

## Pacemaker Reuse for Patients in Resource Poor Countries: Is Something Always Better Than Nothing?

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### Abstract

Cardiovascular disease is the most common cause of death across the globe. Large disparities in access to cardiovascular care exist in the world. An estimated one million people die each year due to lack of access to life saving pacemaker therapy. We discuss the concept of justice in health and health care as it relates to the use of refurbished pacemakers in patients in low- and middle- income countries, where financial circumstances severely limit access to brand new devices. Egalitarianism, utilitarianism, and justice as fairness are examined, as they relate to provision of re-processed pacemakers. This practice, since it holds promise to improve human functioning and capabilities, can be morally justified with some conditions: transparency, further research in its safety and efficacy, and its impact on other needs and priorities in those countries. (Prog Cardiovasc Dis 2012;55:300-306)  
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“Technical excellence and political commitment have no value unless they have an ethically sound purpose” Lee Jong-Wook, Director General of the WHO (2003–2006)

Ask most people what health problems are found in low- and middle- income countries (LMIC) and, chances are, you will hear about HIV, malaria, and diarrhea. Some might mention starvation, impure water, or famine, violence and injury, or Ebola virus. The leading causes of death worldwide, however, are not these but non-communicable diseases (NCDs) — cardiovascular and respiratory disease, diabetes and cancer. Together they killed 36 million people in 2008. Almost 80% of those

deaths occurred in LMIC.<sup>1</sup> Of these, cardiovascular disease (CVD) is the most common, contributing to 17 million deaths annually. It is estimated that, even in Africa, where there are still more deaths from infectious diseases than NCDs, the latter diseases will kill more people than communicable diseases by 2030.<sup>1</sup> This epidemic has become so dire that in September 2011, the United Nations General Assembly held a high-level meeting about the global health crisis of NCDs. The only other UN General Assembly meeting focused on a global health crisis, held in 2000, focused on HIV/AIDS.<sup>2</sup> Not only are NCDs more common in LMIC than in well-off countries, they are also more likely to cause premature death. Twenty-nine percent of NCD deaths in LMIC occur under the age of 60, affecting people in their most productive years, compared to 13% in high-income countries.<sup>1</sup>

The United States and other advanced economies have generally managed the challenge of the increasing NCD

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**Abbreviations and Acronyms****CVD** = cardiovascular disease**GDP** = gross domestic product**HIV/AIDS** = human immunodeficiency virus/acquired immune deficiency syndrome**ICD** = implantable cardioverter defibrillator**LMIC** = low- and middle-income countries**NCD** = non-communicable diseases**WHO** = World Health Organization

burden with high cost therapies. NCDs garner millions in research and development, which produce a panoply of effective – but expensive – drugs and devices. Nowhere is this more evident than in the field of electrophysiology. Implantable devices prolong life and improve its quality for many patients with brady- and tachyarrhythmias in the developed world. As with many higher-cost therapies, however, access to pacemakers is highly skewed across the globe.

A 2009 survey of pacemaker implantation performed in 61 countries showed widely disparate rates of device implantation; for example 782 implants per million of population in France compared to 4 implants per million in Pakistan.<sup>3</sup> It has been estimated that more than one million people die each year due to lack of pacemaker therapy.<sup>4</sup> 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,<sup>5–9</sup> symptoms that can debilitate those living in demanding environments in the developing world. The global impact due to lost economic opportunity from untreated bradyarrhythmia adds to the rising disability burden in many countries where patients in their productive years do not have access to this costly therapy. In other words, “those most in need of care have least access.”<sup>10</sup>

How should profound disparities between countries be addressed? Unlike the need to address communicable diseases, the prevention and treatment of non-communicable diseases, which “cannot spread” across national borders, have not been prioritized by donors. Only 3% of global development assistance for health went towards combating NCDs in 2007.<sup>11</sup> Some would argue that the most cost-effective approach to this growing epidemic involves public health measures to *prevent* cardiovascular disease. However, humanitarian considerations justify treatment of those already affected. Margaret Chan, Director-General of the World Health Organization (WHO), eloquently stated the need for both prevention and care: “We need population-wide preventive measures for NCDs, developed with other sectors, but we also need to help individual people. We need to detect early, treat, manage complications and often provide prolonged or even life-long care.”<sup>10</sup>

Appreciation of the unmet need for pacemakers in LMIC has led to the establishment of reuse programs for

such devices. Although pacemaker reuse was once standard of care in some countries such as Sweden and Canada, their reuse is not approved in the United States or the European Union.<sup>12,13</sup> Pacemakers have been explanted post-mortem, interrogated for adequate battery life, and sterilized with the intent to send them to implanting centers in resource poor countries.<sup>14,15</sup> A recent meta-analysis has found the reuse of pacemaker associated with infection rates similar to unused devices, but with a slightly increased risk of mechanical malfunction. Reused devices malfunctioned at a rate of 0.68% (compared to new, OR 5.80 [1.93 to 17.47],  $P=0.002$ ); none of these malfunctions led to death or severe harm.<sup>15</sup>

In the United States, attention to medical devices tends to focus on quality and safety, not cost, with predictable consequences for the price, and therefore access to these products, as well as consequences for medical waste. Policies to enable safe reuse include requiring that medical device reproducers comply with the same requirements that apply to original equipment manufacturers, including a pre-market 510(k) clearance.<sup>16</sup> When done properly, the reuse of medical devices is legal and generally accepted by healthcare professionals in the United States.<sup>13</sup> It is estimated that at least 20–30% of U.S. hospitals reprocess single use devices.<sup>13,17,18</sup> While preliminary data suggest safety and efficacy of pacemaker reuse for devices that have adequate remaining battery life, to date implantable pacemakers are not approved for reuse in the U.S. or European Union. Many other devices, such as electrophysiology catheters, endoscopes and hemodialyzers, are approved for reuse.

Does donating a device not approved for use in the donor country create a double standard too great to be morally acceptable?<sup>19,20</sup> Or, when the likely alternative is no device at all, is something always better than nothing? Besides the moral requirement of transparency – that both patients and professionals using such devices know that they are used, and are aware of the risks and uncertainties – the refurbishment and reuse of medical devices in LMICs require attention to distributive justice. In this paper we examine how device reuse might be judged using egalitarianism, utilitarianism and justice as fairness.

**Justice in health and healthcare**

Why do we need to consider justice when making decisions about health services and resources? A lack of healthcare, like a lack of food, will cause pain and suffering; food stamp programs attest to a social concern that no one should lack that primary good. Healthcare, like education, can be considered a public and private good — a public good because of society's interest in healthy, educated citizens who can participate fully as citizens, and

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