Recovery of Pacemakers and Defibrillators for Analysis and Device Advance Directives: Electrophysiologists' Perspectives

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Background: *Following high-profile device failures, the Heart Rhythm Society emphasized the need for postmarketing surveillance by recommending that physicians return all explanted devices to the manufacturer for analysis.*

Methods: *We conducted a national survey of electrophysiologists (EPs) regarding recovery for analysis of explanted pacemakers and implantable cardioverter defibrillators (devices), and attitudes toward device-specific advance directives to facilitate return of devices. Online survey invitations were sent in four waves from December 2008 to June 2009 to 300 e-mail addresses from the Heart Rhythm Society member database.*

Results: *From 250 invitations, there were 95 responses (38%). Demographics included average age 50 years (range, 31–87); 95% male; 81% Caucasian. Only 23% reported returning all explanted devices to the manufacturers. Of all the respondents, 32% discarded >10 devices/year as medical waste, 42% stored devices in a box in the electrophysiology lab, and 10% donated at least 1 device/year to charity for reuse overseas. Sixty-seven percent felt that it would not be helpful to have an advance directive specifying what the patient would want done with their device postmortem.*

Conclusions: *Few EPs return all explanted devices or send interrogation reports to the manufacturers, though nearly all said it was easy to do so. A majority either dispose of explanted devices as medical waste or store them in laboratories or offices, and a small percentage donate for reuse in underserved nations or to veterinary hospitals. This study suggests a need for initiatives such as educational campaigns to increase the retrieval and return of devices, either for analysis or reuse. (PACE 2011; 34:659–665)*

pacemaker, defibrillator, advance directives, postmortem analysis, reuse

Introduction

Following a series of pacemaker (PPM) and defibrillator (ICD) recalls and extensive press coverage of device failures, the Heart Rhythm Society (HRS) in 2006 recommended the establishment of device performance policies and guidelines applicable to physicians, governmental agencies, and manufacturers. Millions of pacemaker and ICD implants are used worldwide, and there is a general perception that these devices are safe. However, aside from industry-sponsored testing, there are few independent data on long-term reliability.[1] In its report following the device failures, the HRS emphasized the need for postmarketing surveillance by recommending that physicians return all explanted devices to the manufacturer for analysis in order to improve the reporting of device malfunction and enhance patient safety.[2] In addition, the report called for the establishment of a legally binding device advance directive that would allow for postmortem device removal and interrogation. Postmortem device retrieval requires cooperation between manufacturers and governmental agencies but also patients, physicians, and funeral directors. The current literature suggests that even though patients and funeral directors are willing to participate in postmortem device retrieval, devices are often thrown away or kept in the funeral home.[3] Besides return to the manufacturer, explanted devices can also be donated to charities for reuse in underdeveloped nations, or to veterinary hospitals for reuse in animals.

In this study, we describe how electrophysiologists (EPs) report handling devices postexplant,

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and we outline their opinions on device advance directives, postmortem device retrieval and interrogation, and return of device to the manufacturer or for charitable reuse.

Methods

We conducted a national survey of EPs. From December 2008 to June 2009, online survey invitations were sent in four separate waves to 300 e-mail addresses taken from the HRS member database. A total of 32 subjects identified as basic scientists, pediatric EPs, nonimplanting EPs, or retired EPs were excluded, whereas 18 e-mails were not deliverable. To the remaining 250 invitations, there were 95 responses (response rate 38%). The survey included multiple choice, yes/no, Likert scale, and short answer questions. In addition to demographic data, the questions sought information on the number of device implants and explants performed every year, preexplant device interrogation, explanted device destination, and problems encountered in returning explanted devices to manufacturers. In addition, we queried opinions regarding advance directives, which would indicate patients' preferences regarding postmortem device disposition (See Appendix S1).

Results

The average age of the participants was 50 years (range, 31–87 years); 95% of the participants were male; 81% were Caucasian, 11% Asian, and 5% Hispanic; 62% had an academic affiliation; 70% were from urban areas, 25% from suburban areas, and 5% from rural areas. The surveyed EPs performed 98 $\pm$ 75 device implants and 44 $\pm$ 40 explants per year, including generator changes and upgrades (Table I).

With respect to postmortem device disposition, only 23% of the total respondents reported returning all explanted devices to the manufacturers, though 92% believed it was easy or very easy to do so. Only 14% of respondents reported barriers to returning devices to the manufacturers, whereas 55% felt that it would be easy or very easy to return devices to a central agency, which would interrogate each device and forward it to the appropriate manufacturer. Of those returning all devices to the manufacturers, 76% practiced in an urban setting, 14% in a suburban setting, and 10% in a rural setting.

Of all the respondents, 32% discarded >10 devices/year as medical waste, 42% stored devices in a box in the electrophysiology lab or office, and 10% donated at least one device/year to charity for reuse overseas (Table II). When asked about who should have the most influence in determining what happens to a device after it is explanted, 38% of the respondents said it was the explanting physician (Table III). A majority, 67%, felt that it would not be helpful for patients to write an advance directive specifying the patient's wishes regarding the device after his or her death.

Table I.

Characteristics of Surveyed Electrophysiologists

Characteristic	Value
Age, years, median (range)	50 (31–87)
Male, %	95
Academic affiliation, %	62
Ethnicity, %	
Caucasian	81
Asian	11
Hispanic	5
Location, %	
Urban	70
Suburban	25
Rural	5
Estimated procedures per year	
Device implants	98 $\pm$ 75
Device explants	44 $\pm$ 40

Table II.

Disposition of Devices Explanted by Electrophysiologists

Response	Percentage of Respondents
Decisions about explanted devices	
Discarded >10 devices/year as medical waste	32
Stored devices in lab/office	42
Donated at least 1/year to charity for reuse overseas	10
Returned devices to manufacturer	23
Easy or very easy to return devices to manufacturer	92
Location of EPs who returned devices to manufacturers	
Urban	76
Suburban	14
Rural	10

Discussion

Return of Devices

The use of ICDs and PPMs has resulted in improved survival in patients with certain cardiac conditions.[4] However, mortality rates in

Table III.

Postexplant Device Disposition

Who Has the Most Say in Deciding Postmortem Device Disposition?	Percentage of Respondents
Explanting physician	38
Implanting physician	19
Patient or family	13
The Food and Drug Administration	12
Insurance company or medicare	2
Other	16

these patients remain high as they often succumb to progressive cardiac disease or noncardiac comorbidities. With the increase in the use of ICDs and PPMs, questions have been raised regarding the proper handling of these devices at the end of a patient's life. In the past, device recalls have brought national attention to the safety and reliability of these devices. Despite the increasing number of implants used worldwide, a wide array of indications for implantation, and the increasing complexity of the ICDs and PPMs, the overall reliability of these devices is not well defined.[5] Although device malfunction rates are estimated to be low, the clinical consequences of device malfunction can be substantial. Since patients requiring such devices usually have multiple comorbidities, the precise cause of death—device malfunction, progression of underlying disease, or some other factor—sometimes cannot be ascertained without a postmortem examination. Autopsies involve visual inspection of devices and leads but often do not involve device interrogation or bench testing.

The manufacturers of devices are legally obligated to notify the Food and Drug Administration (FDA) about any device malfunction that has resulted in or may result in harm to a patient. When a manufacturer reports a malfunction, the FDA may require the manufacturer to notify the medical community or even to pull the device in question off the market. Hospital entities are legally required to notify the FDA of life-threatening device malfunctions under the Safe Medical Devices Act of 2006.[6] It can be argued that clinicians, though not legally responsible for reporting device malfunctions, do have an ethical responsibility to alert authorities and the manufacturers of malfunctions. However, underreporting of device malfunction by the clinical community as a whole has made it difficult to accurately determine the device-malfunction rate.[7]

The present study suggests that few EPs return explanted devices or send interrogation reports to the manufacturers after a patient's death, though nearly all feel that it is not difficult to do so. This discrepancy may have to do with a low priority placed on device retrieval. EPs may be more focused on the welfare of their patients, not of the devices or future recipients of newer device models. It can be argued, however, that returning suspect devices, if not all devices, may uncover defects in a current patient's device model, which may lead to more frequent device checks, if not generator replacement. Analysis of returned devices may improve future models in which the same malfunctioning component or circuit design is used. Serious malfunctions may present intermittently. These returns, therefore, should be accompanied by as much information as possible (rhythm strips, printouts, stored electrograms, and anything else that may demonstrate abnormal behavior) to help guide the manufacturer in the evaluation of the returned devices.

Lack of unbiased feedback to physicians from manufacturers about the procedures used to examine devices and the results of these examinations may also contribute to a lack of motivation to return devices. One major manufacturer reports communicating the results of analysis in writing to the explanting physician only if the analysis reveals a malfunction, if there is a suspected performance issue with the device, or if the physician requests such communication (Rapallini L. September 8, 2010, Personal Communication). Device company representatives are also not incentivized to encourage the return of devices. In addition, there may not be adequate physician education concerning the recommendation to return all devices.

It should be noted that the survey asked about EPs' experiences, not whether they believed that all potentially retrievable devices can be easily obtained. Clearly, multiple barriers exist to acquisition of all explanted devices, especially for postmortem retrieval (or even interrogation) of devices from morgues and funeral homes, such as lack of a universal programmer capable of analyzing all device models and inadequate interface between the electrophysiology community and the funeral industry.

Although not suggested by our data (in which the plurality of EPs thought the explanting physician had the most influence over device destination), concerns regarding patient or next of kin consent to return devices play a role. Other survey studies suggest that a majority of funeral directors believe that postmortem device retrieval and interrogation are feasible,[3] but that unauthorized postmortem removal of a device without written

consent from the patient constitutes a breach of professional conduct.[8] The HRS recommends that physicians seek patients' consent while they are alive for postmortem return of all explanted devices to the manufacturer for analysis, but few physicians discuss end of life consideration of devices with patients who are dying.[9] Few EPs in our study supported the idea of an advance directive by which patients outline what they want done with devices postexplant. These findings are in contrast to patient survey responses, which indicate that most patients are willing to sign device advance directives authorizing postmortem device retrieval and interrogation.[3] It can be speculated that time constraints may, in part, be responsible for the lack of support for advance directives by EPs. It may be feasible to have other health care professionals, such as nurses, play a more active role in obtaining patient consent for postmortem analysis of devices.

Procedures for Return and Analysis

All major manufacturers provide instructions and mailer kits on their websites for return of devices.[10–12] Devices can also be handed to company representatives who are often present in EP labs. Once an explanted device is returned to the manufacturer, return product analysis is performed to determine if the device has malfunctioned or has reached normal battery depletion. Whether additional bench testing is performed on devices suspected of malfunction depends on the results of initial testing. Each manufacturer is required to establish internal standards for testing procedures that are reviewed and approved by the FDA. Currently, however, the International Standards Organization has set no global standards of evaluation of returned devices.

According to a company official at Medtronic Inc., approximately 1,800 devices are returned each week for analysis.[13] The company official we contacted declined to comment on the financial costs related to this analysis. Based on Centers for Medicare and Medicaid Services (CMS) data, the payment for interrogation and analysis of a single- or dual-lead ICD is $70.06.[14] Using these numbers, the cost related to interrogating devices returned to a single major manufacturer appears to be at least $126,000 per week, but the actual number is likely much higher. Manufacturers are not reimbursed by CMS for postexplant evaluation of a device. The true costs to the manufacturer depend on the amount of work performed to identify potential problems, which may involve considerably more effort than standard programmer interrogation and analysis.

The data extracted from returned devices are used to estimate device survival probability that predicts the length of time over which the product is expected to perform within performance limits established by the manufacturer. All five major manufacturers publish such data on their websites.[15–19] However, most of the testing is performed on devices returned as a result of explant before death, and it is not clear whether devices routinely explanted after death constitute a similar or different population. Return of all explanted devices, regardless of the reason for explant, will likely lead to more accurate device survival estimates that are reflective of the entire population of devices. It may be that inclusion of devices explanted postmortem will lead to calculation of a higher survival probability, but they may also reveal malfunctions that may have contributed to patient death. Furthermore, analysis of these returned devices would reveal the magnitude of inadvertent turn-off of devices caused by poor programming or exposure to electromagnetic energy sources.

The majority of EPs in our sample thought the current ways to return devices were facile. A slim majority thought that it would also be easy to return devices via a central agency that would collect devices and then forward them to the appropriate manufacturers. Our data therefore do not suggest that device return would be significantly increased by creation of a central agency. The advantage of a central agency would seem to lie in the independent and unbiased analysis of devices, but creation of such an entity would be hampered by the need for large amounts of funding required for safe handling and analysis of returned devices. Industry, in all likelihood, would be reluctant to provide the necessary funding and would certainly pass the cost along to consumers. The government may be in a position to contribute funds; however, such a proposal would probably be politically unpopular during a cost-conscious time. It may be possible to administer a central agency under AdvaMed, an industry-funded medical device manufacturer trade group which has, as part of its mission statement, the promotion of compliance with ethical standards. In addition, the manufacturers are unlikely to share proprietary software and design features with an outside agency. More reliable cost-estimates and pilot studies are necessary to justify the cost-effectiveness and feasibility of a central agency.

Remote ICD monitoring and wireless interrogation has the potential to make postmortem device interrogation from hospitals, funeral homes, morgues, and other remote venues more feasible. According to the Heart Rhythm Society Task

Force on Device Performance Policies Guidelines, the primary goal of remote ICD monitoring is to limit underreporting of device malfunctions.[2] In addition, remote device monitoring may allow for easier management of reused devices overseas in developing nations.

Leads

Although the current study focuses on the return of explanted PPMs and ICDs to manufacturers, lead malfunction remains a dominant cause of system dysfunction.[20] The FDA recommends that all leads and lead fragments removed from the body be returned to the manufacturer for analysis.[21] While malfunctioning leads are usually capped and left in the body predeath, except in cases of infection, after death they can be explanted along with the pulse generator. Postmortem lead extraction (if performed en bloc with careful dissection) and return to the manufacturers may play a significant future role in product improvement. Lead extraction is often a technically difficult procedure. Progressive fibrosis and adherence of the lead body to the myocardium and venous endothelium may result in partial extraction or lead damage during the extraction process, rendering the lead virtually unusable for analysis. Pathologists and morticians who are extracting devices should attempt to remove the leads within the vascular system and heart as a block, then carefully dissect out the leads.

Device Donation

In addition to return to the manufacturers, there are other options for postmortem device handling. A small number of EPs in our sample donated explanted devices to charitable organizations that interrogate and sterilize the devices, which are then reimplanted in patients in developing nations. In recent decades, the morbidity and mortality associated with cardiovascular disease has steadily declined in industrialized nations due to technological innovations and widespread access to healthcare.[22] However, cardiovascular disease remains the leading cause of death in low- and middle-income countries.[23] In these developing countries, the cost of devices such as PPMs and ICDs may be the most important limiting factor for patients who require them.[24] Therefore, PPM reuse, the safety and efficacy of which has been reasonably well documented,[25–27] would appear to be a promising solution. ICD reuse is more complicated and may not be advisable.[28] This situation may be advantageous for patients in low- and middle-income countries with limited access to expensive healthcare. Devices may also be donated to veterinary hospitals for use in animals.[3]

Improving Postmortem Device Retrieval

Though the 2006 HRS document outlined the problem and proposed a number of initiatives, it did not appear to affect the practice of the majority of EPs in our sample (surveyed several years after its publication). Our data suggest that more targeted educational campaigns by professional organizations directed toward physicians (and funeral directors) may be necessary. These endeavors could detail the importance of return or reuse of devices and may increase the number of devices retrieved for product improvement analysis and for donation to charities. A simple form which presents the various options for device and lead destination after explant, presented at the time of device implant or during follow-up, may involve patients in the process (see Appendix S2). The timing of presentation of this form to patients may be crucial. If presented at the time of implantation, symptomatic patients may feel pressured to sign. On the other hand, less symptomatic patients may not be very motivated to sign a legally binding document permitting postmortem explant, resulting in excess refusals. Ideally, the document should be presented to the patient during the follow-up period shortly after implantation. Alternatively, this document, consisting of a short form, may be presented at the time of device implantation and sent home with the patient for thoughtful consideration, to be brought back at the initial follow-up visit. Included in the form can be an advance directive discussing specific issues related to device deactivation at the end of life, as suggested by a recent HRS consensus statement.[29] This document should be given the same legal standing as more generalized advance directives.[30] Specific guidelines outlining how to dialogue with patients concerning postmortem device disposition may be necessary.

Manufacturers of ICDs and PPMs should continue to encourage the return of explanted devices for analysis. Company representatives should be incentivized by manufacturers to encourage return of all explanted devices, including those with no known malfunctions. In addition, manufacturers should provide device representatives with preaddressed mailers for distribution to EPs rather than depending on the EPs to obtain mailers from the company website. Manufacturers, via their representatives and via sponsored events at national and regional meetings, can also educate physicians and allied health professionals about returning explanted devices. During educational sessions, physicians

and allied health professionals should be reminded of the wider public health issues involved and the potential benefits of explanted device analysis for future patients. An HRS- or FDA-sponsored award for returning explanted devices may serve as an incentive for physicians and institutions.

Upon completion of analysis of returned devices, manufacturers should provide physicians with detailed feedback, possibly by sending quarterly or semiannual e-mail reports of the analyses performed in a given time period to all HRS members, in addition to individual letters (Appendices S3 and S4).

In addition to relying on device representatives for returns, hospitals and funeral homes should formulate institutional policies that encourage returning explanted devices to the manufacturers. In cases where return of all devices from hospitals, morgues, and funeral homes is not feasible, return of a preplanned fraction of all explanted devices may serve as a semirandom sample for interrogation and bench testing. The returning source should be encouraged to include relevant clinical data with the returned device including presence or absence of suspected malfunction. Devices without suspected malfunction may undergo a simplified screening evaluation by the manufacturer, with further testing performed only if the initial evaluation is concerning for device malfunction.

Study Limitations

The generalizability of this study is limited by its response rate, and the lack of diversity in the gender and ethnicity of the survey responders. As with any survey relying on response to invitations, there may have been a self-selection bias. EPs were asked to recollect numbers from memory, and we did not have records to verify the accuracy of these numbers.

Conclusions

Few EPs return explanted devices or send interrogation reports to manufacturers, though nearly all believe that both may be possible. A majority of the EPs dispose of the explanted devices in medical waste or store them in laboratories or offices, and a small percentage donate them for reuse in underserved nations or to veterinary hospitals. This study suggests a need for initiatives to increase the retrieval and return of devices, either for analysis or reuse. Such initiatives might include educational campaigns by professional societies and manufacturers, patient advance directives to authorize retrieval of devices for analysis and/or reuse, incentivization of company device representatives and, perhaps, clinicians, and timely, unbiased feedback to physicians. In addition, wireless remote interrogation, especially in funeral homes and morgues, may have a role in limiting underreporting of device malfunction in the future.

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Supporting Information

The following supporting information available for this article:

Appendix S1. Living Will for Patients with Pacemakers and Defibrillators.

Appendix S2. Survey Tool.

Appendix S3. Sample Letter from manufacturer regarding returned device with malfunction identified on analysis, edited for anonymity.

Appendix S4. Letter from manufacturer regarding device with no identified malfunction on analysis, edited for anonymity.

Supporting Information may be found in the online version of this article.
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