

Management of cardiac electrical implantable devices in patients nearing the end of life or requesting withdrawal of therapy

Review of the Heart Rhythm Society 2010 consensus statement

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KEY WORDS

advance care
planning, cardiac
implantable electrical
devices, end of life,
ethics

ABSTRACT

Cardiac implantable electrical devices (CIEDs) are increasingly common interventions for a wide spectrum of cardiovascular diseases. Caring for patients with life-sustaining devices such as CIEDs at the end of life raises legal and ethical challenges. In 2010, the Heart Rhythm Society (HRS) published an expert consensus statement to review the principles and practice of CIED deactivation. This statement addressed a wide range of ethical and legal principles while providing guidance for communication, decision-making, and procedures in a variety of settings. In this article, we provide a summary of the HRS guidelines and highlight the most important features of CIED deactivation for the practicing clinician.

Introduction Cardiac implantable electrical devices (CIEDs), including pacemakers (PM) and implantable cardioverter-defibrillators (ICD), prolong the lives of patients who have a wide spectrum of heart rhythm problems.¹⁻³ Millions of patients have these devices,⁴ and worldwide annual implantation rates continue to grow due to an aging population and expanding clinical indications.^{5,6}

Despite the efficacy of heart rhythm devices in treating dysrhythmias, all patients treated with CIEDs will eventually die, many from progression of their underlying heart condition or development of another terminal illness such as cancer or severe infections. Clinical studies demonstrate 5% to 20% annual mortality rates for device recipients, meaning that tens of thousands of deaths occur annually among these patients.^{1-3,7}

Some patients (or their surrogates), fearing that their devices may prolong the dying process or cause significant discomfort, may request that their devices be deactivated. Indeed, caring for patients with life-sustaining devices, including

CIEDs, at the end of life raises difficult clinical as well as legal, religious, and ethical questions.⁸ In recognition of the complexity of caring for these patients, the Heart Rhythm Society (HRS) convened a panel of experts in law, philosophy, religion, palliative care, and clinical cardiology. This working group published a consensus statement in 2010⁸ in order to identify the legal and ethical foundation for CIED deactivation, outline strategies for communication and advance care planning, and provide guidance on the logistics of performing CIED deactivation.

This brief review will provide an overview of this consensus statement. We have approached this topic primarily from an American perspective, with identification of areas throughout where a European approach to these patients may differ.

Ethical and legal principles **Autonomy, informed consent, and informed refusal** In both legal and ethical analyses, respect for patient autonomy provides the foundation for decision-making

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Received: October 6, 2010.
Accepted: October 7, 2010.
Conflict of interest: Paul S. Mueller reports serving as a member of the Boston Scientific Patient Safety Advisory Board, and is Associate Editor, *Journal Watch General Medicine*.

Pol Arch Med Wewn. 2010; 120 (12): 497-502
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surrounding CIEDs. At the time of recommending implantation, informed consent maximizes autonomy by helping patients understand their disease and the available treatment options, allowing patients to participate fully in decision-making alongside their caregivers. An important component of informed consent is *decision-making capacity*, a clinical assessment of a patient's ability to make a specific decision regarding his or her health care. This standard may vary with the complexity of the clinical question and the consequences for specific choices.

A related concept to informed consent is that of informed refusal, also described as "the right to be left alone". Patients may refuse therapies, even those that are life-prolonging, and even if the patient has previously consented to that same therapy.⁹⁻¹² Chemotherapy, for example, is frequently consented to and then later abandoned as a patient's clinical course and health care goals evolve. Informed refusal is a very common feature of day-to-day care, as patients often opt to stop taking medications, or choose to defer invasive procedures, such as cardiac catheterization, after weighing the risks and benefits.

American courts have determined that patients have the right to make decisions regarding medical treatments, including treatment refusals. Cases involving feeding tubes¹³ and ventilator support¹⁴ specifically have emphasized that a patient's right to refuse ongoing therapy derives from constitutional rights of privacy and liberty, rights which extend to surrogate decision-makers in cases in which patients lack decision-making capacity.^{11,15,16} Though no case in the United States (US) has specifically addressed CIEDs, in no prior case have courts distinguished between the types of life-sustaining treatments. Thus, in the US these precedents apply to contemporary decision-making with CIEDs. Notably, there is no known case in which legal action has been brought against a physician in the US for deactivation of a CIED under circumstances in which removal or withdrawal of a different life-sustaining therapy would be deemed acceptable.

The HRS task force emphasized that religious beliefs inform many patients' views regarding CIED deactivation, and that support from clergy should be made available when necessary. In general, major Western religious traditions support the legal and ethical reasoning for respecting patients' rights to refuse medical treatments, placing a particular emphasis on weighing the benefits and burdens of therapy from patients' perspectives.

Surrogate decision-making Patients who lack decision-making capacity still deserve the same opportunity to express their values and preferences in their health care decisions, but can only do so through an established surrogate decision-maker. From a moral perspective, surrogates have the same rights to accept or refuse therapies as the patients for whom they speak. Ideally,

patients would identify their preferred surrogate, as can be done with an advance directive, a written document that typically identifies a surrogate decision-maker for events in which a patient loses decision-making capacity. This assignment is referred to as a "durable power of attorney for health care" in the US. Another version of an advance directive is 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. The values and goals expressed in a living will may help guide a surrogate in making decisions consistent with a patient's wishes. At the very least, patients with CIEDs should be encouraged to identify their preferred surrogate decision-makers, and to discuss their preferences regarding therapy openly and, if possible, in writing. In the absence of an advance directive, the US state law dictates identification of the patient's surrogate.

Common concerns related to withdrawing cardiac implantable electrical device therapies Objections to withdrawing CIED therapy may arise from arguments focused on an assortment of variables thought (erroneously) to influence the ethical status of device deactivation. These might include degree of illness, duration of therapy, consequences of deactivation, the exact function of the device, and others. Full refutation of each of these arguments would be beyond the scope of this review but are provided in the full HRS guidelines⁸ and in discussions by Sulmasy et al.^{17,18} However, state and federal law as well as general ethical consensus affirm that patient autonomy is the primary concern when withdrawing any medical therapy under any conditions. The law does not recognize any important patient- or device-specific characteristic that renders device deactivation inappropriate when requested by a patient or the legally-authorized surrogate.^{17,18}

Preventative ethics and advance care planning Whenever possible, ethical conflicts or confusion should be avoided through advance care planning. This process promotes patient autonomy through formal identification of a patient's values, preferences, and goals regarding future health care (e.g., at the end of life). Advance care planning should include discussing and documenting (in an advance directive) these values and preferences, and formally identifying potential surrogate decision-makers. Clinicians should view the advance care planning as providing an extension of the autonomous person – and thus an appropriately identified surrogate has the same rights as the patient for whom he or she speaks.

Studies have illustrated that relatively few patients with CIEDs engage in advance care planning specifically related to the devices,^{19,20} despite evidence that patients with ICDs who have engaged in advance care planning are less likely

to experience shocks while dying because ICD deactivation has occurred.²¹ Therefore, clinicians who care for patients with CIEDs should encourage their patients to engage in advance care planning, complete advance directives, and address and document device management specifically in their advance directives.

Rights and responsibilities of conscientious objectors Clinicians and others (e.g., device industry professionals) should not be compelled to carry out device deactivations if they view the procedure as morally objectionable or contrary to their religious beliefs.^{18,22} However, under these circumstances clinicians still have an obligation to provide for alternative personnel with the expertise to perform a deactivation if requested. This does not necessarily imply a complete transfer of care or severing of what may be a close and otherwise collaborative patient-doctor relationship, but merely affirms the obligation to respect a patient's wishes while also recognizing the moral agency of clinicians.²³

Decision-making and communication **General considerations** Conversations regarding CIED deactivation may be very difficult, and a systematic assessment of the elements of these discussions promotes better communication and supports shared decision-making.²⁴ A stepwise approach is provided here; this is not meant to be applicable to all patients, but may serve as a guide to the components that such discussions may include.

Ideally, the possibility of CIED deactivation should be noted at the time of device implantation as part of informed consent. It is important to make patients aware of the ability to cease what would seem to be a permanent and irreversible therapy. Similarly, if a physician objects to CIED deactivation, this should also be disclosed to patients. It may also be appropriate to provide clarification of options for deactivation by other providers should it be requested. Future conversations will depend on the evolution of a patient's clinical status and health care goals, and will ideally involve family members, nurses, social workers, and clergy as is deemed appropriate to each case.

Assessment of benefits and burdens When considering CIED deactivation, patients or surrogates will necessarily evaluate the benefits and burdens of device therapy. This is a highly individualized assessment comparing the treatment's clinical benefits to its current and potential future harms in the context of the patient's overall health care goals.^{24,25} While clinicians frequently provide important medical facts and insights regarding therapeutic options, ultimately the patient or surrogate must make very personal decisions weighing quality and duration of life, for example, as well as other variables such as costs and impact on family members.

Initially, discussion of CIED deactivation involves explicit evaluation of quality of life, functional status, current symptoms, and anticipated changes in disease states. A patient's preferences regarding possible conditions, including the possibility of "fate worse than death" scenarios, help draw the boundaries of patient expectations and overall goals from health care. These goals will frequently be influenced by a patient's family, religious beliefs, financial resources, past experiences with health care, and other factors.

Evaluation of options This overall picture allows for a more thorough exploration of a patient's specific treatment options. Aside from deactivation, some patients may be eligible for modification of either tachy- or brady-therapies or cardiac resynchronization, or non-device treatments such as antiarrhythmic medications, catheter ablation, arrhythmia surgery, ventricular assist devices, or transplant. Consultation with a cardiac electrophysiologist may be particularly important, particularly in cases of arrhythmic storm. Active consideration of these options may suggest that deactivation of a pacemaker or ICD should be deferred.

Logistics and specific settings The HRS guidelines emphasize that any physician or center caring for patients with CIEDs should have a clearly defined process for withdrawing therapy when the need arises. The logistical features of this process are summarized in general terms here, with additional recommendations specific to different settings in which CIED deactivation may occur.

Decision-making and planning The core elements of shared decision-making have been described in previous sections, and include, at a minimum, assessment of the patient's decision-making capacity and identification of a surrogate if necessary. The ultimate decision-maker should be comfortable with the medical facts and the likely consequences of withdrawal of therapy sufficiently to make an informed decision. The HRS guidelines emphasize the importance of engaging physicians with electrophysiology expertise to address any ambiguities about device function, and to ensure that alternatives such as antiarrhythmic medications, catheter ablation, or other device programming changes have been explored if appropriate. As noted previously, clinicians may choose not to participate in CIED deactivation, but in such cases they are obligated to arrange for an alternative clinician to provide the necessary care.

Crucially, the deactivation process should include anticipation of symptoms and appropriate palliative care planning tailored to individual patients' needs, as well as the needs of family members when appropriate. Patients may need access to palliative measures to treat symptoms associated with their underlying illness (cardiac and noncardiac), and in particular any new symptoms

which may emerge when device therapy is withdrawn. Preparation is important to ensure that therapy is available to treat any resultant potential symptoms of arrhythmias, angina, heart failure, confusion, or other conditions.²⁶

As is true for any life-sustaining therapy, it is important to recognize the potential impact of CIED deactivation on family members, particularly those who may have served in a decision-making role. Palliative care, social work, and clergy involvement in these cases may be appropriate, and in all cases it is vital to address and attempt to resolve any conflicts between clinicians and family members, or within families, before CIED deactivation occurs. Clinicians involved in CIED deactivation can thus play an important role in preventing feelings of guilt, anger, or confusion among patients' loved ones.

Documentation As would be true with withdrawal of any other life-sustaining therapy, CIED deactivation should occur only with an order from the responsible physician, preferably written in the patient's chart. Emergent situations may necessitate verbal orders, but these should be viewed as temporizing until the specifics can be appropriately detailed. At the very least, documentation should reflect: 1) a physician's determination that either the patient has decision-making capacity or that an appropriate surrogate has been identified; 2) adequate discussion of the clinical situation including alternatives to CIED deactivation; and 3) the expected consequences of CIED deactivation and the planning place for those contingencies.

Importantly, the physician order (written or verbal) must be specific regarding which therapies should be deactivated. "CRT-D deactivation", for example, could plausibly refer just to ICD shocks, biventricular pacing only, any pacing therapy, or some combination thereof. The HRS guidelines differ slightly from prior clinical guidelines,^{4,27} in which written consent by the patient/surrogate was required. However, requiring written consent (above and beyond the documentation outlined previously) is inconsistent with the common requirements for withdrawing other life-sustaining therapies, and thus was not deemed essential for withdrawal of CIEDs.²⁸⁻³⁰

Performing deactivation In general, CIED deactivation takes little time and requires only the programmer specific to a patient's brand of device. Patients and families, and occasionally other physicians, may be surprised to learn that deactivation itself is noninvasive and painless, and does not require surgery of any kind. Antitachycardia therapies may be deactivated by reprogramming therapy detection or application to "off". In emergencies or when a programmer is not available, this may be achieved by sustained application of a magnet, which will suspend tachy-arrhythmia detection but will not ordinarily affect pacing therapies (for ICDs).

Pacing therapy may be deactivated through reprogramming to "off" or other nonfunctioning modes such as subthreshold pacing output. Magnet application may change the mode of pacing (a typical response would be asynchronous pacing), but will not inhibit pacing.

Settings without electrophysiology expertise Hospitals, nursing facilities, or hospices without immediately-available electrophysiology support must contact the responsible physician, who should contact the physician responsible for following the patient's CIED for consultation as to which therapies should be deactivated.

Many patients in these settings may be able to travel to another location with programming expertise, although the outpatient approach may not be appropriate for cases such as PMs in PM-dependent patients. Alternatively, programmers may be brought to these facilities, or to patients' homes when necessary, frequently by device industry professionals. In these cases, medical personnel should perform the actual deactivation with industry employed allied professional assistance. The requirements for documentation are consistent regardless of the setting.

European perspective The European Heart Rhythm Association has developed a document similar to the HRS guidelines. This addresses many of the same principles supporting CIED deactivation while also exploring the differences between countries in advance care planning and the legality of deactivating PMs compared with ICDs.^{23,31} Clinicians caring for patients with CIEDs should familiarize themselves with local laws regarding deactivation, as in some countries deactivation of a PM in a dependent patient (for example) may not be legal. This distinction between PMs and ICDs has been previously described and is one of several areas in need of further research as well as education.^{23,31,32}

Conclusion Millions of patients are living with CIEDs, and for many of these patients eventual deactivation of their device may support their health care goals and accord with their values and wishes. We have described the general moral and legal principles supporting CIED deactivation, along with the logistical framework for doing so with care and compassion. Readers interested in additional details are encouraged to refer to the full HRS guidelines.

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Postępowanie u chorych z elektrycznym wszczepialnym urządzeniem kardiologicznym u schyłku życia lub żądających przerwania leczenia

Podsumowanie stanowiska Heart Rhythm Society z 2010 roku

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SŁOWA KLUCZOWE

elektryczne
wszczepialne
urządzenia kardio-
logiczne, etyka,
planowanie leczenia
w stanie
terminalnym,
schyłek życia

STRESZCZENIE

Elektryczne wszczepialne urządzenia kardiologiczne (*cardiac implantable electrical devices* – CIEDs) są coraz częściej stosowane w wielu chorobach sercowo-naczyniowych. Opieka nad chorymi u schyłku życia, którzy mają wszczepione urządzenia podtrzymujące życie, takie jak CIED, wiąże się z kwestiami prawnymi i etycznymi. W 2010 r. Heart Rhythm Society (HRS) opublikowało uzgodnione stanowisko ekspertów dotyczące zasad i praktyki związanej z odłączaniem CIED. Raport obejmuje szeroki zakres zagadnień etycznych i prawnych i zawiera zalecenia dotyczące porozumiewania się z chorym, zasad podejmowania decyzji oraz procedur odpowiednich w różnych okolicznościach. Artykuł zawiera podsumowanie zaleceń HRS z wyróżnieniem tych zagadnień dotyczących odłączenia CIED, które są najważniejsze z punktu widzenia lekarza praktyka.

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Praca wpłynęła: 06.10.2010.

Przyjęta do druku: 07.10.2010.

Zgłoszono sprzeczność interesów:

Paul S. Mueller jest członkiem
Boston Scientific Patient Safety
Advisory Board oraz Zastępcą
Redaktora Naczelnego *Journal
Watch General Medicine*.

Pol Arch Med Wewn. 2010;

120 (12): 497-502

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