

Reuse of cardiac implantable electronic devices to improve and extend lives: a call to action

Thomas C Crawford, Kim A Eagle

A dramatic increase in the heart disease burden has taken place in the last several decades. Cardiovascular disease is no longer the disease of the affluent world alone. According to WHO, at least three-quarters of the world's deaths from cardiovascular disease occur in low/middle-income countries (LMICs).¹ Patients in those countries, especially the poorest of the poor, experience enormous obstacles in access to essential medical care. Furthermore, disability from cardiovascular disease contributes to poverty through loss of income and high out-of-pocket expenditures. The World Bank views health as a developmental issue, having direct and indirect effects on economic growth.² The Institute of Medicine has issued a call to action for partnership and collaboration among a range of public and private sector entities to address the crisis of rising cardiovascular disease.³ According to the report, inadequate access to advanced cardiovascular technologies is one of the major contributors to cardiovascular disease morbidity and mortality in LMIC. The cost of pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy devices (CRTs), commonly referred to as cardiac implantable electronic devices (CIEDs), presents a grave challenge to strained public and individual finances. In many parts of the world, CIEDs are too expensive relative to the economic output to be available to large segments of society. Medical societies, governments and non-governmental organisations have been toiling on ways to extend costly care to the neglected patients in LMICs.

The study by Raja *et al* published in this issue of *Heart Asia* highlights one such effort with refurbishing and reuse of CIEDs.⁴ The authors present their experience with nearly 900 consecutive patients who underwent implantation of a de novo CIED or a generator replacement over a

span of 5 years in a tertiary care centre in India. In this cohort, 627 (71%) patients received a new device, and 260 (29%)—a refurbished one. Most of the reconditioned CIEDs had been procured from STIM développement, a French voluntary organisation, although some generators were explanted from patients presumably due to eligibility for device upgrades or infections at the Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India, where the study took place. CIEDs were screened for external signs of damage and interrogated with the appropriate programmer. Devices with estimated longevity more than 4 years or battery impedance $<1000 \Omega$ were reprocessed. CIEDs were washed and soaked in an enzymatic detergent, and then underwent two cycles of sterilisation with ethylene oxide.

While the study was not randomised and retrospective, it represents a very large series of patients with *complete* follow-up for 6 months after device implantation. Three patients in the entire cohort developed CIED infection requiring removal: two were pacemakers and one a CRT device. None of the infections occurred with refurbished CIEDs. The infection rate at 6 months was indeed very low by the best of world standards at 0.34%. There were no device malfunctions in either group during the follow-up of 6 months, although during one implant of a refurbished device, loss of capture due to a loose set screw was noted and rectified before completion of the procedure.

The findings of this study add another important piece of evidence to the plethora of reports on the reuse of CIEDs. Ever since the 1970s, multiple investigators on every continent have reported on the safety and efficacy of pacemaker, and more recently ICD reuse. The studies describe cohorts of patients who underwent generator implants, which had been locally refurbished at the authors' institutions. A meta-analysis of 18 such studies pooling 2270 patients has shown that the risk of infection, the primary concern of physicians, is not statistically different between recipients of new and refurbished

pacemakers. Compared with new device implantation, there was a sixfold increase in the risk for malfunction in the reuse group. Still, the risk of malfunction in those devices was only 0.68%. The malfunction was mainly driven by abnormalities in set screws as well as non-specific device 'technical errors'. The present report by Raja *et al* also found a set screw problem during one implant, which was rectified before the completion of the procedure.

The totality of the reports substantiates the claim that CIED reuse should be seriously considered as a means of delivering life-saving and life-enhancing therapy to patients who lack adequate health insurance and personal resources for an out-of-pocket payment for a CIED. Calls for CIED reuse are not new. In 1985, the North American Society of Pacing and Electrophysiology (NASPE) policy conference concluded that based on available literature pulse generator reuse 'should not be considered substandard care'.⁵ The NASPE conference urged the development of comprehensive policies to address the technical and legal issues surrounding the practice of pacemaker reuse. Similarly, the European Society of Cardiology Policy Conference in 1998 encouraged cooperation between the implanting physicians and the industry to create standards and procedures for safe CIED reuse.⁶ Unfortunately, nearly 20 years later, widely accepted standards for safe pacemaker and ICD reuse have not been developed, and there continue to be legal and regulatory barriers to widespread adoption of CIED reuse.⁷

Several steps must take place, however, before CIED reuse for the benefit of patients who lack access to new pacemakers and ICDs can become commonplace. We need to develop and validate protocols and standards for collecting, cleaning, electrically testing and sterilising CIEDs for reuse. The risks of a pacemaker failure in a pacemaker-dependent patient or inappropriate ICD shock present the potential for catastrophic consequences. The evaluation and reprocessing protocols must be peer reviewed, published and vetted by professional societies and regulatory agencies. A legal framework should be developed to assure that the original equipment manufacturers are not liable for potential device malfunction secondary to the reconditioning process. There is also a clear need to develop a network of medical centres of excellence with expertise on CIED reuse, which would enable sharing of the knowledge and experience, training and the development of basic

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competency in implantation, as well as appropriate follow-up.⁸ A multinational registry collecting data on the reprocessed device, its implantation and follow-up has the potential to assure quality, to provide a benchmark and guidance on process improvement and to encourage regulators to embrace the practice of CIED reuse, which could save hundreds of thousands of lives worldwide. Our group at the University of Michigan <http://www.myheartyourheart.org>, our sister organisation in the United Kingdom Pace4Life <http://www.pace4life.org>, Pan African Society of Cardiology <http://www.pascar.org/> and numerous other partners across the world have begun to systematically address some of these challenges and opportunities. No one can do this alone. We applaud Raja *et al* for sharing their experiences, and adding the valuable outcomes data from their cohort. It is through dedicated and charitable work like theirs, that one day we can hope to extend benefits of life-saving and life-

enhancing cardiovascular treatments to those neglected.

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