

## Cardiac Device Reutilization: Is It Time to “Go Green” in Underserved Countries?

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In recent decades, the industrialized world has seen a dramatic decline in the morbidity and mortality associated with cardiovascular disease. Unfortunately, this benefit from preventative therapies and medical technologies has not been witnessed in low- and middle-income countries (LMIC) that account for >80% of all cardiovascular deaths worldwide.<sup>1</sup> What was once thought to be a disease of only affluent industrialized nations has now superseded malaria and tuberculosis as the epidemic of the 21st century.

There exists no greater inequality between industrialized nations and LMIC than in the field of cardiac electrophysiology—specifically device implantation. In 2005 alone, more than 1,050 new pacemakers and implantable defibrillators (ICDs) were implanted per million people in the United States as compared to 111 new cardiac device implants per million people in Brazil.<sup>2</sup> As a result of these gross inequalities, various organizations have recently delivered cardiac devices to those in need in underserved nations: (1) Heartbeat International is a charitable organization that specializes in allocating pacemakers near their “sell-by” date generously donated by device manufacturers. To date, more than 9,000 devices have been implanted through pacemaker banks established by local Rotary International chapters in 24 countries over four continents.<sup>3</sup> (2) World Medical Relief, a nonprofit organization specializing in delivery of medical equipment for distribution to hospitals and clinics in underserved nations, recently delivered 12 resterilized pacemakers to patients in the Philippines who could not afford device therapy.<sup>4</sup> Novel therapies must be considered in order to prevent the estimated one million deaths that occur annually due to a lack of access to bradyarrhythmia therapy.<sup>5</sup> Device reutilization appears to be a safe, feasible, and ethically responsible means of delivering electrophysiological healthcare to those in great need in underserved nations.

In this issue of the Journal, Hasan et al.<sup>6</sup> extend prior observations of device reutilization for those who are unable to acquire brady- or tachyarrhythmia therapy. These investigators acquired antemortem cardiac rhythm devices with  $\geq 70\%$  battery from 17 patients who met criteria for device explantation. The majority of devices were harvested as a result of necessary upgrade; however, seven devices utilized in the study were explanted due to infection. The devices then underwent a superficial cleansing procedure followed by an ethylene oxide protocol. The pacemakers and ICDs were then transported to Centro de Cardiología Nacional and Hospital Militar de Managua in Nicaragua. Patients who were deemed financially incapable of acquiring a new device were then offered a resterilized device. At  $68 \pm 38$  months no patients exhibited signs of infection, early battery depletion, or device malfunction. Three patients died secondary to reasons not attributable to their device. The authors concluded that antemortem device reutilization is a safe and effective method of care for those in underserved nations such as Nicaragua.

So, is device reutilization the panacea for all those in underserved nations who require brady- or tachyarrhythmia therapies? Prior to altruistic electrophysiologists distributing previously implanted devices around the world for reutilization, several issues must be addressed. First, is this practice safe? The authors of this study would lead us to believe that antemortem device reutilization is safe, although they were limited by a small sample size. However, their observations are supported by a meta-analysis that examined four trials and 603 patients with reused devices and found no higher rate of infection when compared to device implantation.<sup>7</sup> Moreover, 5% of all devices implanted in Sweden in 1996 were from a previous recipient; there is no evidence that this practice resulted in any increased patient risk.<sup>8</sup> Larger clinical studies are necessary to further understand the safety of device reuse from an infectious disease perspective.

Second, reutilized device allocation is limited to countries with government-run health facilities as patients presumably will not be able to afford physician or hospital fees. Even with government assistance, the patient would be responsible for obtaining a new lead (\$200); however, we believe

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this is a reasonable expense for most patients and their families.<sup>9,10</sup> Namboodiri et al.<sup>11</sup> showed that dual-chamber pacemaker generators can be effectively implanted as single VDD lead devices resulting in a significant cost savings as compared to the purchase of two new leads, and there was no difference in quality-of-life scores.

Finally, it is conceivable that the allocation of \$10,000–\$25,000 medical devices in an unregulated setting could lead to an inadvertent “black market” resulting in unfair distribution and diversion away from those who are most likely to benefit. Aside from medical factors, determining a hierarchy of “deservedness” in the setting of extreme scarcity may lead to potential abuse and self-gain.<sup>12</sup> However, one must never deny or limit medical technology to those less fortunate due to

a *possibility* of malfeasance, but rather institute safeguards with meticulous chains of custody, proper documentation, and credentialing of each handler. Clear policies for device distribution must be in place, as well as appropriate channels for auditing.<sup>12</sup>

In conclusion, Hasan et al.<sup>6</sup> have provided further evidence that device reutilization can be performed in a safe and efficacious manner with excellent outcomes. From a clinical perspective, the reuse of devices for those in underserved countries, such as Nicaragua, appears to be a safe and effective method of providing healthcare to those with limited options. Large-scale clinical studies are necessary to further understand the efficacy and risk of device reutilization in underserved countries.

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