

# HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy

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## Introduction

*“His defibrillator kept going off . . . It went off 12 times in one night . . . He went in and they looked at it . . . they said they adjusted it and they sent him back home. The next day we had to take him back because it was happening again. It kept going off and going off and it wouldn’t stop going off.”<sup>1</sup>*

Society representation on this document included: American College of Cardiology (Mark H. Schoenfeld); American Geriatrics Society and the American Academy of Hospice and Palliative Medicine (Nathan E. Goldstein); American Heart Association and the Hospice and Palliative Nurses Association (Debra L. Wiegand); European Heart Rhythm Association (Luigi Padeletti and Panos E. Vardas). Endorsed by the Heart Rhythm Society on May 3, 2010.

It is well-documented that implantable cardioverter-defibrillators (ICDs) save lives in multiple populations at risk for sudden death.<sup>2</sup> Pacemakers (PMs) have saved lives for individuals with bradyarrhythmias for five decades,<sup>3</sup> and cardiac resynchronization therapy (CRT) devices more recently have also been shown to improve symptoms and survival.<sup>4</sup> As indications for device therapy continue to expand,<sup>2</sup> the population of patients with these devices continues to grow.<sup>5</sup>

Despite the introduction of new technologies, all patients ultimately will reach the end of their lives, whether due to their underlying heart condition, or development of another terminal illness. In the last weeks of their lives,<sup>1</sup> twenty percent of ICD patients receive shocks which are painful<sup>6</sup> and known to decrease quality of life<sup>6,7</sup> and which greatly contribute to the distress of patients and their families.<sup>1</sup>

Most **physicians, nurses, and other health care providers** (referred to as “clinicians” throughout the document) and **industry-employed allied professionals** (IEAPs) who primarily interact with patients with Cardiovascular Implantable Electronic Devices (CIEDs, which include all PM, ICD, and CRT devices) have cared for dying patients and have participated in device deactivations.<sup>8</sup> However, the understanding of device deactivation varies<sup>8,9</sup> and studies show that many physicians report uneasiness with conversations addressing device management as patients near the end of their lives.<sup>9</sup> Few patients or families discuss the

option of device deactivation with their physicians prior to the days preceding death, even among patients with “do not resuscitate” orders.<sup>1</sup> Among physicians caring for patients with heart failure, few regularly discuss device deactivation with their patients.<sup>10</sup>

The **goals of this document** are:

- 1) To make clinicians aware of the legal, ethical, and religious principles which underlie withdrawal of life-sustaining therapies, including device deactivation, in patients who have made this decision;
- 2) To highlight the importance of proactive communication by the clinician in order to minimize suffering as the end of life nears for patients with CIEDs; and
- 3) To provide a management scheme to guide the clinician in assisting a patient with a request to withdraw CIED therapy.

While this document will focus on patients nearing the end of life, it will also address patients who have made a decision for CIED deactivation at other times, as well as the rights and responsibilities of clinicians (and others, such as industry-employed allied professionals) who may not wish to perform deactivation. To address this topic, a multidisciplinary writing group was convened consisting of electrophysiologists (DH, RH, NK, RL, LP, MS, PV), patients (RZ), and individuals with expertise in the fields of geriatrics (NG, DW), palliative care (NG, DW), psychiatry (LP), pediatrics (RH), nursing (DW), law (GA, RZ), ethics (GA, MF, DK, PM, DW, RZ), and divinity (MF). Input from industry and patient groups was also solicited and incorporated where relevant. Recommendations are based on consensus of the writing group and confirmed by the Heart Rhythm Society’s established consensus process. Agreement was greater than 90% on all recommendations. When using or considering the guidance given in this document, it is important to remember that there are no absolutes with regard to many clinical situations. The ultimate judgment regarding care of a particular patient must be made by the health care provider and the patient in light of all the circumstances presented by that patient.

## Basic principles

### Ethical and legal principles and precedents

- *A patient with decision-making capacity has the legal right to refuse or request the withdrawal of any medical treatment or intervention, regardless of whether s/he is terminally ill, and regardless of whether the treatment prolongs life and its withdrawal results in death.*
- *When a patient lacks capacity, his/her legally-defined surrogate decision-maker has the same right to refuse or request the withdrawal of treatment as the patient would have if the patient had decision-making capacity.*
- *The law presumes that all adults are competent, defined as the ability to understand the nature and consequences of one’s decisions. Only a court can declare an adult patient incompetent. In most situations, however, clini-*

*cians can assess patients’ decision-making capacity and act on these assessments without involvement of the courts.*

- *Ethically and legally, there are no differences between refusing CIED therapy and requesting withdrawal of CIED therapy.*
- *Advance directives should be encouraged for all patients with CIEDs.*
- *Legally, carrying out a request to withdraw life-sustaining treatment is neither physician-assisted suicide nor euthanasia.*
- *Ethically, CIED deactivation is neither physician-assisted suicide nor euthanasia. When carrying out a patient’s request for withdrawal of a life-sustaining treatment that a patient perceives as unwanted (including CIED therapies), the clinician’s intent is to discontinue the unwanted treatment and allow the patient to die naturally of the underlying disease - not to terminate the patient’s life.*
- *The right to refuse or request the withdrawal of a treatment is a personal right of the patient and does not depend on the characteristics of the particular treatment involved (i.e., CIEDs). Therefore, no treatment, including CIED therapies, has unique ethical or legal status.*
- *A clinician cannot be compelled to carry out an ethically-and legally-permissible procedure (i.e., CIED deactivation) that s/he personally views in conflict with his/her personal values. In these circumstances, the clinician cannot abandon the patient but should involve a colleague who is willing to carry out the procedure.*

Four *prima facie* principles have been used to characterize most ethical concerns in medicine: respect for patient autonomy, beneficence, nonmaleficence, and justice. *Respect for patient autonomy* refers to the duty to respect patients and their rights of self-determination, *beneficence* refers to the duty to promote patient interests, *nonmaleficence* refers to the duty to prevent harm to patients and *justice* refers, in part, to the duty to treat patients and distribute health care resources fairly.<sup>11</sup> When applied to the care of an individual patient, however, these principles may conflict with each other. For example, a patient’s values, preferences and goals (e.g., device deactivation at the end of life) may be at odds with a clinician’s perception of how best to help and not harm the patient (e.g., continue CIED therapies). Clinical ethics identify, analyze, and provide guidance on how to resolve these conflicts<sup>12</sup>. The law defines boundaries for clinical practice. Because ethics and law are closely aligned, they are considered together in this section.

A *life-sustaining treatment* is an intervention provided and managed by clinicians that prolongs life but may or may not reverse the underlying disease.<sup>13</sup> Examples of life-sustaining treatments are hemodialysis, mechanical ventilation, and medically assisted nutrition and hydration. Most clinicians who care for patients with CIEDs regard therapies

delivered by pacemakers and implantable cardioverter-defibrillators (ICDs) as life-sustaining.<sup>8,14</sup>

### Informed consent and the right to refuse treatment

Informed consent derives from the ethical principle of respect for persons; autonomy is maximized when patients understand the nature of their diagnoses and treatment options and participate in decisions about their care. Informed consent is the most important legal doctrine in the clinician-patient relationship. Clinicians are ethically and legally obligated to ensure that patients are informed and allowed to participate in decision making regarding their diagnoses and treatment options.<sup>13,15,16</sup>

Elements of informed consent include information, patient voluntariness, and patient decision-making capacity. *Decision-making capacity* is a clinical term and refers to a patient's ability to make informed health care-related decisions. Clinicians determine decision-making capacity by whether a patient is able to:<sup>15-17</sup> 1) make and communicate choices; 2) understand relevant information; 3) appreciate the clinical situation and its consequences; 4) manipulate information rationally; 5) make a decision that is consistent with the patient's values and goals.

Because of these requirements, proof of capacity can vary according to the complexity of the decision to be made; e.g., the graver the consequences of the decision, the greater the proof of capacity the clinician should require. Nevertheless, clinicians should not *presume* incapacity in patients who make decisions contrary to the clinicians' recommendations.<sup>15,16</sup> In contrast, *competence* is a legal term and is determined by courts.<sup>16</sup> In most situations it is acceptable to act on the physician's determination of capacity without formal legal declaration of incompetence.<sup>15,16</sup> Most patients who have lost decision-making capacity due to illness have not been declared incompetent by courts. With few exceptions (e.g., emergencies), a clinician may not treat a patient until the clinician has given the patient (or his/her surrogate) information about the proposed treatment, alternatives, and the risks and benefits of each—after which the patient (or surrogate) has the right to agree, accept an alternative, or refuse treatment altogether.<sup>17</sup>

A corollary to informed consent is informed refusal. A patient has the right to refuse any treatment, even if the treatment prolongs life and death would follow a decision not to use it. A patient also has the right to refuse a previously consented treatment if the treatment no longer meets the patient's health care goals, if those goals have changed (e.g., from prolonging life to minimizing discomforts), or if the perceived burdens of the ongoing treatment now outweigh the perceived benefits of that treatment (e.g., quality of life);<sup>18-21</sup> honoring these decisions is an integral part of patient-centered care. As described in the AMA Statement on end-of-life care, "[patients are entitled] to trustworthy assurances that preferences for withholding or withdrawing treatment will be honored".<sup>14,22,23</sup> If a clinician initiates or continues a treatment that a patient (or his/her surrogate) has

refused, then ethically and legally the clinician is committing battery, regardless of the clinician's intent.<sup>15,17,24,25</sup>

The courts in the United States have ruled that the right to make decisions about medical treatments is both a common law right (derived from court decisions) based on bodily integrity and self-determination and a constitutional right based on privacy and liberty.<sup>17,18,26</sup> Further, U.S. courts have consistently upheld a patient's right to refuse ongoing treatment. In the Matter of Karen Quinlan, Supreme Court of New Jersey, 1976, the Court ruled that the patient had both common law and constitutional rights to refuse continued ventilator support, even though her clinicians believed she would die without it.<sup>27</sup> In *Cruzan v. Director, Missouri Department of Health*, 1990, which involved a feeding tube, the U.S. Supreme Court confirmed that patients have the right to refuse life-sustaining treatments. The Court also ruled that a feeding tube was a medical treatment and that this treatment did not have unique status.<sup>28</sup> In the case of Terri Schiavo,<sup>29</sup> all the courts that reviewed the case ruled that adult patients have a constitutional right to refuse any treatment; including a life-sustaining treatment and that there is no legal difference between withdrawing an ongoing treatment, and not starting treatment in the first place. Finally, these rights extend to patients who lack decision-making capacity through previously expressed statements (e.g., advance directive) and surrogate decision-makers.<sup>20,29-31</sup>

In none of the above cases did the courts distinguish between types of life-sustaining treatments. The law applies to the person, and informed consent is a right of the patient—it is not specific to any one medical intervention.<sup>17,29,32,33</sup> Thus, even though the Supreme Court has not specifically commented on the question of PM or ICD deactivation, because CIEDs deliver life-sustaining therapies, discontinuation of these therapies is clearly addressed by the above Supreme Court precedents upholding the right to discontinue life-sustaining treatment.

### Surrogate decision-making

For patients who lack decision-making capacity and those declared incompetent by a court, clinicians must rely on surrogates to make decisions. If the patient has an advance directive (AD) that identifies a surrogate, legally as well as ethically the patient's choice of surrogate must be respected.<sup>15</sup> In the absence of an AD, clinicians must identify the legally-recognized appropriate surrogate. The ideal surrogate is one who best understands the patient's health care-related goals and preferences. In the United States, most states specify by law a hierarchy of surrogate decision-makers (e.g., spouse, followed by adult child, etc). Clinicians should be aware of the definition of legal surrogate in their states.<sup>34</sup> When making decisions, a surrogate should adhere to the instructions in the patient's AD (if one exists) and base decisions on the patient's—not the surrogate's—values and preferences if known (i.e., the "substituted judgment" standard). If unknown, the surrogate should base his/her decision on



clinical, quality of life, and other factors (i.e., the “best interest” standard).<sup>35</sup>

In the *Cruzan* case, to paraphrase Justice Sandra Day O’Connor’s concurring opinion, had the patient said, “If I’m ever unable to make treatment decisions myself, I would like my mother to make them for me,” that would have been a constitutionally-protected delegation of authority with which the state could not interfere.<sup>28</sup> Justice O’Connor’s opinion helped foster the health care surrogate movement, and now in every state a person can designate another to make healthcare decisions (including treatment refusals) for them when they are unable to make them for themselves. The surrogate has the same rights to accept or reject medical treatments as a patient with decision-making capacity. When the appropriate surrogate makes a decision, clinicians are morally and legally obligated to respect this choice as if it were made by the patient.

### Common concerns related to withdrawing CIED therapies

As described, the legal precedents and ethical principles are unambiguous—a patient has the right to refuse and request the withdrawal of CIED therapies regardless of whether s/he is terminally ill or not, and regardless of whether the therapies prolong life and hence death would follow as a consequence of a decision not to use them.<sup>15,36</sup> However, patients and clinicians may have additional questions about withdrawing CIED therapies, especially deactivating pacemakers in pacemaker-dependent patients.<sup>8</sup> Many of these concerns are addressed by applying the ethical principles and legal precedents described previously.

○ *Concern: Is withdrawing a CIED therapy akin to assisted suicide or euthanasia?*

Clinicians may be concerned that withdrawing life-sustaining treatments such as CIED therapies amounts to assisted suicide or euthanasia. However, two factors differentiate withdrawal of an unwanted therapy from assisted suicide and euthanasia: the intent of the clinician, and the cause of death. First, in withdrawing an unwanted therapy, the clinician’s intent is not to hasten the patient’s death, but rather, to remove a treatment that is perceived by the patient as a burden.<sup>15,21,36</sup> In contrast, in assisted suicide, the patient intentionally terminates his/her own life using a lethal method provided or prescribed by a clinician. In euthanasia, the physician intentionally terminates the patient’s life (e.g., lethal injection). Second, in assisted suicide and euthanasia, the cause of death is the intervention provided, prescribed, or administered by the clinician. In contrast, when a patient dies after a treatment is refused or withdrawn, the cause of death is the underlying disease.<sup>14</sup>

US Supreme Court decisions have made a clear distinction between withholding or withdrawing life-sustaining treatments, and assisted suicide or euthanasia. In the *Vacco* case, Chief Justice William Rehnquist wrote,

“The distinction comports with fundamental legal principles of causation and intent. First, when a patient refuses life-sustaining medical treatment, he dies from an underlying fatal disease or pathology; but if a patient ingests lethal medication prescribed by a physician, he is killed by that medication . . . our assumption of a right to refuse treatment was grounded not . . . on the proposition that patients have a . . . right to hasten death, but on well established traditional rights to bodily integrity and freedom from unwanted touching.”<sup>26,28,37</sup>

The Court ruled that all patients have a constitutional right to refuse treatment, but no one has a constitutional right to assisted suicide or euthanasia. In another case, the Court ruled that clinicians can legally (and should, from an ethical perspective) provide patients with whatever treatments needed to alleviate suffering (such as morphine) even if the treatments might hasten death. Criminality is determined by the clinician’s intent.<sup>38</sup>

○ *Concern: Are there unique factors about CIED therapy that differentiate it from other life-sustaining therapies? Continuity, duration, integration within the body?*

General agreement exists that ICD deactivation in dying patients is ethically permissible, especially if done to avoid uncomfortable shocks.<sup>1,39–41</sup> Less agreement, however, exists that pacemaker deactivation is ethically permissible, especially in pacemaker-dependent patients.<sup>8,14,40,42</sup> One purported rationale for this distinction is that ICD therapies are intermittent whereas pacemaker therapy in a pacemaker-dependent patient is continuous; death might not occur immediately after ICD deactivation, whereas death might occur quickly after pacemaker deactivation. Yet, widespread agreement exists that withdrawing other continuous life-sustaining treatments, such as mechanical ventilation, is ethically and legally permissible.<sup>43</sup> Duration of therapy may also be cited as differentiating PM therapy. However, patients have the right to refuse any treatments to which they previously consented even if they have received the treatment over a long period of time. Similarly, agreement exists that withdrawing other long-term life-sustaining treatments, such as hemodialysis and artificial hydration and nutrition, is ethically and legally permissible.<sup>43</sup> Similarly, there is no ethical or legal distinction between a treatment that’s integrated within the body, versus one which is outside the body.<sup>43</sup> Thus, the fact that pacemakers provide continuous long-term therapy that is integrated within the body, does not detract from the permissibility of carrying out requests to withdraw therapy from patients who no longer want the therapy.

○ *Concerns about other factors: Constitutive versus regulative therapies, replacement versus substitutive therapies*

Regulative therapies “coax the body back toward its own homeostatic equilibrium” (e.g., ICD shocks to restore sinus

rhythm), whereas constitutive therapies “take over a function the body can no longer provide for itself” (e.g., pacemaker therapy for complete heart block).<sup>43</sup> However precedent allows withdraw of other constitutive life-sustaining treatments such as mechanical ventilation and artificial hydration and nutrition from patients who no longer want the treatments.

Constitutive therapies can be further distinguished as therapies that either substitute for a pathologically lost function or therapies that replace a pathologically lost function. Clinicians commonly withdraw substitutive life-sustaining treatments (e.g., hemodialysis for kidney failure). A replacement therapy (e.g., kidney transplantation) literally becomes “part of the patient” and provides the lost function in the same fashion as the patient did when healthy. Replacement therapies also respond to physiologic changes in the host and are independent of external energy sources and control of an expert. Removing or withdrawing a replacement life-sustaining treatment has been characterized as euthanasia.<sup>43</sup> CIED therapies, including pacemaker support in a pacemaker-dependent patient, lack the features of replacement therapies and therefore are most often characterized as substitutive,<sup>14</sup> although this distinction has been questioned.<sup>42</sup> A porcine aortic valve, however, has all of the features of a replacement therapy. Most would regard carrying out a request to deactivate a pacemaker in a terminally-ill patient as far less morally problematic than carrying out a request to remove an implanted porcine heart valve in the same patient. Deactivating a pacemaker is non-invasive and does not introduce a new pathology. Removing an implanted porcine valve, however, is invasive and introduces a new pathology (i.e., a sternal wound). Thus, in this context, it is permissible to carry out requests to withdraw CIED therapies from patients who no longer want these therapies.

○ *Concern: What if a patient requests surgical removal of his/her lead(s) or generator?*

Patients might request removal of generator and/or leads rather than reprogramming. Since the same effect can be obtained by reprogramming and as surgical intervention carries with it significant chance of introduction of a new life-threatening pathology (e.g., infection, and/or mechanical complications of lead extraction), surgical intervention is not recommended. Legally, patients have a right to refuse any treatment, but do not have the right to demand mistreatment. A physician may judge the removal reasonable under the particular circumstances and do so with informed consent, but there is no ethical or legal obligation to meet this request.<sup>15</sup>

### **Withdrawing CIED therapies: Ethical principles underlying the decision-making process**

A helpful algorithm for withdrawing life-sustaining treatments involves answering a series of questions.<sup>19</sup> The first question is “**Who decides?**” Ethically and legally, patients

with decision-making capacity (or their surrogates) have authority to make decisions. Patients’ decisions have priority over clinicians’ decisions.<sup>14</sup> As described in the AMA code of ethics, clinicians should not impose their moral views on patients.<sup>23,33,44,45</sup> A patient, however, cannot demand treatments that are ineffective or compel a clinician to carry out a request that violates reasonable medical practice or the clinician’s conscience.

The second question is “**By what criteria?**” The answer to this question considers a treatment’s effectiveness, benefits and burdens in the context of the patient’s illness and quality of life. A treatment’s *effectiveness* is its ability to alter the natural history of a disease. CIEDs are effective in bypassing life-threatening cardiac conduction abnormalities and treating fatal arrhythmias. *Benefits* and *burdens*, however, are determined by the patient;<sup>46–49</sup> i.e., the patient’s assessment of the treatment’s value versus its existing and potential discomforts, costs and inconveniences associated with his/her illness and its treatment.<sup>19</sup> Each patient is unique and weighs such benefits and burdens in relation to their own values, preferences and health care-related goals.

Requests to deactivate CIEDs occur because patients may reach a point where the therapies delivered by the device become a burden and not a benefit and are no longer consistent with their health care wishes. Take, for example, a request to deactivate a pacemaker in a pacemaker-dependent patient who is terminally ill. The pacemaker is effective in addressing the potentially fatal cardiac conduction abnormality (and therefore is life-sustaining) but will not reverse the terminal illness. While the direct burdens of continuing pacemaker therapy are minimal, the indirect burdens may be substantial: prolongation of a dying process characterized by suffering, interference with a natural death that would occur without the pacemaker, resource depletion (e.g., financial), emotional and spiritual burdens associated with a prolonged illness, such as concerns about loss of dignity and control/identity and, in general, quality of life. The absence of any perceived benefit and the presence of these burdens outweigh the limited effectiveness of the pacemaker in this situation and therefore device deactivation is justifiable.<sup>19</sup> Because benefit and burden can only be determined by the patient, a patient may decide the burden of CIED therapy outweighs the benefit even if the patient is not terminally ill.

The third question is “**How are conflicts between patients and caregivers resolved?**” Such conflicts typically arise when there is misunderstanding among patients and clinicians on goals of care.<sup>19</sup> For example, a clinician may view ongoing CIED therapy in a terminally ill patient as effective, beneficial and non-burdensome. The patient (or surrogate), however, may strongly disagree. Multi-disciplinary care conferences, ethics consultation, and palliative care consultation can be very helpful in resolving these conflicts, especially in clarifying goals of care, establishing the permissibility of withdrawing CIED therapies (and con-

tingency plans if a decision is made not to withdraw CIED therapies), and formulating care plans.

Ethics consultation is not required prior to device deactivation, but may be helpful in situations that are difficult to resolve, such as conflict between members of a family or disagreement between members of the health care team caring for a patient, or when additional support is needed when pursuing a particular treatment course.<sup>50</sup> The Joint Commission requires that health care institutions have processes for addressing ethical concerns.<sup>51</sup> Clinicians should be familiar with these processes at their institutions.

### **Minimizing CIED-associated ethical dilemmas: Advance directives**

Advance care planning is a process that promotes patient autonomy in which a patient identifies his/her values, preferences and goals regarding future health care (e.g., at the end of life) and a surrogate decision-maker in the event the patient loses decision-making capacity.<sup>15</sup> Advance care planning should include discussing these values and preferences with care providers and potential surrogate decision-makers, documenting them in the patient's medical record, and completing an advance directive (AD).

In general, there are two forms of the AD: the durable power of attorney for health care and the living will. The durable power of attorney for health care allows the patient to specify a surrogate in the event the patient loses decision-making capacity. The living will allows the patient to list specific health care-related values, goals and preferences. Some ADs have features of both the durable power of attorney for health care and living will. From an ethics standpoint, clinicians should view the AD as an extension of the autonomous person and, therefore, should respect the values, goals and preferences listed in the AD. From a legal standpoint, all 50 states in the US recognize ADs as an extension of the autonomous person. The Patient Self-Determination Act, passed by Congress in 1990 in response to the *Cruzan* decision, requires that health care institutions that participate in Medicare and Medicaid programs ask patients whether they have an AD, inform patients of their rights to accept or refuse medical treatments and to create and execute an AD, and to incorporate ADs into patients' medical records.<sup>52</sup>

Unfortunately, evidence suggests that few patients with CIEDs engage in advance care planning specifically related to the devices. For example, few patients with ICDs discuss device deactivation with their clinicians or know that deactivation is an option.<sup>53</sup> In addition, while many patients with CIEDs have ADs, very few of them mention the device specifically in their ADs.<sup>54</sup> Most clinicians prefer treatment-specific statements over more general statements in an AD and thus it is likely that they would be more comfortable carrying out CIED deactivations if patients' wishes are clearly documented in patients' medical records or ADs.<sup>55</sup> Patients who complete an AD receive care that is strongly associated with their preferences<sup>56,57</sup> and patients with ICDs who engage in advance care planning are less likely to

experience shocks while dying because ICD deactivation has occurred.<sup>40</sup> Therefore, clinicians who care for patients with CIEDs should ask their patients to engage in advance care planning, complete ADs, and address device management specifically for their ADs. Allied health care professionals (e.g., social workers) should also facilitate the process.

### **Rights and responsibilities of the clinician for whom deactivation is counter to his or her personally held beliefs**

Regardless of the ethical and legal permissibility of carrying out requests to withdraw CIED therapies from patients (or their surrogates) who have made this decision, clinicians—like patients—are moral agents whose personal values and beliefs may lead them to prefer not to participate in device deactivation. A recent survey found that about 10% of clinicians who care for patients with CIEDs view pacemaker deactivation in a pacemaker-dependent patient as a form of assisted suicide or euthanasia.<sup>8</sup> Others object to pacemaker deactivation because they believe pacemaker therapy does not prolong the dying process or cause physical discomfort (unlike ICD shocks) and that pacemaker deactivation may cause discomfort (e.g., worsened heart failure symptoms).<sup>58</sup> Clinicians and others (such as IEAPs) should not be compelled to carry out device deactivations if they view the procedure as morally objectionable.<sup>14,41</sup> Under these circumstances, the clinician should inform the patient of his/her preference not to perform CIED deactivation. However, as described in the AMA code of ethics, the clinician should not impose his/her values on the patient, and must state their objection in a way to avoid causing the patient emotional distress.<sup>23,44,59,60</sup> Further, s/he must not abandon the patient, but rather, the clinician and patient should work to achieve a mutually agreed-upon care plan. If such a plan cannot be achieved, then the primary clinician should involve a second clinician who is willing to co-manage the patient and provide legally permissible care and procedures including CIED deactivation.<sup>13,14,23</sup> If there is difficulty identifying another clinician, the hospital administration and/or ethics committee should be contacted to help identify a willing clinician and resolve the issue. The willingness of the initial clinician to help resolve the issue, even if s/he has moral objections to performing the deactivation would absolve the clinician of any accusation of obstruction or battery. If a clinician knows s/he may have moral/ethical conflict with the discontinuation of therapy, the practice should have a procedure implemented to deal with the issue with specific language created in advance of the event. That a clinician transfers care of the patient for deactivation to another clinician, does not imply that the initial patient clinician relationship should be severed. It is important for the healthcare team to recognize and address any conflicts within the team.

In summary, decisions made by patients (or their surrogates) with respect to the withdrawal of life-sustaining CIED therapies are subject to the same clinical consid-



erations and ethical and legal principles as other life-sustaining treatments. Patients (and their surrogates) have the right to refuse or withdraw any life-sustaining treatment including CIED therapies based on their health-care-related values, preferences and goals. Deactivation of a CIED, whether a pacemaker, ICD or other device is not assisted suicide or euthanasia and is ethically and legally permissible.

### Basic religious principles

- *Legal and ethical rationales for respecting patients' rights to refuse medical treatment are supported by the tenets of major religious traditions in Western culture.*
- *Depending on the significance (to the patient) of religious belief and its bearing on the decision to be made, it can be part of what motivates a patient to choose or refuse deactivation of CIED devices.*
- *The distinction between letting life go (allowing to die) and taking life (intending to actively kill) is religiously important, especially for those who appeal to it as part of their religious understanding of justifiable choices regarding death.*
- *Perception of disproportionate burden caused by continuation of life-sustaining treatment, as determined by the patient, is central to religious justifications of permissibility of letting life go.*
- *A clinician whose own religious beliefs are not in line with the patient's may not override a patient's or surrogate's choice. The clinician may, however, appeal to his/her own right not to participate in deactivation—not abandoning the patient but by involving a colleague who is willing to carry out the procedure.*
- *Patients should be provided the support they want and need in order to make decisions about deactivation of CIEDs that are coherent with their spiritual and moral beliefs.*

The United States is pluralistic in its sub-cultures and in its multitude of faith communities and there is diversity and disagreement within as well as among particular faith communities. However, major religious traditions have recognized grounds within their fundamental convictions and principles for respecting the patient's right to refuse and/or withdraw medical treatment.<sup>61–68</sup>

Religious traditions are like ethical and legal traditions in Western culture today not only in respecting the patient as the primary decision-maker in contexts of medical care, but also in appealing to rationales of bodily integrity and capacity for self-determination in support of patient autonomy. Religious traditions take seriously patients' views of benefits and burdens and goals of care. More particularly, however, religious traditions also offer religious rationales for these ethical principles, which may guide the decisions of patients insofar as they are adherents of specific religious communities or traditions.<sup>61–68</sup>

### Choices regarding death

In considering decisions regarding end of life care, religious traditions offer a framework of meaning regarding death. Despite the variety of specific meanings for death in different traditions, no organized religious tradition considers death to be only and simply a "full stop" to life, or an unmitigated evil. Major religious traditions have endured in large part because they offer some response to central human questions of suffering and death, hope and transcendence.

In medical contexts the question of actively taking life, or killing, is a much more disputed question among religious traditions, and the majority of traditions do not allow taking one's hand to kill even those who are in the process of dying.<sup>45</sup> Religious scholars recognize the distinction between direct killing and allowing death as key to differentiating among choices regarding death. Accordingly since choices to deactivate pacemakers, ICDs, or CRTs are choices to let life go and not directly to kill, religious justifications for such deactivations are explicitly available in many religious traditions and tacitly assumed in others.<sup>61–68</sup>

### Religious traditions and "letting life go"

A key element in a religious as well as secular ethical distinction between killing and letting die, is the conviction that to let die need not be to intend death or actively to cause it even though to let die is to accept death. The religious traditions that want to keep these distinctions argue that to accept death, to allow it and provide an occasion for it by removing unreasonable barriers, is not to violate the value of human life, nor to disrespect the intrinsic dignity of any person. It is, rather, to accept the inevitable process of dying that is a part of human living.

### Relevance of religious perspectives to deactivation of CIEDs in terminally ill patients

In Western societies, major religious traditions support the choice of patients regarding withdrawal of treatment when the burden of the treatment is perceived by the patient to be disproportionate to the benefit.<sup>61–68</sup> Patients who make decisions for deactivation of cardiac devices based on their religious beliefs are to be respected not only in their legal right to refuse treatment but in their appeals to religious reasons for their choices.

Respect for the religious traditions of patients includes respect for patients' own understanding of their religious traditions. If patients (or their designated surrogates) appear to be unclear about the tenets of their traditions, or conflicted in their judgment of what is best for them, they should have access to pastoral counseling and relevant clergy, as well as to ethics consultation.

Religious beliefs and commitments can be profoundly important to clinicians as well. Should a clinician's religious beliefs lead to a different assessment of the situation from the patient's, then what has been said in the previous section on legal and ethical principles regarding

refusal to participate in deactivations would be similarly applicable.

## Effectively putting into practice the device deactivation process

### Communication

- *Communication about CIEDs should be a part of a larger conversation about patients' goals of care. The role of the clinician is to help patients determine how the benefits and burdens of device therapy align with their desired outcomes for their health care.*
- *Communication about CIED deactivation is an ongoing process that starts prior to implant and continues over time as patient's health status changes.*
- *While the role of the clinician is to advise and assist the patient and family, the ultimate decision-making authority rests with the patient; or his/her surrogate, if the patient does not have capacity to make the decision.*
- *Multiple options are available to the patient, family, and clinicians with regard to the extent of deactivation of CIED therapy and the modalities available, ranging from programming off only certain features such as shock therapy, to discontinuation of all therapy to not replacing a depleting device.*

Timely and effective communication among patients, families, and health care providers is essential to ensure informed consent and to prevent situations like the anecdote described in this document's introduction. Effective communication includes taking a pro-active role in determining the patient's goals of care, helping the patients weigh the benefits and burdens of device therapy as his/her clinical situation changes, clarifying the consequences of deactivation, and discussing potential alternative treatments. These conversations improve outcomes for both patients and their families.<sup>69</sup> They should begin at time of implant and should continue over the course of the patient's illness, as part of ongoing patient education on CIEDs. As illness progresses, patient preferences for outcomes and the level of burden acceptable to a patient may change.<sup>70,71</sup> Few patients with CIEDs discuss device deactivation with their clinicians or know that device deactivation is an available option.<sup>1,53</sup> Studies of physicians, demonstrate that while they believe they should engage in these types of conversations with patients, they rarely do.<sup>9,72</sup>

### Discussion of device deactivation in the context of overall goals of care

Communication techniques used to discuss the role of the device need to move from treatment-directed conversations to goal-directed conversations.<sup>46,47</sup> Without a better understanding of their current state of health and the role that the CIED plays within it, patients cannot make fully informed decisions.

Table 1 outlines the steps needed for goal-directed communication and some suggestions of useful phrases to begin con-

versations at each point. These conversations should include a discussion of quality of life, functional status, what elements are important to the patient regarding control and dignity, and both current and potential future symptoms, as each of these elements can influence how patients set goals for their health care, and all have been described by patients as their priorities in end of life care.<sup>73</sup> Step 2 is particularly important, because data shows that some patients with ICDs do not understand the role the device plays in their health, particularly at the end of life.<sup>53</sup> In addition to determining the desired goals of care, it can also be helpful to determine undesirable states. These "fate worse than death" scenarios may be helpful in terms of outlining the parameters within which the patients' treatments should be maintained.

Decision-making conversations are of course more individualized, nuanced and complex than those described in the table, which is provided as a guide. Patients will vary in their degree of health literacy and understanding, and clinicians must individualize the conversation to the patient. The goal is not to overburden patients with decisions, but to determine an overall set of guiding principles by which clinicians can help patients make decisions. This is not to say that all treatment decisions can be generalized. For example, patients may choose to forgo intubation, CPR, and external defibrillation, with a "DNR" order, while at the same time also decide to keep the defibrillation function of their ICD active, as resuscitation interventions and the ICD each carries its own benefits and burdens. Each of these decisions should be made in the context of overall goals of care. In general, if a patient determines that device deactivation is consistent with his/her goals of care, a decision to forgo external resuscitation will also be appropriate.

Particular considerations may apply to older adults. The majority of ICDs are implanted in older adults,<sup>5</sup> and by 2050 it is estimated that there will be 88 million Americans over age 65.<sup>75</sup> Eighty percent of Medicare beneficiaries experience one or more chronic conditions.<sup>76</sup> Conversations addressing device management, therefore, must consider the impact of multiple competing comorbid illnesses on the functional status and quality of life of older adults and how the role of the device relates to these conditions. Functional status is particularly important for older adults, as many decisions about quality of life relate to independence and ability to care for one's self. Older adults should be assessed for frailty, a physiologic process characterized by loss of skeletal muscle, and other changes which can have a considerable impact on their ability to care for themselves and may relate to how they make decisions about their medical care.<sup>77-79</sup> Geriatric consultation can also be helpful in identifying frailty, as well as frequent falls, or memory impairment which may play a role not only in the ways that a patient makes decisions but in their ability to participate in the decision-making process, and in determining how to care for older adults as they transition out of the hospital from rehab, long-term, hospice, or home care.<sup>78,80</sup>



**Table 1** Communicating with patients and families about goals of care relating to CIEDs

Steps	Sample phrases to use to begin conversation at each step
1. Determine what patients/families know about their illness.	"What do you understand about your health and what is occurring in terms of your illness?"
2. Determine what patients/families know about the role the device plays in their health both now and in the future.	"What do you understand the role of the [cardiac device] to be in your health now?"
3. Determine what additional information patients/families want to know about their illness.	"What else would be helpful for you to know about your illness or the role the [cardiac device] plays within it?"
4. Correct or clarify any misunderstandings about the current illness and possible outcomes, including the role of the device.	"I think you have a pretty good understanding of what is happening in terms of your health, but there are a few things I would like to clarify with you."
5. Determine the patient/family's overall goals of care and desired outcomes.	"Given what we've discussed about your health and the potential likely outcomes of your illness, tell me what you want from your health care at this point." For patients or families needing more guidance: "At this point some patients tell me they want to live as long as possible, regardless of the outcome whereas other patients tell me that the goal is to be as comfortable as long as possible while also being able to interact with their family. Do you have a sense of what you want at this point?"
6. Using the stated goals as a guide, work to tailor treatments, and in this case, management of the cardiac device to those goals.	Phrases to be used here depend on the goals as set by the patient and family. 1) For a patient who states that her desired goal is to live as comfortably as possible for whatever remaining time she has left: "Given what you've said about assuring that you are as comfortable as possible it might make sense to deactivate the shocking function of your ICD. What do you think about that?" OR 2) For a patient who states s/he wants all life-sustaining treatments to be continued, an appropriate response might be, "In that case, perhaps leaving the anti-arrhythmia function of the device active would best be in line with your goals. However, you should understand that this may cause you and your family discomfort at the end of life. We can make a decision at a future point in time about turning the device off. Tell me your thoughts about this."

Table adapted from sources in this document's bibliography.<sup>45,47,74,100</sup>

The goal of these conversations is a model referred to in the literature as "shared-decision making" in which clinicians work together with patients and families to ensure that patients understand in the context of their illness the benefits and burdens of a particular treatment and the potential outcomes that may occur as a result of its continued use or discontinuation.<sup>47</sup> Clinicians must also recognize that while the ultimate power for decision-making rests with patients, they may be influenced by factors such as family, culture, religion, etc. Likewise, while cost should not play a role in the ways that clinicians counsel patients and families, clinicians should be aware that cost does influence the way that some patients make decisions. Studies of patients with serious illness often report that a large number of families lose their savings as well as a major source of income due to either the illness itself or from other family members having to care for the patient.<sup>47,81</sup> Many of these factors may influence a patient to cede the power of decision making to other individuals.

An important element of all conversations regarding device deactivation (and goals of care in general), is that the patient understand that no decision-to deactivate or not to deactivate—is binding in any way, and that they are always free to change their mind and reverse or modify a previous directive.

### **Discussion of the benefits and burdens of ongoing device therapy, and the consequences and uncertainties of deactivation**

An important role for the clinician is to provide factual information concerning the beneficial and negative effects of continuing device therapy. By clear explanation to the patient of his/her diagnosis, prognosis, and the impact of each treatment option, clinicians help the patient to assess the benefits and burdens of continued therapy on his/her life in relation to personal healthcare goals.<sup>46,49</sup> It is also vital for both the health care provider and patient to have an accurate understanding of the expected consequences of

device deactivation. Consultation with a clinician with device expertise may help clarify the clinical picture, although it is often difficult to predict a patient's clinical course after deactivation.

The withdrawal of implantable device function must be understood in the context of the particular CIED under consideration, whether pacemaker, ICD, or cardiac resynchronization device,<sup>42</sup> as knowledge about a specific device is essential to determining how to change its settings consistent with the patients' goals regarding survival and quality of life. Pacemaker and CRT therapy are indicated for the amelioration of symptoms due to bradycardia and heart failure respectively.<sup>82</sup> For patients who have no underlying rhythm ("pacemaker-dependent"), pacing also provides life-sustaining therapy. Pacemaker dependence can, however, vary over time.<sup>83</sup> In a completely pacemaker-dependent patient death will follow immediately after the cessation of pacing therapy. If the patient is not pacemaker dependent, his/her dying process is unpredictable and those patients need to be assessed closely for symptoms of distress, such as dyspnea, angina, or syncope which may worsen his/her quality of life. The clinician should ensure the patient understands these potential consequences, and that it is unknown whether continuation of pacing will prolong death. Appropriate symptom control in this group of patients can be used effectively to assure comfort,<sup>41,83</sup> and patients and families should be reassured that symptoms can be managed. If cardiac resynchronization improves heart failure or reduces arrhythmia burden, discontinuation may impact survival as well as symptoms and quality of life.

Unlike pacemakers, ICDs are not implanted for the relief of symptoms (unless they also provide essential anti-bradycardia or CRT pacing) but rather for prevention of sudden death in patients at risk. ICD shock therapy has added to patient and family suffering when the device has fired at the end of life.<sup>1,31,58,84,85</sup> Deactivation of ICD shock therapy may thus improve quality of life in such patients by eliminating the pain and emotional distress associated with the delivery of ICD discharges. Elimination of defibrillation therapy is less likely to result in immediate death unless the patient is experiencing incessant or increasingly frequent ventricular arrhythmias.

### Discussions of options for withdrawal of therapies

In addition to deactivation, there are other options for treatment withdrawal available. Patients and/or their surrogates may choose not to replace the device as their generators become depleted.<sup>86</sup> This applies to all CIEDs. Invasive replacement of a device carries with it potential discomfort, inconvenience and other risks of complication such as infection; it may even hasten death.<sup>87</sup> Further, partial deactivation is an option. Tachyarrhythmia therapy can be disabled while leaving bradycardia pacing functional. Shock therapy can be deactivated without disabling anti-tachycardia pacing function, depending on the patient's goals for prolongation and quality of life.

### Discussion of potential alternative treatments

As part of the decision-making process around deactivation of some or all CIED therapies, the clinician should consider and advise the patient of alternative therapies that might impact their decision. For example, patients with recurrent ventricular arrhythmias resulting in painful ICD shocks may be candidates for reprogramming of antitachycardia therapies, catheter ablation, or pharmacologic treatments and may benefit from referral to a center with expertise in these techniques. Patients with worsening congestive heart failure may be candidates for advanced therapies such as left ventricular assist devices or cardiac transplantation. If the patient and their clinician team are actively considering such options, then deactivation of a pacemaker or ICD may not be consistent with their goals of care. In keeping with the principle of informed consent, alternative therapies should be explained before proceeding with device deactivation.

### Timing of deactivation conversations

Table 2 provides a guide for the timing of discussions about device deactivation. Conversations about CIED deactivation should begin at the time of implantation, as part of the informed consent process. These conversations then change over time as the patient's disease progresses, as part of larger discussions of the patient's overall disease, progression, and goals.

### The role of the family in the decision-making process

While the ultimate decision regarding treatments rests with the patient (or legal surrogate), conversations about device deactivation optimally occur with the support of the family.

Simply signing a health care proxy or living will is not enough; conversations between members of the health care team, patient, and family must occur early enough in the patient's illness so the entire family is "on the same page" in terms of the goals of medical care.<sup>74</sup> Once the patient loses decision-making ability, in defining for a surrogate the basis on which s/he should make decisions, a useful question is: "If your loved one could wake up for 15 minutes to understand his/her condition fully, but then had to return to it, what would s/he tell you to do?"<sup>88,89</sup> Clinicians play an important role in supporting the patient's surrogate and facilitating communication and support of additional family members.

### Role of health care providers in the decision-making process

The patient's electrophysiologist and cardiologist should be included in deactivation conversations whenever possible to assure that all therapeutic options available to meet the patient's goals can be evaluated. Clinicians may differ in their levels of expertise and comfort with these discussions, and as such, consultation with clinicians from other specialties may be helpful. An interdisciplinary approach that includes clinicians: nurses, social workers, and clergy, is essential to support the patient and family. For example, many

**Table 2** Steps for your conversation

Timing of conversation	Points to be covered	Helpful phrases to consider
Prior to Implantation	<ul style="list-style-type: none"> <li>● Clear discussion of the benefits and burdens of the device.</li> <li>● Brief discussion of potential future limitations or burdensome aspects of device therapy</li> <li>● Encourage patients to have some form of advance directive</li> <li>● Inform of option to deactivate in the future</li> </ul>	“It seems clear at this point that this device is in your best interest, but you should know at some point if you become very ill from your heart disease or another process you develop in the future, the burden of this device may outweigh its benefit. While that point is hopefully a long way off, you should know that turning off your defibrillator is an option.”
After an episode of increased or repeated firings from an ICD	<ul style="list-style-type: none"> <li>● discussion of possible alternatives, including adjusting medications, adjusting device settings, and cardiac procedures to reduce future shocks in context of goals of care</li> </ul>	“I know that your device caused you some recent discomfort and that you were quite distressed. Lets see if we can find a correctable reason why this may be happening, and discuss options to decrease the number of firings.”
Progression of cardiac disease, including repeated hospitalizations for heart failure and/or arrhythmias	<ul style="list-style-type: none"> <li>● re-evaluation of benefits and burdens of device</li> <li>● assessment of functional status, quality of life, and symptoms</li> <li>● Referral to palliative and supportive care services</li> </ul>	“It appears as though your heart disease is worsening. We should really talk about your thoughts and questions about your illness at this point and see if your goals have changed at all.”
When patient/surrogate chooses a Do Not Resuscitate Order	<ul style="list-style-type: none"> <li>● re-evaluation of benefits and burdens of device</li> <li>● exploration of patient’s understanding of device and how s/he conceptualizes it with regards to external</li> <li>● defibrillation</li> <li>● Referral to palliative care or supportive services</li> </ul>	“Now that we’ve established that you would not want resuscitation in the event your heart was to go into an abnormal pattern of beating, we should reconsider the role of your device. In many ways it is also a form of resuscitation. Tell me your understanding of the device and let’s talk about how it fits into the larger goals for your medical care at this point.”
Patients at End of Life	<ul style="list-style-type: none"> <li>● re-evaluation of benefits and burdens of device</li> <li>● discussion of option of deactivation addressed with all patients, though deactivation <i>not</i> required</li> </ul>	“I think at this point we need to re-evaluate what your [device] is doing for you, positively and negatively. Given how advanced your disease is we need to discuss whether it makes sense to keep it active. I know this may be upsetting to talk about, but can you tell me your thoughts at this point?”

Adapted from: Wiegand DL and Kalowes P. Withdrawal of cardiac medications and devices.<sup>31</sup>

patients may have formed long-term relationships with electrophysiology nurses, or they may tell the cardiac critical care nurse that they have decided they no longer want the CIED to be active; who will communicate this vital information to the patient’s responsible physician. Social workers can help patients and families cope with emotional reactions to conversations about changing goals of care, and they are also helpful when care plans change to assure appropriate discharge planning and utilization of homecare services. Clergy can provide emotional and spiritual support for all parties involved.

### Role of psychiatric consultation

Routine psychiatric consultation is not needed for patients who are considering device deactivation. Indications for

psychiatric consultation when device deactivation is under consideration include cases where health care providers or families have questions whether a particular psychiatric disorder may be interfering with the patient’s ability to make informed decisions, such as major depression or thought disorders, such as paranoid delusions. Neuropsychiatric disorders including delirium and dementia can impact decision making ability, and when in doubt, a psychiatric consultation can help the team assess for adequate decision-making ability at a specific point of time. Geriatricians are also knowledgeable and skilled at distinguishing between dementia and delirium and thus may be called on to consult on the care of an older adult with cognitive impairment in whom CIED deactivation is being discussed.



## Role of palliative care specialists

While the primary responsibility for proactive communication around device deactivation during the entirety of a patient's clinical course rests with those clinicians responsible for device-related care, cooperative consultation with palliative care services can be beneficial for patients who are considering or have chosen deactivation as end of life nears. Palliative care aims to relieve suffering and improve quality of life for patients with advanced illness, and their families. Unlike hospice or end-of-life care, it can be provided simultaneously with appropriate life-prolonging therapies.<sup>46,48</sup> Palliative care is now readily available across the United States.<sup>90</sup> Because changing or deactivating device settings can result in gradual worsening of symptoms, it is important to involve palliative care in the care of patients before devices settings are altered, as these concerns can often be eliminated with early symptoms assessment and treatment.

In addition to symptom management, palliative care clinicians are experienced in the complex conversations surrounding progressive illness and changing goals of care.<sup>46</sup> Studies show that patients who receive palliative care are more likely to have their treatment wishes followed and have better quality of life at the end of life.<sup>91</sup> Palliative care also plays a key role in supporting families of patients with advanced disease, who themselves undergo declines in physical and mental health, and have an increased risk of death.<sup>91–93</sup> Studies demonstrate that patients and families desire conversations about end-of-life care.<sup>73,94,95</sup>

Discussions about deactivation may be misconstrued by patients and families as the beginning of abandonment. Patients must understand that even if they choose to deactivate the device, the clinicians involved in their care will continue to work with them to assure that their needs (physical and otherwise) are met. Palliative care can assist with safe and seamless transitions from hospital-based to hospice based care.

Hospice care is provided to those patients with a prognosis of six months or less who have decided to forgo all treatments aimed at curing their underlying terminal illness.<sup>48</sup> While these patients may receive some therapies aimed at treating reversible causes, hospice is fundamentally for those patients who are very near the end of life and for whom the primary goal is solely comfort.<sup>46</sup> Hospice clinicians should be included in conversations for patients as they near the end of life to ensure continuity in carrying out the goals of care regarding a CIED. Recent data demonstrate that most hospices do not have practices in place to assure that these conversations occur at the time of enrollment. Both specialists and generalists must partner with hospices to facilitate these conversations and ensure the availability of clinicians who can deactivate CIEDs for patients near the end of life.<sup>9</sup>

Further, both hospice and palliative care clinicians can help clarify concerns and misperceptions about the device after the patient has died. For example, some families have erroneous concerns that they may be shocked by touching

their deceased relative, or that the device must be explanted after death (which is only true in the case of cremation). Likewise, the clinician can dispel the myth that continued pacemaker function after a patient has died is unnecessarily prolonging life, or even that the impulses from the device are causing the heart to continue beating after death.

## Improving communication around end of life care: importance of education

To improve communication about device management for patients with advanced disease, educational endeavors need to be instituted for both healthcare professionals and trainees. Ongoing education for clinicians in practice –physicians, nurses, physicians assistants, social workers, and clergy – should incorporate teaching about the importance of conversations about device deactivation in an effort to improve communication skills and create practice change. Training programs for health care professionals have been shown to improve their knowledge and increase the likelihood they will put new skills into practice.<sup>96–98</sup> In addition, fellows and other clinicians in training must also learn the importance of these conversations as well as undergo training specifically aimed at improving skills in communication. Senior health care providers modeling these conversations to those who are learning are a key to improving trainee education about these complex discussions.

## Logistics of CIED deactivation

- *Any physician or center that implants CIEDs should have a clearly defined process to withdraw therapies at such a time that becomes appropriate.*
- *Deactivation of CIED therapies requires an order from the responsible physician, preferably written, with appropriate documentation. In emergent situations, a verbal order should be followed by written documentation within 24 hours.*
- *Documentation prior to deactivation must include the physician's determination that the patient has the capacity to make the decision or that the appropriate surrogate has been identified; that consequences to deactivation have been discussed; and that alternatives have been discussed if relevant*
- *A physician order for deactivation must include the specific therapies to be deactivated or re-programmed.*
- *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.*
- *Deactivation of anti-tachycardia therapies may be achieved by re-programming or by magnet application.*
- *Deactivation of pacing therapies may be achieved by reprogramming to specific modes or to sub-threshold outputs.*
- *Any uncertainties about the specifics of deactivation should be clarified by the health care team, ideally in consultation with a physician with electrophysiology expertise.*

- *The specific resources of acute care facilities, inpatient hospice, long-term care facilities, or patients at home require careful consideration when planning and carrying out a device deactivation.*
- *All Industry Employed Allied Professionals (IEAP) must work under direct supervision of medical personnel (except in highly rare circumstances).*
- *Each manufacturer has policies that apply to the deactivation of CIED therapies; it is the responsibility of the IEAP to ensure that they adhere to these policies.*
- *Personnel including clinicians and IEAPs who do not wish to personally participate in deactivation should assist in locating qualified individuals who are willing to carry out this request.*

Following initiation of a conversation regarding deactivation by patient, family, or clinician, the member of the health care team should then contact the patient's responsible physician, who assumes the responsibility for addressing the request, counseling the patient, and making a written order in the patient's medical record. In many cases the responsible physician, if not the patient's cardiologist or electrophysiologist, will require consultation with that person to confirm that alternative treatments have been adequately assessed and to determine the specific CIED therapies that are to be deactivated. These specifics should be a part of the written order.

Clinicians, or IEAPs, can choose not to participate in deactivation based on their personal beliefs but are required to arrange for a transfer of the patient's care to another clinician (or IEAP), as described in the ethics section.

## General considerations in deactivation

### Confirm capacity requirements to make the decision to withdraw CIED support/Define legal surrogate

The clinician should assess whether the patient or surrogate adequately understands the facts of his/her medical condition and the likely consequences of the withdrawal of therapy, and is free of coercion by others. Accurately gauging patient understanding in this context requires that the clinician is qualified to discuss in detail the benefits and any potential negative effects of ongoing device therapy. This may require consultation with a clinical electrophysiologist. Patients who have psychological or cognitive problems who may benefit from counseling or pharmacologic therapies should have these addressed before deactivation proceeds. If the patient lacks capacity, the legally-recognized surrogate decision-maker should be identified as described previously.<sup>34</sup>

### Documentation requirements when withdrawing or withholding a CIED

Deactivation of CIED therapies requires a written order from the responsible physician. This should preferably precede deactivation. In emergent situations a verbal order should be followed by written documentation within 24 hours. The person responsible for ordering device deactivation

may be the patient's primary care physician, cardiologist, cardiac electrophysiologist, a hospitalist, or a palliative care specialist. The written documentation in the medical record needs to address:

1. Confirmation that the patient (or legal surrogate) has requested device deactivation. This requirement differs from that in prior clinical guidelines,<sup>82,87</sup> which specified written consent by the patient/surrogate, but is consistent with common practice for withdrawal of other life-sustaining therapies, which do not require written consent.<sup>15,22,99</sup>
2. Capacity of the patient to make the decision, or identification of the appropriate surrogate.
3. Confirmation that alternative therapies have been discussed if relevant.
4. Confirmation that consequences of deactivation have been discussed.
5. The specific device therapies to be deactivated.
6. Notification of family, if appropriate.

## Establishing palliative care interventions and providing patient and family support

Patients must be offered the full range of palliative measures to treat symptoms associated with the progression of their underlying illness, and in particular any new symptoms which may emerge from cessation of device therapy, as discussed prior. Whatever the setting of deactivation, preparations should be made to ensure that appropriate pharmacological therapies are available to treat any resultant potential symptoms of arrhythmias. Clinical care of patients with arrhythmias does not end with device deactivation, and patients may benefit significantly from pharmacologic measures that minimize symptoms, such as opioids for pain or dyspnea, anxiolytics for fear or agitation, and antipsychotics for delirium.<sup>100</sup>

In addition, the families of patients may often require considerable emotional support, especially if they have acted as the patient's decision-making surrogate. Setting expectations for family members regarding the consequences and uncertainties of deactivation is imperative. Arrangements for palliative care consultation, and involvement of other support, such as members of clergy, may also be helpful.

It is generally appropriate to discontinue rhythm monitoring when pacing therapy, and often tachyarrhythmia therapy, is withdrawn.

## How to deactivate the device

Deactivation should be performed whenever possible by individuals with electrophysiological expertise such as physicians or device-clinic nurses or technologists. When this expertise is not available, deactivation should be performed by medical personnel (such as a hospice physician or nurse) with guidance from industry-employed allied professionals.<sup>101</sup>

Pacing therapy, given the caveats indicated for a patient who is pacemaker-dependent, may be withdrawn by programming to specific modes (OOO, ODO, or OSO). If such

modes are not available for the device in question, the rate can be lowered and the output adjusted to sub-threshold levels so as to render the pacemaker non-functional. Deactivation of shocking and antitachycardia pacing functions in an ICD may be accomplished by reprogramming the device or, for certain pulse generators, by continuous application of a magnet over the device generators. Notably, there may be differences in the response to magnet application between different manufacturers' devices and individual device programmed features. This further emphasizes the importance of consulting individuals with electrophysiology expertise to ensure that the process is as smooth as possible.

Since one of the most urgent needs for CIED deactivation is when a patient receives repetitive ICD shocks, this writing group suggests that clinicians consider providing a doughnut magnet (along with specific instructions on its use) to patients who are diagnosed with a terminal illness. Application of a magnet over ICDs will, in most cases, temporarily suspend antitachycardia therapies while not disabling bradycardia pacing functions. However, it should be emphasized that while ICD shocks may be very painful and frightening, they may be life-saving; therefore, deactivation of the device is only warranted if the patient has made the decision to forgo further device therapies.

These general considerations will need to be applied to each of the various settings in which patients with CIEDs may find themselves when they or their surrogate request deactivation of their device. How the request for deactivation is handled and who will perform deactivation often depends on the setting, which could be at an acute care hospital with electrophysiological expertise; a patient facility without electrophysiological expertise; or in a patient's home. For each of these settings, the initial steps will be the same, as described above.

### **Role of the industry-employed allied professional (IEAP)**

In many situations, IEAPs may be asked to provide technical assistance for deactivation when electrophysiological expertise is not available. The role of the IEAP is to provide technical assistance to medical personnel<sup>101</sup> who will then perform actual deactivation. While available data, from a survey of Heart Rhythm Society members and IEAPs, suggests that IEAPs perform deactivation 50% of the time,<sup>8</sup> it is the recommendation of this writing group, consistent with the recent Heart Rhythm Society document on the role of the IEAP,<sup>101</sup> that the IEAP is under direct supervision of medical personnel. Each manufacturer has policies for their personnel that apply to deactivation of CIED therapies and it is the responsibility of the IEAP to ensure that they adhere to these policies. If the IEAP is asked by the patient and the responsible physician to deactivate therapies that conflict with the policies of their company they have the right to object to participation. In this situation, the responsible physician assumes the responsibility to find another mechanism for device programming, usually by contacting the physician who implanted or who follows the patient's

CIED. IEAPs, like clinicians, have the right to refuse participation in device deactivation if counter to their personal beliefs, but, like clinicians, have the responsibility to find an alternate.

Communication with IEAPs by medical personnel at the scene, as well as physicians with electrophysiological expertise, needs to include specific instructions regarding features to deactivate, as well as information about the patient's overall goals. With a better understanding of the purpose of changing a device's settings, the IEAP may be able to provide technical suggestions or clarify misperceptions about the device. The medical provider will then make relevant medical decisions.

### **Considerations in specific clinical settings Acute care hospital with electrophysiological expertise**

When patients are hospitalized in a center with electrophysiological expertise at the time that deactivation of the CIED is requested, the responsible physician (if without EP expertise himself) should arrange for a cardiac electrophysiologist or other clinician with expertise in CIED programming to perform deactivation. An order is documented in the chart by the responsible physician that precisely specifies which CIED therapies are to be deactivated (bradycardia pacing, cardiac resynchronization pacing, antitachycardia pacing, or ICD shocks). The cardiologist, cardiac electrophysiologist, or their trained designee would then program the CIED in accordance with the order and should document the programming in the patient's medical record.

### **Inpatient healthcare facility without electrophysiological expertise**

For inpatients in a facility without electrophysiology expertise, such as a hospital, nursing facility, or inpatient hospice at the time that deactivation of the CIED is requested, their health care provider 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. For patients who are well enough to travel to a clinic with programming capability, an outpatient visit may be acceptable for device deactivation. However, because deactivation of therapies may be followed by the patient's rapid demise, such as deactivation of pacing therapy in a dependent patient, clinic setting may not always be appropriate. For patients who are unable to travel, the responsible physician should arrange for a programmer to be brought to the patient. This may require the assistance of a physician who follows CIED patients. In many cases IEAPs who represent the specific manufacturer of the patient's CIED will be called upon to bring a programmer to the patient's bedside. Medical personnel, ideally, the responsible physician, would deactivate the CIED using the programmer with programming capability provided by the IEAP. These centers should have magnets available on site for temporary suspension of antitachycardia therapies of an ICD.



## Patients at home

Patients who are at home when CIED deactivation is requested may present logistical challenges for device deactivation. For patients who are too ill to travel to a clinic or in whom deactivation would result in rapid demise, arrangements must be made for a programmer to be brought to their home by medical personnel, such as an electrophysiology nurse or physician, or by an IEAP. The responsible physician should write an order in the patient's medical record including specific therapies to be deactivated. This information must be communicated to the on-site personal, preferably in written/faxed format unless the urgency of the situation requires verbal communication. An IEAP then should assist the physician's on-site clinical designee (e.g., a visiting nurse or home-hospice personnel) with the programmer and provide the programming capability necessary to deactivate the specific therapies requested. In the rare situation in which no medical personnel can be available in a timely fashion, IEAPs may be asked to perform deactivation following appropriate communication with and documentation by the responsible physician. In situations where the requested deactivation is not in keeping with the manufacturer's policies, the responsible physician assumes the responsibility for resolving this conflict. This may involve further consultation with a physician who has expertise in CIED therapy.

## Special populations—pediatrics

- *Management of CIEDs in children nearing end of life or requesting withdrawal of treatment requires an assessment of the child's decision-making capacity.*
- *If a child does not have decision-making capacity, a parent or guardian should make decisions in the child's best interest.*
- *Even when a child does not have decision-making capacity, communication of decisions should be provided to the child, recognizing their developmental level and individual preferences.*

## Epidemiology/Magnitude of the problem

While fewer absolute numbers of children than adults die following a decision to withdraw or withhold treatment, it is the commonest mode of death in the pediatric population.<sup>102</sup> Most of these deaths (65%) occur in pediatric intensive care unit. Patients age 24 or under account for 1–2% of device implants,<sup>103</sup> although the frequency of device implants is increasing in children.

## Applying ethics theories and principles to children

Ethical principles previously described also apply to children, but the most common dilemma in pediatric end of life decisions is determination of the minor's autonomy. In addition to developmental age, prior relevant experience is an important determinant of decision-making ability. Chronically ill children have often experienced the benefits

and burdens of medical treatment, and have participated in prior decision making for their illness.<sup>104</sup>

When decisions are needed, parents and clinicians can often control the amount and kind of information that the youth is afforded and, thereby, the degree of his/her involvement in the decision-making process. The legal recognition of parental authority assumes that parents wish to promote their children's interests and are capable of maintaining a relationship of trustee. However, parents may have interests separate from those of their child (their own needs and desires and those of their other family members) that sometimes conflict with their child's best interest. A wish to protect a sick child from disturbing information, guilt, or the emotional threat posed by imminent death may overshadow parental recognition or acceptance of a young person's evolving autonomy, or even his/her welfare.

The principle of beneficence implies making decisions in the best interests of a child. Although these are usually presumed to be life-preserving, in the face of terminal illness, this assumption requires careful examination.<sup>105,106</sup> There are unique issues in applying ethical principles to dying children. For adults, the best interest standard is a reference to the quality of life as determined by a reasonable person.<sup>12</sup> In pediatrics, it is difficult, if not impossible to express preferences for a life whose quality is being assessed almost entirely in the future.<sup>12</sup>

It is assumed that children are supposed to live and grow into adulthood; therefore, death in childhood is perceived by most health-care professionals as the ultimate failure.<sup>107</sup> It should be recognized that there will be unique situations where quality survival may be unattainable even for a child, and "a good death"<sup>108</sup> may be the more appropriate goal.

Two major questions may arise when one is considering forgoing life-sustaining treatment for a seriously ill juvenile: 1) should the young person be informed about the gravity of the illness? If so, 2) to what extent should that young person participate in end-of-life decision-making?

Some minors may desire not to have certain information or not to participate in decision making about forgoing life-sustaining treatment; they may want to deny that they are dying. In such situations, neither the parents nor the physician has a duty or right to force the patient to face reality. When information is expressly requested, it should be provided. When the minor expressly declines information, it usually should not be provided. Between these seemingly obvious extremes, what is required is an ongoing dialogue with the juvenile, in which his/her concerns are probed and assurance is given that any questions that are asked about the illness and its treatment will be answered truthfully.

## Rights of the child

The best interests of children must be the primary concern in making decisions that may affect them.<sup>109</sup> The overriding and ultimate interest of young persons is the development of a capacity for independence or self-sufficiency. The best interest of the child generally is assumed to demand treat-

ment in virtually every case that does not involve continued and prolonged pain and suffering.<sup>17,18</sup>

### **Rights of the parents (justifications for parental authority)**

Because children are persons, parental authority requires some justification as to why it is not simply oppression, even if well-meaning. One argument is that children are prospective or probationary “moral agents” who, although cognitively advanced, may not have the experience or competence to participate in moral decisions. However, parental authority is discretionary, provided that it is not unreasonable, abusive or harmful to the child and the child’s long-term interests. Along with parental authority is a parental duty to promote the interests and protect the rights of the child.<sup>110</sup>

### **Communicating life and death decisions to children: developmental issues**

Informed consent requires understanding, reasoning, voluntariness, and a concept of the nature of the decision (which for end-of-life decisions may be death).<sup>104,111</sup> A child’s understanding of illness develops in stages that parallel conceptual development. Young children understand illness as something that is caused from outside their bodies. Around 11 years or older, children reach a “physiologic” stage, in which there is an understanding of illness as caused by a malfunctioning organ or system. A needed ability for decision making is to be able to reason about medical information, through a formal operations stage of cognitive development, which begins at about 12 years of age (capacities to think abstractly, consider multiple factors, hypothesize, and predict future consequences). Making a free choice, or volunteering, is the next capacity in the decision-making process. Adolescents less than 14 or 15 years of age are more acquiescent than older ones to authority and it is unlikely they will oppose these figures’ wishes. Therefore, only older teenagers can make authentic choices (i.e., those choices that are relatively free of the wishes of authority figures).

### **Procedures/Protocol for EOL decisions in children**

Health care institutions and organizations should develop procedures for end of life decisions in children which should encompass<sup>112</sup> support of the family unit, shared decision-making, relief of pain and other symptoms, potential moral distress of caregivers related to perceived over or under treatment, communication with the child and family about treatment goals and plans, and grief and bereavement support beyond the acute intervention/withdrawal.

### **European Perspective**

The European Committee for ICD deactivation is developing a document for the European Heart Rhythm Association, to address from the European perspective issues similar to those discussed in this current document. Owing to its

unique and varied history, Europe is profoundly pluralistic in its traditions, cultures and in its multitude of faith communities. Against this varied cultural and religious backdrop, the European health care system is undergoing a process of change and consolidation, continuously challenged by many important factors. On the one hand, diagnostic and therapeutic possibilities are continually improving; on the other, as in other parts of the world, Europe faces an “aging society”, with corresponding increasing chronic comorbid conditions. As a result, clinicians are now faced with emerging ethical questions: whether and when to stop the process of care; how to find the balance between inadequate and excessive treatment for our patients’ conditions.

Not all European countries yet have national legislation covering advance directives or “living wills”, which remain a matter of heated debate in some countries. Even in countries that do have such legislation, advance directives are open to very different interpretations and their application differs widely across Europe. Thus, there is an increasing need for a more substantial pan-European agreement on the ethical, legal and political basis of advance directives.

While general agreement exists in Europe, as in the United States, that ICD deactivation in dying patients may be ethically permissible, especially if done to avoid uncomfortable shocks, less agreement exists in Europe for pacemaker deactivation.<sup>8</sup> The practices and attitudes associated with pacemaker deactivation have been shown to differ significantly from those associated with ICD deactivation<sup>8,113,114</sup> and there are European countries where deactivation of antibradycardia pacing in pacemaker dependent patient is prohibited by law. It is therefore crucial that clinicians are aware of the legal situation in the country and jurisdiction in which they are practicing.

Existing guidance has focused on device indications, device implantation and the training of implanting physicians,<sup>4,82,115</sup> but little attention has been paid to the technical, scientific and ethical aspects of device deactivation, especially appropriate topics for patients with incapacitating, irreversible or terminal illness. Thus we need a medical, bioethical, and legal consensus regarding ICD deactivation in such conditions in both cognitively capable patients and those who are cognitively incapacitated. For the terminally ill patient with decision-making capacity, therefore, it is crucially important that clinicians engage in a timely discussion concerning deactivation of the ICD. The patient must receive proper support to help guide him/her through the decision-making process. It is important that the issue be raised sensitively and at an appropriate time with a patient who is reaching the end of life.

Patients who are found to be lacking decision-making capacity are in need of a surrogate decision making process, which can include substituted judgment (aiming at determining what the patient would have wished for) and/or patient’s best interest (what decision best promotes the patient’s overall interests). Physicians must be aware of the relevant legal position in the country and jurisdiction where they are practicing.

Where possible, it is crucial that these treatment decisions be informed by investigation of, and reference to, the patient's own currently or previously expressed thoughts and wishes. Discussions with family, loved ones and members of the health care team may help establish his/her perspective.

The European Committee for ICD deactivation will follow the key principles of liberal democratic societies, which include respect for diversity of values and cultures, rights for all individuals to be considered as being of equal worth, and protection of fundamental human rights.

#### Appendix Author Relationships with Industry

Authors	Consultant fees/ Honoraria	Speaker's Bureau	Research Grant	Fellowship Support	Board member/ Stock Options/ Partner	Other
<b>Rachel Lampert, MD</b>	Boston Scientific Medtronic Corp	None	Boston Scientific* Medtronic Corp* St. Jude Medical*	None	None	None
<b>David L. Hayes, MD</b>	Blackwell Publishing Boston Scientific* Boston Scientific Medtronic Inc. St. Jude Medical Sorin Group Visible Assets	None	None	None	Wiley-Blackwell Publishing	None
<b>George J. Annas, JD</b>	None	None	None	None	None	None
<b>Margaret A. Farley, PhD</b>	None	None	None	None	None	None
<b>Nathan E. Goldstein, MD</b>	None	None	None	None	None	None
<b>Robert M. Hamilton, MD</b>	None	None	None	None	None	None
<b>G. Neal Kay, MD</b>	None	None	None	Biosense Webster* Boston Scientific* Medtronic Corp* St. Jude Medical*	None	None
<b>Daniel B. Kramer, MD</b>	None	None	None	FDA/CDRH	None	None
<b>Luigi Padeletti, MD</b>	St. Jude Medical* Sorin Group*	None	None	None	None	None
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#### \*Significant

A relationship is considered to be "significant" if (1) the person receives \$10 000 or more during any 12-month period or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity or owns \$10 000 or more of the fair market value of the entity.

A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.



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