

Reuse of pacemakers and defibrillators in developing countries: Logistical, legal, and ethical barriers and solutions

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In the wealthy nations of the world, access to implantable cardiac rhythm management devices is widespread. In many underserved low- and middle-income countries (LMIC), where cardiovascular disease is fast becoming a major public health problem, access is often limited. Reuse of pulse generators was practiced regularly in some European nations in the 1990s with good results. It is performed in LMIC, although the rates of device reuse are unknown. The available literature suggests there is no increased risk of morbidity or mortality with the reuse of devices. Donations of pacemaker and defibrillator pulse generators from developed nations constitute an important source of devices for the poor in LMIC. There are opportunities to increase this supply, but logistical barriers and legal and ethical concerns must be

addressed. With proper sterilization, meticulous chains of custody, and advance directives for device handling (pacemaker/defibrillator living wills), patients in LMIC who would otherwise lack access to these devices could benefit from their reuse.

KEYWORDS Pacemakers; Patients; Medical ethics; Reuse of devices; Underserved

ABBREVIATIONS FDA = United States Food and Drug Administration; ICD = implantable cardioverter-defibrillator; LMIC = low- and middle-income countries; SUDS = sudden unexplained death syndrome

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Introduction

In many low- and middle-income countries (LMIC), access to pacemaker and defibrillator devices is often limited, despite increasing need and a high prevalence of conduction system disease. Chagas disease is endemic in many countries in South America, with 200,000 new cases each year.¹ It is an important cause of heart failure, heart block, and arrhythmias in every age group. In a study of 424 Brazilian patients with antibodies to *Trypanosoma cruzi* and evidence of heart involvement, 15% required a permanent pacemaker.² Of the 130 deaths, 62% were classified as sudden. Sudden unexplained death syndrome is the leading cause of death in young, otherwise-healthy Southeastern Asian males. Like most patients resuscitated after sudden cardiac arrest, survivors seem to be at high risk for recurrence. A 2003 randomized controlled trial of survivors in Thailand demonstrated the benefit of implantable cardioverter-defibrillators (ICDs) over beta-blockers for secondary prevention.³

The 2005 World Survey of Cardiac Pacing and Cardioverter-Defibrillators found a rate of new pacemaker im-

plants in the United States, Canada, and Western Europe of over 380 per million population (the United States was highest, at 752 per million), versus Thailand (22 per million), Peru (14 per million), and Bangladesh (4 per million). This disparity is explained in part by cost. Even in their most basic form, pacemaker pulse generators cost around \$2,500 to \$3,000, and leads that connect the pulse generators to the heart cost \$800 to \$1,000. ICD generator list prices range from \$20,000 to \$40,000, and leads can cost over \$10,000 (personal communication, device purchasing agent for the Hospital of the University of Pennsylvania, December, 2009; for competitive reasons, device companies do not publish list prices). LMIC countries with limited health care budgets do not have and are unlikely to develop the financial wherewithal to purchase these devices for poor patients.

The use of donated new devices in LMIC has been practiced for many years. Device shelf life is estimated at between 12 and 18 months, after which a device is considered expired due to loss of battery capacity and inability to ensure sterility.⁴ Manufacturers and hospitals routinely donate late model and expired pulse generators and leads to charity organizations for use overseas. One organization has distributed 10,000 pacemakers to the needy in LMIC since 1984 (Heartbeat International website, <http://www.heartbeatintl.org>).

Reuse of devices has been reported in articles from a number of different countries.⁵⁻⁷ Several charity organiza-

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tions in the United States accept donated used pulse generators from funeral homes, hospitals, clinics, physicians, and patients, combined with lead systems donated by manufacturers. Adequate functionality and battery life are established by interrogation. In some cases, the charity provides a printout of interrogation results to the device manufacturer. Pulse generators with less than 70% to 80% battery capacity or devices involved in a field advisory/recall are returned to the manufacturer. Protected health information is deleted from the device memory, and pulse generators are sterilized and given to physicians to implant into poor patients in LMIC. Leads are not generally reused due to greater difficulty in ensuring sterility.

Data are scarce, particularly on rates of reuse. The number of available expired devices is limited, but there likely exists a very large supply of devices in the developed world that may be available for reuse in LMIC. Efforts to increase the practice of reusing devices have the potential to improve the lives of many underserved patients and reduce disparities in cardiovascular care. This report briefly outlines the current source of donated devices, then presents and addresses barriers to expanded reuse of devices in LMIC and their solutions, including a pacemaker/defibrillator living will.

Sources of donated devices: upgrades, infections, and death

Some patients receiving right ventricular pacing will require device upgrades to an ICD and/or cardiac resynchronization therapy device,⁸ potentially making the old pulse generators available for reuse. The manufacturers usually provide a rebate for upgraded devices still under warranty that are returned to the manufacturer, but some devices with adequate battery life are upgraded after the warranty timeframe.

Rates of device infections requiring explantation range from 0.13% to 12% of implants. In one study, the mean time between implantation and explantation for device infection was 52 days (quartile 1 to 3, 24 to 162 days).⁹ Although not addressed in this study, it is likely that many of these pulse generators had sufficient battery life to be reused, providing they could be adequately sterilized.

Probably the largest source of used pulse generators is obtained postmortem. Patients over 80 years of age comprise 32% of pacemaker implants.¹⁰ Although survival rates after implant vary with population characteristics, the 4-year mortality rate for patients with pacemakers can reach 40% or higher.^{11,12} Depending on patterns of use, pacemakers can have upward of 5 years of function left when patients die (assuming a standard battery longevity of 5 to 10 years).

Defibrillator battery life is obviously more variable because it depends on how often shocks or antitachycardia pacing are delivered. Biventricular pacemakers would only have adequate battery capacity for reuse if acquired shortly after implantation because they are optimized to provide as much pacing as possible. As suggested by the European Society of Cardiology, the reuse of ICDs and biventricular

pacemakers is complicated for other reasons.¹³ The risk of inappropriate ICD shocks is considerable, programming and follow-up of these devices is complex, and defibrillator and left ventricular pacing leads are more expensive than pacemaker leads. Of course, ICD and biventricular pulse generators can still be reused as simple pacemakers if their extra functions are deactivated.

Pacemaker, ICD and biventricular pacemaker pulse generators can be recovered easily from deceased persons by embalmers, and in fact must be removed prior to cremation to prevent explosion in the crematorium chamber.

Barriers and solutions

Although recovery and reuse of pulse generators is currently practiced and could be expanded, significant logistical, legal, and ethical barriers exist. Despite these barriers, expanding reuse is feasible and safe.

Logistical barriers

Reuse is complicated by the fact that most explanted devices are thrown away. A survey of embalmers and funeral directors found that the most common method of device disposal was placement in medical waste (44%). The next most common method was donation for reuse overseas (18%).¹⁴ Unexplanted devices are buried with the patients. These data suggest that changing established practice among embalmers constitutes a significant hurdle.

In the medical literature, there is great emphasis on advance directives in regard to end-of-life decisions. The fate of devices could be given the same consideration, potentially overcoming some of the barriers to device recovery. A "pacemaker/defibrillator living will" filled out by patients at the time of device implantation could be used to authorize pulse generator recovery and reuse or analysis after upgrade or death. This document could include information on where to send the pulse generators for reuse or quality improvement analysis, depending on the patient's wishes. Patients and family members may derive satisfaction from donating life-saving devices after death. A majority (62%) of patients in a recent survey indicated a willingness to sign an advance directive authorizing the removal of their device after death for the purpose of overseas donation.¹⁴ The attention given to advance directives in recent health care legislation may change this percentage and signal an opportunity for public discussion of postmortem device handling.

Furthermore, a pilot program consisting of collaboration between the University of Michigan and a medical supply charity organization (World Medical Relief) has been established to collect used pulse generators from funeral homes and send them overseas to hospitals in the Philippines and Vietnam. The initial experience suggests this form of cooperation is feasible and can increase the number of devices successfully recovered and reused.¹⁵

Another concern is the potential to transmit infection. Most manufacturers of medical devices recommend single use of their products. Adequate sterilization of pacemaker or

defibrillator pulse generators requires removal of all protein material, which is complicated by crevices in the plastic components if the device is grazed or cracked. Transmission of viruses and Creutzfeldt-Jacob-like prion diseases are of particular concern. The US Food and Drug Administration (FDA) compliance policy guide on pacemaker reuse states: “there is a serious question whether pacemakers can be properly re-sterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacemaker.”¹⁶

However, multiple studies have demonstrated that there is no increased rate of infection^{17–19} or in mortality²⁰ in reused versus new pacemakers. A retrospective case control study of 100 reused and 100 new pacemaker pulse generators in Sweden involved sterilization techniques including cleaning with a brush, soap and water, soaking in phenoxopropanol and benzalconiumchloride solution, and wiping with 70% ethanol, packaging and sterilizing with ethylene oxide. There were 3 infections in the reused device population and 7 in the new device population.²¹ A more recent study of pacemakers used debris removal by pipe cleaners, an isopropyl alcohol bath, an overnight soak in Asepti-zyme (Ecolab, St. Paul, Minnesota), a 70% ethanol wipe, and an 8-hour ethylene oxide gas sterilization. There were no infections or other complications during a 2-month follow-up period in 12 patients.¹⁵ It should be possible to develop a standardized cleansing and sterilization protocol for reuse, as has occurred with dialysis filters and other medical devices.

A third logical barrier lies in the fact that leads cannot be reused, presenting a significant cost barrier for impoverished patients. Manufacturers, however, donate thousands of expired leads to charity organizations each year. Whether there is a sufficient supply of expired leads to match a large increase in the reuse of devices is not known, but it is unlikely. A relatively low-cost lead is manufactured in India, and it has been the experience of electrophysiologists at Philippines General Hospital that most families can pool resources to purchase leads if donated ones are not available. With increased awareness of the need, it may be possible to raise money to establish funds for leads.

Legal barriers

Pacemakers, ICDs, and biventricular pacemakers are packaged and sold as single-use devices (SUD), as are other devices that are more commonly reprocessed and reused. Reuse is regulated in the United States in that reprocessors of SUDs must demonstrate the ability to sterilize the device, keep intact the character and quality of the device, and ensure that the device complies with applicable FDA requirements.²² In addition, the Medical Device User Fee and Modernization act of 2002²³ amended the Federal Food, Drug, and Cosmetic Act to add new regulations for reprocessing of SUDs. Organizations responsible for reprocessing devices must adhere to the same handling and product standards as the original manufacturer pertaining to a new device, including quality system regulation, medical device

reporting, registration, premarket approval and notification (including submission of validation data), and listing and labeling. Reuse of dialysis filters follows these regulations and has become commonplace in the United States. However, although technically possible under these regulations, pacemaker reuse is specifically called “an objectionable practice” by the FDA compliance manual.¹⁶ Apart from federal regulations, it is not clear that reuse of devices in a highly litigious society can become commonplace, even if patients provided authorization and informed consent. Aside from the impact on sales of new devices, device manufacturers are concerned about legal action for failures of reused devices.

Although presenting a significant barrier in developed nations, laws concerning regulation of SUDs and product and handling standards for medical devices do not exist in many LMIC. Devices that are collected in the United States but sterilized overseas likely would not fall under FDA jurisdiction. The litigious climate in the United States does not exist in many LMIC. All implantable cardiac rhythm management devices are labeled as single use, no manufacturer sanctions their reuse, and warranties do not cover reuse; therefore, it is unlikely that manufacturers could be successfully implicated in cases of reused device malfunction.

Patients in LMIC otherwise presumably have the same recourse in cases of negligence involving reused devices as they do in cases involving new devices, with the reprocessing institution held responsible. Unless there is improper preimplantation handling of the device leading to damage or battery depletion, there is no reason to suspect that the device would not function as well in a new individual as it did in the old one. Nonetheless, patients in developing nations should be fully informed that the device they are receiving is used and not being deployed according to manufacturer’s recommendations, and that there may be unknown risks associated with the reused devices.

Decisions about ownership of explanted devices present another problem. During the 1990s in Sweden, regulations required that all pacemakers be removed postmortem, and ownership was ascribed to the implanting medical center. In the Netherlands as well as Canada, the device has traditionally been the property of patients or their heirs.²⁴ Although state laws concerning the handling of human remains generally lead embalmers not to remove any implanted devices without permission,²⁵ no United States federal legislation establishes postmortem property rights pertaining to explanted medical devices. It is therefore not clear which party has jurisdiction to decide what is done with an explanted device. As the device was taken out of patients’ bodies, it might logically fall under statutes governing the disposition of personal property. Because insurers or the Centers for Medicare and Medicaid services likely paid for the bulk of the cost of the device, they could claim ownership. The device manufacturer sold the device and could conceivably construct a bill of sale requirement that the device be returned after explantation for quality improvement testing.

Devices involved in clinical trials are sometimes recovered after death or upgrade as part of the conditions for participation. The implanting or explanting physician could insist that devices be returned for analysis as a condition for performing the procedure. In certain civil or criminal actions, devices may be required as evidence.

The tradition in the United States of patient autonomy presumably ensures that no device could be removed from a deceased patient for purposes contrary to what the patient would authorize. Although insurance companies or the Centers for Medicare/Medicaid Services are the actual entities that pay for devices, patients' premium payments and/or taxes fund those entities. Certainly the government may appropriate devices for public health purposes, but other claims do not reasonably outweigh the property rights of an individual. FDA tracking regulations (nonbinding), which provide a regulatory framework for using serial numbers to track devices, state that patients can opt out of having their devices tracked. This clause suggests at least tacit approval of patient sovereignty over implanted medical devices.²⁶ The National Institutes of Health also supported the idea of patient ownership in a consensus development program regarding medical device ownership.²⁷ It may be possible to further clarify patient ownership and control by having the issue addressed by the Uniform Law Commission on Uniform State Laws. Presuming that in most circumstances patients own their devices and may control their disposition after removal, the aforementioned pacemaker/defibrillator living will would allow patients officially to authorize embalmers to remove pulse generators for donation or return to the manufacturers, even though pacemaker/defibrillator living wills currently do not fall under the legal framework supporting standard advance directives.

Theoretically, the use of pacemakers for legal proceedings would trump wishes to donate expressed in a pacemaker/defibrillator living will. The danger of a pulse generator being sent overseas before its use as evidence may be mitigated by a requisite holding period prior to reimplantation. Furthermore, device printouts from analysis prior to reuse would be available to use in court. Devices involved in clinical trials or advisories/recalls are unlikely to be appropriate for overseas reuse and are usually returned to the manufacturers.

Ethical barriers

Psychological benefits of device donation for family members and benefits to patients in LMIC must be balanced against the public interest in the return of devices to improve product reliability and promote the health of future patients. Although interrogation printouts from donated devices are often made available to manufacturers, several of the recent pulse generator recalls involved defects that could not be detected on routine interrogation.²⁸ The Heart Rhythm Society officially recommends that all explanted devices be returned to the manufacturers to guide quality improvement.²⁹ Manufactures could theoretically donate returned pulse generators after extensive testing, but some of

the tests destroy device functionality, and standard practice involves archiving devices (personal communication with a member of the Quality and Reliability Department, St. Jude Medical Corporation, October 7, 2005).

Because each potentially reusable pulse generator is analyzed, however, a substantial amount of data can be provided to manufacturers. Although interrogation printouts may not provide all necessary information on every device, providing this information to manufacturers is surely better for quality improvement than providing no information when devices are buried or thrown into medical waste. The incremental benefit of more extensive testing performed on pulse generators returned to the manufacturers is difficult to quantify. This testing may be more beneficial in ICDs and biventricular pacemakers than standard pacemakers due to their more complex circuitry. Thus, simple, older-model pacemakers with a track record of safety may represent the ideal devices for donation. Conceivably, once a sufficient number of newer devices have been returned for analysis, further testing would be unlikely to yield useful information. These pulse generators may then be routinely donated for reuse, perhaps as a sort of reverse recall program in which return of such devices to manufacturers is unnecessary. The goals of providing devices for quality improvement analysis and for reuse may coincide (the faster devices are returned for analysis, the sooner they may be placed on the reverse recall list). Pacemaker/defibrillator living wills may increase the recovery of devices for donation and also for return to manufacturers.

Concerns over justice, especially the fair distribution of medical resources, also arise. In an unregulated setting overseas, there is a risk that the wealthy (including medical tourists) may receive donated pulse generators, potentially creating a black market. Devices may thereby be diverted from those most likely to benefit to those who need them less. Aside from medical factors, determining a hierarchy of "deservedness" in the setting of scarce resources presents a problem.

But the potential for injustice argues not for a prohibition or limitation of reuse but rather for safeguards to prevent improper distribution. Exploitation can be minimized with meticulous chains of custody, including proper documentation and credentialing of each of the handlers from the point of acquisition to reimplantation. Make, model, and serial number of each device can provide a means to track devices. Participation in a donation program should be contingent on careful patient screening for clinical need and financial hardship, and on detailed preimplantation and follow-up documentation. In creating donation programs, clear policies must be in place for the fair distribution of reused devices, and a process established to audit the distribution. The risk of exploitation by the well-off may be intrinsically minor because those who can afford a new device will probably not steal a used device without a warranty.

Finally, the concern that some patients may simply be unable to care for the devices raises the issue of nonmalefi-

cence (the ethical duty to avoid harming patients). Although most device-related complications can be eliminated or minimized with appropriate follow-up, patients who cannot or will not follow up may be left worse off than before the implant if they develop infection, lead dislodgement, pacemaker-induced arrhythmias, or inappropriate ICD shocks.

The problem of proper follow-up of patients is difficult to solve, but may be mitigated by careful patient selection and restricting the use of reused pulse generators to major hospitals with adequate resources. In the future, the more widespread use of telephonic monitoring should enable follow-up of patients who live in remote areas. The risk of doing more harm than good is ever present but should be reduced by programs that provide intensive follow-up and ongoing, culturally appropriate education about the importance of device care.

ICD reuse should be restricted to secondary prevention of sudden cardiac death, or ICDs should be used as pacemakers, with the shocking function disabled. Biventricular pacemakers are also probably best reused as pacemakers, given the added risk and expense of placing the extra lead in the coronary sinus.

Conclusion

Increasing pulse generator recovery and reuse can have a significant impact on individual lives of poor patients in LMIC, and large-scale increases might help to reduce international global disparities in cardiovascular outcomes. Although not without controversy, the reuse of pacemakers and ICDs for the poor in LMIC seems feasible and safe when guided by proper procedures, including meticulous chain of custody, standardized sterilization, full informed consent, patient education, and adequate follow up. Before reuse of pacemakers and ICDs can have a substantial impact in the LMIC, they must first be recovered in the developed world. The use of a pacemaker/defibrillator living will might facilitate the creation of a large inventory while addressing ethical and legal concerns, especially in light of renewed focus on advanced directives in recent health care legislation. Increasing awareness of potential benefits from reusing pacemakers and ICDs may spur greater willingness to participate in the collection, implantation, and long-term care of devices in underserved populations. In addition to these steps, a roundtable forum or summit with participation by electrophysiologists from the developed world and LMIC, policymakers (specifically representatives of the FDA), device makers, ethicists, funeral directors, and charity organizations may identify other measures to facilitate implementation of device recovery and donation.

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