



End of Life and Heart Rhythm Devices*

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Spring Summit 2014



Disclosures

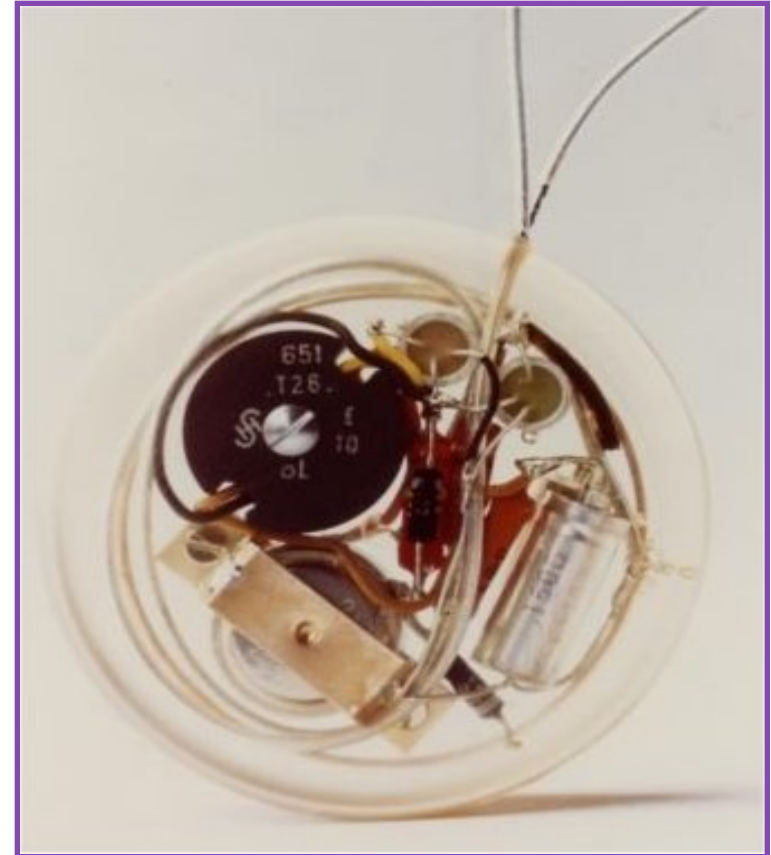
- **None**

Objective

- Describe the ethical and legal acceptability/permissibility of withholding and withdrawing life-sustaining treatments as it relates to Heart Rhythm Devices
 - Most clinicians regard implanted cardiac devices as life-sustaining treatments (PACE 2008;31:560-8)
- Differentiate withholding/withdrawal life sustaining treatments from physician assisted suicide & euthanasia

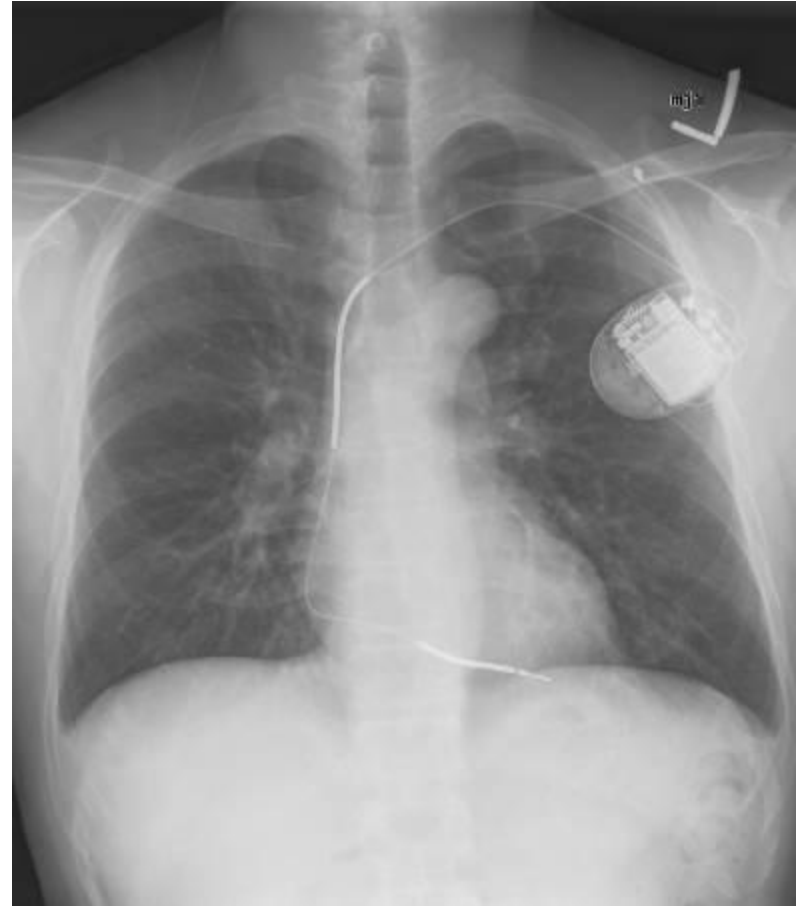
How does this discussion apply to implanted Heart Rhythm Devices?

- Introduction: PM in 1958 and ICD in 1980
- PM and ICD therapies save and prolong life
- The indications for device therapies are expanding
- Population of patients with devices continues to grow



How does this discussion apply to implanted cardiac devices?

- **Nearly 3 million patients with implanted cardiac devices in the U.S.**
- **All patients ultimately will reach the end of their life**
- **More dying patients have devices, increasing the likelihood of device deactivation requests**





Range of device-related requests

Refusals (withhold) to deactivation (withdrawal)

- **Refuse device implantation**
- **Refuses re-implantation after device infection, failure, recall, ERI**
- **Request device deactivation**
 - Non-terminally ill
 - Terminally ill



Deactivating implanted cardiac devices

Concerns raised

- **Ethical? Legal?**
- **Same as physician-assisted suicide or euthanasia?**
- **Do guidelines exist?**
- **Who should carry out deactivations?**
- **What documentation is necessary?**



Case MV

Case MV – 71 yo Male

- **Aortic Valve Endocarditis**
 - s/p mechanical valve – 1988
- **Valvular Cardiomyopathy**
 - LVEF 20%, NYHA Functional Class III
- **Ventricular Tachycardia**
 - ICD implant - 1999
 - CRT-D 2008
 - Last ICD therapy for VT - 10/10
 - Amiodarone 200 mg qd

Case MV - Additional History

- **Congestive hepatopathy**
 - cirrhosis, recurrent ascites
- **Chronic kidney disease, Stage IV**
- **Hypothyroidism**



Case MV - Worsening CHF

- **Advanced Heart Failure Clinic**
 - not thought to be a good candidate for left-ventricular assist device
- **Severe lightheadedness**
 - Markedly hypotensive
 - Recurrent, tense, ascites

Case MV

- **Family meeting held**
- **Decision made to take patient home with home hospice**
- **Request made from family to turn off ICD HV therapies**

How should we proceed?

- **A: Obtain an ethics consult**
- **B: Ask a priest/chaplain to convince the family this is wrong**
- **C: Refuse to comply as the request is akin to euthanasia**
- **D: Deactivate the device**



Discussion



Case MV

- **At the patients EOL, an ICD can cause discomfort to patients, and clinical considerations might dictate its deactivations.**
- **ICD withdrawal is a comfort measure.**
 - Programming renders the device ineffective.
- **Family was consulted, hospice.**
- **Appropriate steps taken**
- **Documentation of encounter**

What should be included in documentation of the encounter?

- **A:** The perception of the caregiver
- **B:** A description of the patient's cognitive and psychological state and decision-making competence
- **C:** Communications with the family; that the consequences of deactivation (including relevant alternatives) have been discussed
- **D:** A written, signed, and witnessed consent by the patient or legal representative
- **E:** All of the above



CASE TZ



Case TZ – 76 yo Male

- **Ischemic cardiomyopathy**
 - LVEF 15-20%
 - NYHA Class III-IV
 - Permanent atrial fibrillation
 - Comorbidities?

Case TZ

- **Single-chamber ICD – 1988 for syncope**
 - Inducible VT at EP study
- **AV junction ablation – 2002**
- **Upgraded to CRT-D– 2002**
- **No VT, VF or ICD therapies for years**

Case TZ

- **Home hospice for end-stage heart failure**
- **Acute deterioration at home for increasing dyspnea and delirium**
- **Over several days there was**
 - Worsening tracheobronchial secretions
 - Severe respiratory distress
 - Progressive confusion and agitation

Case TZ

- **Wife can no longer take care of him**
- **Request made by wife:**
 - Turn off defibrillator therapies
 - Turn off pacemaker

How should we proceed?

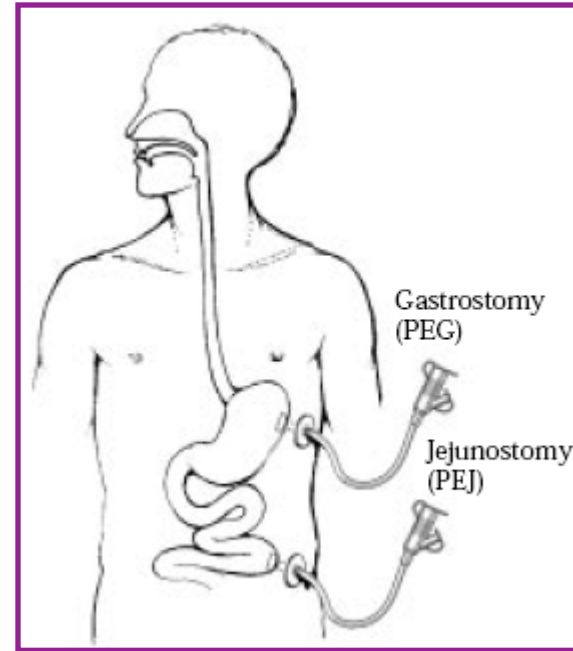
- **A: Comply if the hospital attorney agrees**
- **B: Ask a priest/chaplain to convince the family this is wrong**
- **C: Refuse to comply as the request is akin to euthanasia**
- **D: Deactivate the device**



Discussion

Issues to Consider

- Is it ethical
- And is it legal





Withholding and withdrawing life-sustaining treatments

- **Many types: hemodialysis, ventilators, etc.**
 - Most clinicians regard implanted cardiac devices as life-sustaining (PACE 2008;31:560-8)
- **Ethics principle: respect for the patients **autonomy****
 - the right to refuse, or request withdrawal of unwanted medical interventions even if doing so results in death; should not impose treatments
- **No ethical or legal difference between withholding and withdrawing**
- **Clinician's duty: informed consent (informed refusal)**

Legal Issues

- **Several US court decisions clarified and established a person's right to refuse any and all medical interventions or to request their withdrawal.**
 - The Patient's Self-Determination Act of 1990
 - Healthcare Institutions required to ask Medicare/Medicaid of AD
- **The right to refuse medical interventions or to request their withdrawal, including pacemakers & ICDs, is legal.**
- **No ethical or legal distinction exists between withholding & withdrawing treatment**

Epstein AE et al. Circ 2018;117:e350-e40.

Wilkoff BL, Auricchio A, Brugada J, et al. Heart Rhythm. 2008;5(6):907-926.

Lampert R, Hayes DL, Annas GJ, et al. Heart Rhythm. 2010;7(7):1008-1026

Karen Quinlan

70 N.J. 10 (1976), Supreme Court of New Jersey

- **Found unresponsive; PVS**
- **The family wanted to withhold LST(MV); the institution did not**
- **Court decision:**
 - Patients have the right to refuse treatment
 - Surrogates may exercise the patient's right
 - Such decisions are best made by families, not courts
 - The state's interest in preserving life can be overridden by the patient's right to refuse treatment
 - LST withdrawal without imposing liability



Nancy Cruzan

- **1983: in a motor vehicle accident; never regained consciousness (PVS)**
- **1988: parents sought removal of feeding tube**
- **Hospital refused without court order**
- **Trial court ordered removal of tube**



Nancy Cruzan

Missouri Supreme Court

- Must have clear and convincing evidence of a patient's wishes (e.g., an advance directive) before removing a feeding tube
- Artificially administered hydration and nutrition are not medical treatments

Legal Issues

- In the CRUZAN case, the US Supreme Court affirmed
 - the right of competent patients to refuse medical interventions
 - the right of incompetent persons through surrogates
 - ruled the states should not unduly burden patients who wish to extend that liberty to end-of-life decision making

Landmark Legal Cases Confirming the Right to WH or WD 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



Precedence of landmark cases

Not a right to die, but a right to be left alone

- A competent patient has the right to refuse or request the withdrawal of LSTs*
- The incompetent patient has the same right (exercised through a surrogate)*
- Hierarchy of surrogate decision-making
- The court is not the place to make these decisions
- No case must go to court
- No difference between withholding and withdrawing LSTs*
- Artificial fluid and nutrition are medical treatments
- No physician liability for granting such requests*



Advanced Directives

- The Supreme Court also affirmed the right of an incompetent person to refuse treatment via explicit statements, ADVANCE DIRECTIVES, SURROGATE Decision makers.
- Notably, NO US Court has found a physician liable for wrongful death or murder for honoring a patient's or surrogate's request to refuse or withdraw life-sustaining treatment.



Answers

- **Ethical ? Legal?**

- It is ethical and legal to withhold or withdraw life-sustaining treatments from patients who do not want them.
- Through surrogates, patients without decision-making capacity have the same ethical and legal rights as those with capacity.

Are withholding and withdrawing life-sustaining treatments akin to euthanasia?





Cause of Death: Underlying Disease

- **PAS or euthanasia, causes death, via an externally implemented means**
- **Death after the refusal or withdrawal of unwanted interventions is caused by the patients underlying disease.**
- **No difference between withholding or withdrawal**

End-of-life decisions

	Withhold LST	Withdraw LST	Palliative sedation and 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 patient's life	Termination of patient's life
Legal?	Yes†	Yes†	Yes	No*	No

LST = life-sustaining treatment

‡Palliative sedation and analgesia may hasten death (“double effect”)

†A number of states limit the power of surrogate decision-makers regarding LSTs

*Legal only in Oregon and Washington

Deactivating implanted devices

Common ethics arguments

J Gen Intern Med 2007;23(Suppl 1):69-72.

- **Withholding vs. withdrawing treatment**
 - No ethical or legal differences
 - Devices raise no new moral issues
- **Duration of treatment**
 - Not a morally decisive factor
- **Continuous vs. intermittent treatment**
 - May be a reason for different perceptions regarding deactivating ICDs vs. PMs
 - However, we accept WD of both continuous and intermittent LSTs (e.g., ventilation vs. HD)



Views on PM Therapy

- **PM therapy is different than ICD therapy, ICD therapy is painful, while PM is Painless. So withdrawal of PM is more difficult to comply with.**
- **PM therapy is a comfort measure, to avert symptomatic bradycardia, worsening HF, and syncope.**
- **And at EOL, acidosis and hypoxia will prevent capture and thus the PM itself is not artificially prolonging life.**

Two Analytical Frameworks

- **Rhymes uses benefit burden analysis**
 - If the burden of the PM to the patients outweighs the benefit of a prolonged life, the PM may be deactivated.
 - So the existing disease is the cause of death because it is no longer interrupted by medical intervention.
- **Withdrawal of technology only changes the time of death.....**

Two Analytical Frameworks

- **Sulmasy framework: Replacement therapy vs. Substitutive therapy**
 - Replacement therapy becomes part of the restored physiology of the patient, part of...an intact individual organism., i.e., porcine aortic valve & kidney transplant. It becomes biomechanical.
 - Substitutive interventions provide a lost function and may assist in stabilizing the patient, but they do not become an organic part of the body.
 - HD
 - Pacemakers



If a decision is made to deactivate a device, who carries out the deactivation at your institution most of the time?

- A. Primary care physician**
- B. Palliative medicine specialist**
- C. Electrophysiology physician**
- D. Device Nurse**
- E. Industry employed representative**



Device deactivation in the dying

Survey of practices and attitudes

PACE 2008;31:560-568

- **Web-based survey**
- **HRS members and field personnel of 2 device manufacturers**
- **ICDs and pacemakers**
- **787 respondents, almost all of whom had patient contact**
 - 63% male, 63% worked for industry, and 23% were physicians

Survey results

PACE 2008;31:560-568

Question	% "Yes"	
	PM	ICD
Have you ever been involved in the care of a TI patient who requested device deactivation?	77.6	86.8
Have you ever personally deactivated a PM or ICD in a TI patient?	76.6	92.4
Have you (or patient's physician) ever refused a request for device deactivation by TI patient?	22.1	5.6
Do you consider a PM in a PM-dependent patient, or an ICD in a patient who is not PM-dependent, life-sustaining treatments?	89.4	52.1
Do you believe patients must have a TI in order to undergo device deactivation?	54.9	31.6
Should a DNR order require device deactivation?	29.3	46.2
Should hospice programs require that patients have their PM or ICD deactivated?	4.3	29.8

All differences are statistically significant



Survey results

PACE 2008;31:560-568

In your experience, who deactivates devices most of the time?	PM %	ICD %
Device industry representative *	49.7	59.3
Cardiologist	15.2	13.6
Nurse	8.6	11.9
EP technician	3.7	4.9
Primary physician	1.3	0.5
Other or “I don’t know”	7.7	5.0
I have not encountered this situation	13.8	4.9

*Anecdotal experience indicates that many device industry representatives do not appreciate this task.

Survey conclusions

PACE 2008;31:560-568

- **Device deactivation requests are common**
- **A majority of caregivers have cared for patients who have made these requests and have personally deactivated devices**
- **In dying patients, a distinction is seen between deactivating an ICD and a PM**
- **Device manufacturer field representatives are cited as those who deactivate devices most of the time**

Do Guidelines Exist?

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

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

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Key Points of HRS Statement

- Discussions about deactivation should begin **before** implant and **continue** throughout the course of the patient's illness*
 - Communication about devices should include goals of care
- A patient has the right to refuse or request withdrawal of device therapy regardless of their illness. They do not need our permission.*
- Deactivation, be it for pacing or shocks, is not physician-assisted suicide or euthanasia*
- Physicians dealing with device patients should promote the benefits of advanced directives (ADs).*
 - Studies show that patients with specific Ads are more likely to receive patient-centered & less likely to receive shocks at EOL
- Anticipate symptoms and involve palliative care

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



Basic Principles

Ethical & Legal Principles and Precedents

- **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 views.**
- **In these circumstances, the clinician cannot abandon the patient but should involve a colleague who is willing to carry out the procedure.**

Deactivating ICDs

Literature review

Few patients with ICDs:

- **Have ever discussed device deactivation with their physicians** (*J Gen Intern Med* 2007;23[Suppl 1]:7-12)
- **Know that device deactivation is an option** (*J Gen Intern Med* 2007;23[Suppl 1]:7-12)

But Most

- **Want to be involved in the deactivation decision** (*PACE* 2011;34:1628-33)

Device-Specific advance care planning

Literature review

- **Although 30-60% of patients with device have ADs, few mention the device** (*J Clin Ethics* 2006;17:72-8; *Heart Rhythm* 2010;7(5 Suppl):S11; *Heart Rhythm* 2010;7(5 Suppl):S192; *Hosp Pract* 2011;39:1-7; *Am J Cardiol* 2012;109:91-4)
- **Almost all agree that patients should have the opportunity to execute & AD that addresses ICD management** (*Am J Cardiol* 2012;109:91-4)

Deactivating ICDs

Literature review

Advance care planning:

- **Articulating goals and preferences for care at the end-of-life**
- **Regarding devices:**
 - Rarely happens (*J Clin Ethics* 2006;17:72-78)
 - Patients with all devices (PM, ICD, LVAD, etc)
 - For patients with ICDs, results in fewer shocks at the end-of-life (*Am J Med* 2006;119:892-896)



Heart Rhythm SocietySM
Restoring the Rhythm of Life

End of Life and Heart Rhythm Devices

How do I handle death and dying issues with my implantable cardioverter defibrillator (ICD) and cardiac pacemaker?

Garrett Snipes, MD¹, Jonathan Z. Rosman, MD², & Samuel F. Sears, Ph.D.³



When would I want to turn off my ICD or pacemaker?



ICDs and pacemakers have helped people live longer. Instead of dying from heart rhythm problems, these patients are now dying from other life threatening illnesses such as cancer, lung disease and heart failure. Heart failure is a condition in which the heart muscle becomes weak and the heart is no longer able to pump blood well. This is the most common reason to get an ICD. While the ICD will prevent you from dying before your time from a dangerously fast heart rhythm, it will not stop you from dying from heart failure.

Patients may reach a point in their lives when their goal of care is to be comfortable during their remaining time. The ICD is programmed to prevent death and will consistently attempt to correct the rhythms leading to death using shocks. Studies have shown that about 1 in 5 people with an ICD experience painful shocks which they find troublesome in the last weeks of their lives. Terminally ill patients often have discussions with their primary care doctors regarding end of life issues. By taking some steps outlined below, you can increase the chances of a more peaceful death.

The End.

