650332]
39. Kapa S, Mueller PS, Hayes DL, Asirvatham SJ. Perspectives on withdrawing pacemaker and implantable cardioverter-defibrillator therapies at end of life: results of a survey of medical and legal professionals and patients. *Mayo Clin Proc.* Nov; 2010 85(11):981–990. [PubMed: 20843982]

40. Mueller PS, Jenkins SM, Bramstedt KA, Hayes DL. Deactivating implanted cardiac devices in terminally ill patients: practices and attitudes. *Pacing Clin Electrophysiol.* May; 2008 31(5):560–568. [PubMed: 18439169]
41. Mueller PS, Ottenberg AL, Hayes DL, Koenig BA. “I felt like the angel of death”: role conflicts and moral distress among allied professionals employed by the US cardiovascular implantable electronic device industry. *J Interv Card Electrophysiol.* Dec; 2011 32(3):253–261. [PubMed: 21861198]
42. Goldstein N, Bradley E, Zeidman J, Mehta D, Morrison RS. Barriers to conversations about deactivation of implantable defibrillators in seriously ill patients: results of a nationwide survey comparing cardiology specialists to primary care physicians. *J Am Coll Cardiol.* Jul 21; 2009 54(4):371–373. [PubMed: 19608038]
43. Kelley AS, Reid MC, Miller DH, Fins JJ, Lachs MS. Implantable cardioverter-defibrillator deactivation at the end of life: a physician survey. *Am Heart J.* Apr; 2009 157(4):702–708. e701. [PubMed: 19332199]
44. Kelley AS, Mehta SS, Reid MC. Management of patients with ICDs at the end of life (EOL): a qualitative study. *Am J Hosp Palliat Care.* Dec-Jan;2009 25(6):440–446. 2008. [PubMed: 18812618]
45. Marinksis G, van Erven L. Deactivation of implanted cardioverter-defibrillators at the end of life: results of the EHRA survey. *Europace.* Aug; 2010 12(8):1176–1177. [PubMed: 20663788]
46. Hauptman PJ, Swindle J, Hussain Z, Biener L, Burroughs TE. Physician attitudes toward end-stage heart failure: a national survey. *Am J Med.* Feb; 2008 121(2):127–135. [PubMed: 18261501]
47. Sherazi S, Daubert JP, Block RC, et al. Physicians’ preferences and attitudes about end-of-life care in patients with an implantable cardioverter-defibrillator. *Mayo Clin Proc.* Oct; 2008 83(10):1139–1141. [PubMed: 18828973]
48. Tinetti ME. The retreat from advanced care planning. *JAMA.* Mar 7; 2012 307(9):915–916. [PubMed: 22396510]
49. Kamisar Y. Are the distinctions drawn in the debate about end-of-life decision making “principled”? If not, how much does it matter? *The Journal of law, medicine & ethics : a journal of the American Society of Law, Medicine & Ethics.* Spring;2012 40(1):66–84.
50. Swetz KM, Ottenberg AL, Freeman MR, Mueller PS. Palliative care and end-of-life issues in patients treated with left ventricular assist devices as destination therapy. *Curr Heart Fail Rep.* Sep; 2011 8(3):212–218. [PubMed: 21538039]
51. Swetz KM, Mueller PS, Ottenberg AL, Dib C, Freeman MR, Sulmasy DP. The use of advance directives among patients with left ventricular assist devices. *Hosp Pract (Minneap).* Feb; 2011 39(1):78–84. [PubMed: 21441762]
52. Mueller PS, Swetz KM, Freeman MR, et al. Ethical analysis of withdrawing ventricular assist device support. *Mayo Clin Proc.* Sep; 2010 85(9):791–797. [PubMed: 20584919]
53. Kay GN, Bittner GT. Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated? Deactivating implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness. An ethical distinction. *Circ Arrhythm Electrophysiol.* Jun; 2009 2(3):336–339. discussion 339. [PubMed: 19808484]
54. Sweeney MO. The implantable cardioverter-defibrillator minimalist: an approach to patient follow-up and management of implantable defibrillators. *Circulation.* Jul 17; 2012 126(3):369–377. [PubMed: 22801654]
55. Nietzsche, FW.; Hollingdale, RJ.; Nietzsche, FW. *Twilight of the idols; and, The Anti-Christ.* Harmondsworth: Penguin; 1968.

Abbreviations

CIED	cardiac implantable electrical device
ICD	implantable cardioverter-defibrillator
PM	Pacemaker

US United States
IEAPS industry employed allied professionals

TABLE

Empirical studies regarding CIED deactivation

Reference	Study Methodology	Study Focus	Key Findings	Critique
Clinical experiences of CIED deactivation				
Goldstein NE et al. <i>Ann Intern Med</i> . Dec 7 2004;141(11):835-838.	Retrospective cohort study with telephone survey of next of kin (N = 100) of ICD patients who died	Frequency, timing, and correlates of ICD deactivation discussion	One quarter of contacts recalled deactivation discussions, largely in last days or even hours of life.	Data derived from family recall, median of 2.3 years after patient death
Goldstein et al. <i>Ann Intern Med</i> . Mar 2 2010;152(5):296-299.	Cross-sectional survey of hospice facilities (N = 414) in the US	Frequency of ICD patient admissions, shocks, and deactivation policies	Nearly all admitted patients with ICDs, and a majority reported patients receiving shocks within past year Deactivation policies uncommon	Data provided by hospice administrators without separate validation
Kozba R, Erne P. <i>Pacing Clin Electrophysiol</i> . Jul 2007;30(7):845-849.	Retrospective chart review of oncology patients with ICDs who died (N = 8)	Evaluate discussions regarding ICD deactivation and actual practice	Though most patients discussed ICD deactivation, none had ICD deactivated	Single-center; data derived only from chart documentation
Lewis WR et al. <i>Am J Med</i> . Oct 2006;119(10):892-896.	Retrospective chart review of patients with ICDs who died (N = 63).	ICD shocks, causes and timing of death	More patients whose ICDs were not deactivated received shocks vs those whose devices were turned off. PM-dependence (N = 6) not associated with timing of death	Single-center experience of multidisciplinary approach. Limited numbers for analysis of PM-dependence
Stewart GC et al. <i>J Card Fail</i> . Feb 2010;16(2):106-113.	Written survey of HF patients (N = 105) including 65% with an ICD	Patient expectations of ICD benefits, survival, and deactivation circumstances	Patients overestimated survival benefits of ICDs ~ 10-fold compared with clinical trial evidence. Most patients would not want ICDs deactivated even if experiencing shocks, terminal cancer, or constant dyspnea.	May be unrealistic for patients to predict their own future wishes regarding ICD management
Raphael CE. <i>Pacing Clin Electrophysiol</i> . Dec 2011;34(12):1628-1633.	Interviews with HF patients with ICDs (N = 54)	Patient views on ICD deactivation	Very few patients recalled deactivation being included in consent process	Single-center; data based on patient recall
Patient and provider comparison studies				
Goldstein NE et al. <i>J Gen Intern Med</i> . Jan 2008;23 Suppl 1:2-6	Interviews of physicians (N = 12)	Physician experiences and views regarding ICD deactivation	Participants noted that ICD deactivation should be but is not commonly discussed; distinctions drawn between ICDs and other life-sustaining therapies	Small sample and qualitative assessment inherent to study design
Goldstein NE. <i>J Gen Intern Med</i> . Jan 2008;23 Suppl 1:7-12.	Focus groups of patients with ICDs (N = 15)	Patient views on discussing ICD deactivation	No patient had discussed ICD deactivation, or knew of this possibility	Single-center; lack of patient knowledge may have limited discussion of ICD management
Kramer DB et al. <i>Heart Rhythm</i> . Nov 2010;7(11):1537-1542.	Electronic survey of physicians (N = 185)	Legal knowledge and ethical beliefs regarding ICD and PM deactivation	Physicians less experienced or comfortable with ICD and PM deactivation compared with other therapies. Substantial uncertainty about legal status of deactivation	Single-center; complex topic for which general confusion may have biased responses

Reference	Study Methodology	Study Focus	Key Findings	Critique
Kramer DB et al <i>Am J Cardiol.</i> Apr 1 2011;107(7):1071-1075 e1075.	Electronic survey of patients with hypertrophic cardiomyopathy (N = 546), including 57% with ICDs	Legal knowledge and ethical beliefs regarding ICD and PM deactivation; advance care planning	Patients also uncertain about moral and legal status of ICD and PM deactivation, viewing them as different from other therapies and each other. ICDs uncommonly included in advance care planning activities	Specific, relatively young population at risk for sudden death.
Kramer DB et al <i>J Interv Card Electrophysiol.</i> Dec 2011;32(3):243-252.	Focus groups of cardiology nurses (N = 14)	Clinical, ethical, and legal concerns regarding ICD and PM deactivation	Informed consent considered inadequate. ICDs and PMs viewed as different from each other.	Small sample and qualitative assessment inherent to study design.
Kapa S et al (2010) <i>Mayo Clin Proc.</i> Nov 2010;85(11):981-990.	Survey (mixed paper and electronic) using 5 cases Patients (N = 326), "Medical Professionals" (N = 336), and Lawyers (70)	Hypothetical views on clinical, ethical, and legal appropriateness of ICD and PM deactivation	The majority of all 3 groups supported ICD deactivation for a terminally ill patient. More lawyers supported PM deactivation in PM-dependent patients than medical professionals or patients (. Medical professionals commonly viewed ICD deactivation as legal but not PM deactivation.	Differences in responses may reflect technical knowledge rather than beliefs per se. Patient all recruited from one center.
<u>Stand-alone provider surveys</u>				
Mueller PS et al <i>Pacing Clin Electrophysiol.</i> May 2008;31(5):560-568	Electronic survey of HRS members (N = 787)	Practices and attitudes regarding ICD and PM deactivation	Requests for both were common, and providers more comfortable with ICD than PM deactivation IEAPs most commonly performed deactivations	Relatively knowledgeable study population
Mueller PS et al <i>J Interv Card Electrophysiol.</i> Dec 2011;32(3):253-261.	Focus groups of IEAPs (N = 17)	Perspectives on ICD and PM deactivation	Greater moral distress with PM than ICD deactivation Patients confused about IEAP vs physician role	Small sample, hypothesis generating approach
Goldstein NE et al <i>J Am Coll Cardiol.</i> Jul 21 2009;54(4):371-373	Electronic survey of physicians (N = 147)	Attitudes related to ICD deactivation discussions	Physicians generally viewed patients as knowledgeable about ICD functions and their own ability to discuss deactivation, though non-cardiologists less certain of both	Greater response rate from electrophysiologists than other specialties
Kelley AS et al <i>Am Heart J.</i> Apr 2009;157(4):702-708 e701.	Electronic vignette-based survey of physicians (N = 558)	Views on ICD deactivation	Physicians more likely to discuss advance directives and DNR orders than ICD deactivation specifically, influenced by prior experience with the latter.	Low response rate (12%)
Marinkis PJ et al <i>Europace.</i> Aug 2010;12(8):1176-1177.	Electronic survey administered to European cardiology centers (N = 47) with vignettes	Practices and opinions on ICD deactivation in terminally ill patients	ICD deactivation common at end-of-life, but rarely discussed as an option at time of implant	No N given for number of respondents
Hauptman PJ et al <i>Am J Med.</i> Feb 2008;121(2):127-135	Electronic survey of physicians (N = 734)	Decision-making in end-stage HF	Limited experience discussing or performing ICD deactivation	Data derived largely from physician recall
Sherazi S et al <i>Mayo Clin Proc.</i> Oct 2008;83(10):1139-1141	Paper survey of physicians (N = 87)	Clinical, legal, and ethical beliefs regarding ICD deactivation	Widespread uncertainty about legality of ICD deactivation	Single-center; study performed before current guidelines published

ICD = implantable cardioverter-defibrillator; PM = pacemaker; HF = heart failure; IEAP = industry employed allied professional