

# The ethical and legal implications of deactivating an implantable cardioverter-defibrillator in a patient with terminal cancer

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In this paper, the ethical and legal issues raised by the deactivation of implantable cardioverter-defibrillators (ICDs) in patients with terminal cancer is considered. It is argued that the ICD cannot be well described either as a treatment or as a non-treatment option, and thus raises complex questions regarding how rules governing deactivation should be framed. A new category called “integral devices” is proposed. Integral devices require their own special rules, reflecting their position as a “halfway house” between a form of treatment and a part of the body. The practical problems faced by doctors working in palliative medicine with regard to the deactivation of ICDs are also considered.

full measure of the ethical and legal issues involved. For instance, in the limited literature relating to this subject, significant discomfort has been expressed that a doctor may infer consent to deactivation in a case where the patient has agreed that resuscitation is inappropriate.<sup>1</sup> More contentious still would be a decision to deactivate against the wishes of the patient, even if medically the doctor believed the ICD to be harmful.

In this paper, we consider the current ethical and legal problems raised by ICDs in relation to patients with terminal cancer. It is our contention that ICDs do not fit comfortably in a system that bases its ethical and legal norms on a simple treatment/non-treatment dichotomy; we suggest that they are better considered as an integral device, worthy of a “middle-way” understanding. We explore the ethical and legal implications (in English law) of affording a new status to ICDs, as well as the practical consequences of such an act within a palliative-care setting.

## THE PHILOSOPHICAL AND LEGAL STATUS OF ICDs

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.<sup>8,9</sup> Often philosophers try to rely on established principles, applying them to new situations by analogy. Equally, the courts have looked to long-established doctrine to answer questions that were outside contemplation when it was devised. This means of reasoning is often of great utility, but in some circumstances it is necessarily imperfect and can create intellectually warped outcomes because a new approach is needed.

## Approaches to ICDs

In philosophical terms, there are currently two obvious ways to try to understand ICDs. First, they may be considered a treatment, comparable with other mechanical medical devices, such as external defibrillators, dialysis machines or ventilators, or with anti-arrhythmic drugs. Second, they may be compared with biological transplants; considered, in other words, as a part of the body. This is not because they can be said to replace an organ (or

The implantable cardioverter-defibrillator (ICD) is a “surgically implanted, battery powered device capable of auto-resuscitating a patient by recognizing and terminating lethal ventricular arrhythmias”,<sup>1</sup> established as a life-prolonging technology for patients at risk of such pathological conditions.<sup>2,3</sup> Modern implants have distinct functions, both as cardioverter-defibrillators and as cardiac pacemakers. In this paper, we specifically consider the defibrillator function of the ICD. It may be deactivated by the use of external telemetry: no surgical procedure is necessary. Such an action will not normally lead to the immediate death of a patient, but life may be shortened as a result of the device being disabled.

If a patient with advanced cancer experiences a cardiac arrest, it may be inappropriate to attempt resuscitation, not least because the chance of intervention being successful is extremely low.<sup>4,5</sup> The chance of successful cardioversion (termination of a lethal heart rhythm) by an ICD in such a patient may also be reduced.<sup>6</sup> The American Academy of Hospice and Palliative Medicine suggests that the implant be disabled in four situations<sup>7</sup>:

- (1) when continued use of an ICD is inconsistent with patient goals
- (2) when withdrawing anti-arrhythmic medications
- (3) when death is imminent, and
- (4) when a do-not-resuscitate order has been made.

We contest that these recommendations are dangerously open to interpretation and do not take

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other parts of the body)—they do not—but because arguably they become an equally integral part of the person. Let us consider the effect of these understandings.

### ICD as a continuing medical intervention

If an ICD is deemed to be equivalent to a mechanised life-preserving device that is external (at least in part) to the patient, a degree of control regarding its use remains with the patient's doctors. The same is true if we hold that ICDs are comparable to anti-arrhythmic drugs. Although a doctor is not in a position legally to define all of a patient's interests, it is he who decides whether a treatment or procedure is medically indicated. A patient has no legal right to demand a treatment that is not medically indicated.<sup>10</sup> Indeed, a doctor who provides or prolongs futile treatment is exceeding the scope of his duty, and committing a wrongful battery. Considering an ICD as a continuing medical intervention permits a unilateral decision by a doctor to deactivate the device, even if this is contrary to a patient's wish. It also requires deactivation at the patient's insistence, even if the doctor disagrees with the wisdom of the decision.<sup>11</sup>

### ICD as a part of the body

If an ICD is deemed to be 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.<sup>12</sup>

Consider the analogy of an incompetent patient with renal failure. If he has been receiving haemodialysis, but this is now considered medically futile, the doctor may legally withhold the treatment.<sup>13 14</sup> On the other hand, if the patient has received a transplanted kidney, this may not lawfully be removed (or otherwise "deactivated") by a doctor just because it would no longer be appropriate to replace the kidney were it to cease functioning (unless such deactivation were performed passively, by withholding immunosuppressant treatment, and this was in the patient's best interests). If a doctor were to remove a patient's kidney because he considered the patient's life to be futile, this would constitute murder, and is thus prohibited by the criminal law. The fact that the law may not require the provision of any future treatment does not alter this position.

### Problems with the current approach

By considering ICDs in the conflicting ways posited, we see that deactivation would count at law as an omission if the device were deemed to be a continued medical intervention, but an act if the device were considered to be a part of the body. This raises the risk that an arbitrary choice of analogy will be made so that ICDs conform most usefully with the act/omission distinction. We accept that the distinction between acts and omissions is believed to be an essential element of lawful medical practice by the courts and many medics. Nevertheless, it is undeniable that its plausibility often rests in intuition rather than in anything more concrete.<sup>15</sup> What we have shown in the above discussion is that an omission can become an act merely by an alteration of the way it is described. However, the acceptability at law looks set to endure.<sup>16</sup> We do not seek here to discourage its perpetuation. Rather, we suggest that its appeal is intuitive, and while this in practice forms the basis of ethical decision making, its intellectual imperfections can justify a move away from the existing treatment/non-treatment dichotomy to allow a further category to exist that is somewhere in between treatment and non-treatment.

### A new approach?

In our opinion, ICDs are unique. Though not organic, a patient may consider the implant as a part of his physical being, as with

an artificial hip. Thus, the reaction to a doctor unilaterally deciding to deactivate an ICD would probably be one that could not be mitigated by reference to it being a "withdrawal of treatment". In other words, there could be a real sense that deactivation is an active intervention that the doctor has no right to make. An extension of this argument is that an ICD should be considered as a part of the body. However, this is also difficult: as we have illustrated, the way the law has developed, a patient is not entitled to have a vital part of the body "deactivated", even if he consents. We contend that an absolute prohibition on ICD deactivation would be unjustifiable; the existing legal position recognises that there are circumstances when it is not appropriate to defibrillate a patient.<sup>17 18</sup>

We are not the first to question the status of ICDs. We agree with others that an ICD is neither perfectly analogous with a medical device nor a biological transplant; these two models of thought represent extremes between which we believe ICDs fall. The theory that regulates practice governing them is therefore flawed. A new approach is required to cater for this new technology.

### A model based on property?

Paola and Walker<sup>1</sup> propose an analogy with property law's distinction between chattels and fixtures. Labelling the implants as "biofixtures", these authors argue that the status ascribable to ICDs should be within the privilege of the patient. If the patient considers the implant to have become a part of him, this makes it so. If not, it may be treated as an ongoing medical process. This is problematic. Allowing a duality whose resolution is purely determined by the patient's understanding may lead to a plurality of bad outcomes. Furthermore, at common law, arguments concerning the body as property are notoriously troublesome<sup>19</sup>: it is unlikely that such a position would be adopted by the courts in England and Wales.

Arguably, some other sort of property law model (though not one concerned with fixtures) would be unavoidable in cases where the patient has paid for the device. There, he may be able to claim a physical ownership that would prevent interference by a third party. The model we propose in this paper does not preclude such theoretical considerations, but to contemplate them fully would move us too far from our focus. However, it is worth briefly mentioning some of the relevant considerations that a property model raises.

In some cases—for example, ownership of a car—the law places positive obligations on owners. It might be argued that obligations should likewise fall on owners of ICDs, but it does not necessarily follow. Mandating car maintenance benefits both the owner and wider society, not least in terms of public safety. The main risk of harm associated with an ICD is by the patient to himself. The risks to wider society are less obvious, though relatives may be distressed by the effects of ICD function or non-function. There are many examples of pieces of property that people are fully entitled to harm themselves with, however foolishly and however much distress this causes to others.

Finally, it might be right to assert that a doctor is best placed to judge the appropriate settings of an ICD, but with a competent patient, he may only act on this judgement with consent. Therefore, we may not automatically infer that property law should leave the regulation of the device in the hands of the doctor alone, although we might find that the law could place some restrictions on a patient's freedom of choice.

### A new category: integral devices

We submit that a better model is to consider ICDs as integral devices, representing a middle ground between medical device and part of the body. By defining the technology in this way, it is possible to escape the restrictions of the treatment/non-treatment dichotomy, which is not apt to cover ICDs.

An integral device, though not organic, is part of the patient. We suggest that where technology has been integrated into the physical being, a patient should retain stronger autonomy than he does with external mechanical devices. Interfering with it unilaterally should not be justified on grounds of benevolent paternalism. Nonetheless, an integral device is not truly a part of the body. Thus, deactivation should be permitted in some circumstances. Furthermore, a patient should have the right to demand that his ICD be disabled, even against medical advice, just as he would have the right to refuse external defibrillation in advance.

### PRACTICALITIES OF DECISIONS REGARDING DEACTIVATION OF ICDS IF THEY ARE CONSIDERED TO BE INTEGRAL DEVICES

Our understanding of ICDS as integral devices mandates that any decision to allow deactivation cannot be made unilaterally by clinicians. It also recognises that there are occasions when disabling the technology is appropriate. A major practical implication of this, which comes with its own ethical dilemmas, is the requirement to involve the patient in complex decisions about his implant. Research by Berger *et al*<sup>20</sup> indicates that what patients will want may vary considerably, and that it may be hard to predict what a particular patient may prefer.

Doctors would agree that many of the difficulties encountered when sharing the option of ICD deactivation with a patient could be eased by careful discussion about disabling the device before the diagnosis of terminal disease. Advance directives might prove to be useful tools, although evidence suggests that American patients do not communicate their preferences with regard to ICDS in such instruments.<sup>20</sup> In practice, it is unclear when conversations about “switching off” such equipment should most appropriately take place.

There may be an understandable reluctance on the part of the cardiologist to raise issues of deactivation at the time the ICD is implanted. Existing consent procedures often involve an element of counselling about ICD 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. Concern could be expressed about burdening the patient with too much information at a time when he needs to focus on more immediate complications of device insertion. Furthermore, even if it were standard practice to have an in-depth discussion about all theoretical eventualities, it is unlikely that a patient would be fully able to assimilate such an information load in one sitting.

The primary concern among those providing palliative care is that an active ICD can cause an unnecessarily distressing death.<sup>21</sup> Should a patient with an implant develop a terminal illness, there would be an obligation to broach deactivation. The doctor may legitimately feel that discussing the small likelihood of a death made distressing by repeated defibrillations would cause disproportionate angst. However, communication in difficult situations is an everyday task for the clinician in palliative medicine and avoidance of the subject cannot be excused. With ongoing multidisciplinary care, it should be possible to support a patient through the decision-making process. Ultimately, the doctor’s duty must be to respect the patient’s wishes.

Finally, although we consider the patient to have authority to determine whether his ICD be disabled, responsibility for realising the request remains with the doctor. We question which doctor should be accountable for such a procedure. If a palliative medicine consultant has discussed deactivation, it may be assumed that he has adopted this role. Some would contest, however, that the duty returns to the cardiologist who implanted the device. Our instinct is that it should be a joint decision, although practically it may be difficult to achieve such a combined

judgement in the current National Health Service. This question merits further debate, beyond the scope of this paper.

### CONCLUSIONS

Decisions about deactivation of ICDS will become increasingly common in clinical practice. We have focused on palliative medicine in this paper because it is a setting where many of the troublesome ethical issues are particularly acute, but they will soon affect many medical specialities.

We suggest that the existing analogies used to inform decisions about disabling ICDS are not sufficiently suited to provide satisfactory answers to the ethical problems that may be raised. Hence, we propose that ICDS be treated as integral devices rather than as external machines or parts of the body. Our stance aligns itself better with an intuitive approach to ICDS than one that merely asks whether they are treatments or not. Although such a position asks for different ethical and legal rules, these are not difficult to recognise or apply. When the existing law is not equipped to deal with new technology, it is preferable to acknowledge as much, rather than use imperfect rules to the detriment of good practice.

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