The Ethics of Defibrillators and End of Life Care: the Patient, not the Device

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"Wherever the art of Medicine is loved, there is also a love of Humanity."

- Hippocrates

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Purpose and Overview:

The purpose of this presentation is to educate the clinician about the negative effects of shocks from an implantable defibrillator (ICD) and how they affect patients at the end of life, to reveal patients' knowledge and understanding about the device and deactivation, to reveal physicians' attitudes about defibrillators and end of life, to discuss ethical and legal principles that pertain, and to identify resources available to help navigate physician-patient interactions about defibrillators and end of life care.

Objectives:

1. Describe the effect of defibrillators on quality of life of the patient, particularly the patient at the end of life
2. Discuss the literature about patients' defibrillator knowledge and their attitudes about deactivation
3. Discuss the literature about physician attitudes towards defibrillators and end of life, including the obstructions to physician-patient discussions about deactivation
4. Evaluate the ethical and legal aspects of defibrillator deactivation
5. Identify the resources available to health care providers about defibrillators and end of life care, to utilize in daily practice

In 1970, Dr. Michel Mirowski and his colleague, Dr. Morton Mower conceptualized the implantable defibrillator (ICD)[1]. Together with Mirowski's team, 10 years later the first human implant was performed by Dr. Levi Watkins in Baltimore, USA.[2] Since then, the prevalence of ICDs has steadily grown. Known to deliver shock therapy for malignant arrhythmias, ICDs have the capability of saving lives in the setting of both primary and secondary prevention for sudden cardiac death. In addition, technological advances such as smaller devices and monitoring from home, has led to widespread acceptance of this "therapy". However, death is inevitable for all humans, and we have yet to determine a proper exit strategy for patients with this device. A recent article in the New England Journal of Medicine about dying with dignity[3] discusses the need for effective palliative care, particularly at patients' end of life. The effects of a shock contradict the principle of alleviating suffering near death. It is time we draw our attention to the role of the ICD and the prevention of shocks at the end of life.

The Beneficial Effects of the ICD

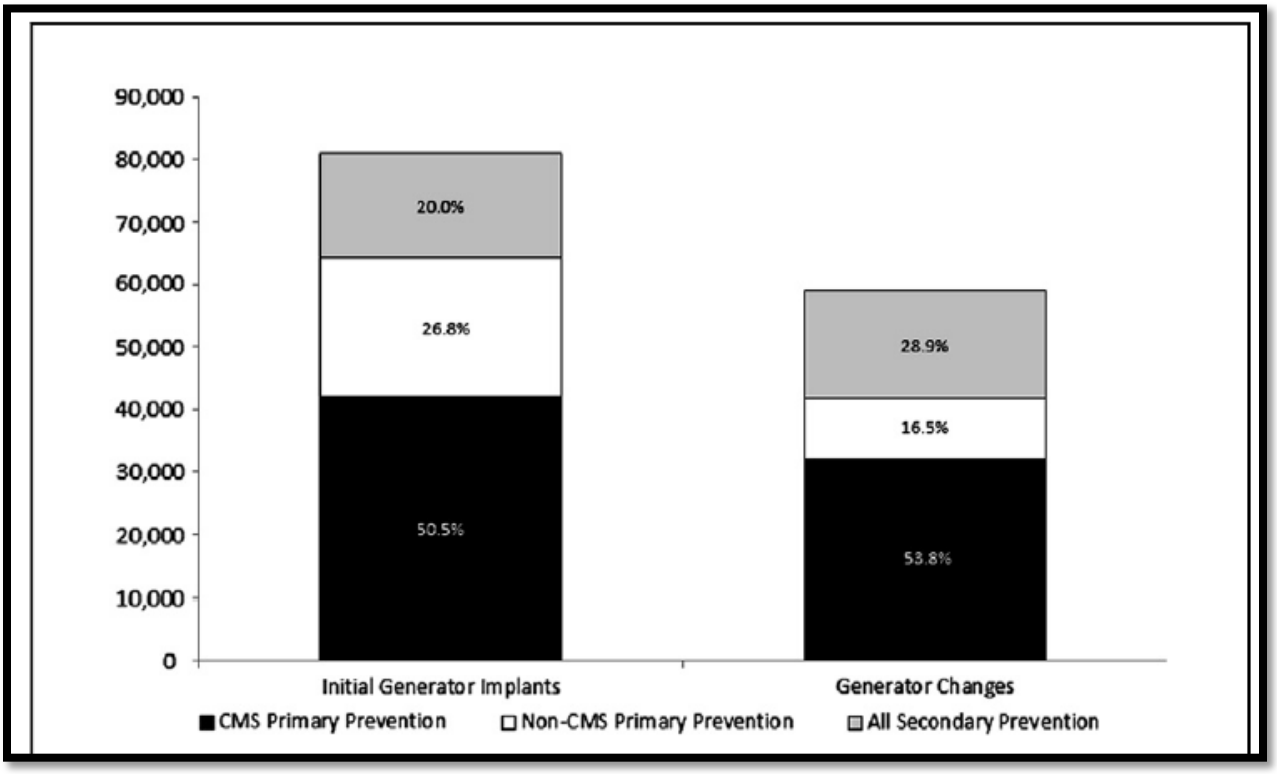
The prevalence of ICD implantations and generator changes has exploded, largely due to the evidence that has been published in the past few decades. For secondary prevention for sudden cardiac death, trials such as CIDS (Canadian Implantable Defibrillator Study), CASH (Cardiac Arrest Study of Hamburg) and AVID (Antiarrhythmic Versus Implantable Defibrillator) show a significant decrease in mortality in the ICD treatment arms[4-7]. Likewise, primary prevention with ICD in the treatment of patients with depressed ejection fractions was proven to save lives in ground breaking trials such as MADIT II (Multicenter Automatic Defibrillator Implantation Trial) and SCD-HeFT (Sudden Cardiac Death-Heart Failure Trial)[8-12].

Figure 1. Major ICD Trials for Prevention of Sudden Cardiac Death[12]

Trial	Year	Patients (n)	Inclusion Criterion: LVEF % Less Than or Equal to	Other Inclusion Criteria	Hazard Ratio*	95% Confidence Interval	p
MADIT I[327]	1996	196	35	NSVT and positive EP	0.46	0.26 to 0.82	0.009
MADIT II[332]	2002	1232	30	Prior MI	0.69	0.51 to 0.93	0.016
CABG-Patch[328]	1997	900	36	Positive SAECG and CABG	1.07	0.81 to 1.42	0.64
DEFINITE[369]	2004	485	35	NICM, PVCs, or NSVT	0.65	0.40 to 1.06	0.08
DINAMIT[331]	2004	674	35	6 to 40 days after MI and impaired HRV	1.08	0.76 to 1.55	0.66
SCD-HeFT[333]	2005	1676	35	Prior MI or NICM	0.77	0.62 to 0.96	0.007
AVID[319]	1997	1016	40	Prior cardiac arrest	0.62	0.43 to 0.82	<0.02
CASH†[323]	2000	191	M: 45±18 at baseline	Prior cardiac arrest	0.77	1.112‡	0.081§
CIDS[322]	2000	659	35	Prior cardiac arrest, syncope	0.82	0.60 to 1.10	NS

As the medical community noticed the forming body of literature demonstrating ICD benefit, the implantation rates grew. From 2006 to 2007, the incidence of ICD implantation in North America increased from 160,000 to 234,780[13]. Currently, it is estimated that over 80,000 new ICD implants are performed each year. ICD prevalence has steadily increased and has become a widely accepted therapy proven to save lives.

Figure 2. National Cardiovascular Data Registry, ICD Implants Performed in 2011[14]



The Negative Effects of ICDs

Just as all therapies have the potential for negative side effects, ICDs also have inherent disadvantages. Increased rates of anxiety and depression have been described in both the patient and the partner. Shocks, however, seem to have the most profound deleterious effect and can occur in the absence of malignant arrhythmias.

Anxiety and Depression

It is widely accepted that ICDs are linked to higher levels of anxiety and depression in patients[15]. Some have reported as high as a 24-87% incidence of anxiety, and a 13-38% rate of clinically significant anxiety disorders in patients with newly implanted ICDs[16]. A review of the literature estimates overall that there is approximately a 20% prevalence of combined anxiety and depressive disorders post-ICD implant[17-20]. The determinants of device associated anxiety or depression is extensive. Poor psychiatric outcome predictors include increased number of discharges, specific personality types, poor physical function, preceding anxiety or depression, low levels of social support and increasing time since implantation[21-24]. Of this list, psychological characteristics are the strongest predictors of quality of life (QOL)[25,26] Knowing the risk factors for poor psychological outcomes following ICD placement allows health practitioners the ability to predict which patients are at risk for device associated anxiety or depression.

Effects on Patients' Partners

The presence of an ICD can also affect patients' partners. Levels of anxiety between the patient and the partner can be equal, or even worse in the partner[27]. Characteristics that predicted increased partner distress were those who had a distressed (Type D) personality type and whose partner received the device for secondary prevention[22,28]. Health care providers' concern should always extend to the partner, since partner distress can also affect the QOL of the patient. Anxious partners have a tendency to become overprotective resulting in limitations on the patient's lifestyle[29]. A distressed partner changes family dynamics and affects the sexual relationship[30-32]. Relationship changes such as these can all have a negative impact on the quality of life of the patient.

Shocks

The sole purpose of the ICD is to deliver a shock to the myocardium when it senses a life-threatening arrhythmia in order to restore a stable rhythm. The effect of a shock and the incidence of shock (both appropriate and inappropriate) are critical in the understanding of how they can influence a patient's end of life.

To better understand a patient's perception of a shock, 119 patients were surveyed retrospectively about their emotional, physical and behavioral responses to ICD shocks[33]. In this study, patients described shocks in many ways. 54% described it as a punch in the belly or chest. 40% felt like it was a shock causing the whole body to jump. A smaller percentage (10%) found the experience to truly feel like an electric shock or like putting their finger into a light socket. Still others described it as being hit by a truck, a baseball bat or being kicked by a mule. When describing intensity of the feeling, shocks were rated as severe. Of this group, 23% dreaded the shocks and 5% said they would rather be without the ICD and take their chances.

Not unexpectedly then, shocks are associated with decreased QOL outcomes[34,35]. Increasing number of shocks correlate with worse reported QOL[36-39]. In addition, shocks are associated with worse mental health[40-42] and a continuum of coping and distress (See Figure 3). Yet another finding, its causation not yet clearly defined, is that shocks (appropriate or inappropriate) have been associated with increased all-cause mortality[43,44].

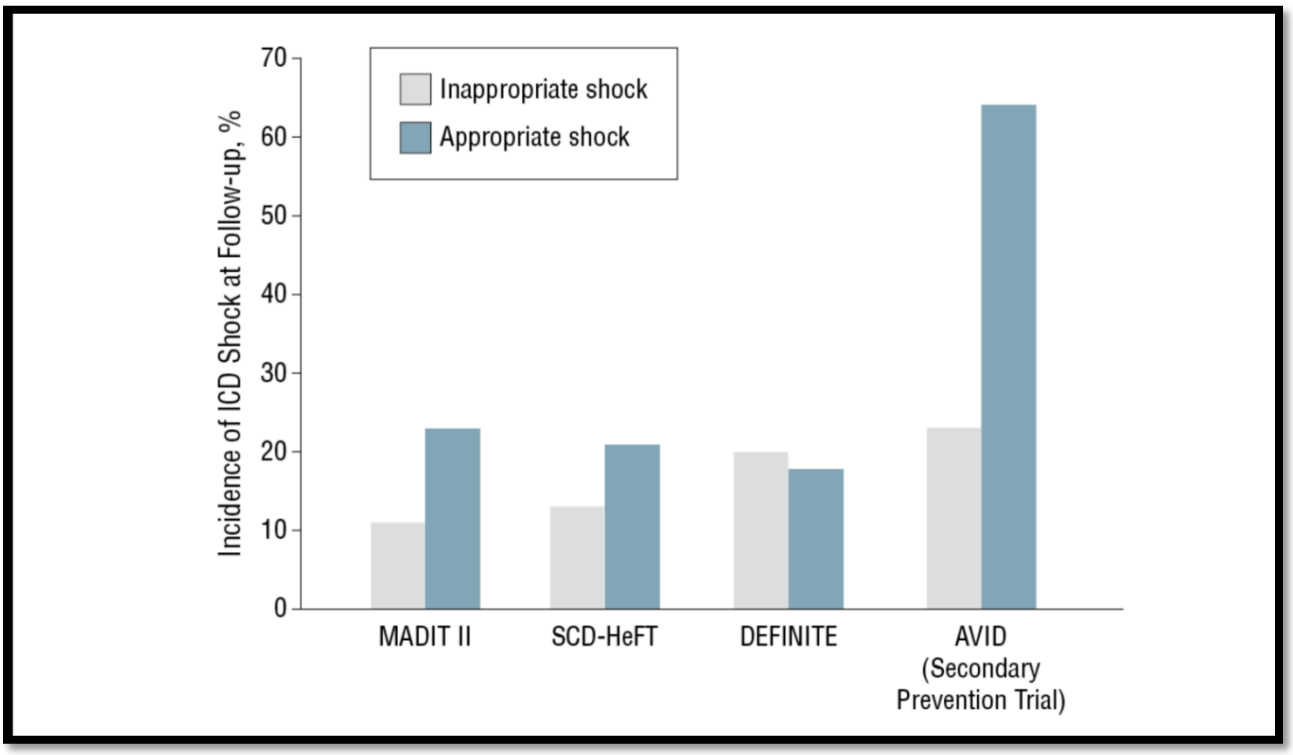
Figure 3. Continuum of Shocks, Coping and Distress[42]

	Arrhythmia	Coping	Distress	Feelings, thoughts, and behaviours
Continuum	No arrhythmia	Optimism	Reassurance	ICD as 'guardian angel'
		Active coping	Successful adjustment	ICD doesn't bother me
	ATP only	Faith in doctors	Realistic fear	ICD may fail
	Single shock	Depressive coping	Adjustment disorder	Uncertain if ICD keeps me safe
			Shock phobia	Avoid activities that might trigger shocks
	Multiple shocks	Distraction/denial	Moderate depression/agoraphobia	Avoid any activities, withdraw
	Electric storm	Catastrophizing	Dysthymia/generalized anxiety	Lose interest/confidence in life, permanent worry
		Resignation	PTSD/personality change	Permanent threat and arousal
			Severe/recurrent depression	Wanting to be dead

The discomfort of a shock or decreased QOL associated with shocks are acceptable to many patients if the ICD functions as it is intended; to convert malignant arrhythmias into stable rhythms to save a life. On occasion, the device misperceives benign rhythms or motion for a malignant rhythm, resulting in an inappropriate shock. Newer technology and higher level programming have significantly advanced the field to avoid these inappropriate therapies, but unfortunately are not 100% effective.

A review published in the Journal of the American Medical Association (JAMA) of some of the major ICD trials showed that the number of patients receiving an inappropriate shock was significant. In the Multicenter Automatic Defibrillator Trial (MADIT II), it was found that over 10% of patients experienced an inappropriate shock. Of the total number of shocks delivered, 31% were inappropriate[43]. SCD-HeFT (Sudden Cardiac Death-Heart Failure Trial), DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Treatment evaluation) and AVID (Antiarrhythmic Versus Implantable Defibrillator) studies reported even higher percentages of inappropriate shocks[45](See Figure 4). When over 1500 patients with ICDs were followed over 5 years, it was found that approximately one in five patients experienced ≥ 1 inappropriate shock [44]. Therefore, patients with ICDs have a high risk of having at least one inappropriate shock in their lives.

Figure 4. Appropriate and Inappropriate ICD shock rates from the Multicenter Automatic Defibrillator Trial (MADIT II), the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial, and the Antiarrhythmics versus Implantable Defibrillators (AVID) trial



Shocks and End of Life

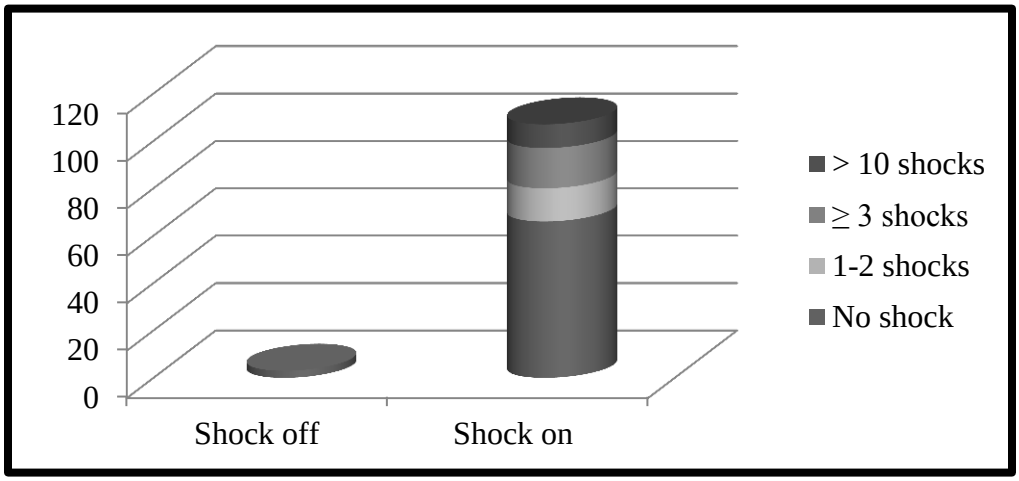
Of the six comprehensive life goals, the beneficial effects of an ICD support the goal to "live longer".(See Figure 5)[46]. However, ICDs do not cure, do not change function or independence and do not provide support to families of patients. Arguably, the delivery of shocks contradict the goal to "Be comfortable", a goal that is often critical at the end of life.

Figure 5. Comprehensive Life Goals[46]

1. Be Cured
2. Live Longer
3. Improve or maintain function/quality of life/independence
4. Be comfortable
5. Achieve life goals
6. Provide support for family/caregiver

A substantial amount of shocks are delivered at the end of life. In the 1990s, patients with Medtronic ICD systems were examined for modes of death. Of the patients who died from a cardiac etiology, 31% of them experienced a shock at the end of life[47]. In MADIT II (Multicenter Automatic Defibrillator Trial), of the 98 patients studied, 11% received a shock in the last week of life. Almost half of patients with a do not resuscitate (DNR) order still had an active ICD in the last 24 hours of life[48]. In the past year, *Circulation* published a study that examined 100 ICDs explanted post mortem with a review of the patients' corresponding charts. In the last week of life, one out of every five patients received a shock. Of those that received a shock, over 30% of had a do not resuscitate (DNR) order. In the last hour of life, 97 out of the 100 ICD patients still had shock programmed as "on". 31 patients (32% of those with shock "on") received a shock in the last hour of life. 14 of them received 1-2 shocks, 17 received ≥ 3 shocks, and 10 patients received > 10 shocks (See Figure 6). One patient with an existing DNR order suffered 42 shocks which were later found to be inappropriately administered for atrial fibrillation[49].

Figure 6. Incidence of Shock in the Last Hour of Life[49]



Patients are not the only ones who suffer when shocks occur at the end of life. For patients who received a shock at the end of life, charts documented at least 35% were witnessed by caregivers. Half of these charts mentioned that caregivers witnessed patient pain or distress[49]. A telephone survey conducted out of Mount Sinai Medical center interviewed over 100 next of kin of patients who had died with an ICD in place. The resulting publication gave personal accounts of the family members as mentioned here[50] (See Figure 6).

Figure 7. Descriptions of Shocks at the End of Life by Patient Family Members[50]

Every 20 minutes, he would [get a shock and get] jolted awake. Meanwhile he was on morphine. . . . I saw this pattern . . . he was waking up from like a really bad dream type of thing . . . and he would say a word or something, and after 20 seconds he would be unconscious again.

His [defibrillator] kept going off. . . . It went off 12 times in 1 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 it wouldn't stop going off.

Appropriate referral and admission into hospice does not preclude patients from suffering from ICD shocks. Of hospices queried in a survey, the majority admitted patients with ICDs, but 40% of these organizations reported at least 1 patient receiving multiple shocks during a single episode in the past year. Only 10% of these hospice organizations had a deactivation policy[51]. ICD shocks at the end of life are frequent and can be a cause for significant distress to both the patient and his/her family, as clearly seen in these articles.

Patient Attitudes and Perceptions

Despite the growing prevalence of ICDs, patients have insufficient knowledge about the function of the device and the option to deactivate the ICD. Deactivating an ICD, in general means to stop its ability to give therapies for malignant arrhythmias (both shock and anti-tachycardia pacing therapy). ICDs also have the capability to pace, but addressing pacing and the choice to stop this therapy is beyond the current discussion.

In general, studies have found that patients have a tendency to overestimate the effects of an ICD. In 67 ICD patients with symptomatic heart failure, 21% confirmed to have had no prior device therapy felt that the ICD had already saved their life. 50% of patients who had only received inappropriate shocks thought that the device had saved their life[52]. A quarter of the ICD patients surveyed in another study with 278 subjects thought that the device was providing a function that if stopped, would be equivalent to suicide[53].

Knowledge about the option of deactivation has been described in other studies. In 2007, a small group of ambulatory patients with ICDs were queried and found that none of them had discussed deactivation with their physician and none of them knew it was possible[54]. Other studies published between 2011 to 2013 quote a wide range of awareness of deactivation, ranging from approximately 15%, all the way up to 69%[55]. Regardless of prior knowledge of the ability to turn off ICD therapies, the majority of patients wanted to participate in the discussion of this option

with their physicians, observed in multiple studies[53,55,56]. The timing of this discussion and which physician should conduct this conversation is less clear.

Figure 8. Awareness of Deactivation in Patients with ICDs

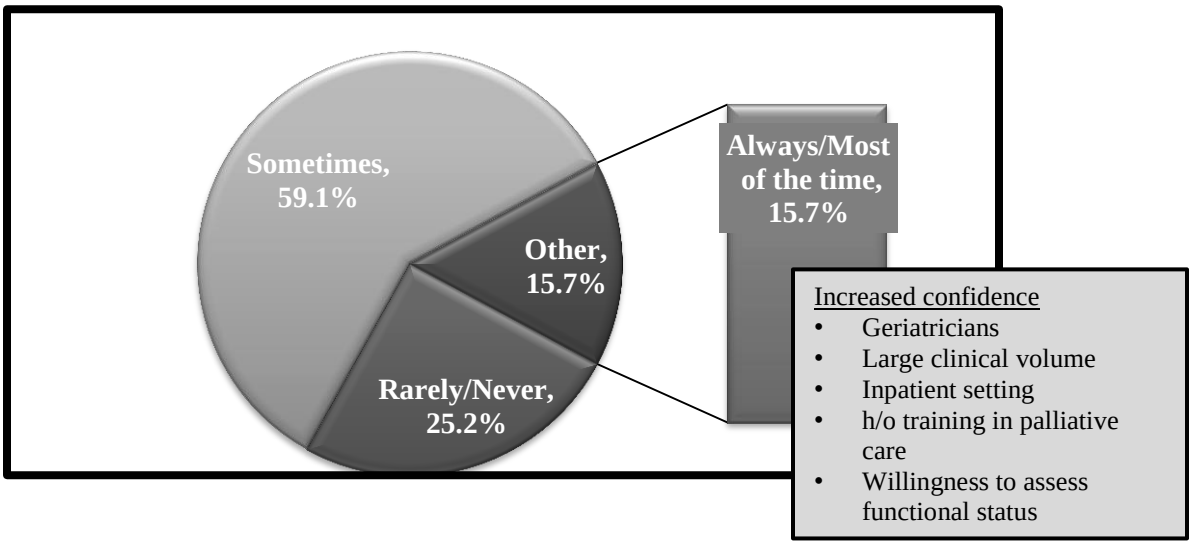
Author	Year # of Subjects	Observations
Goldstein[54]	2007 15	0 aware of deactivation
Raphael[55]	2011 54	38% aware of deactivation
Kirkpatrick[53]	2012 278	4% had discussed deactivation with their MD 15% had considered deactivation as an option
Pedersen[56]	2013 294	69% aware of deactivation 79% in favor of deactivation in correct setting

Physician Attitudes and Perspectives

Deactivation Discussions

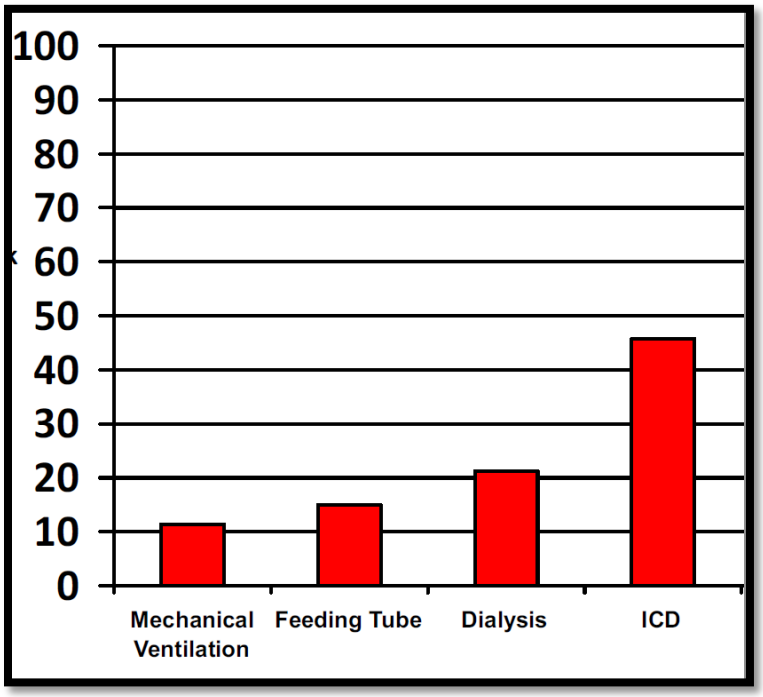
Physician-patient discussions about ICDs and deactivation occur infrequently[53-57]. When a range of physicians (Internists, Geriatricians, Cardiologists and Electrophysiologists) underwent in-depth interviews about deactivation discussions, the majority agreed that these conversations are needed, but admit that they rarely happen[58]. Studies investigating why deactivation discussions are rare reveal multiple contributing reasons. Included in these reasons are lack of adequate time to spend on the conversation, insufficient rapport in the physician-patient relationship and fear of "shutting off hope"[58]. Many physicians also lack the confidence to predict death, implicating a difficulty to predict when to initiate a discussion to change goals of care (See Figure 9)[59].

Figure 9. Physician Confidence, Ability to Predict Death within 6 Months[59]



A challenge specific to an ICD is the ever widening gap between the multiple providers of a patient: i.e. the patient's primary provider may not feel comfortable discontinuing a therapy initiated by a different physician (typically a cardiologist or an electrophysiologist), while a patient's cardiologist may not feel comfortable initiating a goals of care discussion because he/she is not the primary provider. When a group of physicians underwent in depth interviews about the barriers to these discussions, one trend noted was that the "small, unseen nature of the device", and its internal nature make it easy to forget to include in advanced planning conversations. These same qualities also make it, "inherently difficult to think of them in the same context" as other end of life management options[58]. In a survey of attendings and trainees at Beth Israel Deaconess Medical Center, out of 185 physicians, 89% felt comfortable discussing end of life in general. However, the percentage of physicians in this group uncomfortable with ICD discussions was significantly higher compared to discussing other therapies such as mechanical ventilation, feeding tubes and dialysis[60] (See Figure 10).

Figure 10. Percentage of Physicians Who Lack Comfort Discussing Therapy[60]



Of course, physicians' level of deactivation and ICD knowledge, prior experience with device deactivation and experience with these discussions also play a major role in the comfort of the individual to initiate this conversation[61].

Differences in Experience and Attitudes by Specialty

In 2008, a study was published that described a survey of primarily office based, private physicians that included cardiologists, internists, family practitioners and geriatricians. In this survey, the majority of geriatricians (60%) and family practitioners/internists (75%) had never had a discussion about device deactivation. In addition, these same groups also showed that the majority of them had never had a discussion with a patient's cardiologist about deactivation (55%, 70% respectively). 25% of the cardiologists surveyed had never had a deactivation

discussion, and 36% of them had never had a deactivation discussion with a primary care physician[59]. Cardiologists and electrophysiologists may have a greater appreciation for the symptoms associated with shock. When compared with internists and geriatricians, a statistically significant higher percentage of cardiologists and electrophysiologists believe that shocks are painful to most patients and that an ICD shock at the end of life is distressing to a patient and their loved ones[61]. But when asked if information about deactivation options be required during informed consent for ICD implantation, cardiologists, particular electrophysiologists, were less enthusiastic than internists and geriatricians. However, all four groups showed a majority percentage answering in favor of this.

Ethical and Legal

Deactivation of an ICD at the request of a patient is ethical and legal, even if a patient is not terminally ill[62]. Two of the four major principles of medical ethics are relevant to ICD deactivation; 1) respect for patient autonomy and 2) beneficence, i.e. the duty to promote patient interests. If a patient has decision making capacity, he/she has the legal right to refuse any medical treatment, including the function of an ICD. Though seemingly very different, withdrawal of a treatment is ethically and legally the same as a patient refusing such therapy initially. When a patient lacks capacity, as expected, the patient's surrogate decision maker (typically the next of kin) acts on his or her behalf[63,64]. If a patient or surrogate decision maker requests the device to be turned off, failure to do so contradicts the principle of autonomy and self-determination, and therefore is legally considered "assault"[65].

It should also be mentioned that deactivation of ICDs carries moral weight for health care providers. Respect for autonomy must be considered not just for the patient, but for the provider as well. Providers (which include physicians, nurses and industry representatives alike), must reconcile their actions with their inherent personal and professional values. Not all providers are trained in palliation to the same extent, nor do all know how to deactivate a device. A section of the 2010 guidelines about the management of devices in patients at end of life is devoted to the rights and responsibilities of the clinician for whom deactivation is counter to his/her beliefs. It states that the clinician should not impose, as per the American Medical Association code of ethics, his/her values on the patient and, "must state their objection in a way to avoid causing the patient emotional distress"[63]. It also says that the physician cannot abandon the patient. Instead, one should formulate a plan to work together or bring in the care of another physician. When this is not possible, hospital administration and/or the ethics committee should be involved.

Current Guidelines and Resources

Over the past six years, consensus statements, focused updates, guidelines and appropriate use criteria have been published to improve patient care in this area. There are recommendations for health care providers prior to ICD implantation, for patients with ICDs in place and also for the process of deactivation itself.

Prior to implantation, it is recommended that physicians identify individuals who will receive little benefit from the device or who will suffer a worse outcome from the device (such as multiple shocks or significant anxiety/depression). These patients should not be referred for ICD implantation. Examples of these patients include those with a prognosis of less than a year, those with significant psychiatric illnesses, cognitive impairment, incessant malignant arrhythmias and

those whose goal is not prolongation of survival(See Figure 11)[12,66-68]. It is also encouraged to mention prior to implantation that deactivation of the device is possible, should the patient desire this option later[69].

Figure 11. Considerations Prior to Implant

Year	Professional Societies	Title	Patient Factors to Consider before Referring for ICD Implantation
2008	American College of Cardiology American Heart Association Heart Rhythm Society	Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities[12]	• Prognosis < 1 year • Psychiatric illness that precludes follow-up or may worsen with device • Incessant tachyarrhythmias • Ventricular tachyarrhythmias amenable to ablation or reversible (ex. Drugs)
2009	American College of Cardiology American Heart Association	Focused Update Incorporated Into the 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults[67]	Heart Failure Patients • Progressive and irreversible ventricular tachyarrhythmias • Poor clinical function and prognosis • Prolongation of survival is not the goal
2012	American Heart Association	Educational and Psychological Interventions to Improve Outcomes for Recipients of ICDs and Their Families: A Scientific Statement from the American Heart Association[66]	• Type D personality (distressed personality) predicts chronic anxiety post implant • Decreased social support can lead to increased anxiety *Also provides list of discussions points pre-implantation*
2013	American College of Cardiology Heart Rhythm Society American Heart Association American Society of Echocardiography Heart Failure Society of America Society for Cardiovascular Angiography and Interventions Society of Cardiovascular Computed Tomography Society for Cardiovascular Magnetic Resonance	Appropriate Use Criteria for ICDs and CRT[68]	Patients whom it is rarely appropriate to implant ICDs for 1^0 prevention • Life expectancy < 1 year • ≥ 90 years old • Cognitive impairment, unable to consent • Advanced psychiatric impairment • Ongoing IV drug abuse • Noncompliance with medical therapy and follow-up • Refractory heart failure not a candidate for transplant or ventricular assist device (scale = Appropriate→ May be Appropriate→ Rarely Appropriate)

For patients with an ICD in place, it is recommended that in all stages of disease, providers evaluate the prognosis of patient's quality and quantity of life[69]. This information is useful when initiating the conversation to define the patient's goals of care, a necessary step in this process[63]. When needed, use shared decision making to determine appropriate use and the withdrawal of therapies, including ICD function[69]. When planning a discussion with your patient, the 2010

Expert Consensus Statement by the Heart Rhythm Society provides the steps for communicating about goals of care (See Figure 13), as well as the best timing and "Points to be Covered" in physician-patient ICD conversations (See figure 14)[63]. You can also refer to the table outlining core tasks, skills and sample phrases for difficult discussion that can be found in the American Heart Association Scientific Statement, Decision Making in Advanced Heart Failure[69]. At the end of life, multiple guidelines recommend that ICD deactivation be discussed with the patient (or surrogate if necessary), ideally when the patient is still capable of participating in the discussion[63,66,67,69,70].

Figure 12. Resources Recommending Deactivation of ICD Discussion/Education

Year	Professional Societies	Title	Deactivation Discussion or Education Recommended
2009	American College of Cardiology American Heart Association	Focused Update Incorporated Into the 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults[67]	Class I Recommendation- discussion should occur at end of life
2010	Heart Failure Society of America	Comprehensive Heart Failure Practice Guidelines[70]	Also recommends • Discuss quality of life and prognosis at all stages of heart failure • Identify the process for deactivating ICD
2010	Heart Rhythm Society	Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices in Patients Nearing End of Life or Requesting Withdrawal of Therapy[63]	Also includes • Steps for communication about goals of care • Timing/points to be covered in physician-patient ICD conversations
2012	American Heart Association	Decision Making in Advanced Heart Failure: A Scientific Statement from the American Heart Association[69]	Also includes • Assessing prognosis (quantity and quality of life) • Best timing for discussion • Core tasks, skills and sample phrases for difficult discussions
2012	American Heart Association	Educational and Psychological Interventions to Improve Outcomes for Recipients of ICDs and Their Families: A Scientific Statement from the American Heart Association[66]	Also includes • Recommendations for future research

There are also guidelines to help navigate controversial topics surrounding deactivation as well as outline the process of deactivation. Both the Heart Rhythm Society and the European Heart Rhythm Association published statements in 2010 elaborating upon the ethical, legal and religious principles surrounding deactivation of devices. They also define the rights and responsibilities of the participating physician. In the most recent guidelines for device-based therapy, there is a stepwise approach for physician caring for the dying patient who requests device deactivation. The consensus statement about the monitoring of cardiac devices provides a protocol for the providers involved in the act of deactivation (ex. Physicians and industry representatives). The dawning of multiple guidelines and statements including this topic put forth

by highly regarded professional societies makes it very clear that providers must take heed of this burgeoning subject.

Figure 13.Communicating with patients and families about goals of care relating to ICDs[63].

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."

Figure 14. Timing and Topics to Address in ICD Conversations [63].

Timing of conversation	Points to be covered	Helpful phrases to consider
Prior to Implantation	• Clear discussion of the benefits and burdens of the device. • Brief discussion of potential future limitations or burdensome aspects of device therapy • Encourage patients to have some form of advance directive • Inform of option to deactivate in the future	"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	• discussion of possible alternatives, including adjusting medications, adjusting device settings, and cardiac procedures to reduce future shocks in context of goals of care	"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	• re-evaluation of benefits and burdens of device • assessment of functional status, quality of life, and symptoms • Referral to palliative and supportive care services	"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	• re-evaluation of benefits and burdens of device • exploration of patient's understanding of device and how s/he conceptualizes it with regards to external • defibrillation • Referral to palliative care or supportive services	"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	• re-evaluation of benefits and burdens of device • discussion of option of deactivation addressed with all patients, though deactivation *not* required	"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?"

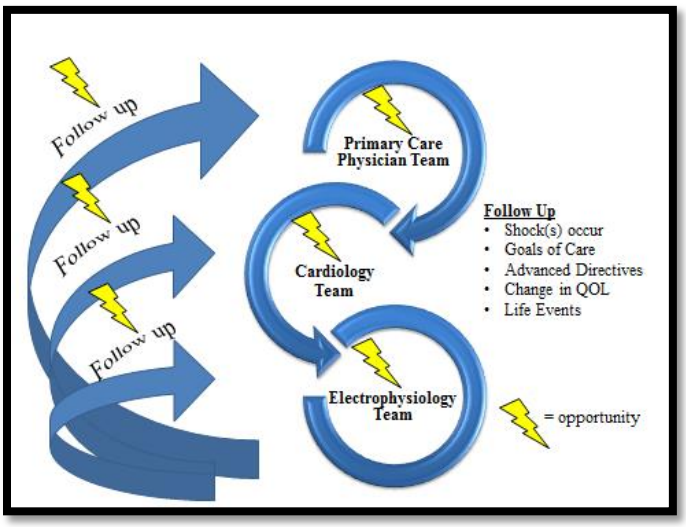
Applying Knowledge to Practice

Multiple hospitals, training levels and interdisciplinary health teams offer innumerable opportunities to improve patient care in this area at UT Southwestern. These opportunities can be broken down into two main groups: opportunities to discuss goals of care and protocols for deactivation.

Opportunities for Goals of Care Discussion

These opportunities are times where providers can assess quality of life and prognosis to broach the topic of patient's current goals of care. Such discussions are not isolated to physicians, but can involve the entire care team. Understanding patient's goals of care is critical in knowing when it is appropriate to assess patient's viewpoint about deactivation.

Figure 13. Opportunities to Initiate Deactivation Discussions



In a traditional outpatient setting, a patient often interacts with a primary care physician, a cardiologist, an electrophysiologist, and all the support staff involved in these visits. Each visit provides an opportunity for discussion.

Once a device is implanted, regular follow up appointments provide additional opportunities. Importantly, this should not be limited to any one physician or his/her team. Given the time constraints that health care providers are under, it may be prudent to consider a simple screening process that occurs during the intake of a patient into clinic. Along with obtaining vitals and reviewing meds, patients can be asked if they have a cardiac defibrillator. If the answer is "yes", then the physician can receive a prompt, asking if he/she has addressed goals of care and if the ICD function is still indicated at this time. This can be done within an electronic medical system or via a pre-determined means of paper/verbal communication, depending on the clinic. Well-constructed informational handouts and "dot-phrase" templates for patient instructions can augment patient education about their device and option for deactivation.

For non-ambulatory patients, despite the difference in setting, the same principles apply. However, location of the patient and the providers involved are highly variable. Hospitals, assisted living facilities and hospice admissions, similar to intake of patients at clinic, could prompt the question of the presence of an ICD. A positive answer would lead to the question of whether the patient feels the device function is harmonious with his/her current feelings about life and medical plans. This line of questioning could also be applied at time of discharge. Most critical, however, is care coordination - where inpatient/facility physicians, caretakers, PCPs and patients' cardiologists/electrophysiologists have a direct line of communication with each other to ensure full awareness of any life events or changes in goals of care.

There are many circumstances when this opportunity to discuss goals of care should not be missed. For example, when the device battery is nearing the time for replacement, a patient

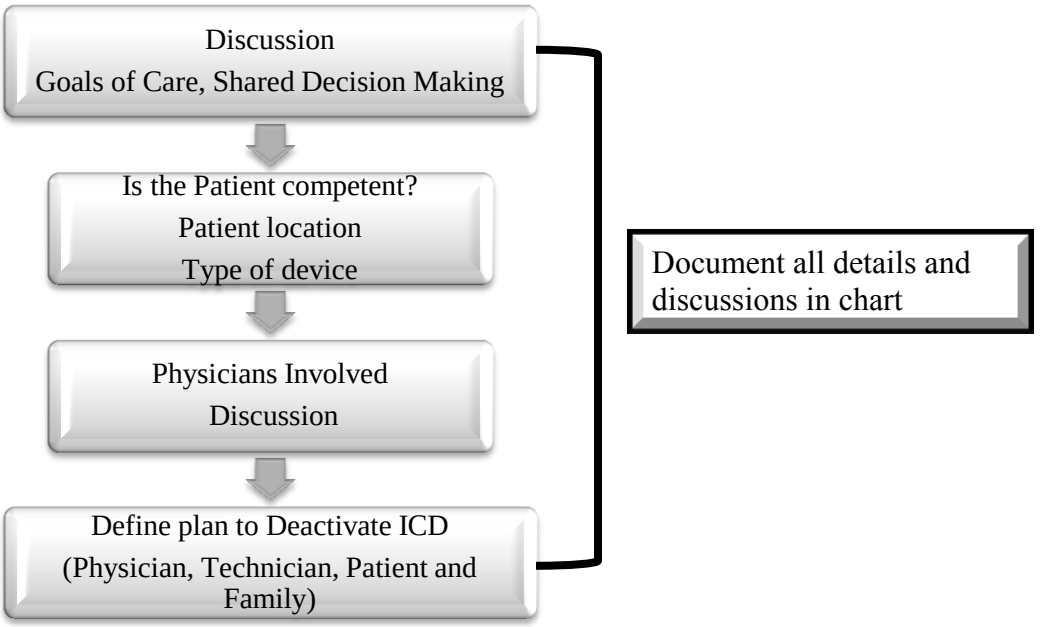
whose goals of care have changed may opt not to replace the generator, leaving the device non-functioning. When advanced directives are created, special attention should be paid to patients with ICDs. Ideally, the patient's feelings about the function of the ICD and when its purpose may no longer be congruent with the patient's goals should clearly be defined in this document. When a shock or multiple shocks are delivered (whether appropriate or inappropriate), when a patient is admitted for decompensated heart failure or for any other diagnosis requiring a hospital stay, if the patient is diagnosed with a terminal or incapacitating illness, if there is a decline in quality of life, or if there is a change in overall function of a patient, a discussion about goals of care should be performed.

Protocols for Deactivation

Coordination of deactivation is much more problematic, given provider time constraints and variable patient location. Protocols are lacking to achieve timely deactivation in the multitude of settings this could occur (i.e. hospital, office, hospice, nursing homes, patient's home, etc.). In addition, the inherent gravity of the discussion, typically involving a change in goals of care, creates a sense of urgency to the situation. The physical act of turning off the device is often performed by an industry representative after being given an order written by a physician[71]. However, both industry policy and recommendations by expert guidelines state that industry representatives should be under direct supervision of medical personnel[13,63]. This leads to the question, which physician should be present? In addition, which physician is most appropriate to write the order (electrophysiologist, cardiologist, primary care physician, hospice physician)? Without a proper algorithm, this process can be cumbersome, time consuming and ultimately rarely done.

In every institution, a protocol should be created to minimize the potential barriers. However, this may prompt the need for industry relationship, which may be an issue for institutions.

Figure 14. Process for Changes in Goals of Care and Deactivation



Conclusions

There are increasing numbers of ICD implantations every year because of their well proven capability of saving lives. However, goals of care tend to change when patients are at the end of life. When goals change toward comfort and alleviation of suffering, the ICD's purpose may no longer be relevant. In fact, it may lead to significant pain and distress for both the patient and the family. All physicians assuming responsibility for informing patients about the option of deactivation is critical for the landscape of patient knowledge to change. Coordination of care and communication amongst health care providers are other key elements to change peoples' knowledge and viewpoints. Professional societies such as the American Heart Association, the Heart Failure Association of America, and the Heart Rhythm Society have issued guidelines and statements to bring attention and help navigate the unchartered waters of this important topic. If that is not enough to convince individuals that we must address ICDs and end of life, then peruse the New York Times where stories of devices and the tribulations of patients and their families are put to ink to spread the word via social media and blogs[72,73]. As Hippocrates once said, "Where there is a love of medicine, there is a love of humanity." **Our love of medicine should cause us to rejoice that we save lives with these devices. Our love of humanity should compel us to know when to turn them off.**

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