

REUSE OF PACEMAKERS IN GHANA AND NIGERIA: MEDICAL, LEGAL, CULTURAL AND ETHICAL PERSPECTIVES

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Keywords

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ABSTRACT

According to the World Health Organization (WHO) cardiovascular disease (CVD) is the leading cause of death globally. Over 80% of CVD deaths take place in low- and middle-income countries (LMICs). It is estimated that 1 million to 2 million people worldwide die each year due to lack of access to an implantable cardiac defibrillator (ICD) or a pacemaker. Despite the medical, legal, cultural and ethical controversies surrounding the pacemaker reutilization, studies done so far on the reuse of postmortem pacemakers show it to be safe and effective with an infection rate of 1.97% and device malfunction rate of 0.68%. Pacemaker reutilization can be effectively and safely done and does not pose significant additional risk to the recipient. Heart patients with reused pacemakers have an improved quality of life compared to those without pacemakers. The thesis of this paper is that pacemaker reutilization is a life-saving initiative in LMICs of Nigeria and Ghana. It is cost effective; consistent with the principles of beneficence, nonmaleficence, and justice with a commitment to stewardship of resources and the Common Good. Used pacemakers with adequate battery life can be properly sterilized for use by patients in LMICs who cannot afford the cost of a new pacemaker.

INTRODUCTION

According to the World Health Organization (WHO) cardiovascular disease (CVD) is the leading cause of death globally. In 2008, an estimated 17.3 million people died from CVDs, representing 30% of all global deaths, and by 2030, more than 23 million people will die annually from CVDs.¹ Over 80% of CVD deaths take place in low- and middle-income countries (LMICs).²

Specifically, it is estimated that 1 million to 2 million people worldwide die each year due to lack of access to an implantable cardiac defibrillator (ICD) or a pacemaker – an implanted device that sends electrical impulses to the heart to help maintain a normal heartbeat.³ The \$15,000 to \$50,000 cost of a permanent pacemaker (PPM) is

¹ World Health Organization (WHO). 2013. *Cardiovascular Diseases*. Fact sheet N.317. Updated March 2013. Geneva: WHO. Available at: <http://www.who.int/mediacentre/factsheets/fs317/en/index.html>. [Accessed 24 Feb 2014].

² Ibid.

³ A.M. Seaman. Can Pacemakers be Used Twice? *Reuters Health* Sept 13, 2012; Available at: <http://www.reuters.com/article/2012/09/13/us-pacemakers-idUSBRE88C19B20120913> [Accessed 24 Feb 2014]; J. Greene. Southfield Cardiologist Leads Effort for Pacemaker Recycling Program in U.S. *Crains Detroit Business* 2010; Available at: <http://www.crainsdetroit.com/article/20101115/HEALTH/101119911/southfield-cardiologist-leads-effort-for-pacemaker-recycling-program-in-u-s>. [Accessed 24 Feb 2014].

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beyond the reach of many people in LMICs.⁴ In the US, when a patient with a pacemaker dies, the device is buried with the body, thrown away or dumped in the closet of the funeral directors. Even in the United Kingdom, Pace4Life, a British charity observed that thousands of life-saving devices (pacemakers) which cost thousands of pounds, are typically thrown away or buried with patients each year in the UK, and plans to send them to developing countries for reuse.⁵ Surveys of morticians in the Midwest reveal that nearly 19% of deceased patients possess a cardiac device, and 85% of these are buried with these patients; 84% of explanted devices are discarded as medical wastes, only 18% are donated to developing nations for reimplantation in humans.⁶ Similarly, a national survey of electrophysiologists (EPs) regarding recovery for analysis of explanted pacemakers and implantable cardioverter defibrillators (devices) reveal that only 23% reported returning all explanted devices to the manufacturers. 32% discarded > 10 devices/year as medical waste, 42% stored devices in a box in the electrophysiology lab, and 10% donated at least 1 device/year to charity for reuse overseas.⁷ With informed consent from patients or families, devices with more than 70 percent battery life, that are not being returned to the manufacturers for analysis, could be effectively sterilized for reuse by patients in LMICs who cannot afford a new pacemaker. A growing body of literature suggests that this can be effectively and safely done and poses no additional risk to the recipient. Studies also show that heart patients with reused pacemakers have an improved quality of life than those without pacemakers.⁸

⁴ University of Michigan Health System. 2009. *Recycling Your Pacemaker? U-M Cardiovascular Center Lays Groundwork for Donation to Needy Nations*. Available at: <http://www.uofmhealth.org/news/1153cvc-lays-groundwork-for-pacemaker-reuse> [Accessed 24 Feb 2014]. The range of \$15,000 to \$50,000 shows that in the United States, the cost of a pacemaker varies from one hospital to another. It is estimated that the surgery to insert a pacemaker, physician's cost and the cost of the device itself can add up to \$20,000 according to Healthcare Blue Book. When deemed medically necessary for a patient, the cost of the device and procedure is fully covered by most insurance plans including Medicare and Medicaid. (Kathryn Hawkins. Would you use a Recycled Pacemaker? InsuranceQuotes.com. Available at: <http://www.insurancequotes.com/recycled-pacemakers/> [Accessed 24 Feb 2014]. Unfortunately, for many patients in LMIC, they neither have an organized public health system, nor health insurance system to cover the cost of a pacemaker.

⁵ Tulip Mazumdar. British Charity Calls for Reuse of Pacemakers Abroad. *BBB News Health*. November 18, 2013.

⁶ J.N. Kirkpatrick et al. Postmortem Interrogation and Retrieval of Implantable Pacemakers and Defibrillators: A Survey of Morticians and Patients. *J Cardiovasc Electrophysiol* 2007; 18: 478–482.

⁷ S. Logani et al. Recovery of Pacemakers and Defibrillators for Analysis and Device Advance Directives: Electrophysiologists' Perspectives. *PACE*, 2011; 34: 659.

⁸ B.K. Kantharia et al. Reuse of Explanted Permanent Pacemakers Donated by Funeral Homes. *Am J Cardiol* 2012; 109: 238–240.

This paper discusses a pilot project sponsored by the Institute of Catholic Bioethics (ICB) at St Joseph's University Philadelphia in collaboration with funeral directors in the greater Philadelphia area. This project aims to collect refurbished pacemakers for reuse in the LMICs of Ghana and Nigeria. Reuse of pacemakers is part of the commitment to stewardship of resources and the Common Good. Distributive justice calls for the fair, equitable, and appropriate distribution of medical resources in society. The reuse of PPMs in the developing world is consistent with that principle.

I. PROJECT DESCRIPTION

This project joins multiple organizations⁹ across the U.S who are committed to saving lives in LMICs through the reuse of pacemakers. The project's intent is to collect, interrogate and sterilize used pacemakers for LMICs in a joint collaboration involving patients, funeral home directors, physicians, and nonprofit charitable organizations. Refurbished pacemakers with 70% battery life or more would be sent to two designated teaching hospitals in Ghana and Nigeria. There are 389 funeral homes in the greater Philadelphia area. The Institute has initiated contacts with funeral directors and some physicians in the Philadelphia area through a questionnaire/survey to inform them of our mission to alleviate the burden of cardiovascular related ailments in developing countries. There is on-going communication with the representatives of the funeral directors about the logistics of the project especially how best to proceed with the extraction and collection of the devices.

Our module is anchored on partnership with a team of cardiologists in Ghana and Nigeria. Caritas International and the Healey Foundation, two international charitable organizations with well established presence in sub-Saharan Africa, will help with the logistics and oversight of the project in these countries. These non-profit organizations will work in tandem with the team of cardiologists to ensure the implementation and sustainability of the project. This project would follow four steps: In the first step, ICB would work with the network of funeral directors in the greater Philadelphia area to collect explanted pacemakers with 70% battery life or more,

⁹ The following organizations are involved in one way or another with the initiative of re-using pacemakers to improve the quality of life of people in LMIC: *Heart Too Heart Aid* (<http://www.hearttoheart.org/>), *Solidarity Bridge* (<http://www.solidaritybridge.org/>), *University of Michigan – Project My Heart Your Heart* (<http://www.myheartyourheart.org/>), *World Medical Relief – Detroit Michigan* (<http://www.worldmedicalrelief.com/>), *Heartbeat International* (<http://www.heartbeatinternational.org/>), *Alternative Solutions USA* (<http://alternativesolutionsusa.net/>) *For Nicaraguan Health*, Christian Machado, M.D (<http://www.fornicaraguanhealth.org/Mission.htm>). This list is not exhaustive.

ascertained through pacemaker interrogation. Interrogation is a process for checking on the function of a pacemaker to make sure it is working properly and the batteries are in good condition.¹⁰

The second step would be sterilization. Two sterilization techniques can be used. First, the sterilization technique used in a study of 100 reused and 100 new pacemaker pulse generators in Sweden includes 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.¹¹ The second technique which was used by University of Michigan include debris removal by pipe cleaners, an isopropyl alcohol bath, an overnight soak in Asepti-zyme (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.¹²

The third step is packaging and shipment. These devices will then be packaged and shipped by the Healey Foundation directly to the hospitals in Ghana and Nigeria for implantation. There are about 10 centers in Nigeria where implants are done. There are trained cardiologists and cardiothoracic surgeons on ground to render these services. All centers have facilities for sterilization, including ETO, and sulphide chambers. Implant indications are mainly acquired causes of arrhythmias with most patients (>80%) presenting with complete heart block and severe bradycardia with syncope. The target patient population is in the thousands as the facility has a combined cardiology and diabetes miletus. Patient population is quite large covering over 4 states of Nigeria with a rough total population of over 10 million.

The international oversight group would work with the local hospitals to ensure that those who really need the pacemakers but cannot afford them are selected after a thorough evaluation. Justice and fairness demand that poor patients are not displaced by the wealthy or middlemen who may want to appropriate these devices for personal gains. It is a known fact that most of those who can afford pacemaker services usually travel outside the country (Europe, United States and India) to procure them. Thus those who will get the refurbished pacemakers will definitely be those who are indigent. However, sharp practices may still occur when these patients are asked to pay various undisclosed fees or costs etc. This may be easily prevented by first educating the

patients that these pacemakers are free and asking them to sign forms clearly stating that they did not pay for the pacemaker. They may be asked to call a number to answer questions about any payment they may have incurred. After these preventive measures, the international oversight committees will liaise with the hospital chief medical director to obtain report on how the pacemakers were disbursed.

The fourth step would be 3 to 6 months evaluation of the patients after implantation by the team, to provide information about the effectiveness of the device and the status of the battery life. Following implantation, the patients are usually discharged from the facility at the third day because of issues of access to the patients immediately post op (there are no ambulance service and patients may not immediately come themselves because of issues with transportation, finance etc) so they will be observed at the facility. They will subsequently be followed up at 3weeks, 6weeks, 3months, and subsequently every 6 months by the electrophysiologists (usually done by the cardiologist or cardiac surgeon). Due to problems with costs and transportation, phone calls are increasingly being used. With the promise of few gifts as incentives (e.g. free vasoprin tablets and pamphlets) they may be encouraged to show up.

The oversight group (Healey Foundation and Caritas International) would give a yearly evaluation of the project. Suffice it to mention that due to the Food and Drug Administration (FDA) regulation on the reuse of pacemakers in the U.S, the sterilization process mentioned in step two above would be undertaken by the recipient institutions. Contracts with the teaching hospitals in Ghana and Nigeria specify that all responsibility for sterilization, testing rests solely with them, with ICB and the international organizations helping with logistics if need be.

II. MEDICAL ISSUES

A pacemaker is a 'small device that is placed in the chest or abdomen to help control abnormal heart rhythms.'¹³ It is an integrated electrical system comprising a pulse generator and a lead.¹⁴ It uses electrical pulses to prompt the heart to beat at a normal rate. Its function is to regulate irregular or slow heartbeat or act as 'an insurance policy by automatically shocking the heart back to a normal rhythm . . . usually implanted after a heart attack or if medications are unsuccessful, and they last 10–15

¹⁰ Wise Geek. What is a Pacemaker Interrogation? Available at: <http://www.wisegeek.com/what-is-a-pacemaker-interrogation.htm> [Accessed 24 Feb 2014].

¹¹ C.L. Linde et al. Re-used Pacemakers- as Safe as New? A Retrospective Case-Control Study. *Eur Heart J* 1998; 19: 154–157.

¹² T.S. Baman et al. Safety and Efficacy of Pacemaker Reuse in Underdeveloped Nations. *J Am Coll Cardiol* 2009; 54: 1557–1558.

¹³ MedicineNet.com. 2013. *Pacemaker Overview*. Available at: <http://www.medicinenet.com/pacemaker/article.htm> [Accessed 24 Feb 2014].

¹⁴ M. Jackson. Issues Affecting Refurbishment and Re-use of Pacemakers. *Australian Health Review* 1996; 19: 69.

years.¹⁵ Some of the reasons why people need pacemakers are bradycardia, heart block, arrhythmia, slow heartbeat, long QT syndrome¹⁶ and a host of other CVDs.

Pacemakers are implanted under the patient's skin and attached to the heart with insulated wire leads. A pacemaker lead is composed of a metal conductor covered with an insulator.¹⁷ The leads, which run between the pulse generator and the heart, allow the device to increase the heart rate by delivering small bursts of electric energy to make it beat faster. In order to perform this function, leads must be in contact with the heart tissue. Most leads pass through a vein under the collarbone that connects to the right side of the heart (right atrium and right ventricle). To remain attached to the heart muscle, most leads have either a small screw or hooks at the end.¹⁸ Once the lead is safely implanted, it is gradually incorporated into the tissues making it difficult to remove without extensive damage to the insulation. Therefore only the pulse generator is suitable for harvesting, cleaning, re-sterilization and re-use.¹⁹ Leads usually last longer than device batteries, so leads are simply reconnected to each new (or refurbished) pulse generator (battery) at the time of replacement.²⁰

Between the leads and pulse generator, pulse generator is the main contributor to the cost of pacemakers. In some cases, the pulse generator makes up to 70% of the total cost. A conservative estimate show that even in their most basic form, pacemaker pulse generators cost around \$2,500 to \$3,000 and lead that connect the pulse generators to the heart cost \$800 to \$1,000. ICD generator list prices range from \$20,000 to \$40,000 and leads can cost over \$10,000.²¹ A relatively low-cost lead is manufactured in India which has made it possible for patients from poor socioeconomic background to afford pacing leads. In the study conducted by Bharat Kantharia and colleagues in Mumbai, India, patients were not charged for the pacemakers but had to pay for the pacing leads.²² ICB intends to operate with this module in Ghana and Nigeria, but in a situation where the patient is incapable of paying for the leads, the Healey Foundation or Caritas International would supplement.

¹⁵ University of Michigan Health System. *op. cit.* note 4. Others say that modern new pacemakers may last from 5–15 years. See: M. Jackson. *op. cit.* note 12.

¹⁶ MedicineNet.com. *op. cit.*, note 11.

¹⁷ Jackson. *op. cit.* note 12, p. 69.

¹⁸ E. Buch, N.G. Boyle & P. H. Belott. *Pacemaker and Defibrillator Lead Extraction*. American Heart Association (AHA). 2011. Available at: <http://circ.ahajournals.org/content/123/11/e378.full>. [Accessed 24 Feb 2014].

¹⁹ Jackson. *op. cit.* note 12, p. 69.

²⁰ Buch, Boyle & Belott. *op. cit.* note 16.

²¹ 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.

²² Kantharia et al. *op. cit.* note 6, p. 239.

One of the greatest concerns raised by critics about the reuse of pacemakers is safety and efficacy. Opponents of pacemaker reuse contend that it is manufactured as a single use medical device; thus, reuse makes them prone to malfunction and infection.²³ They also argue that explanted pacemakers 'be returned to the manufacturer to ensure an accurate performance database prompting improved device reliability and safety to the patient.'²⁴ According to the FDA, 'medical experts have studied this situation and have determined that there is a serious question whether pacemakers can be properly re-sterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacemaker. This also poses the problem of foreign protein matter to the second recipient.'²⁵ By inference, those involved in programs that reuse pacemakers overseas may be perceived as 'exporting harm to developing nations'²⁶ The question then becomes: what is the degree of safety and efficacy of the reuse of pacemakers?

Despite the concerns about safety and efficacy, a growing body of literature suggests that this can be effectively and safely done and does not pose significant risk to the recipient. Many studies²⁷ have shown implanting re-sterilized pacemakers in LMICs to be safe and efficacious.²⁸ The safety of device reutilization is further supported by a recent meta-analysis examining 18 clinical studies from 1970 to 2010 involving 2270 patients with previously reused devices. There was an overall infection rate of 1.97% and device malfunction rate of 0.68%.²⁹

²³ Jackson. *op. cit.* note 12, p. 79.

²⁴ R. Stanyon. Donation of Explanted Pacemakers for Reuse in Underserved Nations. *J Health Risk Manag* 2010; 29: 6–8, 14.

²⁵ Food and Drug Administration (FDA). 1995. *Inspections, Compliance, Enforcement, and Criminal Investigations (CPG Sec. 310.100 Pacemaker reuse)*. Available at: <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073891.htm>. [Accessed 24 Feb 2014].

²⁶ S. Stiles. 2009. Charitable Donation of Pacemakers Harvested after Death Ramps up in the U.S. *Heartwire*, 28 August: 7.

²⁷ T.S. Baman et al. Feasibility of Postmortem Device Acquisition for Potential Reuse in Underserved Nations. *Heart Rhythm* 2012; 9: 211–214; Baman et al. *op. cit.* note 10; R. Hasan et al. Safety, Efficacy, and Performance of Implanted Recycled Cardiac Rhythm Management (CRM) Devices in Underprivileged Patients. *Pacing Electrophysiol* 2011; 34: 653–658; J.N. Kirkpatrick, M.C. Burke & B.P. Knight. Postmortem Analysis and Retrieval of Implantable Pacemakers and Defibrillators. *N Engl J Med* 2006; 354: 1649–1650; J. Balachander. Efficacy and Safety of Refurbished Pacemakers – Report on Collaborative Program with 140 Implantations and 6-year follow up. *Indian Heart J* 1989; 41: 430.

²⁸ Hawkins. *op. cit.* note 4. Dr Gaurav Kulkarni, a surgical resident at Loyola University Chicago's Stritch School of Medicine analyzed the outcomes of 53 patients in Mumbai India who received recycled pacemaker donated from the US between January 2004 and January 2010. The patients were followed for two years. The study showed that the pacemakers significantly improved the patients' quality of life in most cases. All but two patients showed substantial improvement.

²⁹ T.S. Baman et al. Safety of Pacemaker Reuse: a Meta-Analysis with Implication for Underserved Nations. *Circ Arrhythm Electrophysiol* 2011; 4: 318–323.

With proper, careful and robust sterilization methods as used in the studies cited above, the infection rate of refurbished pacemakers has been shown to be less than 2%. This is comparable to that of new implants.³⁰ The data from these studies show that pacemakers with $\geq 70\%$ battery³¹ life, carefully sterilized and interrogated are safe and effective and could be used for patients in LMICs who cannot afford a new pacemaker. The heart surgeon and president elect of the Royal College of Medicine, Babulal Sethia says with safeguards around the re-sterilization and battery-checking process, the idea of a reuse is a good one. He further noted that ‘pacemakers with significant battery life are potentially life-saving devices for people elsewhere’.³² This is true for thousands of patients in Africa. The dire need of pacemakers in Africa makes the reuse of refurbished pacemakers more imperative. For instance, in Nigeria, the need for pacemakers has been reported by most researchers in the Nigerian Journal of Cardiology. This is especially so with the rapid increase in the incidence of diabetes, hypertension and dislipidaemia in patients seen in clinics around the country. Up to 25% of patients may require pacemakers for dysrhythmias and yet only about 10 centers can provide services in a country of about 160 million people, and given the level of poverty of most patients, 80.5% of cases rely on charity for procurement and implantation of pacemakers. Thus a vast majority will die without care. This is mainly because of the cost of pacemakers which range from N300, 000 to N500, 000 (between 2,000 to 4,000 dollars) to procure a pacemaker; excluding the hospital fees and other costs.

III. LEGAL ISSUES

Pacemakers, ICDs, and other allied devices are packaged and sold as single use medical devices. In lieu of this, the FDA mandates that they be used as such. Its policy says the reuse of pacemakers is an ‘objectionable practice’.³³ The greatest concern of the FDA is safety and the possible risk of infection. There are questions raised about the sterilization process. The main question being whether the pacemakers can be properly re-sterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacemaker. If the sterilization falls short, the pacemaker may be a conduit of transmitting disease from the original owner to the new recipient. Moreover, the United States Food, Drug, and Cosmetic Act prohibit the ‘introduction into interstate commerce of any . . . device . . . that is adulterated

or misbranded’.³⁴ The main concern of the FDA on the reuse of pacemakers revolves around safety and the possible risk of infection, but a growing body of literature suggests that this can be effectively and safely done and does not pose significant risk to the recipient. As the studies cited above have shown, implanting re-sterilized pacemakers in LMICs to be safe and efficacious. One could therefore argue that these studies challenge the basis of the ban by the FDA and call for a reevaluation of the prohibition. While there is need for more studies in this regard, lifting the ban would invariably free up more pacemakers for reuse in LMICs.

However, it is clear that the FDA does not have jurisdiction in other countries. One viable option of solving this regulatory quagmire is to collect the explanted devices here in the U.S, and ship them to be sterilized and tested at the receiving institution/country. The weakness of this option may be that the burden of testing and sterilizing the explanted pacemakers falls on the receiving country. This is the option ICB has chosen for this project. We are confident that the receiving hospitals in Ghana and Nigeria have the capability to sterilize these devices properly. They are teaching hospitals and as such have facilities that meet international medical standards. Another option is to apply for FDA approval for export under section 801(e) (1) and 802 of federal food, Drug and Cosmetic Act provided the initiative is not in conflict with the laws of the recipient’s country.³⁵ Apparently there are no laws banning the reuse of pacemakers in Nigeria and Ghana. However, the clearance of the Hospitals Ethics Committee and approval of the Review Board would be sought before disbursement. Also the patient will be required to sign a consent form appropriately disclosing the full details of the device.

IV. CULTURAL ISSUES

Surveys conducted in the United States about explanted pacemakers revealed positive societal views about donating pacemakers to poor patients in underserved nations. A survey done in Michigan shows that a large percentage of funeral directors (89%), patients with implantable devices (87%), and members of the general population (71%) support a pacemaker reutilization initiative.³⁶ The donor nation is ready and willing to donate to needy patients in LMICs, but are there cultural or religious issues in the receiving countries of Ghana and Nigeria that would pose problems in reusing these devices?

³⁴ Food and Drug Administration. *United States Code of Federal Regulations*. Title 21/chapter 9/subchapter VIII/section 331(a).

³⁵ *Ibid*.

³⁶ L. Gakenheimer et al. Societal Views of Pacemaker Reutilization for those with Untreated Symptomatic Bradycardia in Underserved Nations. *J Interv Card Electrophysiol* 2011; 30: 261–266.

³⁰ Linde et al. *op. cit.* note 9.

³¹ Batteries last anywhere from 7 to 15 years.

³² Mazumdar. *op. cit.* note 5.

³³ Food and Drug Administration. *op. cit.* note 23.

Not much has been written of the attitude of Africans with regard to reuse of medical devices from cadavers. One may argue that some in Nigeria and Ghana may be reluctant to use organs or medical devices from cadavers due to superstition and reverence of the dead. A brief look into African cosmology may shed some light on the origin of this attitude about death and cadavers. In most African cultures, death is not seen as annihilation of a person, but merely 'a passing away into another state of existence'³⁷ Furthermore, Africans believe that 'man and nature are not two independent realities, but an inseparable continuum of a hierarchical order by making the visible world continuous with invisible world'³⁸ This notion of inseparability between the living and the dead leads to a 'reverential respect' being given to the dead due to the general belief that 'something of the dead person does not wholly disappear.'³⁹ The ancestors are the 'living dead'⁴⁰ who are believed to wield power and influence over the living. They are accorded respect at death by treating their 'bodies' appropriately with the prescribed rituals and they in turn offer protection to the living. This explains the traditional opposition to autopsy by some Africans because of its perception as a lack of respect for the dead. There is the fear that if the body of the dead is disrespected or 'desecrated' some consequences may befall those responsible for it.

Ancestral reverence in Africa remains incomplete without looking at it through the lens of reincarnation. The idea of reincarnation warrants the unimaginable reverence accorded the bodies of the good dead in anticipation of their return, but, is denied the wicked dead in order to cut them off. This belief in reincarnation explains why some Africans may decline organ donation and by extension devices such as pacemakers from cadavers. The concern would be reincarnating with an organ or device that that is foreign to them. In a study conducted by Aghanwa H. and colleagues in Nigeria, the fear of reincarnating with only one kidney was given as one of the reasons that affect the willingness of some people to donate a kidney.⁴¹ With regard to the issues of reincarnation and related concerns, the superstition does not extend to things that were not originally integral parts of the human person in life. A deceased person does not need the artificial pacemaker in the afterlife, so it is irrel-

evant in considering the concern of the recrimination associated with reincarnation in African cosmology. On the other hand, there are some who still believe that evil consequence may befall people who use personal items taken from the dead. This belief may be extended to used pacemakers. As such, the constant thought that you have a device in you taken from a cadaver may make you jittery.

Furthermore, there is a perception that Africa is the dumping ground of the West. By extension, used pacemakers may be seen as one of those 'second-hand' items that the West is dumping on Africa. This perception may be amplified by the fact that the FDA has banned the reuse of pacemakers in the U.S. Some may argue that if refurbished pacemakers are good, why are Americans themselves are not using them. The truth remains that many countries in Africa use a lot of 'waste' from the West, including cars, fridges, televisions, pots, plates, clothes etc. The concept of used items from the West is common with the people in Africa. Even in some hospitals, the beds, surgical equipment and other instruments were items that were discarded in the West, and were either sold or donated to Africa. The perfect should not be the enemy of the good. It would be against the principle of distributive justice to discard a good device that could save lives solely on the basis that it has been used before. Thousands of patients who need these pacemakers cannot afford them and without them may die, so these refurbished pacemakers become life savers.

The above worldview and perception may explain the reluctance of some people in sub-Saharan Africa in using medical devices from cadavers. However, educating the patient population on how the pacemakers are explanted, interrogated and sterilized would be of paramount importance in diffusing these beliefs and perceptions. The key is education and personal preference. Patient education must be combined with education of the healthcare workers including doctors and nurses. The body language of caregivers go a long way to reassure the patients that the pacemakers are for their benefit and does not in any way desecrate or place any curse upon them. The target recipients are the indigent who may be illiterate in some cases. In sub-Saharan Africa, literacy levels are low when compared to those of the West.⁴² In both developing and developed nations, the complex nature of consent forms, length and legalistic style, illness, nervousness, irrationality and immaturity may inhibit full comprehension of the risks and benefits of a medical procedure. Patients (literate or not) exhibit a wide variation in their understanding of information about risks and benefits of a procedure. When necessary, visual images may be used

³⁷ C. Oniang'o. The Foundations of African Philosophy. In Aone Mokaila *A Clash of World Views: Traditional vs. Western Medicine in the African Context*. Available at: <http://www.drury.edu/ess/irconf/curpapers/AMokaila.html>. [Accessed 24 Feb 2014].

³⁸ Ibid.

³⁹ A. Berg. Ancestor Reverence and Mental Health in South Africa. *Transcultural Psychiatry* 2003; 40: 197.

⁴⁰ P. Charlier, L. Brun & C. Herve. Medical Students from Parakou (Benin) and West-African Traditional Beliefs on Death and Cadavers. *Afr Health Sci* 2012; 12(4): 443-445.

⁴¹ H.S. Aghanwa, A. Akinsola, D. Akinola & R. Makanjuola, 'Attitudes Toward Kidney Donation' *J Natl Med Asso* 2003; 95: 725-731.

⁴² H.S. Aghanwa & O. Morakinyo. Psychiatric Complications of Haemodialysis at a Kidney Centre in Nigeria. *J Psychosom Res* 1997; 42: 445-451.

by physicians to ensure their patients understand the proposed procedures. For the patients in Sub-Saharan Africa, a comprehensive understanding of the pacemaker's explantation, sterilization and interrogation would go a long way to diffuse some of the cultural beliefs and perceptions. As we shall explore in the next section, under the principle of respect for person and informed consent, patients have the right to know the source of the pacemaker and can decline after being told of the source and the sterilization process of the pacemaker.

Some may suggest that another way of minimizing or completely removing the emotional trauma that could result from refurbished pacemakers by patients in the more subjective cultures of non-Western world, is to thoroughly de-personalize or dissociate them from their previous uses. In Africa, is it believed that one does not know does not hurt. By implication, specifically disclosing they came from cadavers should not be paramount. The only necessary knowledge to be presented is the fact that it is not brand new. Besides, as already mentioned above, Africans have since gotten used to 'tokumbo' (Yoruba word for 'used') vehicles imported from abroad without minding the fates of previous owners, The details concerning whom or how they were previously used would be irrelevant especially given the fact that the typical patients that could use them are both desperate and ignorant about the specifics of something as technically and medically sophisticated and complicated as a pacemaker. This suggestion may have some merits to it, but informed consent which is anchored on respect for persons, demands that the patient irrespective of class, race and literacy level be given all information needed to make an informed decision. If an indigent patient declines a refurbished pacemaker solely because it came from a cadaver, there are similar patients whose consideration would not be the source of the device but rather gratitude to have had a scarce and costly device that would improve their quality of life.

V. ETHICAL ANALYSIS

Respect for Persons

This principle incorporates two ethical convictions: first, that persons should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.⁴³

⁴³ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, U. S. Government Printing Office, Washington, D.C., 1979; B-1.

Respect for persons refers to the right of a person to exercise self-determination and to be treated with dignity and respect.

Informed consent which is inextricably linked to respect for personal autonomy is defined by Beauchamp and Childress as 'an individual's autonomous authorization of a medical intervention or of participation in research.'⁴⁴ The principle of informed consent is relevant to the reuse of pacemakers in two senses: first, consent (permission) from the donors/surrogates and second, informed decision by the recipients to accept the devices. Even though there are no United States federal legislation establishing postmortem property rights pertaining to explanted medical devices, yet the tradition in the United States of patient autonomy ensures that no device could be removed from a deceased patient for purposes contrary to what the patient would authorize.⁴⁵ A study found that 91% of device patients were willing to sign an advance directive allowing their device to be donated for human use in LMICs after death.⁴⁶ Respect for persons with explantable devices therefore presupposes either a pre-mortem consent of the donor, or consent of his family to donate the device post mortem. Morticians in the greater Philadelphia area are the liaisons between families and ICB. They obtain the consent from families either orally or in written form on behalf of ICB.

Similarly, respect for the autonomy of the recipients in LMICs demand that they be given all the information needed to make an informed decision whether to accept the refurbished pacemaker or not. They should 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'⁴⁷ Suffice it to say that under informed consent, the patients in LMICs must be *fully informed* of the source of the device and the risks associated with used devices no matter how minimal it may seem. In Ghana and Nigeria where there may be cultural barriers towards devices or organs from cadavers, this principle places an obligation on the sponsors and the clinicians of the project to tell the recipients all they need to know. Anything short of full disclosure violates the principle of respect for persons and the informed consent process.

Beneficence/Nonmaleficence

The principle of beneficence involves the obligation to prevent, remove, or minimize harm and risk to others and to promote and enhance their good. Beneficence includes

⁴⁴ T.L. Beauchamp & J.F. Childress. 2009. *Principles of Biomedical Ethics*, 6th ed. New York: Oxford University Press: 119.

⁴⁵ Kirkpatrick et al. *op. cit.* note 19, p. 1626.

⁴⁶ Kirkpatrick et al. *op. cit.* note 5, pp. 478-482.

⁴⁷ Kirkpatrick et al. *op. cit.* note 19, p. 1625.

nonmaleficence, which prohibits the infliction of harm, injury, or death upon others. In medical ethics this principle has been closely associated with the maxim *primum non nocere* (Above all, do no harm). Allowing sick persons in LMICs in sub-Saharan Africa to endure the pain and suffering of CVDs that could be managed and relieved by refurbished pacemakers violates the principle of beneficence. Multiple studies have shown that CVD patients who receive a refurbished pacemaker have a better quality of life than those without pacemakers. Thus, the benefits of having a refurbished pacemaker outweigh the risks associated with having it. Not coming to the rescue of one to two million people who die annually in LMICs due to lack of pacemakers, when there are many pacemakers as ‘medical wastes’ in funeral homes violates the duty we have as a society to prevent or minimize to others. Our inaction in the face of this cardiovascular epidemic in LMICs causes harm to the millions of people who could benefit from refurbished pacemakers.

The use of refurbished pacemakers is cost effective. In a prospective comparative trial, the use of refurbished pacemakers was shown to save \$33,000.00.⁴⁸ Another trial showed that reuse of devices decreased costs for patients by about \$400.00.⁴⁹ This cost effectiveness benefits not only the poor patients in LMICs but also frees scarce medical resources and finances for other diseases like malaria, tuberculosis and HIV/AIDS.

The Principle of Justice

The principle of justice demands the fair and equitable allocation of resources. This principle recognizes that each person should be treated fairly and equitably, and be given his or her due. The issue of medical disparities among the wealthy and poor nations focuses on distributive justice: the fair, equitable, and appropriate distribution of medical resources in society. Distributive justice requires that everyone receive equitable access to the basic health care necessary for living a fully human life insofar as there is a basic human right to health care.⁵⁰ This disparity in healthcare between the developed nations and the poor nations is glaring in the area of pacemaker implantation. Industrialized nations have seen a decline in deaths from CVDs in recent decades but

those in LMICs continue to bear the brunt of CVDs. The reason is that ‘poor nations have not been able to afford the electrophysiology technology that has reduced cardiac deaths in industrialized nations, while unhealthy lifestyles, as well as infectious diseases contribute to escalating rates of heart disease worldwide.’⁵¹ Simply put, many of these LMICs lack the financial resources to address this epidemic of CVDs, and in essence, resources are directed away from high-cost treatments such as implantable cardiac rhythm management devices.⁵² As has already been stated above, 80% of deaths from CVDs occur in LMICs because they cannot afford the high cost of life-saving devices such as pacemakers. What this means is that ‘those most in need of care have least access’⁵³ People have a right to health care. It could even be the ‘just minimum’ that would make the difference between the quality of life they would have. Given the special moral importance of health, meeting health needs at some level, including ‘preventive, curative, rehabilitative, and compensatory personal medical services (and devices)’ is required for a just society.⁵⁴ A good number of patients in LMICs would have access to pacemakers through the reuse initiative which has been proven to be safe and efficacious. Failure to initiate measures that would recycle ‘medical wastes’ to help indigent patients in sub-Saharan Africa violates the principle of distributive justice.

We now live in a ‘global village’. We are interconnected with one another more than ever before. Justice and global solidarity demand we care about what is happening around the world. If we truly believe in equality, we would insist that all men and women receive equal medical treatment and resources. In an ideal situation, justice would demand that all patients in LMICs who need new pacemakers get them irrespective of their ability to pay. But the reality remains that this is not feasible. The perfect should not be the enemy of the good. Whereas this perfect situation seem elusive given the world we live in, the good remains to be desired. Refurbished pacemakers are safe and effective, and so distributive justice demands we put them into use where they are most needed. As VanArtsdalen and colleagues succinctly put it: ‘there is, at least at some level, “a” global society, necessitating greater attention to the just distribution of social goods, including health and healthcare between,

⁴⁸ M. Rosengarten & R. Chiu. A Prospective Trial of New versus Refurbished Cardiac Pacemakers: A Canadian Experience. *Can J Cardiol* 1989; 5: 155–160.

⁴⁹ K.K. Namboodiri et al. Re-use of Explanted DDD Pacemaker as VDD- Clinical Utility and Cost Effectiveness. *Indian Pacing Electrophysiol J* 2004; 4: 3–9.

⁵⁰ Ascension Health. *Key Ethical Principles: Principle of Distributive Justice*. Available at: http://www.ascensionhealth.org/index.php?option=com_content&view=article&id=80:principle-of-distributive-justice&Itemid=171 [Accessed 24 Feb 2014].

⁵¹ University of Michigan Health System. *op.cit.* note 4.

⁵² Baman et al. *op. cit.* note 10.

⁵³ D. Maher & N. Ford. Action on Noncommunicable Diseases: Balancing Priorities for Prevention and Care. *Bull World Health Organ* 2011; 89: 547-A.

⁵⁴ N. Daniels. 2008. Just Health: Meeting Health Needs Fairly. New York: Cambridge University Press. In J. VanArtsdalen et al. Pacemaker Reuse for Patients in Resource Poor Countries: Is Something Always Better Than Nothing? *Progress in Cardiovascular Diseases* 2012; 55(3): 300–306.

not only within, national borders.⁵⁵ To deny people in LMICs medical treatment, when people in developed nations receive them as a standard of care, is an unjust allocation of resources and violates a basic tenet of justice.

Common Good

Justice demands that we all care for the Common Good of the society. Reuse of pacemakers not only improves the quality life of the individual recipients but also promotes the Common Good of all in LMICs. The annual death of an estimated one to two million people due to lack of pacemakers has devastating effects on the population. Of the estimated 17.3 million people who died from CVDs in 2008, over 80% of them were from LMICs.⁵⁶ Millions of lives could be helped by collecting and sending over to them devices that hitherto were 'medical wastes' in the drawers of funeral directors.

Failure to address the impact of CDVs on LMICs would have an impact on both local and global economies thereby imperiling the Common Good. Jamie VanArtsdalen and colleagues articulate it this way: 'Besides premature mortality, lack of access to pacemaker therapy 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'.⁵⁷ Some of the LMICs are already burdened by other diseases such as HIV/AIDS, malaria, and tuberculosis. Furthermore, sub-Saharan Africa generates no more than one percent of the total wealth produced in the world. Africa is the home of ten percent of the world's population, yet lives on one percent of the global economy, and carries 70 percent of the world's HIV/AIDS burden.⁵⁸ In solidarity with these resource poor nations, pacemakers explanted in the U.S, interrogated for adequate battery life and sterilized could go a long way to improve the health of the individual recipients who cannot afford it, make them more productive members of society and thereby promote the common good of all.

Stewardship of Resources

Distributive justice also demands that we become responsible stewards of resources. Within the context of

⁵⁵ VanArtsdalen et al. *op. cit.* note 50.

⁵⁶ World Health Organization. *op.cit.* note 1.

⁵⁷ VanArtsdalen et al. *op. cit.* note 50.

⁵⁸ 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.

healthcare, stewardship of resources incorporates the responsibility to show concern and care for the scarce medical resources. We have an obligation to use scarce medical resources judiciously. Thousands of explanted pacemakers which have the capacity to save lives in LMICs are abandoned as 'medical wastes' and lie fallow in the closets of many funeral directors. Refurbished pacemakers as the studies cited above show are safe and effective, but new pacemakers are scarce and beyond the reach of many CVD patients in LMICs. As responsible stewards, we have the moral obligation of collecting these 'abandoned' pacemakers, interrogate them for adequate battery life, sterilize and send to LMICs for use. Timir Baman, MD succinctly puts it: 'Undoubtedly, pacemaker reuse can safely and effectively transform a currently wasted resource into an opportunity for a new life'⁵⁹ The inability to transform a wasted resource into a life-saving initiative for millions of people in LMICs violate the principle of the stewardship of resources.

CONCLUSION

CVDs remain the number one cause of death in the world with over 80% of deaths occurring in LMICs. Studies done so far on the reuse of postmortem pacemakers show it to be safe and effective with an infection rate of 1.97% and device malfunction rate of 0.68%. They show that pacemaker reutilization can be effectively and safely done and does not pose significant additional risk to the recipient. The evidence so far indicates that heart patients with reused pacemakers have an improved quality of life compared to those without pacemakers. Pacemaker reutilization is a life-saving initiative. It is cost effective. Consistent with the principles of justice and beneficence and with a commitment to stewardship of resources and the Common Good, used pacemakers with adequate battery life should be properly sterilized for use by the patients in LMICs who cannot afford the cost of a new pacemaker.

Biography

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⁵⁹ University of Michigan Health System. *op. cit.* note 4.