

Using reconditioned pacemakers to treat bradycardia in Africa

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Pacemaker therapy is inaccessible to most patients with bradycardia in Africa. Use of reconditioned pacemakers has been proposed as a safe, efficacious, and ethical means of delivering this therapy. A collaboration between PASCAR, Pace4Life, and Project My Heart Your Heart is working to address this deficit in health care in Africa.

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The African continent is experiencing a dramatic epidemiological transition, with an increasing burden of noncommunicable diseases. These chronic conditions put stress on the economies of countries that are already poor in resources. Access to health care across the continent is heterogeneous. Many countries struggle to fund basic health care, and resources for advanced therapies are very limited. Only eight African countries provide universal health care, whereas health care in the remaining countries is paid for at the direct personal expense of the patient¹.

Six decades after the introduction of cardiac pacing into routine clinical practice in more affluent countries, patients in many countries in Africa still have no access to this technology. The Pan-African Society of Cardiology (PASCAR) carried out a comprehensive assessment of device implantations in all regions of the continent and found that 8 out of the 31 African countries surveyed did not have an established pacemaker implantation centre². The median pacemaker implantation rate was 2.66 per million of the population, which is 200-fold lower than in Europe². The researchers concluded that a lack of economic resources and facilities, the high cost of procedures and devices, a deficiency of trained physicians, and the lack of fellowship programmes were the main reasons for pacemaker underutilization². The enormity and complexity of the problem, they argued, required close partnerships between governments, manufacturers, medical societies, and other invested stakeholders to foster the creation of implantation facilities, to minimize implantation costs, and to increase local expertise.

In 2015, PASCAR established a fellowship in cardiac pacing, which is used to train physicians and technologists from underserved countries, who are trained through a 6-month fellowship in cardiac pacing at Groote Schuur Hospital and the University of Cape Town, South Africa.

PASCAR has embraced a goal to train a team of pacemaker implanters for every country without a pacing service in sub-Saharan Africa by 2030. To date, three physicians have been trained and have subsequently developed pacing services in Kenya, Sierra Leone, and Tanzania.

Pacemaker manufacturers provide a very limited number of pacemakers philanthropically, but this provision is insufficient to meet the requirement on the continent. Pacemaker reuse has been proposed as a reasonable option to deliver this very much needed therapy. PASCAR has forged a partnership with Project My Heart Your Heart based at the University of Michigan, USA, and the UK-based charity Pace4Life, which have worked together to create a standard blueprint for safe pacemaker reconditioning. Medical literature documents successful instances of pacemaker reuse programmes in Asia, Australia, Europe, and North America, starting as early as the 1970s, and continuing to the present day. A meta-analysis performed by the Project My Heart Your Heart investigators included 18 studies published between 1974 and 2008 involving a total of 2,270 patients³. The analysis showed that the risk of infections was similar between reused and new pacemakers, whereas the risk of mechanical malfunction was sixfold greater with reused pacemakers, usually owing to screw malfunction or technical error³. A subsequent study from Groote Schuur Hospital reported clinical outcomes in 102 patients, half of whom underwent implantation of reconditioned pacemakers, and the other half received new pacemakers⁴. No significant differences were observed in the rates of infection, malfunction, early battery depletion, or premature device removal between the reused and new pacemakers over the median follow-up of 36 months⁴.

In Europe and the USA, >350,000 pacemakers are implanted annually, and numbers are projected to continue rising. The pacemakers are implanted mostly in

elderly individuals who tend to have multiple medical comorbidities and, therefore, limited life expectancy: the average age of a pacemaker recipient is 75 years for a dual-chamber device and 80 years for a single-chamber device. Pacemakers now commonly have sufficient battery life for 10–12 years of operation, and many patients die within a few years of device implantation. Post-mortem pacemaker removal before cremation is mandatory because of the risk of explosion. With ~40% of deceased patients undergoing cremation each year in the USA, a large potential source (>75,000 per year) of pre-cremation explanted pacemakers exists for reuse. After the death of a patient, implanted medical devices remain the property of the deceased individual's estate, so pacemaker reclamation requires evidence of the patient's consent before death to donate the device (such as an advance directive), or a similar authority after death from the deceased individual's family or next of kin^{5,6}.

Another potential source of pacemakers for reuse is device upgrade in patients with a pacemaker who develop indications for either an implantable cardioverter-defibrillator (ICD) or a cardiac resynchronization therapy (CRT) device for advanced heart failure. In both circumstances, the explanted pacemaker might have several years of battery life remaining⁷.

The FDA and the European Medicines Agency approved pacemakers as single-use devices. However, this restriction does not necessarily mean that re-implantation of pacemakers is unsafe. Instead, neither the manufacturer nor a third party has sought regulatory approval for reconditioned devices to be used. In addition to the shortened longevity of the refurbished device, two main concerns exist regarding their reuse: the risk of infection and mechanical or electrical malfunction. Project My Heart Your Heart developed a comprehensive protocol for pacemaker cleaning, functional testing, and sterilization to provide a measure of sterility and reliability of the reprocessed devices⁸. In 2015, Project My Heart Your Heart and its sterilization partner NEScientific obtained an export permit from the FDA allowing the reprocessing of pacemakers and their export to low-income and middle-income countries, whose governments provided express permission for pacemaker importation.

The purpose of the device-reutilization programme is to provide potentially life-saving therapy at no cost to patients who have no other means of procuring a device. If a certain standard of sterility and reliability with reused pacemakers can be consistently demonstrated, and with appropriate informed consent from the recipient patient, a device with reduced longevity (compared with a new device) might be a viable alternative to death or reduced quality of life. On the basis of current evidence, the use of refurbished pacemakers provides substantially more benefit than harm and can be ethically justified under the principles of egalitarianism, utilitarianism, and justice in health care⁹. Providing cheaper, less effective treatments can be considered an appropriate response in different economic contexts. According to Persad and colleagues, the application of resource sensitivity supports the provision of refurbished pacemakers, even when they are considered non-standard treatment in high-income countries¹⁰. The providers of reconditioned

pacemakers and their partners must assure safe implantation, appropriate follow-up, and a replacement device when needed.

The delivery of reconditioned pacemakers provided at no cost to indigent patients with bradycardia in Africa is a just cause. Our group's work can be viewed through the prism of the WHO's Sustainable Development Goal of universal access to essential quality care by 2030. The partnership between PASCAR, African governments, Project My Heart Your Heart, and Pace4Life is strong and committed and will ensure the success and sustainability of this initiative far into the future. Our shared goals can be accomplished only through a multilateral approach, maintaining a cardiac pacing fellowship, fostering regulatory approval and infrastructure development on the continent, and providing devices and outcomes reporting through an international registry of reused pacemakers under the auspices of PASCAR and Project My Heart Your Heart. When a successful, scalable model of pacemaker reuse is demonstrated, the project will evolve to include ICDs and CRT devices, which are more complicated and require a greater degree of infrastructure and local expertise.

Tremendous technological progress has been made in the treatment of cardiovascular disease, and millions of people have benefited from longer and fuller lives. Sharing these technologies with all whose lives might be positively influenced is an ethical imperative. Pacemaker reuse is one means of improving the health equity on the African continent. To achieve this goal, African governments must work to create the appropriate legal framework.

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Competing interests

The authors declare no competing interests.

RELATED LINKS

NEScientific: <https://www.smarthealth-care.com/>

Pace4Life: <http://www.pace4life.org/>

Pan-African Society of Cardiology (PASCAR): <http://www.pascar.org/>

Project My Heart Your Heart: <http://www.myheartyourheart.org/>

WHO's Sustainable Development Goal: <https://sustainabledevelopment.un.org/?menu=1300>