Cadaveric Donation and Post-mortem Reuse of Pacemakers and Defibrillators in Nepal: Medical, Legal and Ethical Challenges

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ABSTRACT

Cardiovascular diseases (CVDs) are the number one cause of death globally. An estimated 17.5 million people died from CVDs in 2012, representing 31% of all global deaths. Over three quarters of all deaths related to CVDs take place in low- and middle-income countries (LMICs). Studies have estimated that 1 to 2 million people worldwide die each year due to lack of access to cardiac rhythm management devices (CRMDs) i.e. implantable cardiac defibrillator (ICD) or pacemaker. The principal challenge is the high cost of these devices and the resource constraint in LMICs. A growing body of literature, mostly single center, uncontrolled and retrospective studies has suggested reuse of CRMDs from deceased donors as a safe and effective alternative. This paper seeks to propose the concept of post-mortem CRMD donation and reutilization program within Nepal as a life-saving initiative. Though the spirit of the program is in line with the ethical principles of respect for persons, beneficence, justice, and the common good, it is challenged with several logistical barriers and legal concerns. In this paper we have discussed the clinical, legal and ethical perspectives with a literature review on similar programs.

INTRODUCTION

According to the World Health Organization Cardiovascular disease is the number one cause of death globally. An estimated 17.5 million people died from CVDs in 2012, representing 31% of all global deaths and over three quarters of CVD related deaths take place in low- and middle-income countries (LMICs). There is high prevalence of CVDs including conduction system diseases in LMICs but the access to cardiac rhythm management devices (CRMDs) i.e. pacemaker and defibrillator is often limited. The 2009 World Survey of Cardiac Pacing and Cardioverter-Defibrillators found a rate of new pacemaker implants in the United States, Canada, and Western Europe of over 380 per million populations (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 can be explained in part by the cost of device and socio-economic situation of the developing world. The cost of a bradycardia pacemaker in its basic form in India varies from INR 60,000/- to 1.5 lakhs; the implantable cardioverter defibrillators (ICD) cost from INR 2 lakhs to 5...
lakhs, the bi-ventricular pacemakers from INR 2.5 to 7 lakhs (COMBO devices) in India\(^4\) (equivalent cost in US dollars are $600 to 1500 US $ 2000 to $ 5000 to $ 2500 to 7000). This cost can be prohibitive to many given Nepal’s GDP per capita of USD 732.00\(^5\), and more importantly because there is no uniform policy of insurance and re-imbursement. This cost can be prohibitive to many given Nepal’s GDP per capita of USD 732.00\(^5\), and more importantly because there is no uniform policy of insurance and re-imbursement. Moreover, a country like Nepal with their limited health care budgets does not have or cannot afford the expense of providing devices for free or at a subsidized rate. In this context reuse of CRMDs from deceased donors may serve as a feasible and cost effective option. The reuse of devices has been in practice for many years\(^1,4,5\). Several charity organizations in the west like My Heart Your Heart, Pace4Life are involved in harvesting CRMDs from deceased donors through funeral homes, hospitals, clinics, physicians, and distributing them to LMIC for reuse. One such organization has distributed more 10,000 pacemakers to the needy in LMIC since 1984 (Heartbeat International website, http://www.heartbeatintl.org). A growing body of literature, mostly single center, uncontrolled and retrospective studies has suggested reuse of CRMDs as a safe and effective option. The thesis of this paper is to propose the concept of post-mortem CRMD donation and reutilization program within Nepal as a life-saving initiative. Though the spirit of the program is in line with the ethical principles of respect for persons, beneficence, justice, and the common good, it is challenged with several logistical barriers and legal concerns. In this paper we have discussed the medical, legal and ethical perspectives along with a review of literature on reuse programs in similar socioeconomic circumstances.

**SOURCE OF DEVICE AND ITS REUSE:**

One of the largest sources of CRMDs in Nepal can be postmortem donation. Although survival rates after device implantation vary with population characteristics, European studies have reported 4-year mortality rate for patients with pacemakers being as high as 40%\(^6\). Based on this data, pacemakers can have upward of 5 years of function left when patients die (assuming a standard battery longevity of 5 to 10 years). Implantable Cardioverter Defibrillator (ICD) battery life varies, as 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. According to the European Society of Cardiology, reuse of biventricular pacemaker and defibrillator can be further complicated for other reasons\(^5\). Programming these devices and its follow up can be complex and there is considerable concern for inappropriate shocks. Moreover, defibrillator and left ventricular pacing leads are more expensive than pacemaker leads. ICD and biventricular device can still be used as simple pacemakers if their alternative functions are deactivated.

Most of the device reuse programs have used devices acquired from deceased donors in the West through charitable organizations\(^4,5\). Starting an indigenous program with deceased Nepalese subjects as donors and underprivileged Nepalese patients as recipients would require designing the structure and process from the scratch. Nearly 200 implantable electrophysiological devices are implanted in Shahid Ganga Lal National Heart Center annually. In recent years there has been a surge in centers capable of performing interventional electrophysiological procedures. Thus, the number of procedures and patients living with devices will increase in years to come. This bodes well for the feasibility of a cadaveric pacemaker donation program in Nepal. One of the initial hurdles would be acquiring the device from the donors and convincing the patient and family to donate the device after death. In the Western medical literature, there is a lot of emphasis on advance directives in regard to end-of-life decisions. A similar model can be undertaken in Nepal to decide the fate of the devices, 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 device recovery and reuse after death.

As a general rule, CRMDs must be explanted prior to cremation to prevent explosion during cremation. A physician or a mid-level health provider can easily remove it from the deceased for the deaths occurring at a healthcare facility. However, for deaths occurring at home or in the community a pacemaker donor card, a telephone hotline and a pacemaker retrieving crew can be useful. Patients and family members may derive a sense satisfaction from donating life-saving devices after death.

**CLINICAL CONCERNS AND LITERATURE REVIEW:**

According to the manufacturers, CRMDs are single use devices. Such devices are not intended to be disassembled, cleaned, reassembled, and reused\(^10\). Doing so may jeopardize its physical and/or chemical integrity, performance, safety, and effectiveness\(^10\). However, it is estimated that nearly 1 to 2 million people die annually in the developing world due to lack of access to the pacemakers\(^11\). This gap can be effectively bridged by reuse of devices and such practice in India is well acknowledged by the Western published literature\(^9\).
A growing body of evidence show that resterilized devices are safe for reuse, with nominal increase in risk of infection, mortality or difference in safety and efficacy compared to new device implantations. Kantharia et al. assessed the reuse of donated pacemakers (n = 121) acquired from funeral homes in the United States and implanted in patients in Mumbai, India. Improved quality of life without any significant complications (infections or device malfunction/failures) was reported over a mean follow-up of 661 days. Similarly, Pavri et al. described a consecutive series of 81 patients who underwent implantation of 106 properly sterilized ICDs acquired either postmortem or during device upgrades. Reuse of ICDs (with more than 3 years of estimated remaining battery life) had reported association with appropriate therapy (shocks or antitachycardia pacing) in 54.3% of patients. Shocks delivered by those reused ICDs were life-saving. No infectious complications occurred during a mean follow-up of 825 days, and there was no malfunction related to the reused device. In a recent 6-month outcome analysis of patients who underwent implantation of a new or reused pacemaker, ICD, cardiac resynchronization therapy device in 5 years (n = 887 of which 260 devices were reused) at JIPMER, Puducherry, no difference in rate of infection, device malfunction, or device-related death was observed as compared to those with a new device. It is important to note that none of these three studies had control arms.

Nava et al. had a better study design with study and control group. They presented data on 603 consecutive patients in an ambispective noninferiority study. The study group patients (n = 307) received resterilized pacemakers, 96% of them from cadaveric donation, and the control group patients (n = 296) received a new pacemaker. A combined end point of three major outcomes, unexpected battery depletion, infection, and device malfunction was reached in 5.5% in the control group and 7.2% in the study group (P = 0.794). Five new pacemakers (1.7%) and 11 resterilized pacemakers (3.6%) had unexpected battery depletion (P = 0.116); 3.7% new pacemakers and 3.2% reused pacemakers had a procedure-related infection (P = 0.466); and one pacemaker in the study group malfunctioned. The authors concluded that other than the expected shorter battery life, reuse of pacemaker generators was not inferior to the use of new devices.

Feng et al. reported a study on patients (n=212) treated for CRMD infection at the Peking University People’s Hospital, Beijing, China. This study addressed the concerns regarding device infection after sterilization. In the study, all the patients underwent a removal of their CRMD. 113 patients could afford and underwent implantation of a brand new CRMD (control group). 99 patients underwent reimplantation of the infected device after cleaning and resterilization (study group). The primary end point in the study was a composite of infection, unexpected battery depletion, or device malfunction, and was reached in 10 patients and five in the study group and five in the control group. Recurrent infection occurred in 3 patients in the study group and 2 patients in the control group (3.0% vs 1.7%; relative risk, 0.96; 95% confidence interval, 0.35–2.03; P = 0.561). There was no premature battery depletion in either group. 5 patients experienced device malfunction high pacing threshold and/or failure to sense two of them were in the study group and three in the control group. This study is a valuable addition to the growing body of evidence supporting CRMD reuse. A meta-analysis of 18 studies (n = 2270 patients) with reused devices reported an infection rate of 1.97% and device malfunction rate of 0.68%, further highlighting the safety profile of these devices.

In spite of the growing body of evidence, it is pertinent to emphasize that none of these studies are randomized; the assignment into the treatment group was made based on the patient’s inability to afford a new implant. Though studies thus far have shown reimplantation of CRMD as a safe and effective option, there is still need for further studies, including a prospective multicenter trial, using a standardized device sterilization protocol. Considering the pronounced public health potential, we cogitate results of the studies and advocate the prospect of a similar project in Nepal.

DEVICE SELECTION AND STERILIZATION:

Devices should only be considered for reuse if the previous clinical record has been reliable, without any documented malfunction, and it has an adequate remaining life often arbitrarily set at more than 4–5 years or cutoff of more than 70% battery life. Reuse should be avoided when the device has been recovered from a patient who has died suddenly (since in such cases device malfunction cannot be ruled out with certainty). Adequate sterilization of the device with removal of all protein material is necessary before reuse. It may be difficult if the device is grazed or cracked. Reuse of such devices should be avoided.

After an appropriate and careful selection of the device, it should be reserialized. Several sterilization techniques have been described. Feng et al. described their protocol as following extraction, CRMDs were placed in a solution of 70% ethanol for 30 minutes, then washed with pipe cleaners and other instruments to make sure that all debris was removed from the orifices of the devices. Basman et al. in University of Michigan described a protocol with debris removal by
constraints. It is important to note that there are no laws or world, reuse products marketed as SUD is a very common
in Nepal. The dearth necessity in LMICs is far beyond the complication rates in studies done, similar to our proposal
The greatest concern of the FDA is safety and the possible
level of the European Union (EU) resulting in heterogeneous
practice of reprocessing SUDs is not presently regulated at the
reprocessing of SUDs under a regulatory framework
for reprocessing SUDs, which has brought commercial
facilities were reprocessing SUDs in an in-house unit
According to Canadian survey 25% of Canadian healthcare
in other parts of the developed world are more flexible.
Another logistical challenge lies in the fact that leads cannot
be reused due to difficulty in ensuring sterility and mechanical integrity17. Manufacturers, however, donate thousands of
expired leads to charity organizations each year. It did not pose
much logistical challenge in an experience at the Philippines
General Hospital, as most families were able to afford low cost
leads manufactured in India.19 This may not completely apply
to Nepalese scenario and need-based financial aid program
may be necessary for smooth operation of the program.

LEGAL CHALLENGES:

Pacemakers, ICDs, and biventricular pacemakers are packaged
and sold as single-use devices (SUD). In lieu of this, the United
States Food and Drug Administration (FDA) mandate that they
be used as such. Its policy states that the reuse of pacemakers
is an objectionable practice20. However, legal restrictions
in other parts of the developed world are more flexible.
According to Canadian survey 25% of Canadian healthcare
facilities were reprocessing SUDs in an in-house unit21. Recently
there is an ongoing advocacy for federal regulatory oversight
for reprocessing SUDs, which has brought commercial
reprocessing of SUDs under a regulatory framework21. The
practice of reprocessing SUDs is not presently regulated at the
level of the European Union (EU) resulting in heterogeneous
practices throughout Europe.
The greatest concern of the FDA is safety and the possible
risk of infection. We have already reviewed the infection and
complication rates in studies done, similar to our proposal
in Nepal. The dearth necessity in LMICs is far beyond the
regulatory quagmire of the developed world. In the developing
world, reuse products marketed as SUD is a very common
practice due to shortage of medical supplies and financial constraints. It is important to note that there are no laws or
a regulatory framework ensuring quality, safety and efficacy
of reused devices in Nepal. The authors of this paper strongly
advise the governmental agencies in Nepal to lay down norms
concerning regulation of SUDs and product handling standards
for medical devices.

Donation and reuse of CRMDs involve explantation of devices
from the deceased. It may raise several legal queries like
ownership of the device after death and laws pertaining to
handling of human remains. It also involves reimplantation of
a device from a deceased subject into a living individual which
further raises ethical concerns.

Provisions for a “pacemaker/defibrillator living will” can be
made to decide the fate of the device and solve legal and ethical
quandaries at the donors’ end. Also the patient receiving the
donated device should be clearly 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.” Norms
should be laid down to formalize a chain of custody of these
procedures. These issues fall beyond the scope jurisdiction of
human organ transplant act of Nepal22. A formal legislation
would be necessary to facilitate and legitimize reuse of CRMDs
especially in the currently evolving litigious climate.

ETHICAL JUSTIFICATION:

The proposed CRMD reuse in Nepal can be justified, based
on the ethical principles of respect for persons/autonomy,
beneficence, justice and Common Good.

Respect for persons entails the right of a person to freely
exercise self-determination, and to be treated with
fundamental dignity and respect. The principle of respect for
persons has two integral but separate moral requirements: the
requirement to acknowledge autonomy, and the requirement
to protect those with diminished autonomy23. In other words,
to respect autonomous agents is to acknowledge their right
to hold views, to make choices, and to take actions based on
their personal values and beliefs24. Thus, respect for persons
with implantable devices, presupposes either a pre-mortem
consent of the donor, or post-mortem consent of the family
to donate the device. Similarly, respect for the autonomy
of the recipients demand that they be given all the relevant
information needed, to make informed decision on whether to
accept the refurbished devices or not. They have the right to
know that the device they are receiving is used and not being
fully deployed according to manufacturer’s recommendations,
and that there may be unknown risks associated with the
reused devices25. Anything short of full disclosure of the
possible risks and benefits of receiving the device violates the principle of respect for persons, and the informed consent process.

In addition, the principle of beneficence entails the moral obligations to confer benefits and to prevent, remove, or minimize harm and risk to others. It also incorporates weighing an action’s possible good against its costs and possible harms\(^26\). Beneficence, whose focus is the promotion and enhancement of the good of others, encompasses nonmaleficence, which specifically prohibits the infliction of harm, injury, or death upon others. This ethical principle traces its roots to the Hippocratic Oath that stipulates, “Above all, do no harm” (primum non nocere). In clinical practice and biomedical research, this principle demands that as moral agents, physicians have an ethical responsibility to treat their patients in a way that will maximize benefits and minimize harm. Allowing sick persons in Nepal to endure the pain and suffering of CVDs that could be relieved with refurbished CRMDs, violates the principle of beneficence. Multiple studies cited in this paper, show that CRMDs are not only safe and effective, but also patients who receive them have a better quality of life than those without them. The risk-benefit calculus demands that the potential benefits of any procedure, be weighed against its risks and disadvantages. With regard to this proposal, scientific evidence indicates that the benefits of having a refurbished device outweigh the risks associated with having it. In essence, the lives of thousands of Nepalese who die annually due to lack of CRMDs would be saved when this initiative is implemented. Failure to deploy this proven and effective alternative, to help the suffering patients in Nepal, violates the duty we have, both as a society and a medical community, to prevent or minimize harm. Furthermore, the cost effectiveness of refurbished CRMDs makes it a moral imperative to consider. As indicated above, the cost of a new pacemaker or ICD is beyond the reach of many patients in Nepal, and without a uniform insurance policy and limited health care budgets, many CVDs patients would succumb to their diseases. But the reuse of CRMDs from deceased donors would not only save lives, but also free up scarce medical resources and finances needed to combat other diseases in Nepal.

Furthermore, the principle of justice recognizes that each person should be treated fairly and equitably, and be given his or her due. Distributive justice requires that everyone receives equitable access to the basic health care, which is necessary for living a fully human life\(^27\). It also demands the fair and equitable distribution of medical resources in society. The disparity in the treatment of CVDs between developed nations and LMICs such as Nepal is huge. These disproportionate mortality statistics for CVDs patients is traceable to endemic infectious diseases that contribute to escalating rates of heart diseases, as well as the fact that poor nations have not been able to afford the electrophysiology technology, that has reduced cardiac deaths in developed countries\(^28\). Justice demands that viable alternatives be considered, to stem CVDs-related deaths of 1 to 2 million people annually from LMICs. Reuse of CRMDs has been proven to be safe and effective. Failure to initiate this life-saving measure of recycling what would ordinarily be “medical wastes,” to improve the quality of life of CVD patients in Nepal, is a violation of the principle of distributive justice.

Finally, we all have an obligation to care for the Common Good of the society. Thousands of Nepalese, who suffer from CVDs and cannot afford CRMDs, gradually become less productive, until they finally succumb to the disease. When individuals who should contribute to the welfare of the society fail to do so due to the burdens of CVDs, the Common Good is imperiled.

The inability of underprivileged patients to afford CRMDs not only leads to premature mortality, but greatly impacts an individual’s ability to function, due to poor exercise tolerance, persistent fatigue, and recurrent syncope - symptoms that can debilitate those living in demanding environments, in the developing world\(^29\). The annual death of an estimated one to two million people due to lack of CRMDs not only deplete the population of these countries, but also negatively affects the economy. Care and concern for the Common Good of all Nepalese, demand that CRMDs be harvested from deceased donors and reused for sick Nepalese patients, guided by informed consent. This safe and cost effective initiative will prevent premature deaths of these patients, improve their quality of life, and promote the Common Good, by making them productive members of the society.

**CONCLUSION:**

Donation and reuse of CRMDs can have a significant impact on individual lives in Nepal. Programs like this done on a multinational scale may reduce the global disparity in outcomes in CVDs. Based on the experiences from India and the developing world reviewed in this paper, a similar program may be feasible in Nepal. However, the program must be guided by procedural details pertaining to meticulous chain of custody, standardized sterilization technique, informed consent, patient education, and adequate follow up. An advance directive crafted as “a pacemaker/defibrillator living will” becomes a *sine qua non* in deciding the fate of the device after death. Furthermore, creation of a device donor registry may be essential in addressing ethical and legal concerns. All of these would require appropriate legislation and support from
governmental agencies to ensure quality and safety.

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List of Abbreviations:

CVD: Cardiovascular Diseases

CRMD: Cardiac Rhythm Management Devices

ICD: Implantable Cardioverter Defibrillator

LMIC: Low and Medium Income Countries