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

Yub Raj Sedhai, MD[1*]; Aloysius Ochasi, DBE[2]; Soney Basnyat, MD[3]; Deepak Acharya, MBBS[4]; Peter Clark, PhD[5].

Resident, Internal Medicine; Mercy Catholic Medical Center, Philadelphia USA,[1]
Bioethicist, Institute of Clinical Bioethics, St. Joseph's University / Ph.D. Candidate, Eastern University, St. David's PA, USA,[2]
Resident, Internal Medicine; St. Mary Mercy Hospital, Livonia, USA,[3]
Volunteer Physician, Linden Medical Associates, New York, USA,[4]
Director, Institute of Bioethics, St. Joseph University, Philadelphia, USA,[5]

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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 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 a 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[1]. An estimated 17.5 million people died from CVDs in 2012, representing 31% of all global deaths[1] and over three quarters of CVD related deaths take place in low- and middle-income countries (LMICs)[1]. 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)[3]. 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

*Corresponding author
Yub Raj Sedhai, MD
Resident, Internal Medicine; Mercy Catholic Medical Center, Philadelphia USA
Email: dr.sedhai@gmail.com

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 [30], 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 [30], 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[3, 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%[5, 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[7]. 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[8, 9]. 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[8, 9, 12]. Kantharia et al.[9] 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[9].

Similarly, Pavri et al.[13] 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[14]. 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.[16] 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[15].

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[4], [8]. 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)[4]. 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[4].

After an appropriate and careful selection of the device, it should be reserialized. Several sterilization techniques have been described. Feng et al.[16] 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.[17] in University of Michigan described a protocol with debris removal by

pipe cleaners, an isopropyl alcohol bath, an overnight soak in Aseptizyme (Ecolab, St. Paul, Minnesota) at a concentration of 1:128, a 70% ethanol wipe, air dried, packaged in gas permeable envelopes and decontaminated via an 8-hour ethylene oxide gas sterilization protocol. A sterilization technique used in a study of 100 reused and 100 new pacemaker pulse generators in Sweden included cleaning the device with a brush, soap and water, soaking in phenoxypropanol and benzalconiumchloride solution, and wiping with 70% ethanol, packaging and sterilizing with ethylene oxide. Kapoor et al. [4] have described a sterilization protocol suitable for Indian subcontinent. It may be advisable for the professional societies to lay down norms and standardized sterilization protocols based on the locally available resources.

Another logistical challenge lies in the fact that leads cannot be reused due to difficulty in ensuring sterility and mechanical integrity[4]. 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 practice[20]. 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 unit[21]. Recently there is an ongoing advocacy for federal regulatory oversight for reprocessing SUDs, which has brought commercial reprocessing of SUDs under a regulatory framework[21]. 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 Nepal[22]. . 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 autonomy[23]. 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 beliefs[24]. 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 devices[25]. 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 CDVs, 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.

REFERENCES:

1. World Health Organization, 2013. Cardiovascular disease. Fact sheet N 317. Geneva: WHO. Available at: www. who. int/mediacentre/factsheets/fs317/en/index. html (2008, consulted August 2012).
2. Forouzanfar, M.H., Alexander, L., Anderson, H.R., Bachman, V.F., Biryukov, S., Brauer, M., Burnett, R., Casey, D., Coates, M.M., Cohen, A. and Delwiche, K., 2015. Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet, 386(10010), pp.2287-2323.
3. Mond, H.G. and Proclemer, A., 2011. The 11th World Survey of Cardiac Pacing and Implantable Cardioverter-Defibrillators: Calendar Year 2009–A World Society of Arrhythmia's Project. Pacing and clinical electrophysiology, 34(8), pp.1013-1027.
4. Kapoor, A., Vora, A., Nataraj, G., Mishra, S., Kerkar, P. and Manjunath, C.N., 2017. Guidance on reuse of cardiovascular catheters and devices in India: A consensus document. Indian Heart Journal.
5. Brunner, M., Olschewski, M., Geibel, A., Bode, C. and Zehender, M., 2004. Long-term survival after pacemaker implantation. European Heart Journal, 25(1), pp.88-95.
6. Pyatt, J.R., Somauroo, J.D., Jackson, M., Grayson, A.D., Osula, S., Aggarwal, R.K., Charles, R.G. and Connelly, D.T., 2002. Long-term survival after permanent pacemaker implantation: analysis of predictors for increased mortality. Europace, 4(2), pp.113-119.
7. Ryden, L., 1998. Re-use of devices in cardiology. European heart journal, 19(11), pp.1628-1631.
8. Baman, T.S., Romero, A., Kirkpatrick, J.N., Romero, J., Lange, D.C., Sison, E.O., Tangco, R.V., Abelardo, N.S., Samson, G., Grezlik, R. and Goldman, E.B., 2009. Safety and efficacy of pacemaker reuse in underdeveloped nations. Journal of the American College of Cardiology, 54(16), pp.1557-1558.
9. Kantharia, B.K., Patel, S.S., Kulkarni, G., Shah, A.N., Lokhandwala, Y., Mascarenhas, E. and Mascarenhas, D.A., 2012. Reuse of explanted permanent pacemakers donated by funeral homes. The American journal of cardiology, 109(2), pp.238-240.
10. Knox, A., 2011. Guidelines on single use devices. NHS Dumfries & Galloway, June 2010.
11. Heartbeat International (2009) Available at: http://www.heartbeatintl.org/mission.htm
12. Nava, S., Morales, J.L., Márquez, M.F., Barrera, F., Gómez, J., Colín, L., Brugada, J. and Iturralde, P., 2013. Re-Use of Pacemakers: Comparison of Acute and Long Term Performances. *Circulation*, pp.CIRCULATIONAHA-113.
13. Pavri, B.B., Lokhandwala, Y., Kulkarni, G.V., Shah, M., Kantharia, B.K. and Mascarenhas, D.A., 2012. Reuse of Explanted, Resterilized Implantable Cardioverter-DefibrillatorsA Cohort Study. *Annals of internal medicine*, *157*(8), pp.542-548.
14. Selvaraj, R.J., Sakthivel, R., Satheesh, S., Pillai, A.A., Sagnol, P., Jouven, X., Dodinot, B. and Balachander, J., 2017. Reuse of pacemakers, defibrillators and cardiac resynchronisation devices. *Heart Asia*, *9*(1), pp.59-62.
15. Nava, S., Morales, J.L., Márquez, M.F., Barrera, F., Gómez, J., Colín, L., Brugada, J. and Iturralde, P., 2013. Re-Use of Pacemakers: Comparison of Acute and Long Term Performances. *Circulation*, pp.CIRCULATIONAHA-113.
16. Ze, F., Li, X., Zhang, P., Zhang, H., Wang, L., Li, D., Duan, J., Guo, F., Yuan, C. and Guo, J., 2014. Reuse of Infected Cardiac Rhythm Management Devices in the Same Patients: A Single-Center Experience. *Pacing and Clinical Electrophysiology*, *37*(8), pp.940-946.
17. Baman, T.S., Kirkpatrick, J.N., Romero, J., Gakenheimer, L., Romero, A., Lange, D.C., Nosowsky, R., Fuller, K., Sison, E.O., Tangco, R.V. and Abelardo, N.S., 2010. Pacemaker reuse. *Circulation*, *122*(16), pp.1649-1656.
18. Linde, C.L., Bocray, A., Jonsson, H., Rosenqvist, M., Rådegran, K. and Ryden, L., 1998. Re-used pacemakers as safe as new. *European heart journal*, *19*(1), pp.154-157.
19. Kirkpatrick, J.N., Papini, C., Baman, T.S., Khota, K., Eagle, K.A., Verdino, R.J. and Caplan, A.L., 2010. Reuse of pacemakers and defibrillators in developing countries: logistical, legal, and ethical barriers and solutions. Heart Rhythm, 7(11), pp.1623-1627.
20. Food and Drug Administration. United States Code of Federal Regulations. Title 21/chapter 9/subchapter VIII/section 331(a).
21. The Agency, Ottawa (2008) [HTA Technology Report No. 104, cited 7 November 2014] http://www.cadth.ca/media/pdf/334A_Reprocessing-SUDs%20National-

Survey_tr_e.pdf

22. Sharma, V.K., 2005. Need for renal transplantation programme in Bir Hospital. Kathmandu Univ Med J (KUMJ), 3, pp.191-3.
23. United States. (1978). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Bethesda, Md.: The Commission.
24. Beauchamp, T. L., & Childress, J. F. (2009). *Principles of Biomedical Ethics*, 6th ed. New York, N.Y: Oxford University Press.
25. J. N. Kirkpatrick et al. Reuse of Pacemakers and Defibrillators in Developing Countries: Logistical, Legal and Ethical Barriers and Solutions. *Heart Rhythm* 2010; 1623- 1627: 1623.
26. Beauchamp, T. L., & Childress, J. F. (2009). *Principles of Biomedical Ethics*, 6th ed. New York, N.Y: Oxford University Press.
27. Ascension Health. *Key Ethical Principles: Principle of Distributive Justice*. http://www.ascensionhealth.org/index.php?option=com_content&view=article&id=80:principle-of-distributive-justice&Itemid=171
28. University of Michigan Health System. 2009. *Recycling Your Pacemaker? U-M Cardiovascular Center Lays Groundwork for Donation to Needy Nations*. http://www.uofmhealth.org/news/1153cvc-lays-groundwork-for-pacemaker-reuse
29. C. Edwin. 2005. Foreword. In *Ethics and AIDS in Africa: The Challenge to Our Thinking*. A.A.Van Niekerk & L. M. Kopelman, eds. CA: Left Coast Press: iii.

List of Abbreviations:

CVD: Cardiovascular Diseases

CRMD: Cardiac Rhythm Management Devices

ICD: Implantable Cardioverter Defibrillator

LMIC: Low and Medium Income Countries