Article

Heartbeats, Burdens, and Biofixtures

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Abstract: This paper addresses a dichotomy in the attitudes of some clinicians and bioethicists regarding whether there is a moral difference between deactivating a cardiac pacemaker in a highly dependent patient at the end of life, as opposed to standard cases of withdrawal of treatment. Although many clinicians hold that there is a difference, some bioethicists maintain that the two sorts of cases are morally equivalent. The author explores one potential morally significant point of difference between pacemakers and certain other life-sustaining treatments: specifically, that the former are *biofixtures,* which become *part of the patient* in a way that the latter do not. The concept of the pacemaker as biofixture grants pacemakers a unique moral status that gives reason to treat a pacemaker the same as other parts of the patient that are necessary to sustain life. The author employs this biofixture analysis to affirm the intuition that deactivating a pacemaker in a highly dependent patient at the end of life is, in moral terms, more analogous to active euthanasia than it is to standard cases of withdrawal of treatment. The paper concludes with consideration of potential implications for further implantable medical technologies, such as ventricular assist devices and total artificial hearts.

Keywords: pacemakers; end-of-life; euthanasia; implantable medical technologies; ventricular assist devices; total artificial hearts

Some bioethicists have argued that deactivating a pacemaker at the end of a patient's life would be no more morally problematic than taking the patient off ventilator support or removing a feeding tube.[1] Moreover, a recent expert consensus statement from the Heart Rhythm Society (HRS) states that deactivation of cardiac implantable electronic devices (CIEDs) at the end of life is legally and morally permissible.[2] However, some clinicians express serious discomfort with requests to deactivate pacemakers in highly dependent patients.[3] Although not all divergence from the conclusions of academic bioethics points to something of genuine moral significance, there is reason to think that the intuitions of clinicians here track something of moral substance. This paper explores one potential morally significant point of difference between pacemakers and other treatments typically withdrawn at the end of a patient's life, and contends that there is good reason to conceive of a pacemaker as a *biofixture*, an object that becomes part of the patient in a way that accords it special moral status, comparable to that of a native "fixture" of one's body.

Pacemakers Versus Implantable Cardioverter Defibrillators

CIEDs are a part of life for millions of patients.[4] Given the advanced age of most of this patient population, many patients with CIEDs (or their surrogates if patients do not possess the capacity to make their own decisions) must make end-of-life decisions regarding whether and under what circumstances particular medical treatments should be withdrawn. Such decisions are ideally made while working

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out an advance directive to guide end-of-life care. In practice, however, advance directives rarely mention CIEDs.[5]

It is important to be clear on what exactly is under discussion here. "CIED" is a blanket term that covers all implantable electronic cardiac devices. Both pacemakers and implantable cardioverter defibrillators (ICDs) are implantable devices that help to control arrhythmias (abnormally slow, fast, or irregular heartbeat). Pacemakers provide a pacing function whereby they regulate slow heart rhythms. ICDs monitor the heart's rhythm and deliver a shock if the heart reaches a dangerously fast rate. Current ICD devices always have a pacing function as well, although pacing is neither used nor needed in most ICDs. In ICDs, the shocking mechanism and the pacing function can be deactivated independently. For the purposes of this paper, "pacemakers" refer to both the discrete implantable devices that serves as pacemakers and the pacing function of ICDs. The conclusions drawn regarding pacemakers will thus apply equally to the pacing function of ICDs, although most ICDs do not perform an ongoing pacing function.

Much of the literature on the moral status of deactivating cardiac devices at the end of life has focused on the less controversial example of ICDs.[6] Deactivating an ICD is less morally fraught than deactivating a pacemaker because near the end of life, ICDs may inflict on the patient a series of painful shocks which provide clear justification for its deactivation out of a concern for the patient's comfort: "In the last weeks of their lives, 20 percent of ICD patients receive shocks which are painful and known to decrease quality of life, and which greatly contribute to the distress of patients and their families."[7] The pain of shocks at the end of life will often override any potential benefits associated with continued functioning of the ICD. This is especially true in the most common cases where the patient is shocked multiple times. Here, the ICD attempts to correct for arrhythmias that cannot be permanently corrected as the patient's heart is failing. This leads to a series of repeated and painful shocks. It is also worth noting that, in cases where a patient has an advance directive or physician order for life-sustaining treatment (POLST) specifying that all attempts to resuscitate the patient be foregone in cases of cardiac arrest, it makes sense that this would apply to an ICD as well. If the patient wants to forego *external* defibrillation due to potential burdens (especially pain of shock), it makes sense that the patient would also want to forego *internal* defibrillation that would deliver a series of painful shocks. In both cases, patients do not wish to have their lives extended by treatment of a cardiac arrest and would rather expire rapidly.

Pacemakers as Biofixtures

The moral status of pacemakers and the moral permissibility of deactivating them depends heavily upon the relation that these devices have to the patient. Assuming a moral distinction between killing and allowing to die, stopping a patient's heart with an injection at the end of life would be morally different from withdrawing care such as ventilator support.[8] Stopping the patient's heart is a situation where a native fixture of the patient's body is being actively compromised in order to cause the patient's death. It is clear that such interference with the functioning of a bodily system would uncontroversially amount to active euthanasia.[9] It is further the case that stopping a *transplanted* heart through the same method would likewise be tantamount to active euthanasia. There is no morally significant difference between

the heart a patient is born with and the heart a patient receives as a transplant when it comes to questions of cessation or withdrawal of treatment at the end of life.

A transplanted heart is a paradigm example of a *biofixture*—something that has become a part of the patient such that the way we are morally permitted to treat that thing will not differ from the way in which we are permitted to treat other parts of the patient that are necessary to sustain life. In the same way that compromising the functioning of an organ in order to bring about a patient's death would amount to euthanizing the patient, so would doing the same to a transplanted organ. But what about deactivating a pacemaker? The pacing that would be stopped upon deactivation serves the same function as would stopping a healthy heart by injection. In both cases, an abnormal heart rhythm is produced through intervention and the patient, if dependent upon their pacemaker to live, will likely die as a result of severe bradycardia (slow heart rate) or asystole ("flat line"). Does this mean that a pacemaker is a biofixture like a transplanted heart? In order to answer this question, we must pin down what is required in order to count as a biofixture and determine whether pacemakers fulfill those criteria.

The notion of a biofixture was first put forward by Frederick Paola and Robert Walker.[10] Paola and Walker draw on the notion of property law to draw an analogy between fixtures of property and biofixtures in human beings. Daniel Sulmasy proposes criteria for determining whether a technological intervention is a part of the patient (i.e., a biofixture).[11] According to Sulmasy, for a technological intervention to be a part of the patient, it must be a *constitutive* therapy that is also a *replacement* therapy. A therapy being constitutive is best understood by contrast with regulative therapies. An ICD is a regulative therapy because it only operates intermittently to shock and reset the heart when necessary; in doing so, the ICD "coax[es] the body back toward its own homeostatic equilibrium."[12] Constitutive therapies, by contrast, "take over a function that the body can no longer provide for itself."[13] A pacemaker is a constitutive therapy because it stimulates a continuous heart rhythm in essentially the same manner as the heart. Pacemakers replace the function of the conduction system of the heart similarly to the way that a heart transplant replaces the overall function.

Under the umbrella of constitutive therapies, Sulmasy draws a further distinction between substitutive therapies and replacement therapies. He argues that for something to count as a part of the patient, it must constitute a replacement therapy, meaning that it "provides the function that has been pathologically lost, more or less in the same manner in which the patient was once able to provide this function when healthy."[14] A substitutive therapy, by contrast, provides a substitute for some function in the body that does not resemble the way in which the body provides that substitute for itself. Hemodialysis for kidney failure and insulin injections for diabetes are examples of substitutive therapies. Sulmasy provides the following indicators of whether something constitutes a replacement therapy:

> Additional signs suggestive of an intervention being a replacement therapy might include: (1) its responsiveness to changes in the organism or its environment, (2) properties such as growth and self-repair, (3) independence from external energy sources and supplies, (4) independence from external control by an expert, (5) immunologic compatibility, (6) physical integration into the patient's body.[15]

Sulmasy characterizes these properties as *indicators* that are meant to serve as "rules of thumb rather than a list of necessary and sufficient conditions."[16] Nonetheless, it is evident that HRS has adopted Sulmasy's indicators as *criteria* for replacement therapies.[17] Others in the debate also seem to understand Sulmasy's indicators as criteria.[18] In light of this misunderstanding and acceptance of these indicators as criteria in the public forum, it is worth looking at the entailments of accepting these indicators as individually necessary and jointly sufficient criteria for pacemaker status. I take particular issue with the entailments of indicators (2–5), which hardly seem to be reliable identifiers of biofixtures for the following reasons.

"(2) Properties such as growth and self-repair"

Indicator (2) basically amounts to a presupposition that a biofixture must be made of flesh, blood, and/or other organic materials (or something similar enough to them) to be integrated into the body in the same way as would an organ, bone marrow, blood, or stem cells. This is too restrictive a definition to be plausible and will not serve for the future. It seems merely to reinforce unfounded pretheoretical intuitions about the importance of material over function and is not based on a reality where progressively better artificial therapies and materials are being developed. Both growth and self-repair serve as inadequate focal points when what is of far greater importance to biofixture status is the relation between the fixture in question and the surrounding body. Integration to the body is a universal characteristic of biofixtures, although growth and self-repair apply to only a limited class of biofixtures. Artificial joints cannot grow or repair themselves, but they are surely part of the patient's body in the sense relevant to biofixture status.

Suppose that a fully implantable permanent total artificial heart developed out of entirely synthetic materials were approved for widespread use in patients in need of heart transplants. (Although total artificial hearts are now primarily used as a temporary measure while patients await heart transplants, the technology is developing at such a rate it would not be surprising to see fully implantable permanent total artificial hearts become viable within most of our lifetimes).[19] After all, total artificial hearts that rely on an external power source are already being used as a destination therapy in some patients. Suppose further that this fully implantable permanent total artificial heart remained one size and, rather than repairing itself if damaged, had to either be repaired by the surrounding body or through surgery. It seems that this total artificial heart would clearly be a biofixture, despite lacking the capacity for growth and self-repair. Bound into the body both by vascular pathways and scar tissue it would fulfill the same role in the body as a heart made of organic tissue. The only substantive difference would be what the heart was made of, and this alone does not appear sufficient to call the biofixture status of this total artificial heart into question.

"(3) Independence from external energy sources and supplies; (4) independence from external control by an expert"

Indicators (3) and (4) could perhaps be adequate as heuristics for identifying replacement therapies, but would require further specification in order to be genuinely helpful. Depending on how dependence upon external energy sources and expert control are characterized, this could have the effect of ruling out many

interventions that require charging and/or monitoring, even if infrequent and only taking place during regular check-ups. It is worth noting that optimal upkeep of native body fixtures also requires regular check-ups, monitoring, and maintenance. Of course, if there were some type of device that required constant remote control by a professional or had to be plugged into a wall in order to function, this would call into question its status as a replacement therapy. However, in some cases, devices with batteries can run for months or even years without needing to be recharged. Typical pacemakers, for instance, have 8–12 years of battery life and most pacemakers require very little adjustment after the initial 3 months.[20] And, some devices, although they may require regular calibration from a professional, may not need the sort of constant control or adjustment that would reasonably qualify a fixture as a substitutive therapy rather than a replacement therapy.

"(5) Immunologic compatibility"

Indicator (5) is problematic because, understood strictly, it would rule out most organ transplants from counting as biofixtures. This would be an undesirable result; surely, if anything should count as a biofixture, a transplanted organ should. However, with organ transplants, in all but the most exceptional cases of immunologic matching, the patient must take immunosuppressants for the rest of their life in order to keep their body from rejecting the transplant.[21] An object like a titanium knee replacement would be, strictly speaking, more immunologically compatible with a patient than would a standard organ transplant, since an artificial knee does not require that the patient take immunosuppressants in order to prevent rejection. The immunologically benign nature of such inorganic materials leads to the odd implication that if we chose to adopt immunologic compatibility as one of the individually necessary and jointly sufficient criteria for something to count as a replacement therapy, and further construed this requirement in terms of *strict* immunologic compatibility, then immunologically benign fixtures made of metal or plastic might count as biofixtures, whereas organic fixtures like organ transplants might not count as biofixtures unless they were a near-perfect immunologic match to the patient.

Modified Criteria for Biofixture Status

I agree with Sulmasy that a biofixture must constitute a constitutive therapy and a replacement therapy. That is, a biofixture must fulfill a constitutive function and be a replacement that does so in roughly the same way as would the system it is replacing. However, I disagree on how exactly replacement therapies ought to be characterized, and endorse a wider conception of what it is to be a replacement therapy. This conception neither implicitly nor explicitly implies that for something to count as a replacement therapy it must be constituted of organic material. The position proposed here adopts and expands upon two of Sulmasy's indicators: (1) "responsiveness to changes in the organism or its environment" and (6) "physical integration into the patient's body" as indicators of something counting as a replacement therapy. It further stipulates that, in order to be *a biofixture worth having*, a fixture ought not to impose burdens on the patient disproportionate to the burdens imposed by the systems or functions that it is replacing, and further that the

burdens imposed by the biofixture ought not to be disproportionate to the benefits of having that fixture in place.

"(1) Responsiveness to changes in the organism or its environment"

I want to specify that for an object to count as a replacement therapy, it must respond to changes in the patient's body or environment and it must respond roughly in the way that the function it is replacing would. It need not be responsive to each and every change in the organism. A replacement therapy need only be responsive within the ordinary domain of the function it is replacing. This means that a knee replacement would only need to be responsive to changes in the adjoining bones and muscles (e.g., adjusting to shifting weight, moving with muscle tension) and a porcine valve would only need to be responsive to changes in the surrounding heart (e.g., accommodating higher or lower blood pressure). In the same way, a pacemaker replacing the pacing function of the heart would need to be responsive to fluctuations in heart rhythm and not (at least not in any direct way) to, for example, changes in the patient's gut flora.

"(6) Physical integration into the patient's body"

My argument is that although it is the case that something need not be strictly or wholly internal to the patient in order to count as a biofixture, it must be integrated with the patient in such a way that it is attached the patient's body in a semi-permanent to permanent manner and removal would be invasive. Pacemakers sit below the skin and become further integrated into the patient's body by the encapsulation of the pacemaker itself and connected leads by scar tissue, and so fulfill this integration requirement.

Comparable Burdens

Moving from expanding upon two indicators of replacement therapies adopted from Sulmasy, I propose a criterion of my own for biofixture status: *comparable burdens*. For a heart to be a heart worth having, it ought to fulfill the basic functions of a heart without imposing disproportionate burdens on the patient. Similarly, in order for a transplanted heart to be a heart worth having, it ought to do the same. To extend this analogy to biofixtures generally, in order for something to be a biofixture worth having, it ought not to impose disproportionate burdens on the patient.

If a native heart is failing, it ought to be either repaired or replaced. A biofixture that replaces the function of a failing heart should be at least competent to stave off death or serious suffering, and, ideally would bring the patient up to the quality of life they would have enjoyed with a healthy heart. Functioning well qua biofixture requires that such a fixture not be the sort of thing that the patient would be better off not having. In the same way that a heart's functioning poorly and painfully in a patient does not undermine that heart's status as a body part, a biofixture that functioned poorly and/or painfully would not necessarily thereby lose its status as a biofixture. However, a biofixture that functioned poorly enough or imposed enough burdens on the patient might rightfully lead us to question whether it can be properly characterized as a biofixture at all. On the account proposed here, some devices might perform so poorly as to fail to qualify as biofixtures, and some

devices, although they perform well enough to, strictly speaking, qualify as biofixtures, will not perform well enough to count as biofixtures worth having.

In the same way that there are better and worse functional objects of all sorts, there are surely better and worse biofixtures. This is evident from the fact that a highly immunocompatible organ transplant is surely better than a less immunocompatible organ transplant, in that the former will not impose the lifelong burden of immunosuppressant therapy on the patient. However, both of these are totally adequate biofixtures, precisely because they meet the basic criteria of being constitutive replacement therapies and having benefits that clearly outweigh their burdens. No stance is offered here on just how poorly something must function in order to compromise its status as a biofixture. I will only state that a biofixture worth having ought not to impose burdens disproportionate to its benefits or disproportionate to the burdens that would be imposed by the system it is replacing. And, if something fulfilled its function poorly enough in terms either of its direct medical function or burdens imposed apart from its direct function, that thing might, as a result, not warrant the status of biofixture.

For it to be worth incorporating into the patient's body, a biofixture must not be burdensome to the patient to an extent that is substantially greater than the burdens that the system or function it is replacing would impose. Further, a biofixture must at the very least not impose burdens on the patient that outweigh the benefits of having it. Now, depending on the status of the system or function being replaced, and thus the burdens imposed on the patient prior to implantation of a biofixture, the latter may be an easier or more difficult requirement to meet. After all, if a patient has a heartbeat so slow as to make even the ordinary activities of daily life a challenge, a device that imposed significant burdens but allowed the patient to perform the activities of daily life would be preferable to the *status quo.* Ideally, the biofixture will impose burdens not much more substantial than those imposed by a basically normally functioning (and normally aging) instantiation of the system or function it is replacing. By this is meant that, in the same way that upkeep of normal bodily functions and systems may require medication or supplementation or exercise or various lifestyle changes, especially as the patient ages, upkeep of a biofixture might require things to be done of a similar degree of burden or inconvenience. Of course, if the patient would receive only marginal benefit from having a fixture implanted, the risks of surgery should not be undergone, but this is a background consideration.

The requirement that something reach a threshold of proper functioning in order to be properly considered a biofixture can be made sense of, at least in part, in light of the requirement, adopted from Sulmasy, that in order for something to count as a replacement therapy, it must serve the function of the thing it is replacing in roughly the same way that thing originally fulfilled (or would have fulfilled) its function. If a transplanted heart had a defect where it made an earsplitting and persistent whistling noise every time the patient's heart rate went above 80 bpm, the question might be raised how adequate a replacement that heart actually was, despite clearly seeming to be integrated into the patient's body and sensitive to the relevant changes in the body. The same might be asked of a transplanted heart that caused a sharp stabbing pain every time it beat or a transplanted kidney that—despite causing no lasting physical harm to the patient—somehow produced urine with roughly the consistency of wet sand. These sorts of shudder-inducing examples are admittedly unlikely, but the point here is that burdens of a thing may actually

compromise its functional status, even when the defects or additional burdens in question do not strictly compromise essential functioning. In the same way, a pacemaker that made an obnoxious noise or had flashing LED lights that constantly shone through the patient's skin might be good qua heart-rhythm-replacer but not necessarily qua biofixture. Presumably, one important part of replacing the function of something in roughly the same way the original thing functioned is that the replacement does not come along with additional disproportionate or even intolerable drawbacks.

This burdens-related requirement is best demonstrated by the example of a transplanted heart. In cases of organ transplant, in all but the most exceptional cases, the patient must take immunosuppressants for the rest of their life. Although this is a burden that the patient would not have had if their heart had functioned normally, the burden imposed here seems proportional to the benefit derived from the transplanted organ. Further, especially as we age, different bodily systems may develop dysfunctions that require medications and monitoring. The burden of having an aging heart that does not work perfectly, which may require lifelong medication, seems comparable to the burden of taking immunosuppressants to keep one's body from rejecting a transplanted heart. Medications will have side effects, some more severe than others, but the benefit derived from having a bodily system that functions normally will outweigh these downsides. So, in the case of a transplanted heart, the requirement of immunosuppressants is comparable to the burdens imposed by the system it is replacing, and the benefits of having the transplanted heart outweigh the burdens it imposes. As will be made clear in the next section, pacemakers also impose burdens comparable to the system they replace and the benefits of having a pacemaker characteristically outweigh the burdens imposed by the device.

Burdens of Pacemakers

A pacemaker is a low-burden intervention. When a pacemaker is implanted, the surgery itself presents risks to the patient. The healing period lasts approximately 6 weeks, in the course of which the patient may potentially dislodge leads or develop an infection. But these complications are rare and can be rectified, although this usually requires surgery.[22] There are risks to having a pacemaker, even once the healing process is over, but these risks are minimal.[23] A patient will have to return in 8–12 years once the pacemaker's battery runs out and standard of care regarding regular monitoring is to check every 3–4 months to ensure the pacemaker is working properly.[24] These checks can take place either at a clinic or in the patient's home through a remote monitoring system. Ideally, patients will go through their daily lives forgetting that the pacemaker is even there.

Pacemakers clearly have benefits that outweigh their burdens. A patient typically opts for a pacemaker because they are suffering from symptomatic bradycardia, which may cause shortness of breath, loss of consciousness, severe lightheadedness, and fatigue.[25] These symptoms can have a substantial negative impact on the patient, and so the burdens imposed by surgery, recovery, and check-ups will be outweighed by the improvement in the patient's day-to-day functioning and quality of life. Moreover, these burdens, and especially the long-term burdens once the patient has healed from surgery described above, are comparable to, and in some

cases less, than the burdens imposed by a normally aging heart. A pacemaker is thus clearly a biofixture worth having.

Why Biofixture Status Matters

As argued, on my conception a biofixture must be: (1) a constitutive therapy; (2) a replacement therapy; and (3) not impose burdens disproportionate to its benefits or disproportionate to the burdens that would be imposed by the system it is replacing. Pacemakers meet the above criteria as they provide a continuous pacing function in much the same way the heart itself would (without imposing additional substantial and disproportionate burdens on the patient) and are physically integrated into and responsive to relevant changes in the patient's body and its environment. Additionally, pacemakers are clearly *biofixtures worth having* since they impose burdens comparable to the burdens imposed by the bodily function being replaced, as well as proportional to the benefit derived from the fixture. Although it is perhaps not on its own fully explanatory, the concept of pacemaker as biofixture helps to make sense of the distinction many clinicians are inclined to draw between pacemakers and other CIEDs regarding permissibility of deactivation at the end of a highly dependent patient's life. The idea that a pacemaker is part of the patient in the same way that a transplanted heart would be may, at least in part, explain and ground the intuition that deactivating a pacemaker under such circumstances would be more akin to active euthanasia than deactivating an ICD or removing the patient from ventilator.

Application to Other Technologies

It is worth acknowledging that I have remained agnostic regarding concrete implications of understanding pacemakers as biofixtures for clinical practice. Clinicians who experience distress at the prospect of deactivating a pacemaker in a highly dependent patient on the basis of its similarity to active euthanasia should be able to decline to do so on moral grounds and in line with applicable law and policy regarding conscientious objection. However, any substantive conclusions regarding entailments for clinical practice or policy should be drawn bearing in mind the wider context in which pacemaker deactivation may take place, particularly in a landscape where medical aid in dying is limited. The central aim here is to prompt reflection and provide groundwork for future research on what it means for something to be a biofixture and what may be the moral and pragmatic implications of biofixture status.

One important implication for future research is that as medical technology advances and progressively better implantable devices are developed, more artificial therapies may become "part of the patient" in a way that may have potential moral implications in situations of withdrawal of treatment. One clear candidate for such a device is the ventricular assist device (VAD). Currently VADs rely on external energy sources—battery packs—in order to operate. This necessitates leads that go into the body, creating significant risk of infection over time. Further, the requirement of an external energy source to power a VAD casts doubt on whether current VADs would qualify as biofixtures since they are not integrated into the body in the same way as a pacemaker or transplanted organ would be. Further, charging battery packs can prove burdensome to the patient and limit their

activities. The presence of external battery packs and the need to charge their VAD regularly would seriously hinder a patient in "forgetting it is there" on a day-to-day basis.

The risks and burdens of VADs are currently significantly higher than those of pacemakers, but have already been greatly reduced across generations of devices. VAD technology is advancing at breakneck speed, and VADs may soon be as low-burden and integrated into the patient's body as pacemakers. [26] There is good reason to think that VADs will someday bear the same sort of relationship to the patient as part of the patient's body as pacemakers currently do, and thus qualify as biofixtures. Fully implantable VADs are now under development by multiple companies, including Medtronic, Abbott, and a collaboration between Leviticus Cardio and Jarvik Heart.[27] Similarly, a total artificial heart (particularly as a destination therapy) would be a solid candidate for biofixture status, if the device were liberated from the need for frequent external charging and maintenance.[28] The future may be abundant with biofixtures. This calls for serious thinking now regarding how, morally speaking, we ought to treat life-prolonging biofixtures in patients at the end of life.

Notes

1. See, for example, Zellner RA, Aulisio MP, Lewis WR. Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated? Deactivating permanent pacemaker in patients with terminal illness. Patient autonomy is paramount. *Circulation Arrhythmia and Electrophysiology* 2009;2(3):340–4; discussion 340.; Benjamin MM, Sorkness CA. Practical and ethical considerations in the management of pacemaker and implantable cardiac defibrillator devices in terminally ill patients. *Baylor University Medical Center Proceedings* 2017;30(2):157–60; discussion 158–9.; Rhymes JA, McCullough LB, Luchi RJ, Teasdale TA, Wilson N. Withdrawing very low-burden interventions in chronically ill patients. *JAMA* 2000;283(8):1061–3.; Ballentine, JM. Pacemaker and defibrillator deactivation in competent hospice patients: An ethical consideration. *American Journal of Hospice & Palliative Medicine* 2005;22(1):14–9; discussion 17–8.
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3. See, for example, Hester M, Swota A. Choosing to stop a heart: The ethical status of deactivating an implantable cardiac device. *Cambridge Quarterly of Healthcare Ethics* 2019;28:327–8; discussion 327.; Kapa S, Mueller PS, Hayes DL, Asirvatham SJ. Perspectives on withdrawing pacemaker and implantable cardioverter-defibrillator therapies at end of life: Results of a survey of medical and legal professionals and patients. *Mayo Clinic Proceedings* 2010;85(11):981–90.; Mueller PS, Jenkins SM, Bramstedt KA, Hayes DL. Deactivating implanted cardiac devices in terminally ill patients: Practices and attitudes. *Pacing and Clinical Electrophysiology* 2008;31:560–8.; Whitlock SN, Goldberg IP, Singh JP. Is pacemaker deactivation at the end of life unique?: A case study and ethical analysis. *Journal of Palliative Medicine* 2011;14(10):1184–8.
4. "More than 4.5 million people worldwide live with an implanted pacemaker, including >3 million in the United States alone. Also, >0.8 million people in the United States have an implantable cardioverter defibrillator." Benjamin MM, Sorkness CA. Practical and ethical considerations in the management of pacemaker and implantable cardiac defibrillator devices in terminally ill patients. Baylor University Medical Center Proceedings 2017;30(2):157–60; discussion 157.
5. See Pasalic D, Tajouri TH, Ottenberg AL, Mueller PS. The prevalence and contents of advance directives in patients with pacemakers. *Pacing and Clinical Electrophysiology* 2014;37(4):473–80.; Buchhalter LC, Ottenberg AL, Webster TL, Swetz KM, Hayes DL, Mueller PS. Features and outcomes of patients who underwent cardiac device deactivation. *JAMA Internal Medicine* 2014;174(1):80–5.
6. See, for example, Daeschler M, Verdino RJ, Caplan AL, Kirkpatrick JN. Defibrillator deactivation against a patient's wishes: Perspectives of electrophysiology practitioners. *Pacing and Clinical Electrophysiology* 2015;38(8):917–24.; Strömberg A, Fluur C, Miller J, Chung ML, Moser D, Thylén I. ICD recipients' understanding of ethical issues, ICD function, and practical consequences of

withdrawing the ICD in the end-of-life. *Pacing and Clinical Electrophysiology* 2014;37(7):834–42.; Svanholm, JR, Nielsen JC, Mortensen P, Christensen CF, Birkelund R. Refusing implantable cardioverter defibrillator (ICD) replacement in elderly persons-The same as giving up life: A qualitative study. *Pacing and Clinical Electrophysiology* 2015;38(11):1275–86.

7. See note 2, Lampert et al. 2010, at 1008.
8. For an in-depth debate regarding the moral permissibility of deactivating CIEDS which focuses on the distinction between killing and allowing to die, see Hester D, Swota A, Huddle TS, Sulmasy DP, Courtois MA. The great debates. *Cambridge Quarterly of Healthcare Ethics* 2019;28:327–60.
9. I am here relying on the concept of "active euthanasia" as explicated by James Rachels in Rachels J. Active and passive Euthanasia. *New England Journal of Medicine* 1975;292:78–80.
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12. See note 11, Sulmasy 2008, at 70.
13. See note 11, Sulmasy 2008, at 70.
14. See note 11, Sulmasy 2008, at 71.
15. See note 11, Sulmasy 2008, at 71–2.
16. Sulmasy DP, Courtois MA. Unlike diamonds, defibrillators are not forever: Why it is sometimes ethical to deactivate cardiac implantable electrical devices. *Cambridge Quarterly of Healthcare Ethics* 2019;28:338–46; discussion 342.
17. E.g., "A replacement therapy (e.g., kidney transplantation) literally becomes "part of the patient" and provides the lost function in the same fashion as the patient did when healthy. Replacement therapies also respond to physiologic changes in the host and are independent of external energy sources and control of an expert. Removing or withdrawing a replacement life-sustaining treatment has been characterized as euthanasia." (See note 2, Lampert et al. 2010, at 1012).
18. For example, "[A] 'replacement' must be capable of growth and self-repair and must be independent from external energy sources and expertise. Pacemakers are not capable of growth or self-repair. They rely on batteries that deplete. Pacemakers are subject to malfunction, often need expert intervention, and are subject to recall. Thus, pacemakers are not 'replacements'." (Zellner RA, Aulisio MP, Lewis WR. Response to Kay and Bittner. *Circulation Arrhythmia and Electrophysiology* 2009;2:339).; See also Kay GN, Bittner GT. Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated? Deactivating permanent pacemaker in patients with terminal illness: An ethical distinction. *Circulation Arrhythmia and Electrophysiology* 2009;2:336–9.
19. Struber M, Meyer AL, Malehsa D, Kugler C, Simon AR, Haverich A. The current status of heart transplantation and the development of "artificial heart systems". *DeuDeutsches Arzteblatt International* 2009;106(28–29):471–7.; Copeland JG, Smith RG, Arabia FA, Nolan PE, Sethi GK, Tsau PH, et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. *The New England Journal of Medicine* 2004;2009;351(9):859–67.
20. See, for example, Ganz LI, Hayes DL. Cardiac implantable electronic devices: Patient follow-up. In Downey BC, ed. *Up to Date*; 2018; available at https://www.uptodate.com/contents/cardiac-implantable-electronic-devices-patient-follow-up?csi=af56db72-f28d-4b5c-ba84-5220e038c3c0&source=contentShare (last accessed 9 Jun 2018).
21. See Enderby C and Keller CA. An overview of immunosuppression in solid organ transplantation. *The Americal Journal of Managed Care* 2015;21(1):S12–3.; van Sandwijk, MS, Bemelman FJ, Ten Berge IJM. Immunosuppressive drugs after solid organ transplantation. *The Netherlands Journal of Medicine* 2013;71(6):281–9.
22. For a thorough treatment of potential complications of pacemaker implantation, see Ellenbogen, KA, Kay GN, Wilkoff BL. *Clinical Cardiac Pacing and Defibrillation*, 2nd ed. Philadelphia, PA: Saunders; 2000; discussion 669–94.
23. One such risk, which is rare, is of the pacemaker eroding through thin skin and thus causing a situation where the pacemaker and leads must be removed and re-implanted. (See note 22, Ellenbogen et al. 2000, at 673–4, 676).
24. Ganz LI, Hayes DL. Cardiac implantable electronic devices: Patient follow-up. In Downey BC, ed. *Up to Date*; 2018; available at https://www.uptodate.com/contents/cardiac-implantable-electronic-devices-patient-follow-up?csi=af56db72-f28d-4b5c-ba84-5220e038c3c0&source=contentShare (last accessed 9 Jun 2018).

25. See Mangrum JM and DiMarco JP. The evaluation and management of Bradycardia. *The New England Journal of Medicine* 2000;342(10):703–9.
26. For a thorough treatment of the current state of VAD technology, see Eisen, HJ. Left ventricular assist devices (LVADS): History, clinical application and complications. *Korean Circulation Journal* 2019;49 (7):568–85.
27. See Densford, F. Leviticus Cardio, Jarvik Heart unveil wireless LVAD. *Mass Device*; 2019 Feb 7; available at https://www.massdevice.com/leviticus-cardio-jarvik-heart-unveil-wireless-lvad/ (last accessed 24 Jun 2020).; Smart, F. Fully implantable LVAD nets FDA breakthrough device designation. *Cardiology Today*; 2019 Oct 31; available at https://www.healio.com/news/cardiology/20191031/fully-implantable-lvad-nets-fda-breakthrough-device-designation (last accessed 24 Jun 2020).; Rachal, M. Abbott wins breakthrough tag for fully implantable LVAD system, following Medtronic. *MedTech Dive*; 2020 Feb 4; available at https://www.medtechdive.com/news/abbott-wins-breakthrough-tag-for-fully-implantable-lvad-system-following-m/571670/ (last accessed 24 Jun 2020).; Kelly, S. Medtronic developing fully implanted LVAD with FDA breakthrough support. *MedTech Dive*; 2019 Oct 30; available at https://www.medtechdive.com/news/medtronic-developing-fully-implanted-lvad-with-fda-breakthrough-support/566131/ (last accessed 24 Jun 2020).
28. For a discussion of some of the moral issues around total artificial hearts and end-of-life care, see Finder SG, Nurok M. Death, devices, and double effect. *HEC Forum* 2019;31:63–73.