

The ethics of pacemaker reuse: might the best be the enemy of the good?

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Symptomatic bradycardia contributes significantly to mortality and decreased functional status in many low and middle income countries (LMIC). In contrast to the developed world, where bradycardia often results from sinus node dysfunction, patients requiring pacemakers in LMIC more commonly present with complete heart block.^{1–3} Yet many patients in LMIC have little to no access to electrophysiological therapies, as the cost of one device often exceeds the annual income of the average citizen.⁴ Several countries—including Sweden, India and Canada—have previously explanted and reutilised pacemakers from deceased donors for reutilisation.^{5–7} With increasing global disparities in medical care, post mortem explantation and reuse of pacemakers presents a potential means for mitigating the rising burden of cardiovascular disease in LMIC.

Recent survey data indicate that almost 45% of deceased pacemaker patients in the USA have their devices extracted for reasons including family request and risk of device explosion during cremation. Notably, over 80% of these extracted devices are discarded or stored as waste. The vast majority of funeral directors, device patients and the general population support donation of explanted pacemakers to LMIC.⁸ ‘Project My Heart—Your Heart’ is a proof of concept pacemaker donation initiative that allows funeral directors to send explanted devices to an academic centre for evaluation and reutilisation before donation to underserved patients in LMIC.⁹ A recent case study of 12 reutilised pacemakers donated through this programme to indigent patients in the Philippines demonstrated successful implantation with no complications.¹⁰ Given such pacemaker availability, public support and potential efficacy, a pacemaker donation effort appears quite viable.

With growing evidence to suggest the plausibility of pacemaker recovery and reuse, it is imperative to reflect on whether, ethically, it ought to be done. Surely pacemaker donation promotes the well being of recipients with no access to therapy. And based on the available data, reutilised pacemakers do no harm provided there is adherence to protocols regarding standardised sterilisation, proper device handling and implantation, oversight to prevent diversion or re-sale, and patient education and follow-up. Furthermore, informed consent by both donors and recipients ensures respect for autonomy.¹¹

The primary ethical justification for pacemaker reuse involves the principle of distributive justice, or the fair allocation of resources within society. In

a seminal 1972 essay entitled ‘Famine, affluence and morality,’ philosopher Peter Singer bases an argument for global distribution and liberalism on two simple premises: (1) “[S]uffering and death from lack of food, shelter, and medical care are bad,” and (2) “[I]f it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it”. Certainly, one can debate what constitutes a ‘morally important’ purpose or need. While it could be argued that pacemaker reuse might aid domestic populations with less access to healthcare, uninsured patients in the USA still have better access to devices than most patients in LMIC through governmental services and charity programs. Moreover, given a safety regulation by the US Food and Drug Administration that prohibits domestic reuse of pacemakers, explanted devices remaining in the USA could only serve the purpose of promoting future quality improvement if returned to manufacturers. If, rather, they are discarded, then, by Singer’s definition, there exists a moral duty to donate them abroad to those most in need.

Several device companies oppose pacemaker donation, preferring instead the return of explanted devices for assessment and quality improvement. While returning pacemakers to manufacturers for quality improvement is endorsed by the Heart Rhythm Society, only a tiny fraction of funeral directors currently do so.^{8,9} The increased public awareness created by a charitable pacemaker donation initiative would likely influence funeral directors to allocate more devices for potential donation. As only the devices with battery life $\geq 70\%$ are selected for donation, the rest could be returned to manufacturers. With a significant increase in devices returned for quality improvement, the marginal benefit of returning those with $\geq 70\%$ battery life would be diminished. Donation of these pacemakers to needy recipients in LMIC might then be possible without sacrificing anything of ‘comparable moral importance.’

Still, there is concern that expanded pacemaker reuse overseas may lead to domestic reuse in developed nations, and that such a practice is below the standard of care in these countries. A recent meta-analysis of studies investigating pacemaker reuse (several of which were performed in Sweden prior to its integration into the European Common Market) demonstrated low absolute rates of infection and device malfunction but also raised the following concerns¹²: (1) there was a significantly higher rate of device malfunction with reutilised

devices when compared with new device implantation; (2) although no evidence of prion transmission was reported, there remains considerable concern due to the ineffectiveness of prion eradication with standard cleaning protocols¹³; and (3) re-sterilised devices, due to battery life less than full capacity, are likely to require more frequent generator replacements, thus putting recipients at a greater lifetime risk for surgical complications and infection.

The apparent difference in efficacy of new versus re-sterilised pacemakers raises a pressing question pertaining to distributive justice. Should re-sterilised pacemakers be donated to LMIC when they are below the domestic standard of care?

An illustrative parallel may be drawn between the use of suboptimal, but more available, pacemakers and the current use of expanded criteria donor (ECD) organs for solid organ transplantation. Organs defined as 'expanded criteria donor' as opposed to 'standard criteria donor' (SCD) are those that carry additional risks for transplant failure due to associated donor comorbidities.

The ethical justification for ECD organ transplantation rests on a few key principles. Firstly, ECD organs are only offered to patients who may never receive an SCD organ due to lengthy wait times. Secondly, only informed patients who willingly accept the risks of ECD organ transplantation are considered potential recipients. Finally, ECD organ transplantation confers a significant mortality benefit compared with alternative, bridging therapies (ie, dialysis).¹⁴

Similarly, re-sterilised pacemakers are offered only to patients in LMIC who cannot access a new device, and only after informed consent. Furthermore, these devices also confer a mortality benefit as patients with symptomatic bradycardia denied pacemaker therapy would likely succumb to their arrhythmia or suffer significant morbidity limiting their ability to work.

We therefore believe that charitable donation of explanted pacemakers for reuse in medically underserved nations represents an ethical endeavour that maintains respect for both donors and recipients, and is consistent with the tenets of distributive justice. Despite these assurances, there remain questions about how best to allocate pacemakers with differing battery lives to the patients who receive them in LMIC.

Analogous discussions regarding donor organ allocation focus on an *equal access* versus a *maximum benefit* theory of distributive justice. The former is a bias free approach that disregards gender, race, income, geographical distance from organ and even medical condition, while emphasising factors such as length of wait time. The latter focuses on medical need and the potential success of a transplant to maximise the life years gained by the limited supply of donor organs. Recent support for a maximum benefit approach to donor kidney allocation promotes stratifying donor organs based on viability—beyond the ECD/SCD dichotomisation—and matching them to the predicted survival of intended recipients. It is argued that fewer cumulative life years would be lost from using less viable organs on patients with greater expected survival, and vice versa.¹⁵

Given their differing battery lives (70–99%) and an inability to recharge devices and/or replace solely the batteries, re-sterilised pacemakers could be placed on a similar viability spectrum, raising a question that may require future consideration: Which

patient in LMIC should receive which donated pacemaker? Limiting donation to expired new devices—as preferred by device manufacturers—or re-sterilised devices with near 100% battery life might avoid this dilemma but the demand far outstrips the supply of such devices.

It seems that pacemaker donation may induce lingering discomfort about donating devices that are not 'the best' in some way. The French philosopher Voltaire, in his *Dictionnaire Philosophique* (1764), wrote that "the best is the enemy of the good", a saying often invoked in the context of resource limited healthcare. In our case, an overemphasis on the optimal treatment—whether a new pacemaker or the 'best' available re-sterilised pacemaker—may impede the substantial benefits to be gained from an otherwise effective treatment, particularly when the target population has no present alternative for therapy. Thus, when 'the good,' a re-sterilised pacemaker with $\geq 70\%$ battery life, can improve or save a life without sacrificing anything of comparable moral worth, we are ethically obligated to provide this valuable resource.

Competing interests HO was a founder of Ablation Frontiers, Inc, and is now a consultant for Medtronic Ablation Frontiers.

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