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Societal views of pacemaker reutilization for those with untreated symptomatic bradycardia in underserved nations

Lindsey Gakenheimer · Dave C. Lange · Joshua Romero · James N. Kirkpatrick · Patricia Sovitch · Hakan Oral · Kim A. Eagle · Timir S. Baman

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Abstract
Purpose Significant healthcare disparities exist between the developed world and low and middle income countries (LMIC), specifically in the field of cardiac electrophysiology. As a result, pacemaker reutilization has been proposed as a viable option for those in LMIC and no other means of obtaining a device. Little data exist regarding the feasibility of establishing a reuse program in addition to understanding the views of society on device reutilization. This study investigated the views of funeral directors, patients with cardiac devices, and members of the general population regarding reutilization of previously implanted pacemakers.
Methods Ninety funeral directors in Michigan were surveyed regarding current practice as well as preferences for post-mortem device disposal. One hundred and fourteen patients with devices and 1,009 members of the general population were surveyed regarding post-mortem device handling.
Results Funeral directors had an average of 21 years of experience with an annual volume of 120 deceased persons per year, with a cremation rate of 35%. When asked about disposal methods of explanted devices, the majority of devices (84%) were discarded as medical waste or stored with no intended purpose, with a total of 171 devices currently in possession at the funeral homes. Eighty-nine percent of funeral directors expressed a desire to donate devices for reuse in LMIC and 10% acknowledged previous device donation. Eighty-seven percent of device patients and 71% of the general population also expressed a desire to donate devices.
Conclusions The results of our survey show that a large percentage of funeral directors, patients with implantable devices, and members of the general population support a pacemaker reutilization initiative. This study lends further evidence that collection of devices for reuse is feasible and that establishing a framework for regional pacemaker reutilization program is warranted. If successful, the feasibility of this model should be investigated in other parts of the country in order to alleviate the burden of untreated symptomatic bradycardia in our world.

Keywords Pacemaker reuse · Underserved nations · Societal views

L. Gakenheimer · D. C. Lange · J. Romero · P. Sovitch · H. Oral · K. A. Eagle · T. S. Baman
Division of Cardiovascular Medicine, University of Michigan, Ann Arbor, MI, USA

J. N. Kirkpatrick
Division of Cardiovascular Medicine, University of Pennsylvania, Philadelphia, PA, USA

T. S. Baman (✉)
UM Cardiovascular Center,
1500 E Medical Center Drive SPC 5852,
Ann Arbor, MI 48109-0644, USA
e-mail: timir@med.umich.edu

1 Introduction

Cardiovascular disease (CVD) is the leading cause of mortality worldwide and will account for an estimated 20 million deaths in low and middle income countries (LMIC) by 2030 [1]. Many patients and physicians in LMIC lack access to treatment strategies that have lead to a significant decrease in morbidity and mortality associated with CVD in developed nations—specifically in the field of cardiac electrophysiology. In 2005, LMIC countries such as Peru and Nepal had <15 newly implanted pacemakers per million population, compared with 752 new implants per million in the USA [2].

As a result of this significant healthcare disparity, initiatives examining the feasibility of pacemaker reutilization have been explored on a limited basis in numerous settings worldwide [3–15]. These initiatives have demonstrated initial safety and feasibility of pacemaker reuse and there exists the potential to expand these efforts to LMIC. Limited work by our group suggests that patients and funeral directors would be willing to participate in a program that would expand the inventory of devices acquired for potential reuse [16]. In order to further investigate the potential for such a program on a large scale, we sought to determine the views of funeral directors, patients with implantable devices, and members of the general population regarding the allocation of devices for reutilization in underserved nations.

2 Methods

2.1 Study design

This prospective study is composed of three independent surveys distributed to funeral directors, patients with an implantable cardiac device, and members of the general population. Surveys were adapted from a previous study by Kirkpatrick et al. [17] examining the post-mortem management of cardiac devices. All surveys distributed were approved by the University of Michigan Institutional Review Board.

2.2 Funeral director survey

A mail survey was sent to all funeral directors within a 50-mile radius of Ann Arbor, Michigan, totaling 152 surveys. Funeral directors were also given a pre-addressed postage-paid envelope and a $20 gift card irrespective of participation in the study.

The survey consisted of 34 questions with two being optional follow-up questions concerning participation in a future device donation project. Questions were asked regarding experience in embalming services, the removal and handling of cardiac devices, and device donation. Other questions asked funeral directors' opinions on managing devices upon patients' death, device donation, fees for device removal, reimbursement to families who donate a loved one's device, ownership of cardiac devices upon removal, and advance directives stating patients' wishes for their device post-mortem.

2.3 Patients with implantable devices survey

Over a 3-month period, an anonymous 30-question survey was provided to all patients with an implantable cardiac device who were presenting for a routine appointment at the University of Michigan Device Clinic. Patients were surveyed regardless of the type of device they had. Patients who agreed to participate completed the survey in the waiting room and returned completed surveys to the clerk upon check-out. No compensation was provided for participation.

The survey assessed patients' opinions regarding device reuse for philanthropic causes, payments to funeral directors for post-mortem device removal, reimbursements to families who donate a loved one's device, advance directives stating patients' wishes for their device post-mortem, and ownership of devices upon removal. Other questions requested demographic information including age, sex, ethnicity, health status, income, educational level, type of device they owned, if they have children and/or pets, religious affiliation, if they are organ donors, and if they have a living will (LW) or durable power of attorney for healthcare (DPAHC).

2.4 General population survey

Over a 2-month period, an anonymous 28-question survey was provided to individuals in the waiting rooms of the University of Michigan General Medicine clinics. Participants returned surveys to the research assistant, a clerk at the clinic, or a box marked "Completed Surveys." No compensation was provided for participation.

The survey assessed patients' opinions regarding device reuse for philanthropic causes, payments to funeral directors for post-mortem device removal, reimbursements to families who donate a loved one's device, advance directives stating patients' wishes for their device post-mortem, and ownership of devices upon removal. An additional question asked if the post-mortem donation of a loved one's device would help the respondent cope with a device patient's death. Other questions requested demographic information including age, sex, ethnicity, health status, income, educational level, type of device they owned, if they have children and/or pets, religious affiliation, if they are organ donors, and if they have a LW or DPAHC.

2.5 Statistical analysis

Continuous variables were compared using the t test and expressed as mean±1 SD. Categorical variables were compared using the chi-square or Fisher's exact test where appropriate. Logistic regression analysis was performed to determine predictors of device donation. All analyses were performed using SPSS (15.0) for Windows (SPSS Inc. Chicago, Illinois). $P<0.05$ indicated statistical significance.

3 Results

3.1 Funeral director demographics

Ninety funeral directors (59%) returned completed surveys, and five individuals returned the gift card and a blank

survey. Funeral directors reported that, on average, 19% of deceased individuals were found to possess a cardiac device, and 85% of them were buried with their device. Funeral directors reported removing an average of 27 devices each year for reasons such as cremation and family request. Every funeral director in the study had experience removing devices, but only 31% had received formal training in device removal (Table 1).

When asked about disposal methods for explanted devices, the majority of devices (84%) were discarded as medical waste or stored with no intended purpose, with a total of 171 devices currently in possession at the funeral homes. Only 3.3% of funeral directors reported returning devices to the manufacturer. Other methods of device disposition included return to implanting physician (6%) or donation to veterinarians (3%) (Table 2).

When asked to rate the difficulty of returning devices to the manufacturer, only 13% found the process to be difficult. Seventy-one percent of funeral directors stated that it would be possible to return every device that they encounter to its manufacturer; however, 56% described barriers such as shipping costs, lack of information, time, infection concerns, paperwork, and mistrust which prevented device returns. Eighty-one percent of funeral directors would be willing to send devices to a central organization designed to distribute them to their respective manufacturers instead of shipping devices directly to the manufacturers.

3.2 Device patient demographics

Out of 301 surveys distributed at the University of Michigan, 114 (38%) were completed and returned. The average age of device patient respondents was 60 years with 64% being male and 95% of Caucasian ethnicity. Seventy-four percent of respondents had received at least a college degree, while 39% had an annual income of at least $51,000. Approximately 46% were registered organ donors, and 61% had a LW, DPAHC, or both. Forty percent had a pacemaker, 36% had an ICD, and 24% had a biventricular ICD.

Table 1 Characteristics of surveyed funeral directors

Characteristics of funeral directors (n=90)	
Number of years licensed to perform embalming services	21±12
Number of embalmings per year	120±87
Cremation rate	35±11%
Percent of deceased with a cardiac device	19±13.6%
Percent of deceased buried with his/her device	85±29%
Number of devices removed per year at funeral homes	27±20
Percent of funeral directors with experience in device removal	100%
Percent of funeral directors with formal training on identification and removal of cardiac devices	31%
Total number of devices stored in funeral directors' funeral homes	171
Percent of funeral directors with experience in donating devices to underdeveloped countries	10%

Table 2 Methods of device disposal by funeral directors (n=90)

Disposal method	Number (%) of funeral directors reporting disposal method
Discarded as Waste	69 (77)
Stored in Office	6 (7)
Given to Other Physician	5 (6)
No response	4 (4)
Returned to Manufacturer	3 (3)
Given to Veterinarian	3 (3)

3.3 General population demographics

At the University of Michigan General Medicine clinic waiting rooms, 2,643 individuals were approached to participate in the study with 1,009 (38%) completing surveys. The average age of general public respondents was 52 years with 61% being male, 79% of Caucasian ethnicity and 10% of African American ethnicity. Sixty-nine percent of respondents had received at least a college degree, and 41% had an annual income of at least $51,000. Forty percent were registered organ donors and 47% had a LW, DPAHC, or both.

3.4 Views of funeral directors, device patients, and the general population regarding device disposition

The majority of device patients (68%) and of the general population (56%) were unaware of the options for device disposal after death (Table 3). A high proportion of funeral directors (89%), device patients (87%), and the general population (71%) expressed a desire to donate devices to patients with financial need in underdeveloped countries (Table 4). When asked to select only one method of device disposition, funeral directors (82%), device patients (73%), and the general population (53%) preferred donating devices to patients in underserved nations. Forty-five percent of the general population felt that device donation would help them cope with the loss of a loved one. There was no association between each groups' clinical characteristics and propensity to choose to donate to LMIC (p>0.20).

Table 3 Current beliefs of patient and general population regarding post-mortem device handling

Survey response	Patients with devices (n=114 (%))	General population (n=1,009 (%))
Do not know	77 (68)	565 (56)
Buried with patient	22 (19)	333(33)
Removed and returned to family	0 (0)	10 (1)
Removed and returned to device manufacturer never to be used again	5 (4)	20 (2)
Removed and returned to device manufacturer in order to be recycled for future devices	9 (8)	61 (6)
Donated to underdeveloped nations for use if battery life is acceptable	1 (1)	20 (2)

4 Discussion

4.1 Main findings

The results of our survey show that a large percentage of funeral directors (89%), patients with implantable devices (87%), and members of the general population (71%) support a pacemaker reutilization initiative if given the opportunity. Funeral directors removed an average of 27 devices yearly, 84% of which were disposed as waste or kept in their funeral home. This study lends further evidence that collection of devices for reuse is feasible and supports a framework for a regional pacemaker reutilization initiative in southeastern Michigan.

4.2 Previous studies

A previous study by Kirkpatrick et al. [17] found that 91% of device patients were willing to sign an advance directive allowing their device to be donated for human use in an underdeveloped country. Moreover, 52% of funeral directors in this study disposed of medical devices in waste or in the mortuary. Safety issues regarding the possibility of device infection and/or device failure are often discussed when considering pacemaker reutilization. However, a recent meta-analysis examined 18 trials and found an overall infection rate of 1.97% and device malfunction rate of 0.68% among reutilized devices [18].

Current recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines advise funeral directors and physicians to return devices to the original manufacturer for a functional analysis, ideally contributing to improvements in future technology [19]. Our present study found that only 3% of funeral directors reported returning devices to the manufacturer. A device-specific LW or DPAHC may be beneficial in overcoming legal obstacles associated with device retrieval for reutilization [17].

4.3 Views of funeral directors on pacemaker reutilization

The funeral directors surveyed estimated that approximately one in five of the deceased they encounter have a cardiac device and, overall, 35% of families request cremation for their loved one (necessitating device removal due to the risk of explosion in the crematorium). The vast majority of these explanted devices are discarded as waste or stored with no intended purpose. As a result, an estimated 171 devices were available in southeast Michigan funeral homes at the time of the survey administration. When questioned about post-mortem device disposal, funeral directors expressed a strong interest in donating devices for pacemaker reutilization in LMIC.

Table 4 Preferences of funeral directors, patients with cardiac devices, and general population regarding post-mortem device disposal (respondents could choose more than one answer)

Survey response	Funeral directors (n=90 (%))	Patients with devices (n=114 (%))	General population (n=1,009 (%))
Donate device to an organization which gives it to health professionals for use in underserved nations	80 (89)	99 (87)	716 (71)
Donate device to an organization which gives it to health professionals for use in underserved nations (when given only one option)	74 (82)	83 (73)	535 (53)
Check device with a computer device but do not remove it	11 (12)	10 (9)	172 (17)
Remove device and send it to the manufacturer for analysis	50 (56)	66 (58)	525 (52)
Remove device and send it to the manufacturer for analysis; but, after the analysis, I want it sent back to my family	7 (8)	2 (2)	61 (6)
Donate device to be put into an animal at a veterinary school	55 (61)	42 (37)	424 (42)
Do not check device with a computer or remove it	19 (21)	0 (0)	10 (1)
I do not care what happens to the device	8 (9)	25 (22)	131 (13)

4.4 Current models for donation of pacemakers to underserved nations

Heartbeat International is a charitable organization that specializes in allocating nearly expired pacemakers and delivering them to underserved nations. These devices are generously donated by device manufacturers. To date, >9,000 devices have been implanted through pacemaker banks established by local Rotary International chapters in 24 countries over four continents [20]. Despite these laudable efforts, limited device supply is a significant obstacle in delivering bradyarrhythmia therapy to the one million people currently in need in underserved nations.

Project My Heart–Your Heart is a joint collaborative between the Citizens, Physicians, and Funeral Directors of the State of Michigan, the University of Michigan Cardiovascular Center, and World Medical Relief, Inc [21]. The goal of our proposed initiative is to create a reproducible model where funeral directors are given a framework to consent families of loved ones for pacemaker removal prior to burial or cremation. To date, the collaborative has generated a small case series which illustrates the efficacy of such a model [4].

In the initial *Project My Heart–Your Hear*t model, funeral directors download a consent-for-explant form and request a postage-paid envelope from www.myheartyourheart.org. Once devices are received, battery life interrogation is performed by trained personnel. We use a battery life >70% based on longevity of used devices in previous studies [6]. After undergoing validated cleaning, performance testing, and sterilization processes, devices are sent to World Medical Relief Inc—a nonprofit charitable organizations specializing in delivery of medical equipment for distribution to hospitals and clinics in underserved nations. These hospitals are prohibited from charging for the devices and are required to follow-up with patients to ensure efficacy and safety of reuse. Funding for this program is provided by philanthropic donation and grants.

Despite the initial success with device reutilization [4], there exist many limitations to large-scale device donation. Firstly, device allocation is limited to underserved nations with government-run healthcare in order to pay for the hospitalization and physician costs. In addition, patients must be able to afford the approximately $200 cost of the device leads. Based on discussions with implanting physicians in developing world nations, this amount appears to be a reasonable expense for most patients and their families (personal correspondence, University of Philippines, Philippines General Hospital, November 15, 2008, and Vietnam Heart Institute, February 10, 2010). With regards to the legal issues surrounding the establishment of a large-scale donation operation, our program is considering an investigational device exemption from the Food and Drug Administration to perform a clinical investigation in order to validate the safety and feasibility of the pacemaker reuse. Other options include application for an export certificate. Other legal and ethical considerations exist and must be further explored when considering large-scale pacemaker reutilization [22].

4.5 Limitations

The study has the following limitations: (1) our study population was limited to one geographical area and may not be generalizable to other areas of the country; (2) funeral directors provided estimations without confirmation of numbers of devices; (3) the devices currently in funeral homes were not interrogated, and we are unable to determine how many have adequate battery life for reuse; (4) funeral directors and patients who support this initiative may have been more likely to answer our survey; thus, these results may not truly represent the views of these populations; (5) our patient populations were ethnically homogenous and may not represent the views of populations from other ethnic groups. However, the results of our patient survey mirror those of a study performed in a more urban and racially diverse setting.

5 Conclusions

A significant healthcare disparity exists between the developed world and LMIC with regards to pacemaker implantation. The results of our survey show that funeral directors, patients with implantable devices, and members of the general population support a pacemaker reutilization initiative. In addition, funeral directors are able to supply a significant number of devices, if given the appropriate framework. This study lends further evidence that collection of devices for reuse is feasible and supports a framework for a regional pacemaker reutilization initiative in southeastern Michigan. If successful, the feasibility of this model should be investigated in other regions of the country as well as other developed nations.

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References

1. Joshi, R., Jan, S., Wu, Y., & MacMahon, S. (2008). Global inequalities in access to cardiovascular health care: our greatest challenge. *Journal of the American College of Cardiology, 52*(23), 1817–1825.

2. Mond, H. G., Irwin, M., Ector, H., & Proclemer, A. (2008). The world survey of cardiac pacing and cardioverter-defibrillators: calendar year 2005 an International Cardiac Pacing and Electrophysiology Society (ICPES) project. *Pacing and Clinical Electrophysiology, 31*(9), 1202–1212.
3. Anilkumar, R., & Balachander, J. (2004). Refurbishing pacemakers: a viable approach. *Indian Pacing Electrophysiol J, 4*(1), 1–2.
4. Baman, T. S., Romero, A., Kirkpatrick, J. N., Romero, J., Lange, D. C., Sison, E. O., et al. (2009). Safety and efficacy of pacemaker reuse in underdeveloped nations: a case series. *Journal of the American College of Cardiology, 54*(16), 1557–1558.
5. Costa, R., Moreira, L. F., Pego-Fernandes, P. M., Martinelli Filho, M. M., Stolf, N. A., Verginelli, G., et al. (1983). Reuse of pacemaker generators. *Arquivos Brasileiros de Cardiologia, 40* (5), 317–318.
6. Linde, C. L., Bocray, A., Jonsson, H., Rosenqvist, M., Radegran, K., & Ryden, L. (1998). Re-used pacemakers–as safe as new? A retrospective case-control study. *European Heart Journal, 19*(1), 154–157.
7. Mond, H., Tartaglia, S., Cole, A., & Sloman, G. (1980). The refurbished pulse generator. *Pacing and Clinical Electrophysiology, 3*(3), 311–317.
8. Mugica, J., Duconge, R., & Henry, L. (1986). Survival and mortality in 3, 701 pacemaker patients: arguments in favor of pacemaker reuse. *Pacing and Clinical Electrophysiology, 9*(6 Pt 2), 1282–1287.
9. Namboodiri, K. K., Sharma, Y. P., Bali, H. K., & Grover, A. (2004). Re-use of explanted DDD pacemakers as VDD—clinical utility and cost effectiveness. *Indian Pacing Electrophysiol J, 4*(1), 3–9.
10. Panja, M., Sarkar, C. N., Kumar, S., Kar, A. K., Mitra, S., Sinha, D. P., et al. (1996). Reuse of pacemaker. *Indian Heart Journal, 48*(6), 677–680.
11. Pringle, R. A., Leman, R. B., Kratz, J. M., & Gillette, P. C. (1986). An argument for pacemaker reuse: pacemaker mortality in 169 patients over ten years. *Pacing and Clinical Electrophysiology, 9*(6 Pt 2), 1295–1298.
12. Rosengarten, M., Chiu, R., & Hoffman, R. (1989). A prospective trial of new versus refurbished cardiac pacemakers: a Canadian experience. *The Canadian Journal of Cardiology, 5*(3), 155–160.
13. Rosengarten, M. D., Portnoy, D., Chiu, R. C., & Paterson, A. K. (1985). Reuse of permanent cardiac pacemakers. *Canadian Medical Association Journal, 133*(4), 279–283.
14. Sethi, K. K., Bhargava, M., Pandit, N., Mohan, J. C., Arora, R., Khanna, S. K., et al. (1992). Experience with recycled cardiac pacemakers. *Indian Heart Journal, 44*(2), 91–93.
15. Romero, J., Romero, A., Kirkpatrick, J. N., Lange, D. C., Eagle, K. A., & Baman, T. S. (2009). Pacemaker Reuse in a 65-year-old woman in the Philippines with severe medical need. *Pacing and Clinical Electrophysiology, 33*(1), e8–e9. 10.
16. Kirkpatrick, J. N., Burke, M. C., & Knight, B. P. (2006). Postmortem analysis and retrieval of implantable pacemakers and defibrillators. *The New England Journal of Medicine, 354* (15), 1649–1650.
17. Kirkpatrick, J. N., Ghani, S. N., Burke, M. C., & Knight, B. P. (2007). Postmortem interrogation and retrieval of implantable pacemakers and defibrillators: a survey of morticians and patients. *Journal of Cardiovascular Electrophysiology, 18*(5), 478–482.
18. Romero J., Meier P., Gakenheimer L., Kirkpatrick, J.N., Sovitch, P., Oral, H., et al. (2010). "Pacemaker reutilization is a safe and effective means of delivering electrophysiological healthcare in Third World countries: a meta-analysis (Abstract P96)" Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Scientific Sessions, Washington, DC
19. Carlson, M. D., Wilkoff, B. L., Maisel, W. H., Ellenbogen, K. A., Saxon, L. A., Prystowsky, E. N., et al. (2006). Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines Endorsed by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) and the International Coalition of Pacing and Electrophysiology Organizations (COPE). *Heart Rhythm, 3*(10), 1250–1273.
20. Mond, H. G., Mick, W., & Maniscalco, B. S. (2009). Heartbeat International: making "poor" hearts beat better. *Heart Rhythm, 6* (10), 1538–1540.
21. Baman, T. S., Kirkpatrick, J. N., Romero, J., Gakenheimer, L., Romero, A., Lange, D. C., et al. (2010). Pacemaker reuse: an initiative to alleviate the burden of symptomatic bradyarrhythmia in impoverished nations around the world. *Circulation, 122*(16), 1649–1656.
22. Kirkpatrick, J. N., Papini, C., Baman, T. S., Khota, K., Eagle, K. A., Verdino, R. J., et al. (2010). Reuse of pacemakers and defibrillators in developing countries: logistical, legal, and ethical barriers and solutions. *Heart Rhythm, 7*(11), 1623–1627.