

A Community Level Sample Survey to Determine Current Understanding About Medical Recycling of Cardiovascular Implantable Electronic Devices

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Abstract

Background: Medical recycling and reutilization of cardiovascular implantable electronic devices (CIEDs) have a significant impact not only in patients of low-income countries but may also in certain patients in the United States who do not have sufficient medical insurance coverage. The main determining factor for future utility and popularity of recycled medical devices is thorough understanding about this topic amongst public and healthcare professional. To the best of our knowledge, there has been no study conducted so far at a community level to determine the understanding in public and healthcare personnel about recycling of medical devices including CIEDs. We sought to determine existing knowledge and attitude about recycling of CIEDs amongst representative sample population in a community.

Methods: A questionnaire was sent for online completion to multiple people in the community, healthcare and funeral home in Lehigh Valley, Pennsylvania, USA. The questionnaire was designed in order to assess three main categories; knowledge, attitude and practice. We called this a KAP study which is an acronym for knowledge, attitude and practice survey.

Results: We got 117 responses to our questionnaire from community members (55.45%), 89 responses (42.18%) from the healthcare personnel and five responses (2.37%) from funeral homes. About 30.77% community participants had heard about medical devices recycling compared to 57.30% participants from healthcare sector. A total of 88.64% of medical professionals were aware that there are people in the world who die because they cannot afford CIEDs while 73.50% of community participants were also found to be aware of this fact. Higher percentages of healthcare professionals were found to be willing to personally consider a decision about medical device donation compared to community participants.

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Conclusions: CIED reutilization can improve quality of life among many patients with low or medium socioeconomic status. People should be made more aware about the benefits of CIED reutilization. Concerns about device-related infections, complications and law suits should be addressed to help improve their utility.

Keywords: Medical device recycling; Cardiovascular electronic implantable devices; Sample survey; Quality of life

Introduction

With technological advancement in healthcare industry, there is an increasing need of systematic disposal of old medical devices. In cases of medical devices that can be sanitized and verified for significant functionality, the concept of reuse for the benefit of low- and medium-income communities, who are neither able to afford medical insurance nor able to buy such devices, can be of tremendous help. This concept of medical recycling has been found to be promising in cases of cardiovascular implantable electronic devices (CIEDs) explanted from a deceased person as evident in multiple studies published previously [1-3]. Permanent pacemakers (PPM) and implantable cardioverter defibrillators (ICD) are primarily referred to as CIEDs. Their recycling and reutilization can make a significant impact in terms of health-related quality of life and longevity of the patients suffering from cardiovascular diseases [1, 4]. An ICD generator may cost between 20,000 US dollar (USD) and 40,000 USD while a PPM can cost 2,500 to 3,000 USD on an average [1]. The average costs of CIEDs exceed the per capita annual income of most of the people living in low- and middle-income countries [5]. Thus, medical recycling and reutilization of CIEDs can have a significant impact not only in patients of low-income countries but also in certain patients in the United States (USA) who do not have sufficient medical insurance coverage. This can also decrease cost of healthcare in the USA that is spiraling out of control. According to a study published in 2015, the total health care cost of patients undergoing revision of CIED itself was approximately 185 million USD between 2004 and 2014 [6]. The main determining factor for future utility and popularity of recycled medical devices is thorough understanding about this topic amongst general public and healthcare professional. To the best of our

Table 1. Questionnaire Used for Survey

- 1 Before beginning this survey, have you heard the term “medical device recycling” and/or “medical devices recycling?”
- 2 Do you have any medical devices implanted in you like pacemaker or implantable cardioverter defibrillator?
- 3 Do you know any family members or friends that have medical devices implanted in them like pacemakers or defibrillators?
- 4 On review of it is that these devices could potentially be removed after death and donated to other people?
- 5 Before this questionnaire, were you aware that there are people in the world who die of heart diseases because they cannot afford pacemakers or defibrillators?
- 6 On a scale of 1 - 5, how likely are you to personally consider/influence a decision about medical donation?
- 7 Do you think participation in medical device donation adds meaning to one’s life?
- 8 Do your beliefs (religious or otherwise) potentially disallow you from participating in device donation?
- 9 In your mind, what is the most important concern about medical device donation?
- 10 What do you think mostly happens to these medical devices?
- 11 Roughly what percentages of it do you think are trashed?
- 12 Roughly what percentages do you think that given to other people in need?
- 13 If there was a mechanism where medical devices and/or devices could be donated legally to poor and needy people overseas, would you be willing to spread the word and/or participate in the same?
- 14 If there was a mechanism where medical devices and/or devices could be donated to needy people locally in the community, would you be willing to spread the word and/or participate in the same?
- 15 Do you think participation in device donation adds meaning to your organization’s core mission?
- 16 Would the hospital or healthcare organization you associate with be willing to potentially implement a program of post-mortem CIED donation?
- 17 Would the hospital or healthcare organization you associate with be willing to potentially implement a program of post-mortem CIED donation?
- 18 Would your organization’s beliefs and values potentially disallow you from participating in device donation?
- 19 We would welcome your additional input on the topic. Questions? Ideas? Thoughts? Concerns?

knowledge, there has been no study conducted so far at a community level to determine the understanding in general public and healthcare personnel about recycling of medical devices including CIEDs. In this study, we sought to determine existing knowledge and attitude about recycling of CIEDs amongst representative sample population in a community. We also aimed to determine factors affecting current attitude towards this approach and main concerns about reutilization of CIEDs.

Materials and Methods

A questionnaire was sent for online completion to multiple people in the community, healthcare and funeral home in Lehigh Valley, Pennsylvania, USA. The questionnaire was designed in order to assess three main categories; knowledge, attitude and practice. We called this a KAP study which is an acronym for knowledge, attitude and practice survey. This survey intended to assess baseline knowledge, measure attitude and recognize any barriers to practice. Questionnaire had common set of questions as well as those modified to suit the nature of the responder given the fact that the participants were both healthcare professionals and community members. Categorical data obtained in the study have been presented as frequencies and/or percentages. Where ever applicable, P-value was calculated by t-test and a P value of < 0.05 was considered statistically

significant.

Questionnaire used for survey

Table 1 shows the questionnaire used for survey.

Results

There were totally 211 respondents in the survey. All the participants in the survey were more than 18 years in age. We got 117 responses to our questionnaire from community members (55.45%), 89 responses (42.18%) from the healthcare personnel and five responses (2.37%) from funeral homes. Amongst the healthcare professionals, 59 (66.29%) were physicians, 11 (12.36%) were healthcare administrators while 19 (21.35%) were non-physician healthcare providers. About 30.77% community participants had heard about medical devices recycling compared to 57.30% participants from healthcare sector (Fig. 1).

Only 1.71% of healthcare professionals were found to have CIEDs implanted in them compared to 14.61% participants from community and funeral homes. Totally 41.88% of community participants group had family members or friends with CIEDs compared to 80.90% of health professionals.

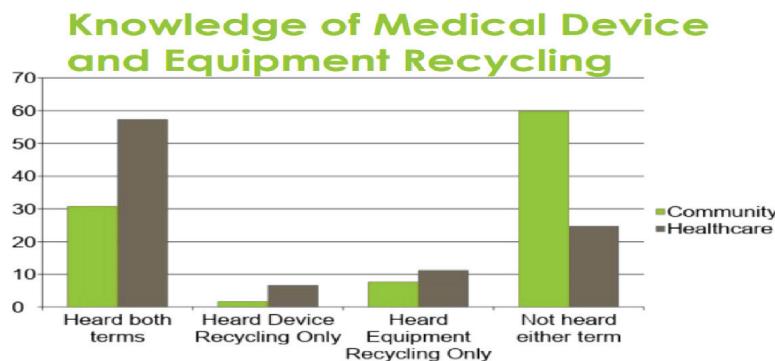


Figure 1. Bar diagram showing comparative responses about pre-existing knowledge about medical device and/or medical devices recycling among responders from community (including funeral homes) versus healthcare personnel.

There were 51.69% of medical professionals said they were aware that CIEDs could potentially be removed after death and donated to other people compared to 20.51% of non-medical professionals; and 88.64% of medical professionals were aware that there are people in the world who die because they cannot afford CIEDs while 73.50% of community participants were also found to be aware of this fact. Higher percentages of healthcare professionals were found to be willing to personally consider a decision about medical device donation compared to community participants (Fig. 2a,b).

There were 78.63% of community participants who thought that participation in medical device donation adds meaning to one's life while 67.42% of medical professionals agreed that device donation adds meaning to their organization's core mission. About 13.48% of healthcare professionals believed that hospital or healthcare organizations that they were associated with would be willing to potentially implement a program of post-mortem CIED donation and 20.22% only believed that their values would potentially disallow them to personally participate in CIED donations. Only 2.59% of non-medical participants in the survey believed that their religious or any other beliefs would disallow them to participate in device donation. The most common concern about CIED donation amongst both the groups was "risk of infection" followed by "potential lawsuits due to

device malfunctions." All 89 participants amongst medical professionals responded to this question but only 115 participants amongst community/funeral homes responded to this question. All the responses to this question are summarized in Table 2.

Twenty-six healthcare professionals (29.55%) estimated that around 60-80% of medical device and devices are trashed while one did not choose to answer this question. Thirty-four non-medical professional participants in the survey (29.31%) estimated that around 60-80% of medical device and devices are trashed. Most healthcare professional (53%) estimated that around 2-10% of devices are given to other people in need while most community/funeral homes participants (50.44%) estimated that 10-50% of these devices are given to people who were actually in need. A total of 83 (93.26%) of healthcare professionals preferred the medical devices to be donated to people in need within the community and similar results were obtained amongst community participants as 113 out of 117 total responders to this question (96.58%) opted for local donation (Fig. 3). Notably, 90.91% of healthcare professionals and 97.44% of total community/funeral homes participants were found to be in favor of a sound mechanism to deliver CIEDs to poor and needy people overseas and were willing to spread the word and/or participate in the same. It was also noticed that people that their family/friends with implantable cardiac de-

1. NOT AT ALL.	2. NOT LIKELY BUT THERE IS A POSSIBILITY	3. NOT SURE. UNDECIDED.	4. LIKELY BUT NOT ONE HUNDRED PERCENT CONVINCED.	5. INCOMPLETE SUPPORT.	TOTAL	WEIGHTED AVERAGE
2.56% 3	6.84% 8	15.38% 18	18.80% 22	56.41% 66	117	1.00

a

1. NOT AT ALL.	2. NOT LIKELY BUT THERE IS A POSSIBILITY	3. NOT SURE. UNDECIDED.	4. LIKELY BUT NOT ONE HUNDRED PERCENT CONVINCED.	5. INCOMPLETE SUPPORT.	TOTAL	WEIGHTED AVERAGE
0.00% 0	6.74% 6	15.73% 14	14.61% 13	62.92% 56	89	1.00

b

Figure 2. (a) Response among community participants about how likely they are to personally consider/influence a decision about medical device donation (on a scale of 1 - 5). (b) Response among healthcare professionals (lower table) about how likely they are to personally consider/influence a decision about medical device donation (on a scale of 1 - 5).

Table 2. Concerns About CIED Donation

Answer choices	Responses by healthcare professionals	Responses by community members
I am concerned about disfiguring one's body after death	4 (4.49%)	8 (6.96%)
I am concerned about risk of infection	40 (44.94%)	57 (49.57%)
I think this may be illegal	9 (10.11%)	3 (2.61%)
I think there may be potential threat of lawsuits in device malfunctions	39 (43.82%)	25 (21.74%)
I have no concerns	26 (29.21%)	0
Multiple above concerns	11 (12.36%)	22 (19.13%)

vices are more likely to be positive in that support for medical recycling 93.88% compared to those people who did not have a family member or friends with such devices (79.141%) ($P < 0.05$). About 9.09% of healthcare administrators were willing to implement the medical device recycling in their respective institutions despite their appreciation about the idea *per se*.

Discussion

Reutilization of CIEDs is a very feasible option and a great source of healthcare resource for underprivileged communities. Postmortem extraction of CIEDs is a prime source of explanted devices for reutilization [1]. In the United States, around 225,000 PPMs are implanted every year [5] and these devices have average longevity of 11.2 ± 2.6 years [7]. It has been estimated that around 85% of deceased with CIEDs are buried without getting these devices removed [3]. According to a study in 2012, funeral homes in Michigan were able to collect 3,176 devices, out of which 21% had good battery life [8, 9]. Thus, there are feasible options to obtain CIEDs for the purpose of recycling and utilization. In spite of this feasibility, awareness regarding the benefits of recycled CIEDs is low in our community as evident in our sample study. Even amongst people who know about reutilization of CIEDs, there exist a disparity between belief and implementation. As seen in our study as well, over 90% of participants were found to be personally supporting

medical recycling and around 55% think that medical recycling is in line with their organization's score mission but only 9% out of these want to definitely support implementation in their hospitals. The main concerns among healthcare professionals and community members regarding implementation of medical recycling of CIEDs are infections and malfunctions related to the devices. Several studies have shown that reutilization of CIEDs do not actually increase the risk of infection or mortality in comparison to newer surgical implantation of device. As per a meta-analysis regarding reuse of PPMs performed on a pooled data of 2,270 subjects, there was no significant difference in infection rate between recycled PPMs and new ones [9]. The concern for legal lawsuit due to malpractice associated with CIEDs is higher among healthcare professionals. To increase the popularity of medical recycling and negate the fear of increased infection risk and malpractice suits, there is a need for standardized disinfection process for recycled devices that is approved and accepted by a governing legal body. There has to be a formal process to re-certify these devices and devices. The United States Food and Drug Administration (US-FDA) considers CIEDs as single-use devices and thus views it as an objectionable practice to reutilize them [10]. Since there are no federal laws to address the ownership of CIEDs after a patient's demise, there is no definite individual or company who can solely lay claim to explanted CIEDs [11]. Thus, an advanced directive outlining the patient wishes about reutilization of implanted cardiac devices has been suggested by some authors to help guide funeral homes in the process of retrieving CIED for the purpose of donation. Efforts have to be made to convince people that there is nothing illegal about medical recycling and subsequent reutilization of devices like CIEDs. Awareness regarding these issues can be made more rampant with help of larger group of volunteers who can spread the message effectively. Electronic media, websites dedicated to medical device recycling and education tools like brochures and pamphlets can be utilized to spread the message. The concern about supporting medical recycling overseas can be minimized by standard device procurement, re-implantation and follow-up process.

Overall Attitudes

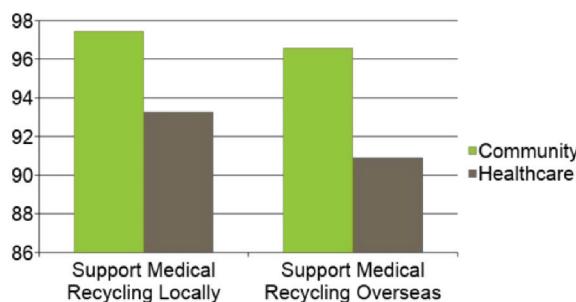


Figure 3. Both healthcare and community level participants in the survey heavily preferred the donation of medical devices to local people over sending them to foreign countries.

Reutilization of medical devices like CIEDs is a noble cause which has widespread support of both community people and

healthcare personnel. It is very feasible to obtain CIEDs from a deceased person and this can improve the quality of life of many patients. However, there remain some concerns, mainly infection and legal concerns among healthcare administrators which we should address before implementing this on a large scale.

Conflict of Interest

The authors declare no conflict of interest.

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