The ethics of implantable devices

Eugene B Wu

Both the doctor and the patient have rights to terminate an implantable cardioverter-defibrillator (ICD) device for reasons of futility or autonomy

Implantable devices have a long history in medicine with artificial hips being implanted since 1925, pacemakers since 1957, Starr-Edwards heart valve since 1961, artificial hearts since 1982 and ventricular assist devices since 1991. The ethics of deactivation or removal of these devices were not an issue until the use of implantable cardioverter defibrillator (ICD) device, as the ICD can produce considerable distress from defibrillation shocks in end-of-life patients. However, development of a clear ethics for ICD is critical as the massive technological advances in implantable heart failure devices will soon produce an epidemic of patients with implanted devices and end-of-life diseases. Should one turn off a biventricular pacer at the request of a patient who is having recurrent disabling heart failure? Should one turn off an AbioCor (AbioMed, Danvers, Massachusetts, USA) artificial heart in a patient who developed a severe disabling stroke from the device? Who has the right to turn off the device? Does the doctor have the right to turn it off, against the patient's wishes, for reasons of futility? Does the patient have the right to turn it off, against the doctor's wishes, and if so, for what reasons?

In this issue of the *Journal of Medical Ethics*, England *et al*¹ argue that the classification of an implantable device determines the rights of device deactivation. At the one end of the spectrum, there are semi-implanted devices like an intra-aortic balloon pump or a ventilator, where the doctor has the right to turn off the supportive therapy by commission on grounds of futility and the patient also has the right to refuse the device on grounds of autonomy. At the other end, there are fully implanted devices like a renal transplant where neither the doctor nor the patient have the right to have the kidney removed. England *et al*¹ propose an intermediate status of the integral device for the ICD and argues that such devices should be deactivated at the patient's request but not upon the doctor's judgment of futility.

They further argue that patients who have purchased the device have property rights over the device and as such should have maximal autonomy over the device.

From the broader perspective of the wide range of new implantable devices available, one can see the limitations of a new "integral device" category. The dividing line between an intra-aortic balloon pump to an AbioCor artificial heart is not nearly as clear-cut as the integral device category would suggest. There are devices that are semiexternal (intra-aortic balloon pumping), externally powered (early ventricular assist devices, and even early pacemakers), intermittently externally powered (AbiCor), and completely internally powered (like the ICD). Devices also have a wide spectrum of adjustability. Some devices can be turned on and off (ICDs), others have a threshold that can be changed (pacemakers), still others can be turned off by withholding medication (artificial valves and renal transplants), and some cannot be turned off at all (atrial septal closure devices and hip replacements). These differences in availability and ease of disabling the device influence the ethics of device disabling more so than a new category of integral devices. The principles can be the same as they have been for the past few decades. If a device has an "off" button, then the doctor has the right to terminate the medical device for reasons of futility against the patient's wishes. Although, under all circumstances, the doctor should seek to resolve these conflicts of opinion before terminating the device. Similarly, the patient has the right to refuse treatment and request the termination of a device if the device has an off button. In a device without an off button, but is sustained by continuing therapy, the doctor can turn off the continuing therapy for reasons of futility, just as he can discontinue any medication for reasons of futility. This principle has long been used in the situation of the artificial heart valve and is now applicable to left ventricular assist

devices (LVADs) and AbioCor. The patient also has the right to refuse medication and other supportive treatment for the device to terminate the device's function. In devices that do not have an off button or require sustaining therapy, neither the doctor nor the patient has the right to remove it for futility or autonomy reasons, just as the practice has been for renal transplants for the past few decades.

The expanded perspective helps us use previously established ethical practice to guide our practice for ICDs. Therefore, the doctor and the patient both have rights to terminate an ICD device for reasons of futility or autonomy.

The ownership argument for ICD disabling is also invalid. Car owners are required to drive safely to protect others and to keep a seat belt on to protect themselves. Self-protection is a requirement of the law for car owners. Similarly, ownership of an ICD does not give the owner a right to misuse the ICD to harm oneself. More than that, like car owners, they are obliged to protect themselves, whether they are using the ICD or the car, properly.

The reason why the patient does not have complete rights over implantable devices is because of consent. By consenting to having an implantable device placed, the patient is indirectly giving up the right to autonomous control of the device. Therefore, the patient forfeits the right to request removal of the device without due cause. A doctor should not entertain requests for removal of a pacemaker which is functioning perfectly, just because the patient changes his mind after informed consent. In this issue of the *Journal of Medical Ethics*, Ågård *et al*² explore the issue of consent in patients with ICDs. In all, 31 patients with ICD implants were interviewed to determine their understanding of their consent. They found that the patients were poorly aware of the risks and benefits of the ICD. However, their desire to live over-ruled their concerns about risks. Most of the patients had no regrets regarding their consent and most of them trusted their doctors. This study reflects the real-world consent for ICDs. Consent is more about trust than about balancing risks and benefits. Many of the cardiologic implantable devices are life saving, and the desire to live often overwhelms other concerns during consent. Despite this, once consent is given, the device should continue to function unless there is an "off button" or "sustaining therapy" that can disable it.

Therefore, in this article, we have extended the futility and autonomy

principles from other implantable devices to ICDs, giving both the doctor and the patient rights to terminate a device therapy. Patients do not have the right to insist upon continued ICD therapy if the doctor deems that this is futile. The doctor has no right to insist upon continued ICD therapy if the patient has refused further ICD discharges. These circumstances rarely occur in real life, as usually doctors underuse the principle of futility to disable devices and patients underuse autonomy to request device termination. For example, in the long and illustrious history of the pacemaker, there have been very few cases of doctors disabling a pacemaker in patients with terminal malignancy. Similarly, very few patients have requested termination of their pacemaker device to shorten their

unnecessary suffering from incurable malignancy. Although, philosophically, turning off a device is an act of omission, there are circumstances where the effect of turning off a device is acute and the similarity to an act of commission or euthanasia is uncanny. For example, turning off a pacemaker in a pacemaker-dependent patient or not connecting the battery pack to the AbiCor artificial heart can be very similar to euthanasia. Therefore, there could be great reluctance for a doctor to turn off these devices at the patient's request. However, we must respect the difference between commission and omission and the patient's right to refuse therapy even under these circumstances. In the end, our philosophical ethics, and not our emotions, should guide our practice.

J Med Ethics 2007;**33**:532–533.
doi: 10.1136/jme.2006.019000

Correspondence to: Dr E B Wu, Department of Medicine and Therapeutics, Prince of Wales Hospital, Ngan Shing Street, Shatin, Hong Kong; ebwu@netvigator.com

Received 12 September 2006

Accepted 22 September 2006

Competing interests: None declared.

See linked articles, p514 and p538

REFERENCES

- 1 England R, England T Coggon J. The ethical and legal implications of deactivating an implantable cardioverter-defibrillator in a terminally ill cancer patient. *J Med Ethics* 2007;**33**:538–40.
- 2 Ågård A, Löfmark R, Edvardsson N, *et al.* Views of patients with heart failure about their role in the decision to start implantable cardioverter defibrillator treatment: prescription rather than participation. *J Med Ethics* 2007;**33**:514–18.

Stay a step ahead with *Online First*

We publish all our original articles online before they appear in a print issue. This means that the latest clinical research papers go straight from acceptance to your browser, keeping you at the cutting edge of medicine. We update the site weekly so that it remains as topical as possible. Follow the Online First link on the home page and read the latest research.