Ethics and Pacemakers

Disclosures

The speaker is biased towards hospice and palliative care
the speaker is biased towards respect for patient autonomy
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No other relevant disclosures

Goals

Discuss the ethics of pacemaker deactivation
Discuss the ethical principles
Discuss legal precedent
Why Is This Important

Survey of Hospices
900 surveys sent out, 414 returned
97% of 414 admitted patients with pacemakers
58% had reported in the past year a patient being shocked while in hospice care
20% had a question on intake to identify patients with AICDs
10% of reporting hospices had a policy to address AICD/pacemakers deactivation
42% of patients had the AICD function deactivated

Ann Intern Med. 2010;152:296-299

Patient Case

The Pt is an 88y/o female admitted with CHF, delirium, and anorexia. Swallow study did not show sig. aspiration, just refusing to eat. Dobhoff tube placement failed. PEG placement attempted but Pt went apnic with propofol sedation. Poor response to TPN. Echo EF 20-25%. Pt’s health fails during hospitalization. Pt becomes obtunded. Pacemaker/AICD shows...

Case Cont.

Intermitant demand pacing, 14 events recently. Family considering hospice and cardiology offers deactivation of AICD function of the pacemaker/AICD. Pt goes to comfort care status and AICD function is deactivated at 16:45. The following day the patient appears to be actively dying. The family now requests that the pacemaker function also be deactivated.
Case Cont.

The nurse calls the cardiologist and relates family request for pacemaker deactivation to prevent prolonged dying and suffering. The cardiologist responds.....

<table>
<thead>
<tr>
<th>Status of Pacemaker/AICD</th>
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<tr>
<td>Ordinary treatment?</td>
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<td>Part of the body since implanted and self contained?</td>
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<td>(replacing part of the body's function)</td>
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<td>Substitutive therapy vs replacement therapy</td>
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<td>A person has a moral obligation to use ordinary or proportionate measures. – Directive 56</td>
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One definition of extraordinary from the ERDs: extraordinary/disproportionate measures are those that in the patient’s judgment do not offer a reasonable hope of benefit or entail an excessive burden, or impose excessive expense on the family or the community.

A person may forgo extraordinary or disproportionate means of preserving life. – Directive 57

Competing ethical obligations
- Patient autonomy
- Beneficence (promoting patient wellbeing)
- Nonmaleficence (avoiding patient harm)
- Justice (societal needs and distribution of resources)


The ethical propriety of withdrawal of other similar life-sustaining treatments, such as ventilator support and ICD shock therapy, is now well established. Despite this, withdrawal of pacemaker therapy remains controversial.

**Problem**

Physicians are understandably uncomfortable when faced with a request for deactivation of pacing therapy provided to pacemaker dependant patients whose death will likely ensue from their underlying disease. Allowing death to occur, even at the end of life, runs against the grain of a physicians training to heal patients and often is perceived as a form of failure.


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**Ethics**

Autonomy is paramount for competent adults because of their politically sanctioned right to live by their values. Based on personal preferences and goals, an informed patient, with the requisite mental capacity for decision making, can refuse treatment, including life-sustaining interventions.


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**Respect for Autonomy**

The conditions necessary for “respect for autonomy” for patients with decision-making capacity: patients make decisions intentionally, patients make decisions with understanding, and decisions are made without controlling influences that determine their action.

The withholding and withdrawing of life-sustaining treatments...from terminally ill patients, who do not want the treatments, is ethical and legal.

*Ethics*


Physicians define the medically acceptable treatment options that will promote patient well-being. However, because of autonomy, competent well-informed patients may identify a particular treatment option as best for them or refuse treatment altogether. Thus, patients define "beneficence" for themselves in light of their own values.

*Beneficence*


Prohibits acts or omissions that harm the patient. In ethics, the concept of harm refers primarily to moral harm and not merely to the occurrence of an adverse outcome. Thus, withdrawal of care is nonmaleficent if done in accordance with the wishes of a competent patient, even when an existing pathology runs its course and results in the patient’s death. Under this circumstance, the withdrawal does not cause moral harm to the patient.

*Nonmaleficence*

Biotechnology, Ontology and Ethics

“As technology progresses, some interventions seem to become a part of the patient as a unified whole person, completely replacing body parts and lost physiological functions rather than merely substituting for impaired structure and function.” If the intent is to replace function “then it seems that deactivation is better classified as a case of killing rather than a case of foregoing a life-sustaining treatment.”

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

Replacement Therapy

Replacement therapies become a part of the restored physiology of the patient, part of the integrated unity of the patient as an intact individual organism.
Signs suggestive of replacement
1- Its responsiveness to changes in the organism or its environment
2- Properties such as growth and self-repair
J Gen Intern Med 23(Suppl 1):69-72

Replacement Therapy

3- independence from external energy sources or supplies
4- independence from external control by an expert
5- immunologic compatibility
6- physical integration into the patient’s body

J Gen Intern Med 23(Suppl 1):69-72
"As technology becomes more sophisticated, however, and new interventions come to be best classified as 'replacements' (a heart transplant would be a good example), ‘discontinuing’ these interventions should be much more morally troubling for those clinicians who oppose euthanasia and assisted suicide.”

*J Gen Intern Med 23(Suppl 1):69-72*

To discontinue replacement therapies is better understood as introducing a new lethal pathophysiological state rather than discontinuing a treatment that is merely substituting for a preexisting lethal pathophysiological lack of that function.

“The discontinuation of a replacement therapy thus becomes an act of killing.”

*J Gen Intern Med 23(Suppl 1):69-72*

Previous discussions have dismissed these new arguments “using standard bioethical categories such as patient’s rights, refusal of unwanted therapy, autonomy, futility, and nonmaleficence.” However cardiologists and patients discuss the possibility of deactivating AICDs very infrequently.

*J Gen Intern Med 23(Suppl 1):69-72*
Research

Patients and cardiologists alike seem to view implanting an pacemaker/AICD as a “bridge” that one crosses with no possibility of return. Qualitative data suggests that there may be more going on here from a moral point of view than the ethics of the 1970s can handle.

*J Gen Intern Med 23(Suppl 1):69-72*

New Concerns

Does internalized technology “become a part of the patient”- a biofixture

Challenges to our notions about the difference between killing and allowing to die

*As a general rule, philosophers have suggested that the conditions under which one could justify withholding a treatment are those under which one could justify withdrawing a treatment.*

*J Gen Intern Med 23(Suppl 1):69-72*

Examples

- Pacemaker/AICD vs. heart transplant
- Insulin injections vs. islet cell transplant
- LHRH implant for prostate cancer vs. skin transplant
- Pacemaker in a patient with dementia- the pacemaker does not cure the heart nor the dementia and is thus futile treatment relative to curing dementia.
Discontinuation of AICD vs. Pacemaker and allowing to die
And yet, many patients and physicians readily perceive that there is an ethical difference that makes one action morally acceptable and the other unacceptable.

*J Gen Intern Med* 23(Suppl 1):69-72

Although the pacemaker prolongs life, it does not cure the existing cardiac pathology or halt the progressive effects of dementia. Given this fact, withdrawal of pacing therapy results in no moral harm.

The withdrawal of technology only changes the time of death and the physician is not deemed to kill the patient.


A pacemaker is not a resuscitative device
In general, pacemakers do not keep patients alive At the time of death, the myocardium is usually too sick to respond to the pacemaker generated signals
In patients with irreversible cognitive failure, where continued pacemaker activity is not meeting the goals of care, it may be appropriate to discuss the option of Deactivation.

www.eperc.mcw.edu fast fact #111
### EPERC Fast Facts #111

Deactivation is usually not indicated since the result is likely to be a symptomatic bradycardia (heart failure, fatigue, dizzy, dyspnea).

In contrast to popular belief, it is rare that disabling the pacemaker will result in a swift and painless death as few patients are 100% pacemaker dependant.

Withdrawal of a life sustaining medical intervention with the informed consent of a patient or legal surrogate is not physician-assisted suicide or euthanasia.

[www.eperc.mcw.edu fast fact #111](http://www.eperc.mcw.edu)

### New Framework

A familiar lament of bioethicists is that technology advances at such a rate that it exceeds the realistic bounds of the theoretical framework that contains it.

For example, arguments continue to develop regarding the best definition of death, now that bodies can be maintained despite the loss of major organ function or the capacity for conscious existence.

*J Med Ethics* 2007;33:538-540

### New Framework

Ways to consider pacemakers/AICDs

1. considered a treatment like external defibrillators, dialysis machines, ventilators

2. compared with biological transplants as part of the body- not replacing parts of the body but because they become an equally integral part of the person

*J Med Ethics* 2007;33:538-540
1- As a treatment, a degree of control regarding the use of a pacemaker/AICD remains with the patient’s doctors - the doctor decides if its use is medically indicated.

2- If deemed equivalent to a part of the patient’s body, there will be circumstances in which a doctor will not lawfully be able to deactivate the device, even if it has a negative effect on the patient’s quality of life and the patient consents. This is because of the act/omission distinction and the concept of futility that is used at law to justify decisions of withdrawal or non-treatment.

Though not organic, a patient may consider the implant a part of the body, as with an artificial hip. Thus a doctor probably could not deactivate the pacemaker/AICD as withdrawal of treatment.

In other words, there could be a real sense that deactivation is an intervention that the doctor has no right to make.

The difficulty with this status is not being able to deactivate a device even with the patient’s consent and when it is not appropriate to defibrillate a patient.
Law Concerns

Consider renal failure in an incompetent-hemodialysis Pt, if it became futile, the doctor may legally withhold the treatment. If the patient had a kidney transplant, it lawfully could not be removed or deactivated (unless passively by withholding immuno-suppressant treatment, and this was in the patient’s best interests).

*J Med Ethics 2007;33:538-540*

Law Concerns

If a medical intervention- deactivation would count at law as an omission
If a part of the body- deactivation would count as an act
The distinction between acts and omissions is believed to be an essential element of lawful medical practice.

*J Med Ethics 2007;33:538-540*

Law- Middle Ground

Consider pacemakers/AICDs as **integral devices** to escape treatment/nontreatment dichotomy
An integral device, though not organic, is part of the patient.
A patient should retain stronger autonomy- taking away unilateral action by a doctor- but allowing a patient still to refuse treatment against medical advice.

*J Med Ethics 2007;33:538-540*
Proposed Three Categories

As medical intervention - we can turn it on and off as we need - 1
As integral device - the patient could request deactivation - 3
As part of the body - it could not be deactivated even if causing harm – 2

Informed Consent

Existing consent procedures often involve an element of counseling about AICD maintenance, malfunction, and deactivation. However, at the moment of asking a patient’s consent to insert a life prolonging technology, it is arguably inappropriate to raise the prospect of having the device disabled.

Three Categories Informed Consent

1 – medical intervention – the physician may unilaterally deactivate
2 – part of the body – the physician may not deactivate even if patient requests and/or it was prolonging death and suffering
3 – integral device – the patient may request deactivation
Informed Consent Problem

If a physician clearly intends never to turn off a pacemaker, it should be clearly stated in the informed consent. PJL

Current law based on the Nancy Beth Cruzan case—the US Supreme Court recognized the constitutional right of a competent person to refuse life-sustaining therapy. J Fins MD, A Palliative Ethic of Care, page 34, Jones and Bartlett; Sudbury, MA; 2006, ISBN 0-7637-3292-3

Ethics

1987 President’s Commission report—bioethicists asserted and the law maintained that the discontinuation of life support was removing an impediment to death. The cause of death was not the removal of a ventilator but the underlying disease process that made the ventilator necessary in the first place.

J Fins MD, A Palliative Ethic of Care, page 32, Jones and Bartlett; Sudbury, MA; 2006, ISBN 0-7637-3292-3

Counter Point

For pacemaker-dependent patients, the progression of their underlying disease will eventually result in failure of pacing stimuli to capture the heart, and death will occur naturally. In contrast, to intentionally interrupt pacing in such a patient probably will result in their nearly instantaneous death, regardless of their underlying medical illnesses (if any). To stop pacing in such a patient is a deliberate act that is intended to hasten death.

Substitutive vs. Replacement

Substitute – temporarily substituting for impaired structure and function.
Replacement – intended to become part of the patient as a unified whole person.

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Counseling the Family

Patients, surrogates, and families should be counseled that, at end of life, acidosis and hypoxia will prevent capture and thus the pacemaker itself is not artificially prolonging life.


Case Conclusion

The cardiologist declines to turn off the pacemaker. The nurse relates the message to the family. The family becomes upset and argues that the pacemaker is prolonging suffering. The nurse calls a palliative care physician to speak with the family. The family is counseled that turning off the pacemaker will not effect dying. The patient could still live for hours or days.
The family still requests the withdrawal of the pacemaker. The patient's vital signs are RR-7, pulse-70's, shallow agonal breathing. The patient is unresponsive and actively dying. The pacemaker is set to sub-threshold levels "deactivated" that night. The patient dies the next afternoon.

How will ethics change in response to progression in technology?

References

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www.eperec.mcw.edu fast fact #111
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