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Pacemaker Reuse

An Initiative to Alleviate the Burden of Symptomatic Bradyarrhythmia in Impoverished Nations Around the World

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Health of body and mind is so fundamental to the good life that if we believe men have any personal rights at all as human beings, they have an absolute right to such a measure of good health as society and society alone is able to give them.

—Aristotle, 330 BC

For most of the industrialized world, the morbidity and mortality attributed to cardiovascular disease have declined in recent decades as a result of improvements in technology and a greater emphasis on primary and secondary preventative strategies.¹ Unfortunately, this dramatic improvement in disease burden has not been witnessed in low- and middle-income countries (LMICs), defined by the World Bank as generating a gross national income per capita lower than US \$9200.² Currently, cardiovascular disease is the primary cause of mortality worldwide, accounting for 30% of all global deaths,³ and it has twice the mortality rate of HIV/AIDS, malaria, and tuberculosis combined.⁴ Secondary treatments are often limited because of a paucity of skilled healthcare providers and, more important, the inability of the patient to afford costly medical procedures.⁵

This great disparity in medical health care is clearly evident in the field of cardiac electrophysiology, specifically pacemaker implantation; this specialty is either severely underdeveloped or entirely nonexistent in many LMICs.⁶ As a result, many individuals with symptomatic bradycardia experience a decreased quality of life and/or decreased life expectancy because of a lack of resources (personal correspondence, University of Philippines–Philippine General Hospital [UP-PGH], November 15, 2008). As the epidemic of cardiovascular disease continues to alter the demographics of disease in LMICs, healthcare providers with access to medical technology must investigate novel methods of easing the burden of those less fortunate.

The purpose of this article is to address the concept of postmortem pacemaker use for those in LMICs who otherwise would not have access to bradyarrhythmia therapy. We believe that postmortem pacemaker reuse can be shown to be a safe, feasible, and ethically responsible means of delivering electrophysiological healthcare to those in great need.

Scope of the Epidemic

To help alleviate the overall burden of untreated symptomatic bradycardia, we must understand differences in pathogenesis of cardiac dysrhythmias and their intersection with device implantation. In the United States, the primary indication for pacemaker implantation is sinus node dysfunction⁷; however, in many LMICs, complete heart block is the most common indication, with sinus node dysfunction accounting for only 5%.^{8,9} Part of this difference may be due to infectious diseases leading to severe bradyarrhythmias in Latin American countries. Clinical Chagas disease, caused by an infection of *Trypanosomiasis cruzi*, may affect up to 20 million individuals.¹⁰ One study reported that 72% of pacemaker recipients in a Brazilian cohort displayed seropositivity for *T cruzi*.¹¹ Seropositivity as high as 25% has been reported in Bolivian children 5 to 13 years of age.¹²

Understanding the true prevalence of untreated symptomatic bradycardia can be difficult because of a paucity of clinical data. However, Mond et al⁶ elegantly surveyed 43 countries to determine rates of pacemaker implantation. Countries in Europe reported an average of 475 new implantations per million as compared with 191 new implantations per million in the Americas (excluding Canada and United States). Sixty percent of pacemaker implantation in the Americas was due to high-degree atrioventricular block compared with 27% in Europe, although this may represent an allocation of limited resources to those in greatest need.

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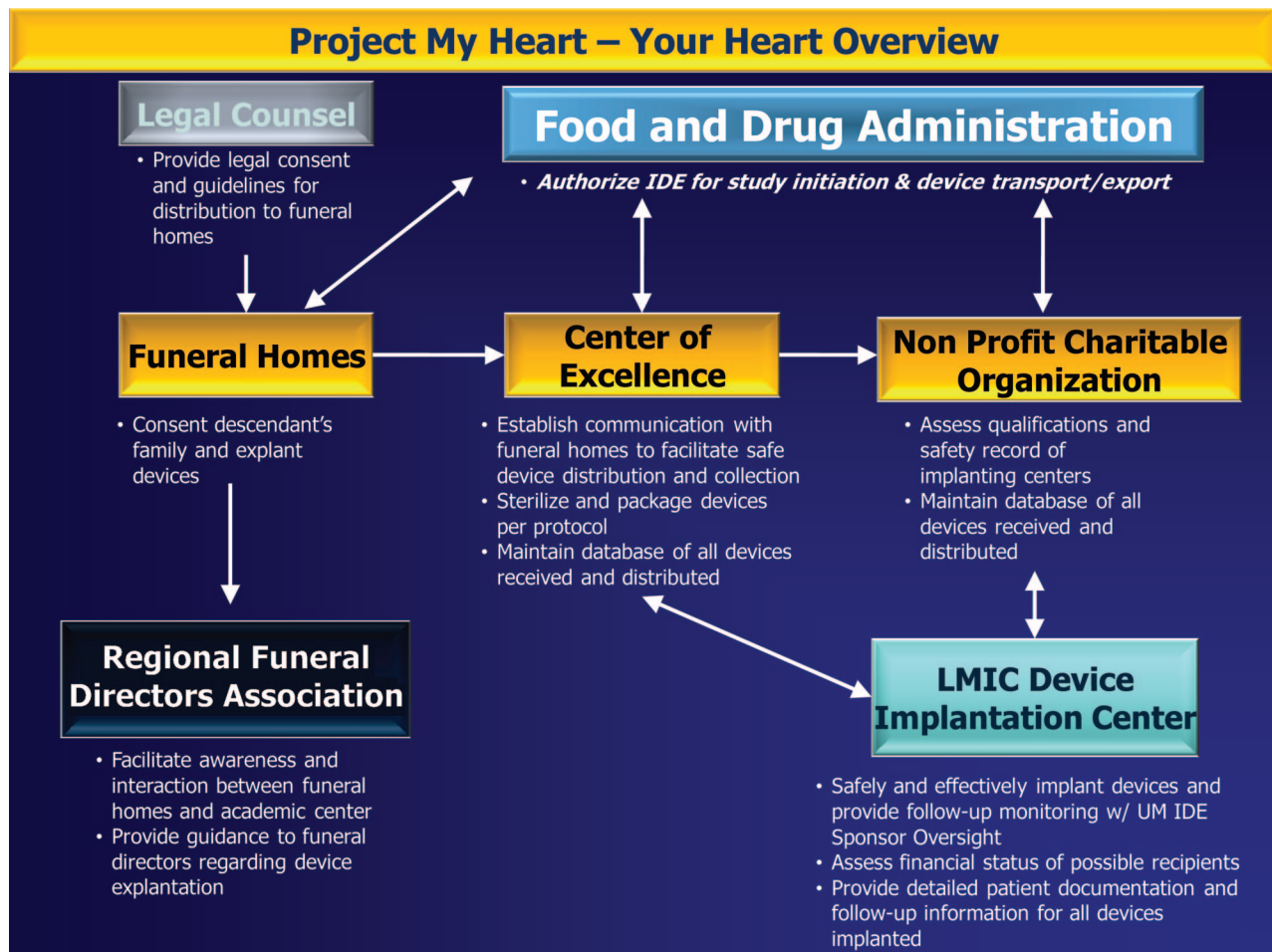


Figure 1. Proposed initiative for delivery of electrophysiological devices to LIMCs.

Expanding Access to Pacemakers

Novel methods of healthcare delivery in the field of electrophysiology must be explored to alleviate the morbidity of those currently unable to acquire pacemakers because of a lack of affordability. However, understanding the scope of the epidemic can be difficult because there are no clinical studies to address prevalence of untreated bradyarrhythmias. Heartbeat International, a nonprofit organization specializing in the delivery of expired devices to third-world countries, estimates that >1 million individuals die annually as a result of a lack of access to pacemakers.¹³

We propose a joint collaboration between patients, funeral directors, physicians, and nonprofit charitable organizations to meet this need (Figure 1). Previous data have shown that patients with pacemakers have overwhelmingly expressed an interest in donating their device postmortem.¹⁴ Moreover, funeral directors have voiced interest in participating in a pacemaker donation initiative if given the proper framework.¹⁵ Finally, a review of the literature shows that the feasibility of this practice has been demonstrated in numerous settings worldwide.

The views and opinions of private citizens encompass a pivotal aspect of any pacemaker reuse initiative. A survey of pacemaker and defibrillator patients by Kirkpatrick et al¹⁴ showed that 91% of patients willing to sign an advanced

directive dictating device handling after death would donate their device to a medically underserved nation. A recent survey of 210 patients with pacemakers and implantable defibrillators (ICDs) at the University of Michigan and University of Pennsylvania found that 84% would donate their device for reuse. In a survey of 1009 members of the general population, 71% reaffirmed the desire to donate postmortem devices to those less fortunate (Figure 2).¹⁶ These results strongly suggest that a great majority of the patient population with devices and the general public is willing to consent to cardiac device removal for philanthropic reuse in underserved nations.

The goal of our proposed initiative is to create a reproducible model in which funeral directors are given a framework to obtain consent from families of loved ones for pacemaker removal before burial or cremation. Under current regulations, all pacemakers and ICDs must be explanted before cremation because of the risk of device explosion.¹⁷ The Cremation Association of North America predicts a cremation rate of 39% in 2010 and 59% for 2025.¹⁸ Therefore, a majority of the nearly 2 million individuals with pacemakers and ICDs expected to be cremated in 2025 will have their device explanted per routine protocol. Our survey found that currently an estimated 45% of the deceased with pacemakers and ICDs will have their device explanted before burial

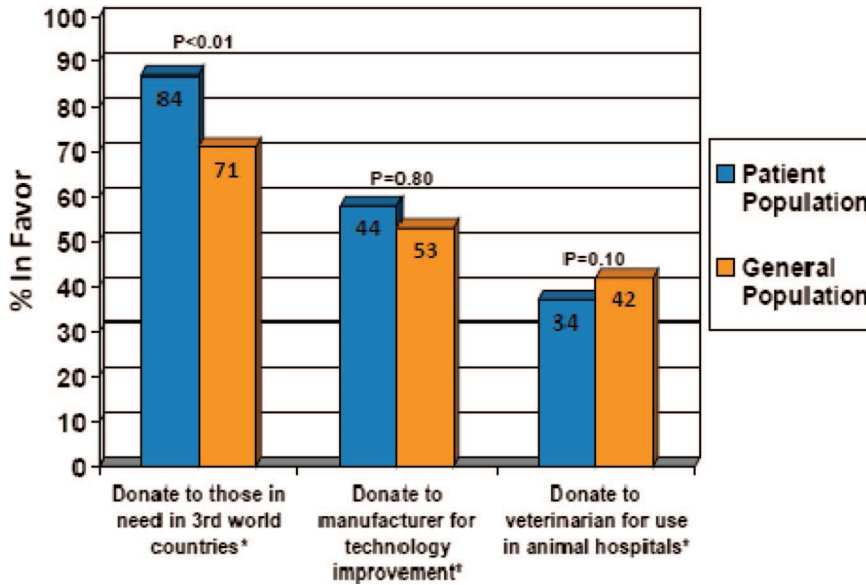


Figure 2. Views of general population and patient population with pacemakers and implantable defibrillators relative to device reuse.

(Figure 3) and that 84% of devices in southeastern Michigan funeral homes were discarded in medical waste or stored with no intended purpose.¹⁵ These results are consistent with a previous study demonstrating that explanted devices are rarely returned to the manufacturer.¹⁹ This practice conflicts with guidelines from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines recommending that funeral directors notify all physicians of patients with cardiac devices and routinely return the device to the manufacturer after proper consent is obtained from the family.²⁰

A University of Michigan survey of 152 funeral directors reaffirmed the previous findings in the literature.¹⁵ This study showed that 69% of funeral directors lacked the knowledge of how to or found it difficult to return devices to the original manufacturer, and 81% supported a central independent organization to regulate device distribution. A large majority (89%) of funeral directors were willing to donate devices to

charitable organizations if given the opportunity (Table 1). Based on estimates from survey responses, a total of 166 postmortem pacemakers and ICDs are currently stored in southeastern Michigan funeral homes with no purpose.¹⁵ These data illustrate that an overwhelming majority of funeral directors have the desire and ability to perform postmortem cardiac device removal for humanitarian reuse in underserved nations if given the opportunity and proper framework.

We propose that the Project My Heart–Your Heart Pacemaker Reutilization Initiative may provide a model for treating those with symptomatic bradycardia in underserved nations. Project My Heart–Your Heart is a joint collaborative between the citizens, physicians, and funeral directors of the State of Michigan, the University of Michigan Cardiovascular Center, and World Medical Relief, Inc. Through collaboration with the Michigan Funeral Directors Association, 1057 funeral directors in the state of Michigan would receive a flyer describing the pacemaker reuse initiative and a referral to <http://www.myheartyourheart.org>, from which a proper legal consent could be downloaded. Funeral directors may request a free postage-paid envelope with instructions for device removal. All funding for this program would be provided by philanthropic donation and grants. Funeral direc-

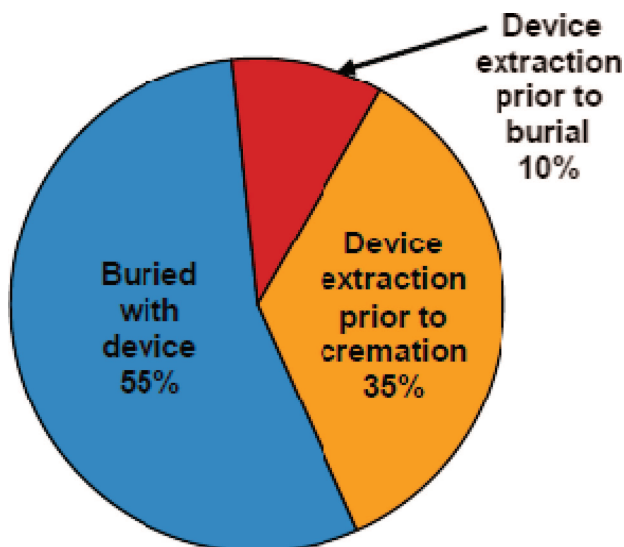


Figure 3. Current rate of device extraction in southeastern Michigan funeral homes.

Table 1. Current Use of Explanted Devices by Funeral Directors and Views Relative to Device Reuse

Survey Questions	Percentage of Funeral Directors (n=90)
Discard pacemakers in waste or store with no intended purpose	84
Return pacemakers to device manufacturer	4
Support a central independent organization to regulate device distribution back to manufacturers	81
Willing to donate the devices to charitable organizations if given the opportunity	89
Have previously donated a device for reuse in third-world countries	10

tors would be assured that no devices would be implanted without the express approval from the Food and Drug Administration (FDA).

Battery life and other performance testing specifications would be the initial criteria to determine whether a device is sent to underserved nations or returned to the manufacturer to evaluate for malfunction or unusual wear. We suggest a cutoff of $\geq 70\%$ battery life for further consideration to reuse. Previous studies have reused pacemakers implanted < 3 years and noted an average longevity of 7 years.²¹ We believe that a 70% cutoff would provide sufficient therapy for symptomatic bradycardia without subjecting patients to an unreasonable number of procedures over their lifetime. Currently, there are no data on the number of pacemakers explanted with a battery life $\geq 70\%$. However, a recent study of 328 implantable defibrillators explanted at the University of Michigan found that $> 50\%$ of devices removed for reasons other than elective replacement interval had an adequate battery life (defined as ≥ 24 months' longevity for Medtronic devices or $> 50\%$ battery life remaining for Boston Scientific/Guidant devices). Specifically, biventricular upgrade and heart transplantation were strong predictors of devices with adequate battery life.²²

Pacemakers would be closely inspected and rejected if there was evidence of exterior loss of integrity or damage, with extra attention paid to the set screws and header connections. All patient-identifying information would be erased from the device to preserve the privacy of the donor. After undergoing validated cleaning, performance testing, and sterilization processes, devices would be sent to nonprofit charitable organizations specializing in delivery of medical equipment for distribution to hospitals and clinics in underserved nations. These hospitals would be required to provide documentation of technical expertise and training with regard to pacemaker implantation and follow-up. All patients considered for charitable device implantation would have to show proof of financial insufficiency. Hospitals would not be able to charge for the donated device. Project My Heart–Your Heart has established relationships with UP-PGH in Manila and the Vietnam Heart Institute in Hanoi as potential implanting centers. Both academic institutions have been visited by members of Project My Heart–Your Heart to confirm adequate facilities and technical expertise. Moreover, the Ministries of Health in the Philippines and Vietnam are aware of a potential clinical trial and have deemed that importation and reuse of previously implanted pacemakers do not violate governmental policies. Finally, all patients would require follow-up for proper monitoring for pacemaker infection and device malfunction. An online registry would be created to track and monitor patients with reused devices. The hope is that this system would limit unauthorized sale or bartering of reused devices and would provide the ability to effectively communicate to the patients and implanting physicians in case of device recall.

When examining the concept of postmortem pacemaker reutilization, we must examine not only the technological aspects of device reuse but also the degree of cost savings associated with such an endeavor. Linde et al²¹ performed a cost-benefit analysis in 1994 and ascertained that 317 reused

devices had an estimated national savings of \$919 300. However, this number denotes only the cost of sterilizing the device itself and does not take into account physician or hospitalization fees. Using these previous factors and intangible factors such as product liability insurance, pacemaker availability, and the effects on hospital procedures, Myers²³ concluded that the savings associated with pacemaker reuse is generally negligible. In addition, low-cost manufacturers around the world have decreased the cost of a device to around \$800 plus the cost of leads and implantation.

We believe that pacemaker reuse can be a cost-effective measure if performed in the appropriate clinical setting. Despite the substantial cost reduction from foreign device manufacturers, a new pacemaker is often more than the annual income of the average citizen in underdeveloped nations. Project My Heart–Your Heart estimates that sterilization and shipping of reused devices to global implantation centers would cost approximately \$75 to \$100, with private donations and grants providing the devices to patients at no charge. In areas such as the Philippines and Vietnam, government-owned medical facilities can provide hospitalization and physician services at no charge to the patient. Moreover, these physicians would provide follow-up services because device companies would likely not be involved owing to liability concerns. The patient would be responsible for obtaining a new lead (\$200); however, we believe this is a reasonable expense for most patients and their families (personal correspondence, UP-PGH, November 15, 2008, and Vietnam Heart Institute, February 10, 2010). Nambodiri et al²⁴ showed that dual-chamber pacemaker generators can be effectively implanted as single-VDD-lead devices, resulting in a significant cost savings compared with the purchase of 2 new leads with no difference in quality-of-life scores. Therefore, if performed in the appropriate clinical setting, pacemaker reuse may be a cost-effective means of providing health care to those who are unable to obtain a new device.

Establishing the Feasibility of the Proposed Initiative

A review of the literature (Table 2) shows that the feasibility of this practice has been demonstrated in numerous settings worldwide.^{21,24–42} Furthermore, a joint collaboration with the ultimate goal of delivering pacemakers to those less fortunate has already been established in the State of Michigan. World Medical Relief is a nonprofit charitable organization with a mission of improving the well-being of medically impoverished individuals on an international scale through the distribution of donated medical commodities.⁴³ Several funeral directors in southeast Michigan have obtained consent for pacemaker donation and subsequently delivered these devices to World Medical Relief. Trained physicians then inspected the integrity of the device, and if battery life was $\geq 70\%$, the pacemaker was cleaned, sterilized with ethylene oxide, and packaged for shipping. World Medical Relief has established a relationship for pacemaker donation with UP-PGH in Manila. Before device implantation, a social work assessment of the financial status of the patient was obtained to validate financial need. All patients receiving charitable devices were documented and monitored for follow-up.

Table 2. Review of the Literature Relative to Pacemaker Reuse

Study	Duration of Study	Country	Pacemakers Reused, n	Follow-Up	Complications Related to Infection	Complications Related to Device Failure Caused by Reuse	Comments
Balachander et al ²⁷	1983–1999	India	453	17 y	Average battery life of refurbished device=8.3 y
Balachander ²⁸	6 y	India	140	6 y	2	0	
Pescariu et al ⁴⁰	1993–2001	Romania	365	35±21 mo	6	0	No statistical difference in infection or device failure rates between device reuse and new implantation
Linde et al ²¹	1998–1993	Sweden	100	32±11 mo	2	1	No statistical difference in infection or device failure rates between device reuse and new implantation
Panja et al ³⁹	1979–1992	India	120	7.5±5.6 y	6	0	Morbidity and mortality were similar to control population
Kruse ³⁶	1969–1985	Sweden	487	...	1	2	Of the 487 patients, 118 had already received a refurbished device
Kovacs et al ³⁵	1975–1980	Hungary	28	...	0	0	
Copperman et al ³⁰	5 y	Israel	78	...	0	0	
Mond et al ³⁷	1975–1978	Australia	83	...	1	0	
Amikam et al ²⁵	1976–1982	Israel	132	5 y	3	0	
Havia and Schuller ³⁴	1968–1974	Sweden/Finland	50	22 mo	1	0	
Grendahi ³³	1974–1993	Norway	310	...	14	4	
Costa et al ³¹	...	Brazil	22	16 mo	1	2	
Rosengarten et al ⁴¹	1981–1987	Canada	18	29 mo	1	3	No statistical difference in infection or device failure rates between device reuse and new implantation
Mugica et al ³⁸	1971–1981	France	151	10 y	No statistical difference in actuarial survival between device reuse and new implantation
Namoodiri et al ²⁴	2000–2001	India	5	19 mo	0	0	
Sedney et al ⁴²	1978–1983	Holland	214	31.5 mo	1	1	
Arén and Larsson ²⁶	1977–1979	Sweden	19	26 mo	0	0	
Ferugilo and Pagani ³²	1971–1978	Italy	87	14 mo	1	0	
Baman et al ²⁹	2008	Philippines	12	4 mo	0	0	

During January 2008 to July 2008, 50 pacemakers were donated from funeral homes to World Medical Relief. Twelve pacemakers were found to have a battery life $\geq 70\%$ and were subsequently cleaned and sterilized for use at UP-PGH in patients with inadequate financial means of procuring a device. Pacemakers were implanted in 12 patients (age, 62 ± 10 years) without complication. At the 4-month follow-up, none of the patients had evidence of pacemaker infection or device malfunction.²⁹

For decades, charitable organizations such as Heartbeat International⁴⁴ have successfully distributed devices close to expiration from a sterility standpoint that are donated from

pacemaker manufacturers. The group works through pacemaker banks established via local Rotary chapters in 24 countries. To date, Heartbeat International has donated >10 000 devices to those in great need throughout the world. Despite these great efforts, the surplus of expired devices donated from manufacturers is unable to meet the rising demand seen in third-world countries.¹³

Our preliminary experience with implantation of previously used devices at UP-PGH and the success of Heartbeat International support the safety and feasibility of a joint collaboration to effectively deliver health care to citizens in LMICs. Using a similar validated model, we believe that

many LMICs around the world could benefit from an organized regional, if not national, initiative to alleviate the prevalence of symptomatic bradycardia.

Obstacles to Pacemaker Reuse

Infection and Device Malfunction

One of the most feared complications of device placement is infection, which can be associated with a substantial mortality rate ranging from 2.6% to 18%.^{45–47} However, numerous studies worldwide have shown that pacemaker reuse is not significantly associated with infection or higher mortality compared with new device implantation.^{21,33,40,41} Linde et al²¹ found no statistical difference in infection rate or other complications between those with new devices and those with used pacemakers at 32±11 months of follow-up; interestingly, none of the 100 reused pacemakers had to be replaced because of premature battery depletion. Rosengarten et al⁴¹ performed a prospective trial comparing resterilized devices and new implants and noted no significant difference in infection or device malfunction rates at 36 months of follow-up. Moreover, other studies have shown no significant difference in survival with used device implantation.^{38,39} A recent meta-analysis of 18 studies including 2270 patients with previously reused devices found an overall infection rate of 1.97% and device malfunction rate of 0.68%.⁴⁸

However, this safety profile does not hold for used pacemakers implanted within the same individuals. Although Panja et al³⁹ found no difference in infection rates in a comparison of postmortem extraction and new device implantation after a 7.5-year follow-up, an 11.8% infection rate was noted in devices implanted within the same patient. These patients presented with pacemaker infection and subsequently underwent device removal and resterilization. The device was then implanted in the opposite side after an unspecified period of time. Possible causes of reinfection included hematogenous or lymphatic spread of infection from the original site to the new pocket or existing infection on the device despite attempted sterilization.³⁹

Legal Considerations

The 1985 North American Society of Pacing and Electrophysiology Policy Conference examined nearly 2000 patients with previously used pacemakers and concluded that reuse is not a risk factor for device infection.⁴⁹ The meeting determined that “the world experience indicates that the reuse of cardiac pulse generators is medically efficacious and safe if they are properly cleansed, sterilized, and reliably tested for function and battery life.”⁵⁰ Subsequently, the 2002 American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology guideline update for implantation of cardiac pacemakers acknowledged that pacemaker reuse “may eventually add significantly to the cost-effectiveness of cardiac pacing.”⁵¹

However, the US Food, Drug, and Cosmetic Act prohibits the “introduction into interstate commerce of any ... device ... that is adulterated or misbranded.”⁵² Although there are arguments that humanitarian donation for international use would not be considered “interstate commerce” for purposes of FDA jurisdiction, concerns have been raised that

involvement in this kind of initiative could impose on participants the responsibilities of manufacturers or distributors that they are not equipped to assume and possibly subject them to civil or even criminal penalties under the Food, Drug, and Cosmetic Act. In other words, the FDA might consider the acts of transporting an explanted device for processing, checking battery life, performance testing, and sterilizing as regulated activities even if the intent is humanitarian export. Moreover, before embarking on this type of initiative, participating institutions must consider whether they are prepared to assume potential product liability exposure for their role in “manufacturing” the devices or challenges from manufacturers with whom they contract to secure new devices for local patients.

There are several ways to address the regulatory concerns. For example, all parties could ship the devices without testing or sterilization as biohazardous material labeled “not for human use.” Contracts with the recipient institution would specify that all responsibility for sterilization, testing, and manufacturing rests solely with the institution. Unfortunately, this does not eliminate all regulatory risk and puts the onus of testing and sterilization on the party that may be least able to shoulder the burden. Alternatively, the participants in the initiative could seek FDA approval for export.^{53,54} This might be forthcoming but requires the participants to demonstrate, among other things, that the initiative is not in conflict with the laws of the recipient’s country, something that may be difficult to accomplish. Finally, the participants can seek an investigational device exemption from the FDA to perform a clinical investigation to validate the safety and feasibility of the pacemaker reuse. The investigational device exemption would include validated protocols for conducting postmortem device acquisition, cleaning, performance testing, and sterilization. The efforts for preparing the postmortem devices for reuse would be conducted in the United States; the clinical studies would be conducted at qualified LMIC sites. This last alternative is appealing because the process for securing investigational device exemptions is well understood by many academic institutions, and an investigational device exemption would permit prospective data collection to address concerns by manufacturers and others about the appropriateness, safety, and feasibility of device reuse.

Conclusions

Technological advances in the field of cardiac electrophysiology have improved the morbidity and mortality of many individuals in the Western world. However, we must never forget that at the foundation of each technological breakthrough is the need to improve humanity in all corners of our society. Whenever possible, medical therapies should be offered to each and every individual who may derive benefit. Pacemaker reuse is an opportunity for our society to positively affect the lives of many in impoverished countries around the world. Legal liabilities and safe medical protocols must be evaluated to provide guidance to individuals offering this medical technology. Establishing a validated pacemaker reuse program could transform a currently wasted resource into an opportunity for a new life for many citizens in our world.

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Disclosures

Dr Oral was a founder of Ablation Frontiers, Inc and is now a consultant for Medtronic Ablation Frontiers. The other authors report no conflicts.

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