

# Patients' and Family Members' Views on Pacemaker Reuse: an International Survey

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## Abstract

**Introduction** The reuse of cardiac implantable electronic devices may help increase access to these therapies in low- and middle-income countries (LMICs). No published data exist regarding the views of patients and family members in LMICs regarding this practice. **Methods and Results** A paper questionnaire eliciting attitudes regarding pacemaker reuse was administered to ambulatory adult patients and patients' family members at outpatient clinics at Centro Nacional Cardiologia in Managua, Nicaragua, Indus Hospital in Karachi, Pakistan, Hospital Carlos Andrade Marín and Hospital Eugenio Espejo in Quito, Ecuador, and American University of Beirut Medical Center in Beirut, Lebanon. There were 945 responses (Nicaragua – 100; Pakistan – 493; Ecuador – 252; Lebanon – 100). A majority of respondents agreed or strongly agreed that they would be willing to accept a reused pacemaker if risks were similar to a new device (707, 75%), if there were a higher risk of device failure compared to a new device (584, 70%), or if there were a higher risk of infection compared to a new device (458, 56%). A large majority would be willing to donate their own pacemaker at the time of their death (884, 96%) or the device of a family member (805, 93%). Respondents who were unable to afford a new device were more likely to be willing to accept a reused device (79% vs. 63%,  $P < 0.001$ ). **Conclusions** Patients and their family members support the concept of pacemaker reuse for patients who cannot afford new devices.

## Patients' and Family Members' Views on Pacemaker Reuse: an International Survey

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## Abstract

### Introduction

The reuse of cardiac implantable electronic devices may help increase access to these therapies in low- and middle-income countries (LMICs). No published data exist regarding the views of patients and family members in LMICs regarding this practice.

### Methods and Results

A paper questionnaire eliciting attitudes regarding pacemaker reuse was administered to ambulatory adult patients and patients' family members at outpatient clinics at Centro Nacional Cardiologia in Managua, Nicaragua, Indus Hospital in Karachi, Pakistan, Hospital Carlos Andrade Marín and Hospital Eugenio Espejo in Quito, Ecuador, and American University of Beirut Medical Center in Beirut, Lebanon. There were 945 responses (Nicaragua – 100; Pakistan – 493; Ecuador – 252; Lebanon – 100). A majority of respondents agreed or strongly agreed that they would be willing to accept a reused pacemaker if risks were similar to a new device (707, 75%), if there were a higher risk of device failure compared to a new device (584, 70%), or if there were a higher risk of infection compared to a new device (458, 56%). A large majority would be willing to donate their own pacemaker at the time of their death (884, 96%) or the device of a family member (805, 93%). Respondents who were unable to afford a new device were more likely to be willing to accept a reused device (79% vs. 63%,  $P < 0.001$ ).

### Conclusions

Patients and their family members support the concept of pacemaker reuse for patients who cannot afford new devices.

**Key Words:** pacemaker, reutilization, reuse, views, global health

### Introduction

Pacemakers remain unaffordable for many individuals in low- and middle-income countries (LMICs), resulting in disparities in pacemaker utilization.<sup>1</sup> The reuse of pacemakers - which involves extraction of devices from deceased donors, resterilization, and reimplantation in recipient patients – has been proposed as a potential solution to this unmet need.<sup>2</sup> Pacemaker reuse has been previously conducted in LMICs on a small scale and these experiences suggest that it is safe, efficacious, and feasible.<sup>3-5</sup>

Previously published survey data have shown that the vast majority of funeral directors, patients with pacemakers, and their families in the United States support donation of explanted pacemakers.<sup>6</sup> An international survey of the members of the Heart Rhythm Society indicated that the concept of pacemaker reuse was well supported by the respondents in potential donor and recipient countries.<sup>7</sup> Yet to our knowledge no study to date has assessed the attitudes toward postmortem pacemaker reuse among potential device recipients LMICs. Understanding these viewpoints is critical to the successful adoption of a wide-scale reuse program, specifically regarding religious, cultural, and psychological factors, which may impact the acceptance of reconditioned pacemakers from deceased persons. In this study we aimed to quantitatively evaluate the opinions of pacemaker reuse among patients and family members in LMICs and to identify demographic factors which may predict these views.

### Methods

## Study Design

This study utilized an anonymous, fourteen-question paper survey originally written in English and translated into Urdu, Spanish, and Arabic. The survey instrument is shown in the Appendix. Demographic questions included age, gender, country of residence, health status, level of education, marital and employment status, the presence of a personal or family history of heart disease, and the ability to afford the full cost of a new pacemaker whose market value was estimated to be \$700 USD (or equivalent amount of local currency). Of note, pacemaker cost is the responsibility of the patient in the absence of private insurance in the countries surveyed. Respondents were asked to rate their level of agreement with five positive statements regarding pacemaker reuse using a five-point Likert-type scale (1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, and 5 = strongly disagree).

The University of Michigan Institutional Review Board (IRB) declared the study exempt from review due to a lack of identifying information collected and no capacity for patient harm. In Nicaragua, the survey was approved by the Ministry of Health; in Pakistan, it was approved by the local IRB; in Ecuador and Lebanon, it was approved by the local hospital administrations.

The survey was administered to patients and family members in the waiting room of the outpatient clinics at Centro Nacional Cardiologia in Managua, Nicaragua (over a two-day period in April 2012), Indus Hospital in Karachi, Pakistan (over a two-week period in May 2012), Hospital Carlos Andrade Marín and Hospital Eugenio Espejo in Quito, Ecuador (over a two-week period in July 2014) and American University of Beirut Medical Center in Beirut, Lebanon (over a two-month period from June to July 2015). The World Bank classifies Nicaragua and Pakistan's economies as "lower-middle income" with per capita gross national incomes (GNI) of \$1,910 USD and \$1,530 USD, respectively; it classifies Ecuador and Lebanon's economies as "upper-middle income" with per capita GNI of \$ 6,080 USD and \$7,600, respectively.<sup>8</sup>

No compensation was provided for participation. Respondents were advised that survey participation was voluntary, responses would remain anonymous, and that their participation and responses would not affect their clinical care or eligibility for charity care. Participants returned surveys to the study personnel distributing surveys. Study personnel assisted respondents who wished to participate in the survey but were unable to do so (generally due to illiteracy or infirmity).

## Data Analysis

Views regarding pacemaker reuse were represented as the number of respondents who indicated "agree" or "strongly agree" for each question as a proportion of non-neutral responses. Demographic variables were analyzed as categorical variables and agreement with each statement regarding pacemaker reuse was tabulated by country of origin and by demographic variables. Differences in opinion across countries or demographic variables were tested using the  $\chi^2$  test. Multivariate logistic regression using the  $\chi^2$  test was performed to assess whether country of residence and/or ability to afford a new device were independent predictors of various opinions of device reuse.

Analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC).  $P < 0.05$  was deemed statistically significant.

## Results

### Respondent Characteristics

A total of 945 respondents participated in the survey (Nicaragua – 100; Pakistan – 493; Ecuador – 252; Lebanon – 100). The demographic characteristics of survey respondents are shown in Table 1. The mean age of respondents was 48. The majority (582, 62%) were women. Less than half of respondents (354, 38%) were married or living with a partner. Most of the respondents had no more than ten years of formal education (536, 57%) and most were not employed outside the home (576, 61%). A majority of respondents classified their own health as fair or poor (565, 60%) and 725 respondents (77%) reported a history of heart

disease either in themselves or a family member. A significant majority of respondents reported being unable to afford the full cost of a new pacemaker (537, 78%).

### Opinions Regarding Pacemaker Reuse

Patient and family members' level of agreement with various statements about pacemaker reuse stratified by country of residence and demographic characteristics is shown in Table 2. Attitudes regarding device donation and reuse were overall positive. A majority of respondents agreed or strongly agreed that they would be willing to accept a reused pacemaker if risks were similar to a new device (707, 75%), if there were a higher risk of device failure compared to a new device (584, 70%), or if there were a higher risk of infection compared to a new device (458, 56%). A large majority would be willing to donate their own pacemaker at the time of their death (884, 96%) or the device of a family member (805, 93%).

### Predictors of Attitude Toward Pacemaker Reuse

Respondents who reported being unable to afford a new pacemaker were more likely to accept a reused device if the risks were similar to a new device (79% vs. 63%,  $P < 0.001$ ), or if the risk of device malfunction were greater (74% vs. 63%,  $P < 0.001$ ). Those with a personal or family history of a heart condition were slightly less likely to be willing to donate a family member's pacemaker (92% vs. 96%,  $P = 0.049$ ). The vast majority of respondents who were married or living with a partner would be willing to donate their own pacemaker at the time of their death but at a slightly lower rate than other respondents (97% vs. 93%,  $P = 0.043$ ). Other analyzed demographic variables including age group, gender, health, level of education, or employment status were not associated with variation in attitude toward pacemaker reuse.

Compared to respondents from other countries, those from Lebanon were more likely to be able to afford a new device (66% vs. 15%,  $P < 0.001$ ) and less likely to be willing to undergo reimplantation with a reused device (51% vs. 78%,  $P < 0.001$ ). Lebanese respondents were also less willing than other respondents to undergo reimplantation if there were a greater risk of device malfunction (56% vs. 63%,  $P < 0.001$ ) or if there were a greater risk of infection (30% vs. 51%,  $P < 0.001$ ).

Multivariable logistic regression was performed to determine whether country of residence or ability afford a device were independent predictors of positive viewpoints of device reuse. This analysis showed that Lebanese residence and ability to afford a new pacemaker were each independent negative predictors of willingness to accept a used pacemaker for two statements regarding reuse ("if risks similar" and "if higher risk of failure";  $P < 0.05$ ) but the ability to afford a new pacemaker did not independently predict the other statements.

### Discussion

#### Major Findings

A large majority of respondents in the four surveyed low- to middle- income countries have positive attitudes towards postmortem donation of pacemakers and embrace the concept of a reconditioned device for their medical care. These positive attitudes persist even in a hypothetical scenarios in which these devices carry a higher risk of device malfunction or infection.

A successful wide-scale pacemaker reutilization program requires participation of patients, their family members, the funeral industry in donor counties, as well as health authorities, physicians, patients, and the families in recipient countries. With regards to patients in potential donor countries, Gakenheimer *et al* reported that 87% of patients with cardiac implantable electronic devices (CEIDs) and 71% of the general population in the United States would be willing to donate them to indigent patients in LMICs.<sup>6</sup> This study also found that 89% of Michigan funeral directors would support a cardiac device reuse initiative. From the physician perspective, in a web based survey of 429 Heart Rhythm Society (HRS) members (primarily cardiac electrophysiologists), 81% of physician respondents reported being comfortable asking their patients to consider donating their CIED and 84% reported willingness to reimplant a resterilized device if the practice were legally sanctioned. Importantly, HRS members from high-income countries supported CIED reuse at rates similar to those from lower- and upper-middle income countries.<sup>7</sup> The present study complements the

existing survey data by demonstrating broad support for pacemaker reuse among patients and their family members in LMICs, where an unmet need for pacemakers persists despite economic progress.

Respondents were less likely to accept a reused pacemaker in a hypothetical scenario in which a reused device is more likely to malfunction and even less likely in a hypothetical scenario in which a reused device is more likely to cause infection, although a majority of respondents were still agreeable to accepting a pacemaker under either of these scenarios. In the aforementioned survey of HRS members, when asked about their potential concerns about CIED reuse, 64% of physicians cited infection and 29% cited device malfunction.<sup>7</sup> In a meta-analysis comprising 18 studies and 2,270 patients who underwent pacemaker reuse, device malfunction was more frequent with reused devices than new ones (odds ratio 5.80 [1.93 to 17.47],  $P = 0.002$ ), but only occurred in 0.7% of reimplanted devices. Most malfunctions were related to set screw abnormalities, which may be identified during a thorough validation process prior to donation, or even during the implantation procedure when the pacemaker with the faulty screw may be replaced by a back-up device. The risk of infection among reconditioned devices was 2.0%, statistically similar to the risk for new devices.<sup>9</sup> Standardized sterilization protocols are needed to minimize the risk of infection. Our group proposed a standardized sterilization protocol to clean, test, and sterilize CIEDs to meet industry standards for sterility of reconditioned implantable medical devices<sup>10</sup> Yet even if the risks associated with reused devices are higher, our survey suggests that patients in LMICs perceive an increased risk of infection or malfunction to be an acceptable tradeoff when the alternative is not receiving appropriate care due to lack of access to a new device. Reconditioned pacemakers should only be offered to patients, who would not otherwise be able to obtain a new device, and such implantation should only be performed following a thorough informed consent.<sup>7</sup> Ethically, we may be obligated to offer such a reesterilized device to those whom no other treatment is available.<sup>11</sup>

The finding that respondents who are unable to afford a new device were more likely to be willing to accept a reused device is not surprising given that the primary justification for device reuse is cost reduction. It is remarkable that the rates of acceptance of a reused pacemaker were greater than 50% even among patients who stated that they *could* afford a new device, suggesting that the cost savings of a reused device is a tangible benefit even when a new device is not prohibitively expensive.

The finding that respondents from Lebanon were less likely than respondents from other countries to be willing to undergo reimplantation is partly due to the fact that these respondents were more likely be able to afford a new device, which we found in logistic regression to be negatively associated with willingness to accept a new device even when accounting for country of residence. Lebanon is the highest-income country among our survey sample and these trends of opinion may be similar in other upper-middle income countries.

### Study Limitations

Since this survey was voluntary, there is a risk of participation bias in that individuals who agreed to complete the survey may have been predisposed to have positive viewpoints of device reuse compared to those who declined, or that the researchers were wanting them to approve of the practice. The response rate was not quantitatively tracked. Our sample was limited to patients and family members in the waiting rooms of a small subset of outpatient clinics in four countries. Many factors – such as the local economy, the healthcare system, level of trust in the healthcare system, and variations in ethical standards and cultural beliefs – may have influenced these opinions and these findings are therefore not necessarily generalizable to all LMICs or the global community. Despite these potential biases, the overwhelmingly positive attitudes toward the donation and acceptance of reused pacemakers among this large and geographically diverse sample suggests that these opinions are likely to at least directionally reflect the views of people living in other LMICs as well.

### Conclusions

Reuse of properly reconditioned pacemakers may allow patients in LMICs to receive essential bradycardia therapy despite their financial inability to obtain a new device. A significant majority of patients and family members residing in countries that could benefit from reuse have positive attitudes toward the postmortem

donation of pacemakers. This finding underscores the importance of further study to better demonstrate the safety of pacemaker reuse and to advocate for changes in the regulatory environment to enable pacemaker reuse for the benefit of needy patients in LMICs.

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#### Author Contributions:

AH – data collection, data analysis/interpretation, manuscript development; PM – concept/design, data collection, manuscript development; critical revision of article; TM – critical revision of article; NB – data collection, critical revision of article; FJ – data collection, critical revision of article; AK – data collection, critical revision of article; QJ – statistics; KH – data collection, critical revision of article; RJ – data collection, critical revision of article; CM – data collection, critical revision of article; AB – data collection, critical revision of article; MR – data collection, critical revision of article; PZ – data collection, critical revision of article; MH – data collection, critical revision of article; KE – concept/design, critical revision of article; TC – concept/design; critical revision of article.

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