Ethics and the Cardiac Pacemaker: More Than Just End-of-Life Issues

Katrina Hutchison and Robert Sparrow

THIS IS A "PRE-PRESS" VERSION OF THE MANUSCRIPT: PLEASE CITE THE PUBLISHED VERSION OF RECORD WHERE POSSIBLE.

This paper appeared as:

> Hutchison, K. and Sparrow, R. 2018. Ethics and the cardiac pacemaker: More than just end-of-life issues. *EP Europace* 20(5): 739–746, 1 May 2018. Published Online First, April 6, 2017, as doi:10.1093/europace/eux019.

Abstract

For many years ethical debate about pacemakers has focused on whether and under what circumstances they may be turned off in end of life care. Several other important ethical issues have been neglected, perhaps because the dilemmas they pose for cardiologists are not so immediate. These include: potential conflicts of interest, particularly those arising from the role of industry employed allied professionals (IEAPs) in pacemaker care; unanticipated impacts of commercial competition and the device improvement cycle; risks associated with remotely accessible software; equity in access to healthcare; and questions about reuse of explanted pacemakers in low and middle income countries. This paper analyses these issues in order to facilitate a more comprehensive approach to ethics and the cardiac pacemaker. Cardiologists should be aware of all of these issues and contribute to ongoing discussions about how they are resolved.

Condensed Abstract

Whereas recent debate about the ethics of pacemakers has mostly concentrated on end-of-life issues, we advocate a more comprehensive perspective. Conflicts of interest, the impacts of commercial interests on device design, remote monitoring, and the reuse of explanted pacemakers all raise important ethical questions which deserve more attention.

Keywords

Ethics; Pacemaker; Data Security; Access to Care; Industry Employed Allied Professional.

Introduction

Although the pacemaker is a safe, effective and long-established treatment for a range of cardiovascular rhythm disorders, implantation gives rise to a number of ethical issues. For many years, the ethical debate about pacemakers has focused on end of life care – whether or not a patient has the right to have their pacemaker disabled, as well as who can disable it and when. While these are important questions, the attention paid to them risks obscuring the existence of other issues. In this paper we review the ethical issues posed by pacemakers, and advocate for clinicians to be attentive to all these issues in their practice. In addition to the ethical challenges associated with pacemaker deactivation in end of life care, we analyse five other issues that have been relatively neglected in the literature: potential conflicts of interest, especially those associated with industry employed allied professionals (IEAPs); unanticipated impacts of commercial competition and the continuing cycle of device improvement; risks associated with remotely accessible software; equity in access to healthcare; and questions about reuse of explanted pacemakers in low and middle income countries. Some of these are most urgent for regulators and manufacturers of pacemakers. However, clinicians should be aware of these issues, and can offer a unique perspective on how to address them. To facilitate better engagement with these issues by cardiologists and other members of the medical profession, we provide tables listing key questions associated with each issue. Our focus is limited to pacemakers, although aspects of the analysis might also be usefully applied to closely related cardiac devices such as implantable cardioverter defibrillators (ICDs), which pose some of the same ethical concerns. Similarities between devices, however, should not be overstated.

Deactivation and end of life care

Recent discussion of ethical issues relating to pacemakers has focused on end of life care and withdrawal of treatment.[1-8] Pacemakers are a difficult case in this context. Implanted devices are more likely to be perceived by both patients and health professionals as part of patients' bodies, and thus may not be straightforwardly regarded as the sort of 'treatment' that can be withdrawn.[6, 9] This is further complicated when patients are pacemaker dependent. In these patients deactivation leads quickly to increased suffering and likely death. Studies with health professionals responsible for device deactivation in end-of-life settings suggest that they are much more reluctant to deactivate a pacemaker in a pacemaker-dependent patient than a device such as an implanted cardioverter defibrillator (ICD) that only intervenes intermittently and might increase suffering by giving shocks to a dying patient.[9]

There is also controversy about who should carry out the deactivation. In some jurisdictions IEAPs are expected to deactivate cardiac devices, and are sometimes inappropriately charged with discussing this with families. This is inconsistent with guidelines about the role of IEAPs, as well as expectations that appropriate counselling be provided by a trained person.[10-12] In a North American survey, for example, half of the respondents said that pacemakers were usually deactivated by IEAPs.[13]

Despite local variations, the principle that under certain conditions an informed and autonomous patient has the right to request the withdrawal of treatment applies to pacemakers in most jurisdictions.[1, 3] The distinctions that clinicians and patients make between pacemakers and ICDs are less often regarded as salient by legal scholars.[9, 14] Clinicians need to be responsive to local regulations as well as their own ethical deliberations when patients request deactivation of a pacemaker. It may also be appropriate to discuss deactivation options before the pacemaker is implanted or replaced, so that patients and their families are not confronting this issue for the first time in the end-of-life setting.[15-17] The key

questions that clinicians should consider in relation to the deactivation of pacemakers in end of life care are summarized in Table 1.

[Table 1 approximately here]

The ethics of the deactivation of pacemakers in the context of end-of-life care is an important issue and discussion and debate about it will undoubtedly continue. Indeed, we believe that device deactivation in end-of-life care is only likely to become more controversial as a wider range of life-sustaining implantable medical devices is developed.[18] As such, it is appropriate that this issue receives significant attention, and that tools are developed for addressing it in clinical contexts (e.g. the decision aid recently developed by an Australian team).[17] Nevertheless, it would be a profound mistake to let a focus on this issue obscure the existence of a number of other ethical issues that are also raised by the pacemaker. It is to these issues, which have been comparatively neglected, that we now turn.

Conflicts of interest

Although partnerships between clinicians and industry facilitate the development and improvement of pacemakers, the potential for conflicts of interest to arise in these relationships is widely acknowledged. The risks of conflicts of interest that arise in interactions with IEAPs have received less attention, despite their often significant role in the care of patients with pacemakers.

Clinician Conflicts of Interest

Clinician conflicts of interest have been a subject of concern across clinical specialisations for some time. In the past pacemakers have been at the centre of specific investigations.[19] The resulting regulatory changes ensure improved transparency and oversight insofar as clinicians remain involved in processes of pacemaker improvement and innovation, activities that can attract financial benefit and esteem.

However, research into conflicts of interests suggests that even casual interactions between industry representatives and clinicians are associated with changes in prescribing patterns.[20, 21] Given the extent and nature of interactions between cardiologists and representatives of companies that manufacture and sell pacemakers, there is a clear danger of conflicts of interest.

In response to this concern, it has been argued by leading cardiologists that clinicians with high professional standards who intend to provide the best possible care to individual patients are thereby protected from conflicts of interest.[22] Unfortunately, however, these admirable commitments are no guarantee against conflicts of interest for two reasons.

First, physicians are often unaware of conflicts of interest where they exist: nor does consciousness of a potential conflict of interest guarantee that it exerts no influence on a clinician's decisions.[23]

Second, the harms associated with conflicts of interests are not limited to specific harms to individual patients that arise from conflicted treatment decisions. A relationship that gives rise to a conflict is harmful partly because it is not possible to determine its impact on decision-making.[24] Perception by the community that clinicians are conflicted is also harmful, as it can undermine patient trust in individual clinicians and the healthcare system.

Conflicts of interest for IEAPs

IEAPs play an important role in the maintenance of pacemakers, including supporting cardiologists during implantation and with follow-up and programming. Despite being a significant point of interaction between industry and clinical staff, there has been little attention paid to risks of conflict of interest that arise in these relationships. IEAPs must balance the expectations of three separate groups: their employers, the health professionals they work with, and the patients whose treatment they support. Often these interests align – everyone wants patients to have good outcomes and for problems that arise with a device to be resolved efficiently without adverse events. Nevertheless, manufacturers stand to gain financially from the use of their company's devices. When it comes to recommendations about device selection, the interests of the patient and manufacturer are not always aligned. In the past pacemakers have sometimes been implanted and replaced unnecessarily.[19] Questions of trust and disclosure also arise when patients are unaware that they are being attended by an IEAP.[10, 12]

In recognition of the expanding and potentially conflicted role of IEAPs, the North American Society of Pacing and Electrophysiology has developed consensus recommendations for these roles.[12, 25] These have also been incorporated into recommendations in Europe, where involvement of IEAPs appears to be more limited in scope.[26, 27] However, these consensus recommendations are not always followed. For example, whereas the recommendations stress that responsibility for clinical decisions lies with physicians rather than IEAPs, recent qualitative research suggests that clinicians may look to IEAPs for significant clinical guidance.[10] The same study also found that IEAPs are sometimes asked to provide services (including device deactivations) when clinicians are not nearby, which is inconsistent with the recommendation that IEAPs should give technical support in close proximity to physicians. Competition between device companies and

infelicitous requests by clinicians have been identified as factors that influence IEAPs to overstep their role.[10, 19]

Institutional conflicts of interest.

Institutions can also benefit from relationships with pacemaker manufacturers that go beyond the mere provision of devices at a price. Many hospitals rely on free training provided by industry representatives for the education of nurses, technicians and allied health professionals. Clinical colleges such as the American College of Cardiology have policies governing the involvement of industry in college-recognised continuing medical education.[28] However, in-hospital device-specific training provided by manufacturers are not governed by these policies. While training provided by manufacturers is an efficient way to ensure that health professionals are proficient with devices they are expected to use in their roles, these training sessions sometimes also function as sales and advertising events.[29] Stronger oversight by hospitals and regulators of what counts as 'training' as opposed to 'marketing' is desirable. This could include, for example, requirements that the manufacturers' employees who provide training are not directly answerable to the sales department or receiving commissions.

Another source of conflict for hospitals is the free provision of pacemaker programmers and other equipment that facilitates the use of a particular manufacturer's devices. This equipment may be proprietary and expensive to purchase. Previously acknowledged as a sales strategy,[19] our conversations with cardiologists, health purchasing bodies and device industry employees in Australia suggest that these strategies are still practised and influence patterns of device choice by administrators.

[Table 2 approximately here]

Conflicts of interests and clinical leadership

In table 2 we suggest a number of key questions to guide clinicians and other stakeholders in identifying possible sources of conflicts of interest in their team and clinic. There are now numerous requirements on clinicians for transparency and disclosure in relation to conflicts of interest. Regulations apply, especially to published research and when clinicians are using products for which they receive a royalty or other direct financial benefit. However, regulation does not apply to everything that patients or the public may find inappropriate so it is important to consider the spirit — and not just the letter — of these regulations and guidelines. There is more to be done concerning the way conflicts of interest are handled in hospitals and in clinics, and the potential for conflicts of interest to arise for IEAPs. Leadership from clinicians will be an important factor in addressing these challenges.

The impacts of competition for market share on the product improvement cycle.

Pacemakers are a highly successful treatment for arrhythmias, and are implanted into hundreds of thousands of patients worldwide each year. As a consequence of their effectiveness and the high demand, a competitive market has emerged. In the context of this market, manufacturers have been driven to iteratively improve the devices they sell to build market share. These improvements are often in the interest of patients. However, the number of manufacturers and devices, as well as the dynamics of the market, also give rise to ethical issues which can have ramifications for clinicians and patients.

Device compatibility and obsolescence

Until the late 1980s incompatibility between new pacemakers and implanted leads was common both when switching manufacturers (cross-platform compatibility) and when switching from an older to a newer device of the same brand (backwards compatibility), with safety implications for patients. The adoption of an ISO standard for pacemaker leads has at least partially addressed this issue. Most pulse generators will now connect to most leads either directly or with adapters that meet the ISO standard.[30-32]

While these particular issues have been largely resolved, there will always be tension between benefit to patients from incremental improvement to medical devices and the impact of improvements on the standard of care available to those with older devices.[33, 34] Moreover, manufacturers are likely to continue to have opportunities to attempt to shape the market for their products via design choices that may not necessarily be in the best interests of all patients. Built in obsolescence is a recognised issue with computer systems, where manufacturers can render hardware and software obsolete by releasing new systems that are not compatible with previous releases. Given that pacemakers run on software, the same tactics are possible. Indeed, in contrast with efforts to standardise leads, the use of proprietary software is rarely questioned. Incremental upgrades could work to encourage — or even force — patients and physicians to purchase new and more expensive devices.

Companies release new pacemaker models approximately every 6-12 months.[35] whereas patients have their pacemakers replaced much less often – usually after 8-14 years due to depleted battery.[36] The striking difference between the commercial and clinical life cycles of pacemakers suggests that manufacturers might be driven in part by the desire to encourage more frequent device upgrades. In fact it has recently been suggested that manufacturer indifference to battery life when improving pacemakers and other cardiac

implants is an example of this: despite the desire of both patients and clinicians to minimize the number of procedures, battery performance (the most common reason for pacemaker replacement) has not improved for decades.[37]

Product familiarity and continuing education

The frequent release of new pacemakers makes it challenging to stay current while also retaining an awareness of legacy devices previously implanted in patients. There are reports of both lithium ion and plutonium pacemakers that have functioned in patients for over 25 years.[38-40] Thus cardiologists might need to have adequate knowledge of a device manufactured over 25 years ago, while also needing to stay up-to-date on newly released devices. The very short commercial life cycle of pacemakers invites ethical critique if it does not provide benefit to patients and adversely impacts clinicians' ability to stay familiar with the various models they will encounter.

Limitations of the evidence recommending specific pacemakers.

The short production life-cycle of pacemakers and the practice of iteratively changing existing devices means that it is not economical for companies to undertake clinical trials on each device. This is compounded by the fact that there has been no requirement by regulatory bodies such as the FDA for independent testing of new models that are judged to be substantially similar to earlier models.[41] Companies rarely undertake trials or collect data that can allow comparison of the effectiveness of new devices in patients (or, indeed, demonstrate that the 'improvements' associated with incremental device change actually deliver improved effectiveness to patients). There has been some concern in the literature about the lack of comparative effectiveness data for high risk cardiovascular devices such as pacemakers and

selective publication of trials.[34, 42, 43] The regulatory context, however, does appear to be changing, with the European Union recently moving to increase the clinical evidence requirements for high risk implantable devices.[44] Meanwhile clinicians and purchasing bodies should prefer devices for which there is good clinical evidence.

[Table 3 approximately here]

The role of clinicians in a rapidly changing environment

In the clinical context, the main thing for cardiologists to be aware of is the way market competition influences the product improvement cycle in ways that may not result in better outcomes for patients. Table 3 lists some key questions that clinicians can ask when deciding whether to recommend a new device to a patient. There is also a political dimension to these issues, and cardiologists are in a unique position to observe the impacts of commercial competition on the evolution of pacemakers. They have an obvious interest in the impacts of this dynamic on their training workload and clinical practice. Through professional bodies it may be possible to advocate for changes to the regulatory environment that make it less attractive for device manufacturers to release new products that do not meaningfully improve upon existing devices, and to tighten requirements for evidence of comparative effectiveness.

Remote accessibility, cyber security and privacy

Cardiologists can now retrieve information about patients' cardiac function and pacemaker function, and reprogram pacemakers from afar. This saves clinicians' and

patients' time by avoiding unnecessary follow-up visits. There is also evidence that it facilitates early identification of device faults and adverse events.[45]

However, remote access to cardiac devices also generates privacy and security issues. The storage of information poses questions about who will be authorised to access it. In addition to concerns about who should be authorised to access this information, there is also the risk of it being intercepted or wrongly delivered to those who are not authorised. Most manufacturers currently host the data on secure internet servers, where clinicians can login to access their patients' data. Some of these systems partly process the data, which ensures that clinicians are not overburdened with the task of scanning and interpreting large amounts of raw data on a daily basis.[46] In some countries data are monitored by employees of manufacturers rather than by clinicians.[47] Manufacturers also use data from pacemakers for quality control and design purposes. There is no reason to think that these activities will harm the patients whose data is used, and quality control measures and design improvements might benefit future patients. Nevertheless, there is a question about the right of companies to profit from such information. These issues are similar in many respects to ethical concerns about use of data stored in genetic databases, where private databases controlled by industry players raise particular concerns.[48]

Unauthorised access of devices inside patients by people within transmission range has also been raised as a potential risk. For example, ethical hackers have demonstrated the possibility of hacking a remotely accessible pacemaker and reprogramming it to give a lethal shock.[49] Similar concerns led doctors to disable the remote accessibility functions of Dick Cheney's cardiac implant while he was Vice President of the USA to ensure he wasn't vulnerable to an attack of this kind.[50] Identifying effective security measures that also allow health professionals access to the device in emergencies is challenging, especially as patient preferences differ.[51] Clinicians are most likely to confront these issues when patients raise

concerns about device security. The hacking of cardiac devices has been the focus of news headlines and television drama storylines, both of which could cause anxiety in some patients. Awareness of these issues can inform device selection and programming, as well as the advice clinicians give to individual patients. The questions listed in Table 4 may be useful in guiding device selection for individual patients.

Whereas professional bodies have developed consensus recommendations for issues such as device deactivation and interaction with industry, there is no equivalent resource outlining the issues arising from functions that enable remote monitoring and data collection.[1, 3, 12, 28] Although such resources are not a magic bullet, it might nevertheless be valuable for the profession to work to develop a consensus statement or set of recommendations as a resource to help clinicians navigate these emerging concerns.

[Table 4 approximately here]

Equitable access to care

The pacemaker is a relatively simple device compared to some implantable medical devices in common usage, such as the cochlear implant. Even so, implantation and follow-up can require interactions between interventional and non-interventional cardiologists, cardiac nurses, radiologists, and technicians. Effective communication between the different parties involved in clinical care is vital, as is the clear delineation of responsibilities.

In the context of scheduled implantations and follow-up it is relatively straightforward to bring together the appropriate personnel and equipment. However, the more people with different skills are required to complete a task, the more risk of delays or unsatisfactory outcomes associated with absenteeism, or intervening duties. There are no universal or generic pacemaker programmers on the market, despite the fact that such devices would be

useful in remote and regional facilities where it is inefficient to maintain multiple programmers for a small number of patients. In emergency settings the risks posed by these features of the modern pacemaker are greater, particularly when non-specialist emergency staff need to keep a patient stable while waiting for specialists and (sometimes) an IEAP or the appropriate pacemaker programmer to arrive. Delays can result in temporary discomfort (e.g. external pacing) or non-optimal solutions to the problem, such as emergency staff cutting the leads of a 'runaway' pacemaker.[52]

The requirement for several specialist staff with different training to work together to treat a patient, the role of IEAPs, and the need to source the appropriate proprietary programmer for the patient's pacemaker are each likely to disadvantage patients who live in regional or remote areas, where services are more spread out and specialist care and equipment is not so readily available. In some cases these areas have proportionally higher populations of individuals from disadvantaged groups, in which case existing social inequities may be compounded.[53]

These issues are partly an unavoidable consequence of implanting computerized medical devices into patients. They become ethical issues when exacerbated by the impact of commercial considerations (e.g. short commercial life cycles for pacemakers and proliferation of models). Dependence on proprietary programmers, with corresponding challenges for clinicians, hospitals, and patients, poses particular challenges in regional and remote areas where IEAPs are not accessible, and in these areas the availability of universal programmers would have the potential to benefit many patients. However, the ethical issues are complex. Even when driven by commercial considerations, there may be legitimate quality-related justification for the use of proprietary software. In particular, use of proprietary software gives the manufacturer unambiguous responsibility for the quality of the

product, and for rectifying any faults. Manufacturers also retain greater control over the integrity of their software.

Another ethical issue arises when public health systems that aim for equity turn a blind eye, and do not take steps to mitigate geographical and social disadvantages in access to care.[54] Cardiologists should be aware of potential disadvantages experienced by pacemaker patients in regional or remote settings and take this into consideration when choosing a device for a patient. Table 5 provides a list of questions to guide reflection on access to care issues when selecting devices for patients who might be affected.

[Table 5 approximately here]

Re-use of explanted devices

Pacemakers are sometimes removed while still functioning and with significant battery life remaining. This can occur either due to the death of the patient, or because the implanted pacemaker is no longer appropriate for their clinical needs. Despite being officially stipulated as a single use device by regulatory bodies in most developed countries, some countries have humanitarian re-use schemes that collect, export and clean explanted pacemakers for re-use in charitable hospitals in developing countries.[55] One organisation operating in the US promotes the donation of devices with at least 70% battery remaining for re-use in low and middle income countries.[56, 57] In Africa, the Pan-African Society of Cardiology also has a taskforce dedicated to a pacemaker and ICD recycling program.[58] Historically the reuse of pacemakers was also accepted in developed countries such as Australia.[59]

A number of ethical issues arise in association with the reuse of explanted pacemakers. First there are issues associated with the safety of potential recipients. There are a number of risks, including evidence that reused devices have a higher malfunction rate than new devices, concern about infections and prion disease transmission, and ensuring appropriate informed consent processes and appropriate patient follow-up.[60, 61] The decision to donate devices to those who may not otherwise have access is typically motivated by moral considerations about the rights of others to affordable healthcare. Thus considerations regarding potential risks to recipients and concerns that patients in the global South are receiving devices that would not meet the standard of care required in wealthy Northern nations must be weighed against the benefit associated with receiving a device in a context where treatment may otherwise be unaffordable. Finally, there are considerations related to ownership and rights over the device – should patients with a pacemaker have the right to decide what happens to it after it is removed or after their death? For at least some devices there is an expectation that the explanted device will be returned to the manufacturer for quality control and post market surveillance. Does this mean that the manufacturer retains ownership rights over the device while it is inside the patient? And are the people who remove devices obliged to respect the interests of either the patient or the manufacturer when they remove a device? Clinicians need to be aware of the contentious issues here. Table 6 provides a list of questions to guide decision making in the context of pacemaker reuse.

[Table 6 approximately here]

Conclusion

This paper offers a more comprehensive account of the ethical issues associated with the implantation, maintenance, deactivation, removal and reuse of pacemakers than has been available to date. While one issue – the deactivation of pacemakers during end of life care – has been the subject of considerable reflection in the literature, the others are relatively neglected. The evolution of pacemakers has given rise to new ethical issues, such as risks to patient privacy and risk of harm from hackers. Other issues that should be attracting greater interest and concern from practitioners include: the potential for conflicts of interest to arise, particularly for IEAPs; unanticipated impacts of commercial competition and the continuing cycle of device improvement; challenges to the equitable provision of best practice cardiac rhythm management; and ethical considerations associated with the re-use of explanted pacemakers. Cardiologists should be aware of all of these issues. We have provided tables summarising some key questions clinicians might use to guide reflection on these issues in the context of patient care and device selection. Cardiologists also have an important perspective to bring to ongoing discussions about how they are resolved.

Acknowledgements

The research for this paper was supported under the Australian Research Council's Centres of Excellence funding scheme (project CE140100012). The views expressed herein are those of the authors and are not necessarily those of the Australian Research Council. We would like to thank Mark Howard for his work as a research assistant in support of the publication of this manuscript.

Funding Sources

The research was funded by the Australian Research Council (project CE140100012).

Disclosures

The authors report no disclosures.

References

1. Lampert R, Hayes DL, Annas GJ, Farley MA, Goldstein NE, Hamilton RM, et al. HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm* 2010; 7(7):1008-1026.

2. Pellegrino ED. Decisions to withdraw life-sustaining treatment: A moral algorithm. *JAMA* 2000; 283(8):1065-1067.

3. Padeletti L, Arnar DO, Boncinelli L, Brachman J, Camm JA, Daubert JC, et al. EHRA expert consensus statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy. *Europace* 2010; 12(10):1480-1489.

4. Bharadwaj P, Ward KT. Ethical considerations of patients with pacemakers. *Am Fam Physician* 2008; 78(3):398-399.

5. Huddle TS, Bailey FA. Pacemaker deactivation: withdrawal of support or active ending of life? *Theor Med Bioeth* 2012; 33(6):421-433.

6. Sulmasy DP. Within you/without you: Biotechnology, ontology, and ethics. *J Gen Intern Med* 2008; 23(1):69-72.

7. Rhymes JA, McCullough LB, Luchi RJ, Teasdale TA, Wilson N. Withdrawing very low–burden interventions in chronically ill patients. *JAMA* 2000; 283(8):1061-1063.

8. Wu EB. The ethics of implantable devices. *J Med Ethics* 2007; 33(9):532-533.

9. Orentlicher, D. Deactivating implanted cardiac devices: Euthanasia or the withdrawal of treatment. *Wm. Mitchell L. Rev.* 2012; 39:1287.

10. Mueller PS, Ottenberg AL, Hayes DL, Koenig BA. "I felt like the angel of death": Role conflicts and moral distress among allied professionals employed by the US

cardiovascular implantable electronic device industry. *J Interv Card Electrophysiol* 2011; 32(3):253-261.

11. McGeary A, Eldergill A. Medicolegal issues arising when pacemaker and implantable cardioverter defibrillator devices are deactivated in terminally ill patients. *Med Sci Law* 2010; 50(1):40-44.

12. Lindsay BD, Estes NM, Maloney JD, Reynolds DW. Heart Rhythm Society policy statement update: Recommendations on the role of industry employed allied professionals (IEAPs). *Heart Rhythm* 2008; 5(11):e8-e10.

13. Mueller, PS, Jenkins SM, Bramstedt KA, Hayes DL. Deactivating implanted cardiac devices in terminally ill patients: practices and attitudes. *Pacing Clin Electrophysiol* 2008; 31(5):560-568.

14. 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): 981-990.

15. Goldstein NE, Mehta D, Teitelbaum E, Bradley EH, Morrison RS. "It's like crossing a bridge" complexities preventing physicians from discussing deactivation of implantable defibrillators at the end of life. *J Gen Intern Med*, 2008: 23(1):2-6.

16. Raphael CE, Koa-Wing M, Stain N, Wright I, Francis DP, Kanagaratnam P. Implantable Cardioverter-Defibrillator Recipient Attitudes towards Device Deactivation: How Much do Patients Want to Know? *Pacing Clin Electrophysiol* 2011; 34(12): 1628-1633.

17. Alhammad NJ, O'Donnell M, O'Donnell D, Mariani JA, Gould PA, McGavigan AD. Cardiac Implantable Electronic Devices and End-of-Life Care: An Australian Perspective. *Heart, Lung Circ*, 2016; 25(8): 814-819.

18. Hutchison K, Sparrow R. Don't go breaking my heart: what pacemakers can teach us about the ethics of maintaining artificial organs. *Hastings Cent Rep* 2016; in press.

19. Heinz J. Fraud, waste, and abuse in the medicare pacemaker industry: An information paper—Special Committee on Aging. Washington, DC: Government Printing Office; 1982.

20. Katz D, Caplan AL, Merz JF. All gifts large and small: Toward an understanding of the ethics of pharmaceutical industry gift-giving. *Am J Bioeth* 2010; 10(10):11-17.

21. Chren M-M, Landefeld CS. Physicians' behavior and their interactions with drug companies: A controlled study of physicians who requested additions to a hospital drug formulary. *JAMA* 1994; 271(9):684-689.

22. Bove AA. President's Page: relations with industry: thoughts on claims of a broken system. *J Am Coll Cardiol* 2009; 54(2):177-179.

23. Chugh D, Bazerman MH, Banaji MR. Bounded ethicality as a psychological barrier to recognizing conflicts of interest. In: Moore DA, Cain DM, Loewenstein G, Bazerman MH, (eds). *Conflicts of interest: Challenges and solutions in business, law, medicine, and public policy*; 2005, 74-95.

24. Brody H. Clarifying conflict of interest. *Am J Bioeth* 2011; 11(1):23-28.

25. Hayes JJ, Juknavorian R, Maloney JD. The role (s) of the industry employed allied professional. *Pacing Clin Electrophysiol* 2001; 24(3):398-399.

26. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, et. al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Europace* 2008; 10(6):707-25.

27. Marinskis G, van Erven L, EHRA Scientific Initiatives Committee. Deactivation of implanted cardioverter-defibrillators at the end of life: results of the EHRA survey. *Europace* 2010;12(8):1176-1177.

28. American College of Cardiology. Principles for Relationships with Industry. http://www.acc.org/about-acc/industry-relations/principles-for-relationships-with-industry.

29. Avorn J, Choudhry NK. Funding for medical education: maintaining a healthy separation from industry. *Circulation* 2010; 121(20):2228-34.

30. Calfee RV, Saulson SH. A voluntary standard for 3.2 mm unipolar and bipolar pacemaker leads and connectors. *Pacing Clin Electrophysiol* 1986; 9(6):1181-1185.

31. Sticherling C, Burri H. Introduction of new industry standards for cardiac implantable electronic devices: Balancing benefits and unexpected risks. *Europace* 2012; 14(8):1081-1086.

32. International Organisation for Standardisation. Implants for surgery – Cardiac pacemakers – Part 3: Low-profile connectors (IS-1) for implantable pacemakers. [Online Browsing Platform]. 2013. http://www.iso.org/iso/catalogue_detail.htm?csnumber=60542

33. Sparrow R. Enhancement and obsolescence: Avoiding an "enhanced rat race". *Kennedy Inst Ethics J* 2015; 25(3):231-260.

34. Rome BN, Kramer DB, Kesselheim AS. FDA approval of cardiac implantable electronic devices via original and supplement premarket approval pathways, 1979-2012. *JAMA* 2014; 311(4): 385-391.

35. Hayes JJ. The role of industry in the implantation and follow-up of devices: A practitioner's perspective. *Card Electrophysiol Rev* 2003; 7(1):58-59.

36. Benkemoun H, Sacrez J, Lagrange P, Amiel A, Prakash A, Himmrich E, et al. Optimizing pacemaker longevity with pacing mode and settings programming: results from a pacemaker multicenter registry. *Pacing Clin Electrophysiol* 2012; 35(4):403-8.

37. Dean J, Sulke N. Pacemaker battery scandal. *BMJ* 2016; 352:i228.

38. Papasteriadis E, Margos P. Pacing and sensing of human heart for over 31 years with the same apparatus (generator and lead). *Case Reports in Cardiology* 2015; 2015:1-3.

39. Katz D, Akiyama T. Pacemaker longevity: The world's longest-lasting VVI pacemaker. *Ann Noninvasive Electrocardiol* 2007; 12(3):223-226.

40. Parsonnet V, Driller J, Cook D, Rizvi SA. Thirty-One years of clinical experience with “nuclear-powered” pacemakers. *Pacing Clin Electrophysiol* 2006; 29(2):195-200.

41. Zuckerman DM, Brown P, Nissen SE. Medical device recalls and the FDA approval process. *Arch Intern Med* 2011; 171(11):1006-1011.

42. Chen CE, Dhruva SS, Redberg RF. Inclusion of comparative effectiveness data in high-risk cardiovascular device studies at the time of premarket approval. *JAMA* 2012; 308(17):1740-1742.

43. Chang L, Dhruva SS, Chu J, Bero LA, Redberg RF. Selective reporting in trials of high risk cardiovascular devices: Cross sectional comparison between premarket approval summaries and published reports. *BMJ* 2015; 350:h2613.

44. European Council of the European Union. *Modernizing EU Rules for Medical Devices* 2016. http://www.consilium.europa.eu/en/policies/new-rules-medical-in-vitro-diagnostic-devices/.

45. Crossley GH, Chen J, Choucair W, Cohen TJ, Gohn DC, Johnson WB, et al. Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers. *J Am Coll Cardiol* 2009; 54(22):2012-2019.

46. Sutton R. Remote monitoring as a key innovation in the management of cardiac patients including those with implantable electronic devices. *Europace* 2013; 15(suppl 1):i3-i5.

47. Lau C-P, Zhang S. Remote monitoring of cardiac implantable devices in the Asia-Pacific. *Europace* 2013; 15(suppl 1):i65-i68.

48. Chadwick R, Berg K. Solidarity and equity: new ethical frameworks for genetic databases. *Nature Rev Genet* 2001; 2(4):318-321.

49. Kirk J. Pacemaker hack can deliver deadly 830-volt jolt. *Computerworld Online.* October 2012. http://www.computerworld.com/article/2492453/malware-vulnerabilities/pacemaker-hack-can-deliver-deadly-830-volt-jolt.html.

50. American College of Cardiology. From IEDs to ICDs? Credible threat led to disabling Cheney's ICD in 2007. http://www.acc.org/latest-in-cardiology/articles/2013/10/20/21/04/from-ieds-to-icds.

51. Denning T, Borning A, Friedman B, Gill BT, Kohno T, Maisel WH. Patients, pacemakers, and implantable defibrillators: Human values and security for wireless implantable medical devices. In: *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems 2010*, p. 917-926. ACM Digital Library.

52. McMullan J, Valento M, Attari M, Venkat A. Care of the pacemaker/implantable cardioverter defibrillator patient in the ED. *Am J Emerg Med* 2007; 25(7):812-822.

53. Australian Institute of Health and Welfare. Rural, regional and remote health: indicators of health status and determinants of health. *Rural Health Series* (9). Canberra: Australian Institute of Health and Welfare; 2008.

54. Hutchison KJ, Johnson J, Carter D. Justice and surgical innovation: the case of robotic prostatectomy. *Bioethics* 2016; 30(7):536-546.

55. Baman TS, Meier P, Romero J, Gakenheimer L, Kirkpatrick JN, Sovitch P, et al. Safety of pacemaker reuse: A meta-analysis with implications for underserved nations. *Circ Arrhythm Electrophysiol* 2011; 4(3):318-323.

56. Hughey AB, Desai N, Baman TS, Gakenheimer L, Hagan L, Kirkpatrick JN, et al. Heart Rhythm Society Members' Views on Pacemaker and Implantable Cardioverter-Defibrillator Reuse. *Pacing Clin Electrophysiol* 2014; 37(8):969-977.

57. Project My Heart Your Heart. *Recycle your Pacemakers!* http://www.med.umich.edu/myheartyourheart/index.html.

58. Pan-African Society of Cardiology (PASCAR). *Report of the PASCAR task force on pacemaker and ICD re-use: October 2015*. http://www.pascar.org/news/entry/report-of-the-pascar-task-force-on-pacemaker-and-icd-re-use-october-2015

50. Mond H, Tartaglia S, Cole A, Sloman G. The refurbished pulse generator. *Pacing Clin Electrophysiol* 1980; 3(3):311-317.

60. Aragam KG, Baman TS, Kirkpatrick JN, Goldman EB, Brown AC, Crawford T, et al. The ethics of pacemaker reuse: might the best be the enemy of the good? *Heart* 2011; 97(24):2005-2006.

61. Kirkpatrick JN, Papini C, Baman TS, Khota K, Eagle KA, Verdino RJ, et al. Reuse of pacemakers and defibrillators in developing countries: Logistical, legal, and ethical barriers and solutions. *Heart Rhythm* 2010; 7(11):1623-1627.

Tables and Figures

Table 1: Pacemaker deactivation: key questions for medical professionals

Ethical Issue	Key Questions:
Pacemaker deactivation in end of life care	What laws or guidelines, if any, apply to deactivation of pacemakers in the jurisdiction?
	Has deactivation been discussed before implantation and/or as part of follow-up care?
	Has the patient requested deactivation of the device? Or, if not is there an advanced directive or a request from an appropriately informed surrogate decision maker?
	Is there an appropriately trained person who can provide information and counselling to the patient and/or family?
	Who will be undertaking the deactivation, and how is the clinician involved? Are arrangements to provide adequate palliative care in place?

Table 2: Conflicts of Interest: key questions for medical professionals

Ethical Issue	Key Questions or Actions:
Conflicts of interest	Do clinicians or policy makers stand to benefit from the decisions they make? If so, how?
	What are the current interactions of the clinician with industry (including casual interactions and small gifts), and how are these being managed to reduce potential conflicts of interest?
	What supports does industry provide to the clinic (e.g. training, loan of programmers)? What measures are in place to monitor influence on purchasing decisions?
	What roles do IEAPs have in the clinic, and what measures are in place to ensure they work within the bounds of their role?
	How are third parties likely to perceive and respond to clinicians' relationships with industry?

Table 3: Commercial competition : key questions for medical professionals

Ethical Issue	Key Questions or Actions:
Impact of commercial competition for market share on clinical practice	Does this device model appear to pose any unique risks or advantages in terms of: • Compatibility with future devices? • Likely future obsolescence?
	What is the training burden associated with adopting this new/improved device? Is it justified by the benefits?
	Are there procedures in place to source or maintain expertise in relation to "legacy" devices?
	What comparative data is available to support adoption of this new iteration? If such data is lacking, what is the basis for selecting the device for patients?

Table 4: Privacy and security: key questions for medical professionals

Ethical Issue	Key Questions or Actions:
Risks to privacy and safety associated with remote accessibility functions and data collection capabilities of pacemakers.	What measures are in place to ensure the privacy of patient cardiac data collected by the pacemaker?
	What can this data be used for and who will benefit? Has the patient been appropriately informed of the uses to which the data may be put?
	Could the device be remotely accessed for malicious purposes? Have access codes been altered from their default settings? Is relevant software maintained and regularly updated?
	Is this patient particularly susceptible to risks of harm associated with privacy and security, and if so how should this be managed?

Table 5: Access to care: key questions for medical professionals

Ethical Issue	Key Questions or Actions:
Risks of harm to patients who cannot access ideal follow-up care.	How are teams responsible for pacemaker implants and follow-up organized, and is this likely to result in delays or other harms to patients?
	Where does the patient live, and how will this impact their access to follow-up care for this device?
	Is this patient likely to experience difficulty accessing follow-up care for any other reasons (e.g. financial) and if so has this been taken into account in device selection?

Table 6: Reuse of explanted pacemakers: key questions for medical professionals

Ethical Issue	Key Questions or Actions:
Harms and/or benefits associated with re-use of explanted pacemakers; questions of justice.	Have the wishes/rights of the person from whom the device has been explanted been appropriately taken into account?
	Is the device suitable and safe to re-use, and what measures (cleaning, battery status) have been taken to ensure this?

	Are recipients of explanted devices receiving a lower standard of care than would be acceptable in the context of the treatment of the original implantee? Can any disparity in the standard of care be justified?
	Will the recipient be monitored for risks of e.g. malfunction and prion disease?
	What follow-up care will be available to the recipient of the explanted device, and is this adequate?