

REVIEW

Reuse of cardiac implantable electronic devices in developing countries perspectives: A literature review

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Abstract

Introduction and Objectives: Access to cardiac implantable electronic devices (CIEDs) is limited in developing countries. Postmortem CIED donation from developed countries to developing countries could be an important resource for those who cannot afford a new one. The objective of this paper was to identify and synthesize the perspectives on the donation of CIEDs for potential reuse in patients without resources living in developing countries.

Methods: A bibliographic review was carried out in the PubMed, Web of Science and Scopus databases. The search strategy was limited to articles published in English or Spanish.

Results: Eight publications were analyzed. The main results were grouped into two large frameworks on perceptions, preferences, attitudes and opinions of developed countries and developing countries towards the donation and reuse of CIEDs. Positive perspectives were identified towards the donation of CIEDs for their reuse in the majority of patients with a CIED, relatives, funeral homes and physicians of developed countries, as well as in physicians and potential recipient patients of developing countries.

Conclusions: This review highlights the positive perspectives on CIED donation from developed countries to patients in need of developing countries among all studied groups. In view of the feasibility of collecting postmortem devices, we advocate studying the feasibility of more local CIED donation initiatives.

KEYWORDS

developing countries, donation, implantable cardiac electronic devices, insights, reimplantation, reprocessing, reuse

1 | INTRODUCTION

Cardiovascular diseases (CVD) are one of the major causes of mortality, accounting for approximately 31% of all deaths registered worldwide.¹ Furthermore, they comprise an important cause of premature death,

disability and healthcare cost.² Although CVD mortality has decreased in recent decades, in developing countries they still are problem of great magnitude, since more than three-quarters of deaths from CVD occur in these countries.^{3,4} The non-existence of risk factor prevention programs, the lack of access to efficient and equitable healthcare

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services or their catastrophic costs are some of the reasons for the high mortality of CVDs in developing countries.^{3,5}

Among CVDs, bradyarrhythmias are a frequent clinical observation and include various cardiac rhythm disorders, such as sinus node dysfunction and atrioventricular conduction abnormalities.⁶ Bradyarrhythmias have a huge impact on the quality of life of patients, due to their low tolerance to exercise, persistent fatigue and recurrent syncope, symptoms that weaken more those living in the demanding conditions of developing countries.⁷ The only actual treatment for bradyarrhythmias in their persistent form is to stimulate the heart using a CIED, such as a pacemaker. CIEDs have shown to prolong life and improve its quality in patients with bradyarrhythmias.^{8,9} Even so, access to CIEDs is still limited worldwide due to the high cost of the devices, which many times exceeds the annual per capita income of individuals in developing countries.¹⁰ Thus, it is estimated that around one million people annually die in developing countries due to the lack of access to cardiac pacing therapy.^{11,12}

In recent years, the literature and interest regarding reprocessing used CIEDs as an alternative to new ones has increased.^{13–15} CIEDs are classified as single-use medical devices, and their reprocessing for reimplantation entails risks, for example, device infection or malfunction.¹⁶ However, in the most recent meta-analysis, no significant differences were found in terms of infection (OR 0.98; 95% CI 0.60–1.60), malfunction (OR 1.58; 95% CI 0.56–4.48), premature battery depletion (OR 1.96; 95% CI 0.81–4.72) or device related deaths between new and reused CIEDs.¹⁷ Therefore, due to the high cost of new devices, the reuse of used CIEDs appears to be a feasible and safe option, especially when the alternative would be not having any device at all.^{18–20} In the European Community there is no uniform policy regarding CIED reuse, while in Romania CIEDs are usually reused, the United Kingdom, France, Spain and Switzerland have published recommendations or prohibitions about reprocessing this type of products.^{21–23} Reprocessing CIEDs for reimplantation is not allowed in the United States either, due to the risk of infection.²⁴ However, there are no prohibitions on collecting used CIEDs and donating them to foreign countries where reutilization is permitted.⁷ For this reason, organizations such as “Project My Heart Your Heart” and “Project Pacer” in the United States (US) or “Stimubanque” in France collect used CIEDs donated by patients, hospitals and funeral homes and ship them to developing countries, so they can be reused in patients in need.^{25,26}

Many CIEDs still have adequate battery life and function when the carrier dies, so, postmortem donation is an important source for developing countries where patients cannot afford a new device.^{18,27} On the other hand, potential health risks and the ethical fact that patients with reprocessed CIEDs would receive a treatment that would not meet the quality standards of developed countries may raise different concerns.²⁸ Therefore, the present work aims to identify and synthesize the perspectives on CIED donation for reuse in patients without resources in developing countries, to contextualize the acceptability of these practices and explore the possibility of advocating for a local postmortem CIED donation initiative, similar to those existing in other countries.

2 | METHODS

A narrative bibliographic review was carried out between the months of January and April 2021 on PubMed, Web of Science and Scopus databases. Mesh terms such as “Pacemaker, artificial”, “Defibrillators, implantable”, “Equipment reuse” and “Public Opinion” were used, in addition to the following terms: “Pacemaker”, “Defibrillator”, “Cardiovascular Implantable”, “Implantable Pulse Generator”, “Reprocess*”, “Recycling”, “Reuse”, “Reutilization”, “Recovery”, “Cadaver*”, “Postmortem”, “Donation”, “Preference*”, “Perspective*”, “Views”, “Attitude*” and “Survey”. The search strategy was established by combining these terms by using parentheses and the Boolean operators AND and OR.

The search was limited to articles published in English or Spanish. The results were not limited in time in order to obtain a broader view of the study subject. Likewise, to avoid ruling out relevant articles, another search was carried out in specialized journals such as Circulation, Pace-Pacing and Clinical Electrophysiology, the Journal of Cardiovascular Electrophysiology or the open access repository Authorea. Finally, using snowball method, references of the articles included in this review were checked to verify if there were additional studies not included using the described search strategy.

All primary studies referring to the perspectives, preferences, attitudes and opinions of patients, general population, physicians, health-care personnel and industry and funeral industry on the reuse of CIEDs were included.

Publications focused on perspectives on other types of pathologies or surgeries, perspectives on deactivation of devices at the end of life, review articles, and grey literature were excluded.

The summary of the search strategy is shown in Figure 1.

3 | RESULTS

Eight publications responded to the objective of this review and were analyzed. The most relevant findings were classified into two main themes:

- Perceptions, preferences, attitudes and opinions of developed countries towards donation of CIEDs for reuse.
- Perceptions, preferences, attitudes and opinions of developing countries towards reception of reusable CIEDs.

Table 1 shows a summary of the most relevant characteristics of the studies analyzed.

- **Perceptions, preferences, attitudes and opinions of developed countries towards donation of CIEDs for reuse.**

Pacemaker manufacturers were surveyed in the 1980s regarding CIED reprocessing for reuse. Some of these companies responded that they routinely reprocess CIEDs whose packages had been opened,

TABLE 1 Main characteristics of the selected studies

Author, country and year	Methodology	Data collection method	Sample	Main results
Mahesh M, et al. US, 2018. ³⁰	Quantitative Descriptive cross-sectional study	Anonymous online questionnaire of 19 questions on knowledge and attitudes towards the reuse of CIEDs.	General population = 117 Healthcare personnel = 89 Funeral homes = 5	Most participants would be willing to consider the decision to donate a heart device. Ninety eight percent of the general population, funeral homes and 91% of health personnel were in favor of a mechanism to send CIEDs to patients without resources in developing countries. Most common concerns about CIED reuse were risk of infection or legality of the practice.
Hughey A, et al. International, 2014. ³²	Quantitative Descriptive cross-sectional study	Anonymous online questionnaire of 29 questions on attitudes and concerns towards the reuse of CIEDs.	“Heart Rhythm Society” members = 429	Eighty one percent of surveyed members would agree to ask their patients about donating their devices after their death. Eighty eight percent considered that sterilizing devices with appropriate battery was ethical, if it was proven to be safe. Eighty four percent would agree to implant a resterilized device in a patient who could not afford one, if allowed by law. The biggest concerns about CIED reuse were the risk of infection 64%, device malfunction 29%, ethical issues 15%, other 12% and religious 3.5%. Twenty two percent expressed no concerns about reuse.
Iyer IR, et al. US, 2013. ³⁶	Quantitative Descriptive cross-sectional study	Anonymous paper questionnaire for patients with CIEDs who attended hospital for device check.	Patients = 94	Seventy nine percent of surveyed patients indicated their preference towards donating their devices after their death. Eighty eight percent would be willing to sign an advances directives document through which they could indicate their preferences regarding postmortem handling of their device after death.

(Continues)

TABLE 1 (Continued)

Author, country and year	Methodology	Data collection method	Sample	Main results
Gakenheimer L, et al. US, 2011. ³¹	Quantitative Descriptive cross-sectional study	Anonymous paper questionnaires. Funeral directors completed a 34-question questionnaire on routine postmortem handling of devices and opinions about donation. Patients with CEIDs who attended hospital for routine device check completed a questionnaire of 30 questions on perspectives and opinions towards the postmortem donation of their devices for reuse. Questionnaires of 28 questions were collected in hospital waiting rooms, in order to collect opinions of the general population about the philanthropic reuse of the CEIDs	Funeral directors = 90 Patients = 114 General population = 1009	Eighty nine percent of funeral directors would be willing to donate the postmortem explanted CEIDs to patients without financial resources in developing countries. Eighty seven percent of surveyed patients with CEIDs would be willing to donate the devices to other patients without economic resources in developing countries. Seventy one percent of general population expressed their desire to donate devices to patients without economic resources in developing countries.
Logani S K, et al. US, 2011. ³³	Quantitative Descriptive cross-sectional study	Anonymous online questionnaire of 15 questions on attitudes and concerns towards the reuse of CEIDs.	"Heart Rhythm Society" electrophysiologists = 95	Ten percent of surveyed electrophysiologists indicated that they donated at least one device per year for patient reuse.
Hughey A, et al. Nicaragua, Pakistan, Ecuador and Lebanon, 2021. ³⁵	Quantitative Descriptive cross-sectional study	Anonymous paper questionnaire of 14 questions on opinions and attitudes towards the reuse of CEIDs to patients and relatives who were in hospital waiting rooms in the studied locations.	Nicaragua = 100 Pakistan = 493 Ecuador = 252 Lebanon = 100	Seventy eight percent of participants were unable to afford the cost of a new CEID. The majority of participants from the four countries had positive attitudes towards the reuse of implantable cardiac devices and would agree to receive a reconditioned device for themselves. Attitudes towards receiving a refurbished device remained positive even in the hypothetical scenario in which it carried higher risk of infection or malfunction.

(Continues)

TABLE 1 (Continued)

Author, country and year	Methodology	Data collection method	Sample	Main results
Kirkpatrick JN, et al. US, 2006, ³⁴	Quantitative Descriptive cross-sectional study	A telephone questionnaire of dichotomous questions, estimates, and opinions on the feasibility of routinely testing and returning explanted devices was made to funeral homes. Patients who went for routine check of their CIEDs answered a questionnaire about perceptions of routine disposition of postmortem devices and preferences regarding the disposition of their devices after death.	Funeral directors and morticians = 71 Patients = 150	Eighty one percent of funeral directors and morticians indicated that it would be feasible to analyze reusability of devices at the funeral home and 87% that it would be possible to remove all devices. Ninety one percent indicated that it would not be appropriate to remove the devices without consent from patient or family. Eighty two percent of the patients were unaware of how postmortem devices were handled, while 91% indicated their desire to have their device removed and donated to poor patients in developing countries after death.
Flink RC, US, 1985, ²⁹	Quantitative Descriptive cross-sectional study	Manufacturers responded a six-question questionnaire on reuse practices, estimations in number and percentages of reprocessed devices, and perception of obstacles to the reuse of CIEDs in the US.	Members of the pacemaker interest group of the "Health Industry Manufacturers Association" = 9	CIED manufacturers showed concerns related to health risks for patients and the responsibility of the remanufacturer, derived from the quality assurance of the reprocessing process, traceability and control of the necessary locations for a reutilization model; a morgue, central services and reprocessing. They also expressed concerns about the ownership of explanted devices and the need of an informed consent about the associated risk of a reprocessed device for the recipients.

Abbreviation: CIED, cardiac implantable electronic devices.

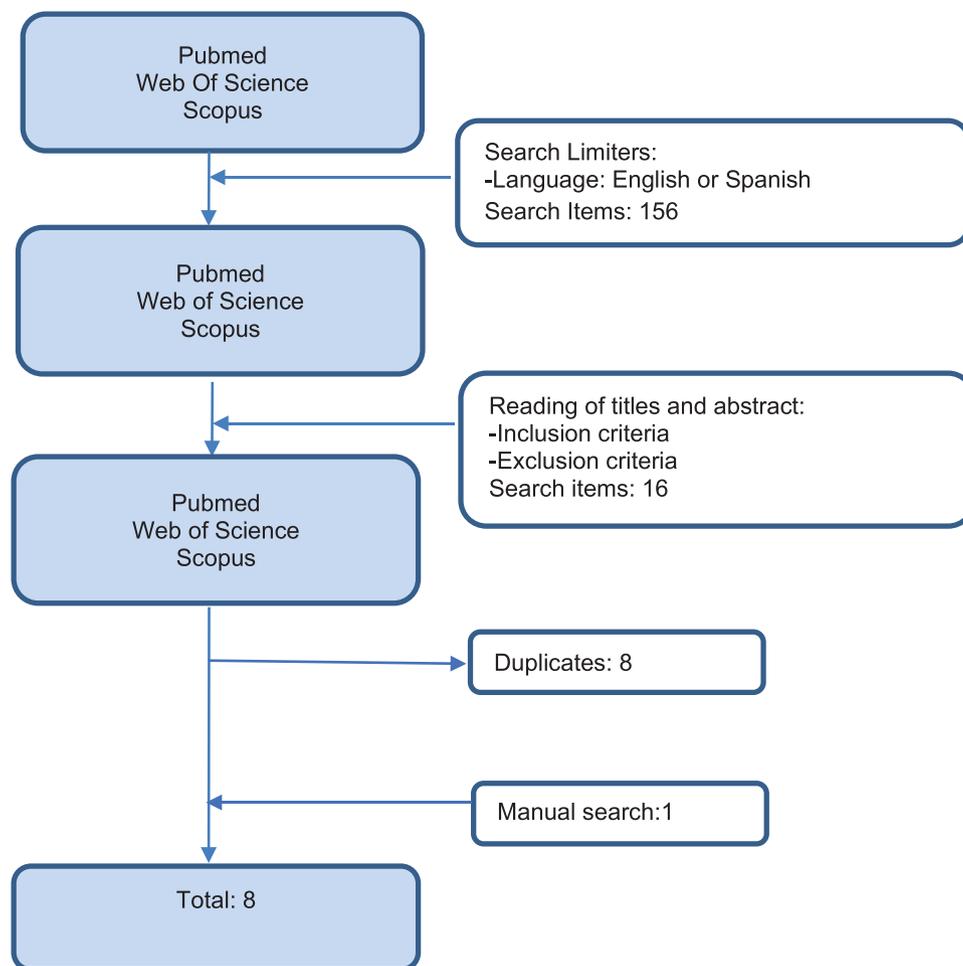


FIGURE 1 Study selection process [Color figure can be viewed at wileyonlinelibrary.com]

because they could guarantee quality control on the process, but not those that had already been in contact with a patient. Among the reasons for not reprocessing used devices, concerns related to the quality control of the devices were described; traceability and control of the devices during explanation and reprocessing, in addition to health risks of the potential recipient, due to the lack of security evidence at the time.²⁹

Nowadays, and due to the increase in evidence on safety, reutilization of explanted used devices is an alternative to consider.³⁰ With respect to the general population of developed countries, the majority are willing to consider the donation of an implantable heart device and are in favor on implementation of initiatives to donate reusable devices to patients without resources in developing countries, since they consider that it adds meaning to one's life.^{30,31} In the same way, general population with family members or friends who are cardiac devices carriers, shows more positive attitudes towards the donation of CIED.³⁰

As for healthcare personnel, the majority is in favor on reusing devices in people in need, believing that it is something that adds value to the main mission of their respective organizations.³⁰ A large number of electrophysiologists of developed countries support the concept of CIED reuse in developing countries, even a small number of profes-

sionals in the United States donate devices for reuse.^{32,33} Nonetheless, a large number of electrophysiologists also indicate concerns about CIED reuse, like; the risk of infection, device malfunction, religious or ethical issues and legality of the practice.³²

On the other hand, patients with CIEDs generally do not know how devices are handled after death.³⁴⁻³⁶ Stands out the observation that the vast majority wish to have their device explanted after death.³⁶ Furthermore, a large number of device carriers express wishes to donate them to patients without resources in developing countries after their death.^{31,34,36}

Regarding funeral professionals, approximately 18% of the surveyed indicate that they donate CIEDs to organizations dedicated to reutilization in developing countries. Likewise, the vast majority indicated that it would be feasible to interrogate and remove all the devices of deceased carriers, emphasizing in the importance of the corresponding consent to do so.³⁶ Another similar study also indicated that the majority of funeral directors in developed countries are willing to donate the devices they routinely explant to patients without financial resources in developing countries.³¹

- **Perceptions, preferences, attitudes and opinions of developing countries towards reception of reusable CIEDs.**

As for specialist electrophysiologists from developing countries, and in line with what was previously stated, they consider device reutilization a safe and ethical practice and a reasonable alternative when new devices cannot be accessed.³² The same study shows that if allowed by law, the majority would be willing to implant reconditioned devices in patients who cannot access a new one, in contrast with mentioned concerns about infection and malfunction.

Finally, potential recipient patients, and family members in developing countries, most of them unable to afford a new device are in favor of getting a reconditioned device, even if the risks of infection or malfunction of the reprocessed device are higher.³⁵ In addition, the majority indicated their willingness to donate their device or the device of a relative after death, so it could be reconditioned and reused in another patient again.

4 | DISCUSSION

CIED reuse is a life-saving initiative. It is profitable, consistent with the principles of beneficence, non-maleficence and justice with a commitment to the administration of resources and the common good.³⁷ However, CIED donation initiatives require participation of device carrier patients, their families, funeral industry, local authorities, specialists, and potential recipients.³⁵ This review synthesizes the studies carried out to date, underlining the social acceptability of donating postmortem explanted CIEDs from developed countries to developing countries, reprocessing and reimplanting them in patients who cannot access a new one.

In most developed countries, CIEDs must be explanted at funeral homes before cremation, due to the risk of explosion of the devices in the crematorium.^{18,27} The explanted devices have to be handled as biological risk waste, and reutilization is commonly not allowed locally, which means they are discarded.³⁸ Despite the fact that explanted CIEDs are discarded, a considerable number of explanted devices have shown to be reusable and could comprise a vital resource for other patients.¹⁰ On one hand, due to property rights, carriers or family members of a deceased carrier could claim the ownership of the implant once it is removed from the body.³⁹ On the other hand, even if reutilization of CIEDs is usually not allowed locally, nonprofit donation of used devices to developing countries is not prohibited.⁷ Therefore, this may open the door to the implementation of CIED donation initiatives in many developed countries.

For the implementation of a national CIED donation initiative, local regulatory aspects and property rights must be addressed.³⁷ It seems feasible to provide and get an informed consent document from patients or family members on hospitals and funeral homes, due to collected data in favor of reutilization.^{18,30-32,34,36} This consent, could imply the ownership transference of the explanted device to a reprocessing nonprofitable organization and set the legal framework for the donation process. CIEDs could then be explanted, primarily cleaned and shipped, following local medical waste regulations, to a the reprocessing organization.¹⁰ Collected devices could then be standardly

analyzed, reconditioned, cleaned and sterilized using a validated protocol and transferred to specific hospitals in developing countries for reimplantation.⁴⁰

Most common concerns raised by healthcare personnel and electrophysiology specialists and against CIED reutilization are the risk of infection and malfunction of reprocessed devices.^{30,32} Published systematic reviews and meta-analysis have shown that under rigorous protocols reutilization is safe in terms of infection, malfunction, battery depletion and mortality.^{17,19,41} Although reused CIEDs have been studied in several case series and cohort studies, no randomized controlled trials have been published to date.¹⁷ The randomized trial being carried out by the University of Michigan in Kenya and Sierra Leone may provide valuable data in this regard.⁴² However, actually and for previously mentioned reasons, CIED reuse should only be considered in situations where benefits outweigh potential risks and these are adequately informed to the recipient patient.^{28,43} Likewise, it is important to guarantee a quality reconditioning and traceability of reprocessed devices and a rigorous follow-up of patients who receive a reprocessed device.¹⁴ Therefore, implanting hospitals in developing countries must assure that reprocessed CIEDs are only offered to patients who cannot afford a new device, as well as informing them about the risks of reprocessed devices and collecting the respective informed consent before reimplantation.⁴³

Among the limitations of this review, it is worth noting the type of studies identified, since all of them are descriptive and do not allow a complete analysis of the subject under study. Another limitation is the location of the studies in developed countries, since most have been carried out in the United States. Therefore, in order to study the perspectives on CIED donation for reuse in greater depth, it would be advisable to continue research on this topic, for example with qualitative methodology. In addition, it is encouraged to describe the perspectives and opinions of patients, funeral professionals and health professionals in other developed countries where an CIED donation initiatives could be implemented, as they comprise key parts of the donation process.²⁶⁻²⁸

5 | CONCLUSIONS

The reuse of reprocessed CIEDs could allow many patients with bradyarrhythmias in developing countries receive a treatment that they lack nowadays. The results of this review highlight the positive perspectives of general population, device carrier patients, healthcare professionals, electrophysiologists and funeral industry on the donation of used devices to developing countries. Potential recipient patients also have favorable opinions towards used and reconditioned devices. In view of the feasibility of collecting postmortem explanted devices from developed countries, local models of CIED donation initiatives are encouraged.

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CONFLICT OF INTEREST

None

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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