Turning Off ICDs

Guidelines and Rules in the Dying Patients

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MAYO CLINIC

DISCLOSURE

Relevant Financial Relationship(s)

None

Off Label Usage

None

Objectives
Deactivating ICD

- Complexity of the issue
- Ethics and legality
- Who turns off the device, and when?
- Guidelines

Deactivating ICD
Complexity in Medical, Ethical and Legal Issues

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.

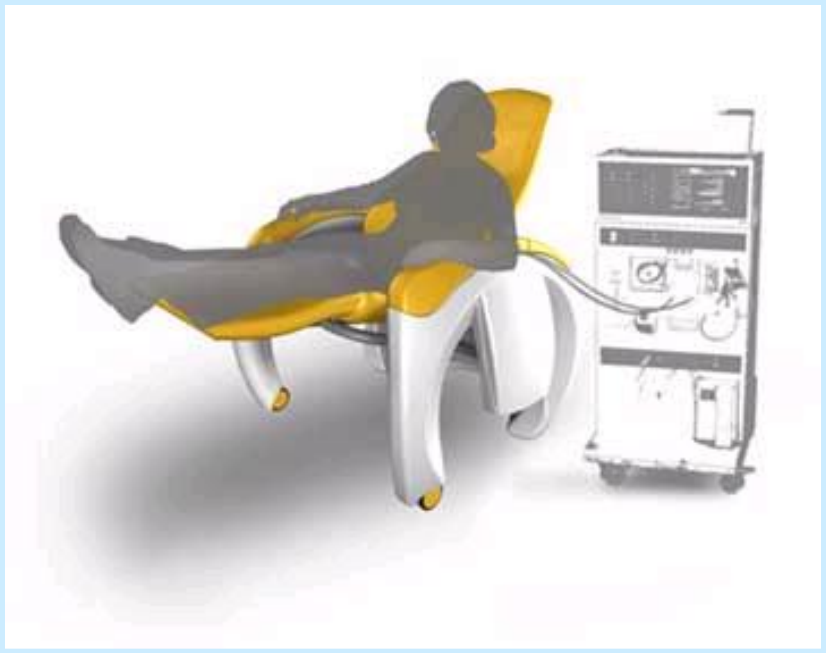
Goldstein et al: Ann Intern Med 141:835, 2004

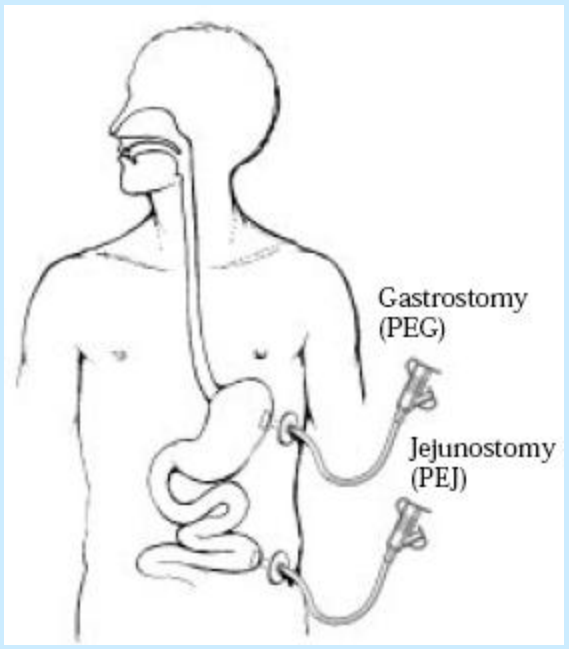
Case

Request for withdrawal

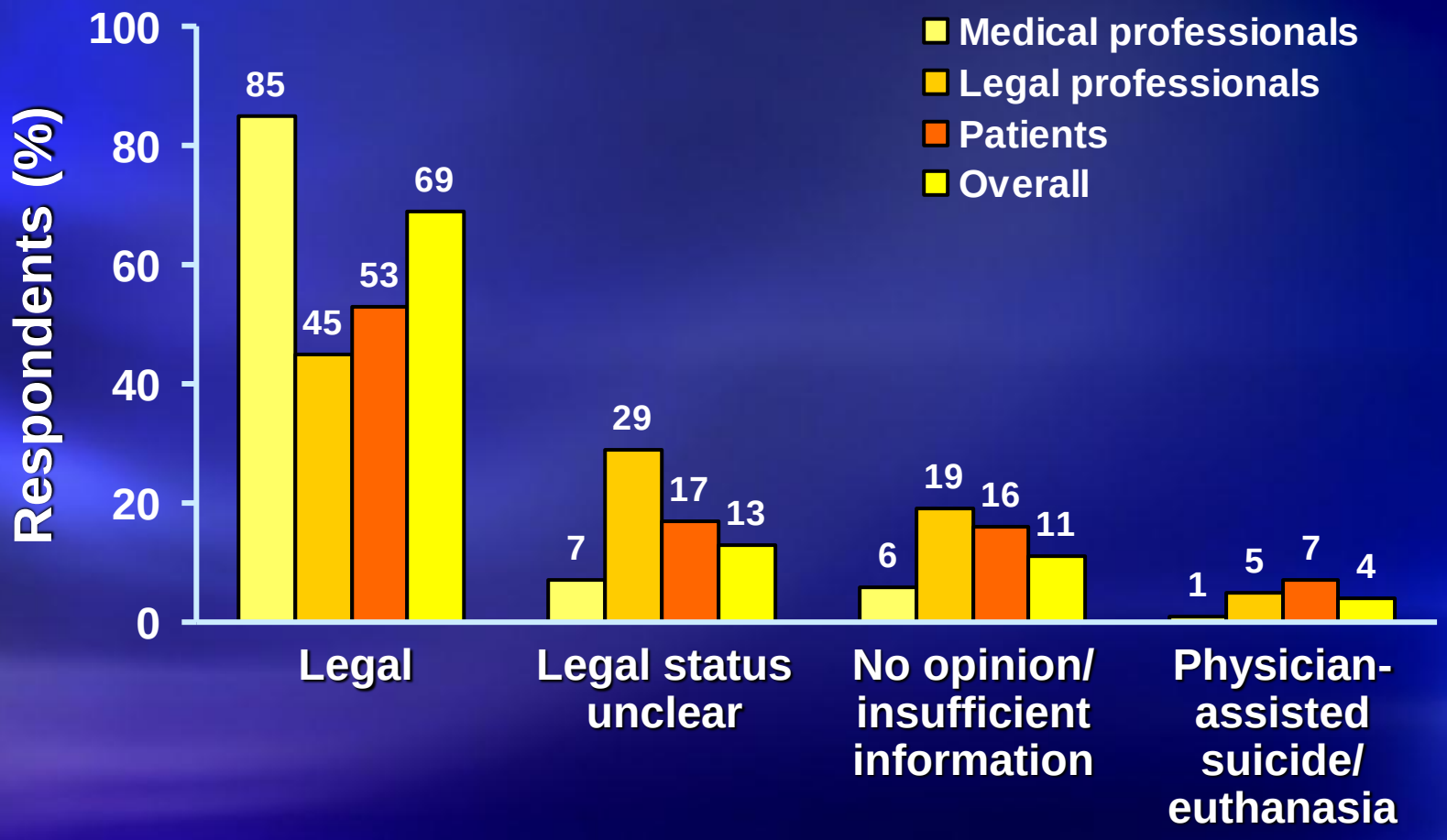
- 75-year-old man with CHF has an ICD for ventricular dysrhythmias
- Now hospitalized with cancer and sepsis, he is delirious and dying
- There is no advance directive
- Fearing shocks during the dying process and citing the patient's values and goals, his family requests ICD deactivation
- They understand the implications of ICD deactivation
- How do you respond?

Is it ethical and legal to withhold or withdraw life-sustaining treatments?





Withdrawing ICD



Kapa et al: Mayo Clin Proc 85(11):981, 2010

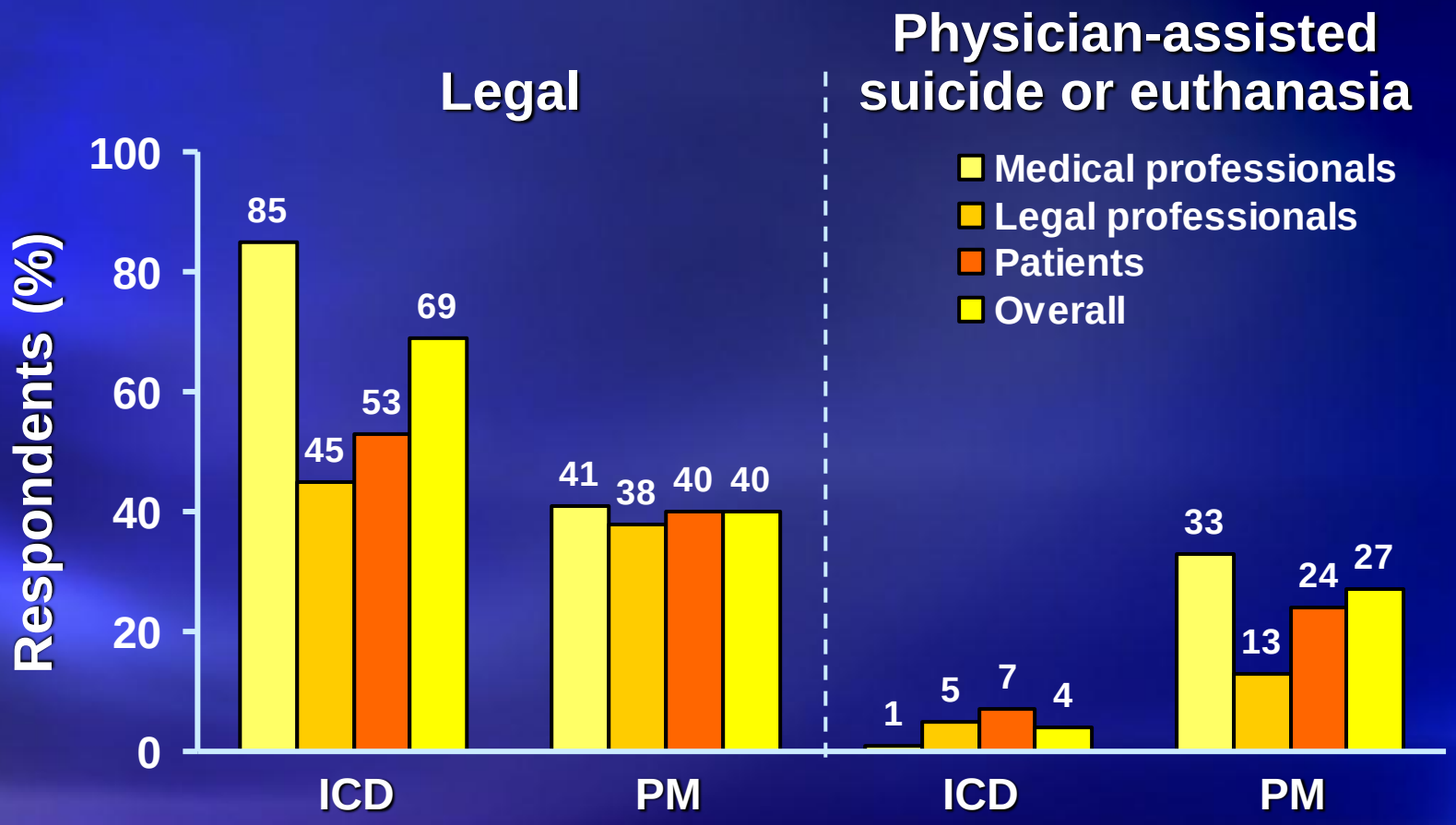
Case
Request for withdrawal

- 79-year-old man with terminal lung cancer has a PM for syncope due to complete heart block with unstable escape
- Fearing the PM will prolong the dying process, he requests PM deactivation
- He understands the implications of PM deactivation
- How do you respond to his request?

Ethical Aspects Of Deactivating Implanted Cardiac Devices

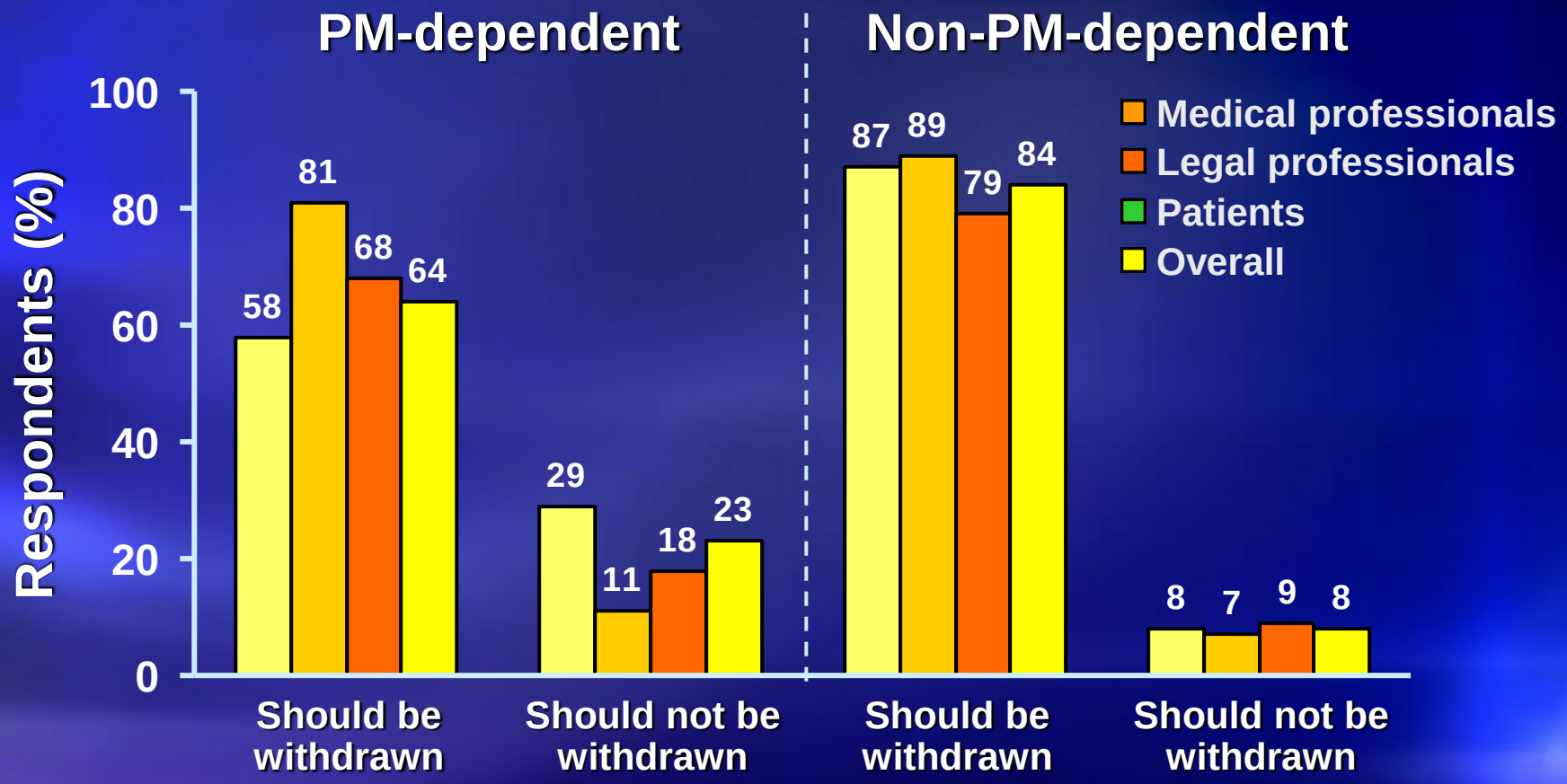
- Is deactivation of a pacemaker the same as deactivating an ICD or CRT?
  - Perform different functions
  - Deactivation may have different outcomes if the patient is pacemaker dependent
  - Some argue devices do not prolong the dying process
  - What about the patient who refuses a device (withholding treatment)?

Turning Off ICD vs PM



Kapa et al: Mayo Clin Proc 85(11):981, 2010

Pacemaker Withdrawal at End-of-Life



Kapa et al: Mayo Clin Proc 85(11):981, 2010

Withholding And Withdrawing Life-sustaining Treatments (LST)

- Many types of LSTs: dialysis, ventilation, artificial nutrition, etc
- In the US, withholding and withdrawing LSTs ethical and legal:
  - Respect for patient autonomy
  - Famous legal cases; not a "right to die," but a right to be left alone (liberty interest)
  - There is no ethical or legal distinction between withholding and withdrawing

Withholding And Withdrawing Life-sustaining Treatments

- Dying patients frequently make such requests
- Honoring these requests is not the same as physician-assisted suicide (PAS) or euthanasia
- The clinician is obligated to ensure the patient [surrogate/family] understands the consequences and alternatives to the request

W/W LSTs
Legal permissibility

Quinlan	1975	WD ventilator
Saikewicz	1977	WH chemotherapy
Dinnerstein	1978	WH CPR
Spring	1980	WD hemodialysis
Barber	1983	WD IV fluids
Bouvia	1985	WH/WD feeding tube
Cruzan	1990	WD feeding tube
Schiavo	2005	WD feeding tube

WD=withdrawal, WH=withhold

Withholding And Withdrawing Life-sustaining Treatments

	Withhold LST	Withdraw LST	Terminal analgesia	Physician-assisted suicide	Euthanasia
Cause of death	Underlying disease	Underlying disease	Underlying disease‡	Intervention prescribed by physician and used by patient	Intervention used by physician
Intent/goal of intervention	Avoid burdensome intervention	Remove burdensome intervention	Relieve symptoms	Termination of the patient's life	Termination of the patient's life
Legal?	Yes†	Yes†	Yes	No*	No

LST = life-sustaining treatment
‡Terminal analgesia may hasten death ("double effect")
†A number of states limit the power of surrogates regarding LSTs
*Legal only in Oregon, **Washington and Montana**

England Eases Rules On Assisted Suicide

By Jeanne Whalen

LONDON—English authorities made it easier for a family acting out of compassion to help a terminally ill relative to commit suicide, marking a victory for advocates of assisted suicide.

While it will continue to be illegal to help someone commit suicide, England's top prosecutor said the state will be unlikely to prosecute someone for helping a relative who had a clear wish to die, and also a terminal illness or "severe and incurable physical disability."

Keir Starmer, director of public prosecutions for England and Wales, said the state will be more likely to prosecute cases in which the victim wasn't mentally able to make up his own mind, or where the victim was pressured, or didn't have a "clear, settled and informed wish to commit suicide," or was under 18 years old.

Mr. Starmer issued the guidelines after a court ordered him to this summer. The new guidelines, which also apply to Wales, went into force Wednesday, though they are technically interim guidelines that will be open to public debate before final guidelines are issued next year.

Debate about assisted suicide has come to a head here in recent years, as a number of families have helped terminally ill or paralyzed relatives travel to Switzerland to commit suicide at a clinic called Dignitas.

This has put the relatives in a legal gray area. England has never chosen to prosecute any families for this, but the threat of prosecution has hung over them. That has led to calls for the chief prosecutor to clarify the rules.

Dignity in Dying, a nonprofit group that supports assisted suicide, welcomed the new guidelines. "In order to protect the public there will understandably be some situations where prosecutions are warranted. The guidelines sensibly distinguish between compassionate behavior and behavior which is potentially malicious," said Sarah Wootton, chief executive of Dignity in Dying, in a statement.

But she added that England should still change the law to clearly legalize assisted suicide when it is motivated by compassion. Thus far, attempts to change the laws have either stalled or been shot down in Parliament.

England is the latest country to grapple with the ethics of assisted suicide. Several European nations, including the Netherlands, Luxembourg and Belgium, have passed laws in recent years allowing for some forms of doctor-assisted suicide. In the U.S., Oregon has made it legal for doctors to prescribe life-ending drugs to some mentally competent but gravely ill people.

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Wall Street Journal, Sept. 2009

Conscientious Objection

- You cannot compel a clinician to perform a medical procedure he or she views as morally unacceptable
- What to do if this is the case?

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

This document was developed in collaboration and endorsed by the American College of Cardiology (ACC), the American Geriatrics Society (AGS), the American Academy of Hospice and Palliative Medicine (AAHPM); the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), and the Hospice and Palliative Nurses Association (HPNA).

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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."[1]

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

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,[1] twenty percent of ICD patients receive shocks which are painful[6] and known to decrease quality of life[6,7] and which greatly contribute to the distress of patients and their families.[1]

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.[8] However, the understanding of device deactivation varies[8,9] and studies show that many physicians report uneasiness with conversations addressing device management as patients near the end of their lives.[9] Few patients or families discuss the

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.

1547-5271/$ -see front matter © 2010 Published by Elsevier Inc. on behalf of Heart Rhythm Society. doi:10.1016/j.hrthm.2010.04.033

Europace (2010) **12**, 1480–1489
doi:10.1093/europace/euq275

CONSENSUS STATEMENT

EHRA Expert Consensus Statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy

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Online publish-ahead-of-print 30 July 2010

The purpose of this Consensus Statement is to focus on implantable cardioverter-defibrillator (ICD) deactivation in patients with irreversible or terminal illness. This statement summarizes the opinions of the Task Force members, convened by the European Heart Rhythm Association (EHRA) and the Heart Rhythm Society (HRS), based on ethical and legal principles, as well as their own clinical, scientific, and technical experience. It is directed to all healthcare professionals who treat patients with implanted ICDs, nearing end of life, in order to improve the patient dying process. This statement is not intended to recommend or promote device deactivation. Rather, the ultimate judgement regarding this procedure must be made by the patient (or in special conditions by his/her legal representative) after careful communication about the deactivation's consequences, respecting his/her autonomy and clarifying that he/she has a legal and ethical right to refuse it. Obviously, the physician asked to deactivate the ICD and the industry representative asked to assist can conscientiously object to and refuse to perform device deactivation.

Keywords CIED management • ICD deactivation • end of life patients

Introduction

There is a large body of evidence demonstrating that the implantable cardioverter-defibrillator (ICD) is the treatment of choice for patients who are at risk of sudden cardiac death due to ventricular arrhythmias. Randomized prospective trials have established that the ICD is superior to antiarrhythmic drug therapy in both primary and secondary prevention. Eucomed data (http://www.eucomed.org/) indicate that in 2008, ICD use, alone or associated with cardiac resynchronization therapy (CRT), continued to grow in Europe (14% more than in 2007). Implantable cardioverter-defibrillator-implanted patients may later develop terminal illness due to worsening of their underlying heart disease or other chronic non-cardiac disease. Terminally ill patients are more likely to develop conditions such as hypoxia, sepsis, pain, heart failure, and electrolyte disturbances predisposing them to arrhythmias and thus increasing the frequency of shock therapy. Shocks can be physically painful and psychologically stressful, without prolonging a life of acceptable quality, a result which is inconsistent with comfort care goals. Therefore, it is appropriate to consider

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Goals of New Consensus Guidelines

- 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
- 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
- To provide a management scheme to guide the clinician in assessing a patient with a request to withdraw CIED therapy

Basic Principles

Ethical & Legal Principles & Precedents

- A pt with decision-making capacity has the legal right to refuse or request the withdrawal of any medical tx or intervention, regardless of whether terminally ill or whether the treatment prolongs life and its withdrawal results in death
- When pt lacks capacity, a legally-defined surrogate decision-maker has the same right to refuse or request the withdrawal of tx as the pt would have had they been able
- 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 the pt incompetent but usually the clinician can assess capacity and act on that assessment.

Basic Principles

Ethical & Legal Principles & Precedents

- Ethically and legally, there are no differences between refusing CIED therapy & requesting withdrawal of CIED tx
- Advance directives should be encouraged for all pts with CIEDs
- Legally and ethically, carrying out a request to withdraw life-sustaining tx is neither physician-assisted suicide nor euthanasia. When carrying out such a pt request because the pt perceives the tx as unwanted, the clinician's intent is to discontinue the unwanted tx and allow the pt to die naturally of the underlying disease – not to terminate the pt's life

Basic Principles

Ethical & Legal Principles & Precedents

- The right to refuse or request the withdrawal of a tx is a personal right of the pt and does not depend on the characteristics of the particular tx involved, i.e. CIEDs. Therefore, no tx, including CIED therapies, has unique ethical or legal status
- A clinician cannot be compelled to carry out an ethically- and legally-permissible procedure, e.g. CIED deactivation, that he/she 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.

Written Documentation

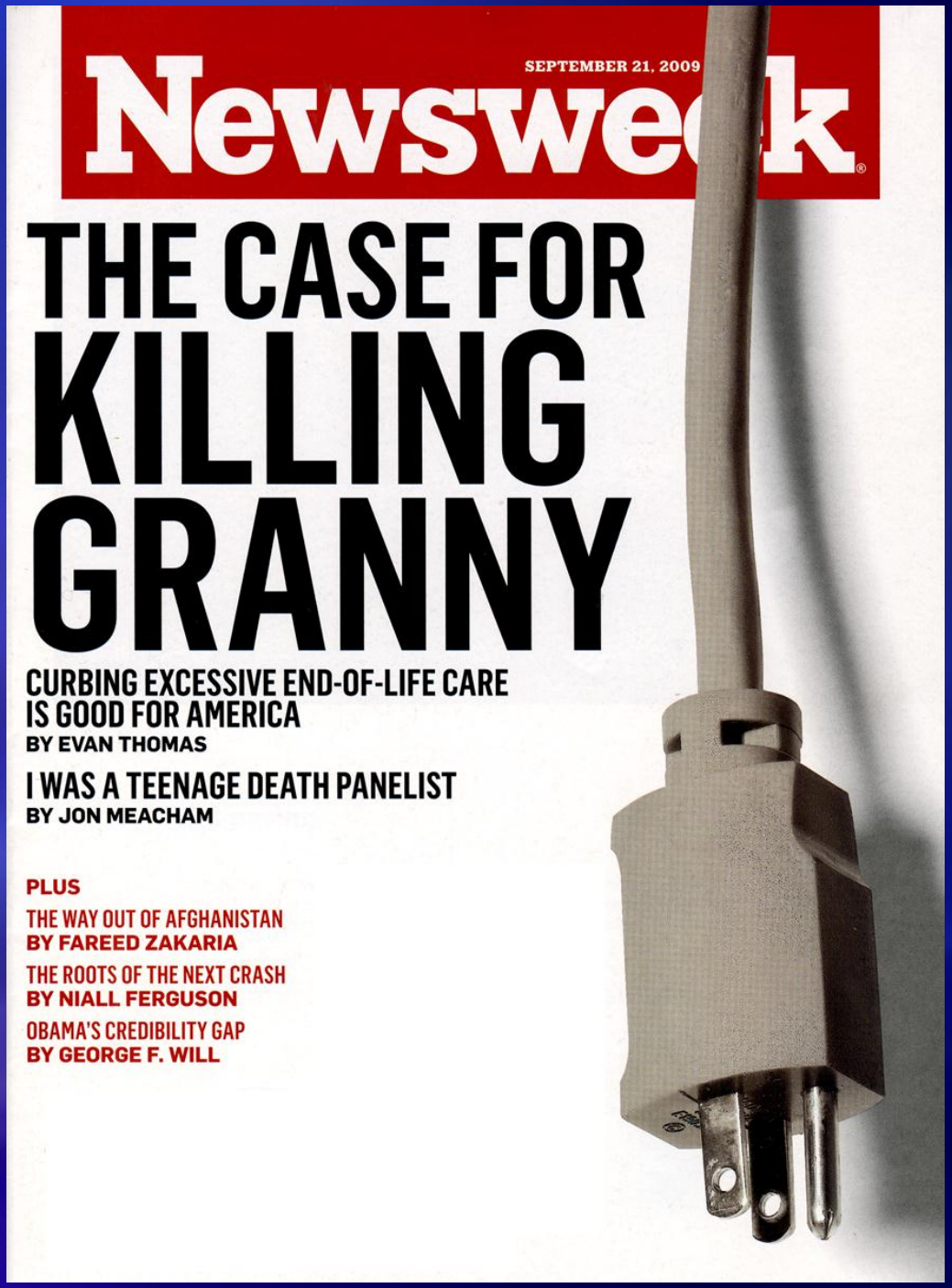
1. Confirmation that the pt or surrogate has requested device deactivation
2. Capacity of the patient to make the decision, or identification of the appropriate surrogate
3. Confirmation of the alternative therapies have been discussed if relevant
4. Confirmation that consequences of deactivation have been discussed
5. The specific device therapies to be deactivated
6. Notification of family, if appropriate

Logistics of CIED Deactivation

- 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

My XX year old patient just asked me to turn off his ICD because…..

- *Legally the answer would be the same for all scenarios, i.e. the patient owns the decision*
- *Practically and clinically, different approaches may be appropriate, e.g. if the patient just lost his spouse, assess psychiatric status and treat if needed*
- *Moral appropriateness can only be determined by the caregiver involved*
- *Many caregivers would perceive the pacemaker dependency issue differently, even if legally there is no distinction*


Newsweek
SEPTEMBER 21, 2009
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Cardiac Device
End of Life Management

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