

Complementary role of governments, non-governmental organizations, industry, and medical societies in expanding bradycardia therapy access

Jitendra Singh Makkar¹, Goran Milasinovic², and Chi Keong Ching^{3*}

¹Eternal Hospital, Chainpura, Malviya Nagar, Jaipur, Rajasthan, 302020, India; ²Referral Pacemaker Center, Clinical Center of Serbia, Koste Todorovica 8, 11000 Belgrade, Serbia; and ³Department of Cardiology, National Heart Centre Singapore, 5 Hospital Drive, Singapore, 169609, Singapore

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As the aging population continues to grow, so has the incidence of cardiovascular diseases, including bradycardia, with much of the burden falling on low- and middle-income countries (LMICs). Pacemaker therapy remains the only guideline-recommended therapy for symptomatic bradycardia, but due to the cost and expertise required for pacemaker implants, patients in LMICs have less access to pacemaker therapies. However, with the concerted effort of organizations (governments, non-governmental organizations, industry, and medical societies) strides can continue to be made in improving access to care. Governments play a role in extending health coverage to its citizens and improving their physical and digital healthcare infrastructure. Non-governmental organizations promote access and awareness through charity and advocacy programs. Industries can continue innovating technology that is both affordable and accessible. Medical societies provide guidelines for treatment and necessary educational and networking opportunities for physicians who serve in LMICs. All of these organizations have individual responsibilities and goals in expanding access to bradycardia therapy, which can be more easily realized by their continued collaboration.

Introduction

Developing countries and low- and middle-income countries (LMICs) face a growing incidence of non-communicable diseases (NCDs) such as heart and lung disease. Making the problem worse is the fact that LMICs are at a marked disadvantage in terms of resources, physician expertise, hospitals, primary care, education, and healthcare training, which has created a health crisis in many regions.¹ Over 40 million people die from NCDs annually, with 85% of these deaths occurring in LMICs.² The most common NCD, cardiovascular disease, accounts for a third of all deaths globally, with LMICs carrying a majority of that burden.²

Soaring rates of cardiovascular deaths in developing countries are fuelled by underdeveloped and underpenetrated treatment. Guideline-recommended treatments for cardiac arrhythmias require immense resources and specialized facilities and physicians, which puts a further strain on delivering this care to patients in LMICs. Thus, underutilization of pacemaker therapy in LMICs is leading to untimely deaths due to life-threatening bradyarrhythmias. In the USA and Western Europe, the rate of pacemaker implant ranges from 62 to over 100 per 100 000 people,^{3,4} whereas developing regions such as parts of Africa (0-15 per 100 000),⁵ Eastern Europe (19-50 per 100 000),⁴ Latin America (3-13 per 100 000),⁶ Central/Southern Asia (0.7-16 per 100 000),⁷ and the Middle East (3-5 per 100 000)⁶ it is significantly lower.

Most of these resources, expertise, hospitals, and training universities to provide high quality, state of the art pacemaker therapies are concentrated in high-income

*Corresponding author: Tel: +65 67048875, Fax: +65 68449069, Email: ching.chi.keong@singhealth.com.sg

countries. In LMICs, the high cost of these devices and lack of awareness, infrastructure, and skilled professionals may explain the disparate adoption rates. Even if some geographies have access to this therapy, most of the use is limited to single chamber pacemakers. For example, a multicentre survey in India showed that 54% of all cardiac electronic implantable device (CIED) implants were single chamber pacemakers, with males receiving 67% of these implants. Additionally, 76% of total pacemakers implanted were for atrioventricular blocks.⁸ Sinus node dysfunction (SND) or sick sinus syndrome is a less appreciated and treated aetiology in these geographies, hence being an important reason for the small number of total implants. While SND may not cause mortality, those with symptomatic bradycardia will benefit from pacemaker implants by experiencing a significant improvement in their quality of life, a fact that may be less well known in developing countries.

The expansion of pacemaker therapy access in LMICs requires the collective efforts of various stakeholders, including governments, non-governmental organizations (NGOs), industry, and medical societies. Each of these entities plays a crucial role in different aspects of the development process. Their roles should complement each other and foster collaboration to achieve increased penetration of pacemaker therapy.

Role of governments

Health policies

Establishing a health policy for a country or state is entirely the government's perspective. In general, there are four main dimensions of access including geographic accessibility, availability of CIED service, financial affordability, and acceptance of the therapy.⁹ All four are heavily influenced by governments and their policies that pertain to health insurance and infrastructure.

Health insurance coverage is low in LMICs, ranging from 7.9% in low-income countries to 27.3% in lower middle-income countries.¹⁰ In India, the number of households with one insured individual is 41%.¹¹ The most common insurance model in India is a government aided system where citizens are insured by a public or private insurance company, for which government pays the premium. In such policies there is a cap on the prices of certain devices, which may hinder the use of more modern CIEDs, but they still prove beneficial for people in need of the therapy who cannot afford it. Government-sponsored plans such as this are templates for other LMICs to replicate to expand health insurance coverage. In the Indian state of Rajasthan (population over 80 million), over 80% of families are covered by a health insurance scheme, but only approximately 2500 pacemaker implants are performed annually and about half of these are implanted under the government-funded scheme. Thus, the cause of the small number of pacemaker implants here, where health coverage is relatively high, is not just the affordability but the lack of awareness and facilities. Another issue facing LMICs that impacts access to health coverage is the high number of citizens who have informal employment, which constitutes 93% of the workforce in these regions.¹² Informal employment makes it difficult to extend health insurance coverage to these people, and

this is especially pronounced in Southeast Asia. Countries with high numbers of informal workers that committed to universal health coverage saw the highest expansion of healthcare coverage for these workers and this may be a model other LMICs can follow.¹³ Another option, which has been proposed in Pakistan to help address the burden of paediatric patients with congenital heart defects (CHDs), is using a value-based healthcare approach. In this approach, reimbursement is patient-focused, where physicians are rewarded for patient outcomes and not just for the number of patients they serve. As noted by Hasan *et al.*,¹⁴ such an approach may not be easily implemented in LMICs and would require a change in culture and dedicated funding from governments into healthcare systems.

Healthcare infrastructure

Governments need to invest in healthcare infrastructure, including hospitals and electrophysiology (EP) labs, to enable the implantation and maintenance of pacemakers. In LMICs, EP labs are only available in teaching hospitals and big private hospitals. In Africa, there is less than 1 pacemaker centre per million people, with at least four countries having no centre, and in Latin America less than 50% of hospitals have access to a dedicated EP lab.^{5,15} These facilities are crucial for extending bradycardia therapy and governments must work to develop more of these centres not only in major cities, but extend them to tier two cities and to district level hospitals. Also, LMIC health officials must work to establish, as a preventative measure, a well-functioning primary care system that can provide essential services at affordable costs. Regions that have worked to implement robust primary healthcare systems show an overall improvement in health, which can help reduce the need for more expensive, specialist interventions.¹⁶

Geographic access to EP services is a major factor. The distance and travel time to health facilities is an important barrier to access.¹⁷ Good roads are necessary for patient travel to health facilities, distribution of medical supplies by governments and organizations, and timely referrals in cases of emergency. The use of telemedicine through smartphone technology can help overcome some of these geographical barriers. Government health officials in LMICs can work to develop digital health systems in accordance with recommendations from the World Health Organization, which ultimately could improve awareness and diagnosis of bradycardia.¹⁸

Apart from the infrastructure, training of physicians and paramedics for implanting a pacemaker is an important target area for the government. A basic cardiology degree should include a curriculum for pacemaker training, which might require shifting of fellows or students from one centre to another if their parent institute is not capable of providing adequate training in this field. Additionally, the government can fund research programs, training programs, and merit-based scholarships for fellowships in pacing and EP.

Non-governmental organizations

Awareness and education

Like governments, NGOs play a vital role in improving access to bradycardia therapy by raising awareness

about the risks associated with untreated bradycardia and the benefits of pacemaker therapy among the general population and healthcare providers in developing countries. These NGOs may identify elements in their campaign to increase pacemaker therapies. In general, key interventions include education around detection, diagnosis and management of bradycardias, identification of knowledge-practice gaps, understanding healthcare system bottlenecks to implementation, and working to find solutions to overcome the bottlenecks.¹⁹

The NGOs can organize campaigns, workshops, and training programs to disseminate knowledge about the benefits and usage of pacemakers. Patient-to-patient interactions between those who have benefitted from this therapy and those who are about to receive a pacemaker is very important for developing this therapy. Where NGOs can potentially make the most impact, with very little cost, is through social media. Smartphones are a household commodity becoming accessible almost everywhere, which allows broader access to social media platforms. Groups and communities can utilize social media platforms to help spread awareness and education about the therapy. However, organizations must avoid the spread of disinformation on social media by working in concert with government health officials and therapy experts to provide accurate and up-to-date information.²⁰

Access to care

Organizations can work to improve access to pacemaker therapy in underserved areas by collaborating with governments, healthcare providers, and manufacturers. This may involve setting up mobile clinics, subsidizing treatment costs, or providing financial assistance to patients in need through fundraisers. Around 86 NGOs are known to be involved with cardiac surgical care, and for those that report statistics, they contributed to just over 10 000 additional cardiac procedures per year in LMICs.²¹ For example, the Brave Heart Fund, based in Lebanon, raises funds to provide congenital heart surgery for free and the Haiti Cardiac Alliance covers the medical cost, in addition to food and accommodations, incurred during surgery.²² With the increasing burden of arrhythmias in LMICs, these initiatives are a start, but clearly more work is needed by NGOs to further increase access to cardiac procedures.

Donating near-expired devices, which are due to expire for their sterilization, is not at all a bad idea for such parts of the world where affordability is a major issue. Two such NGOs, Pace4Life based in London and Project My Heart Your Heart formed out of the University of Michigan, were the first organizations established to collect pacemakers from funeral homes for reuse in LMICs.²³ Efforts such as these figure to help thousands of people annually in LMICs obtain access to pacemaker therapy, a number that could grow with collaboration from other entities.

Advocacy

Advocacy plays an increasing role in improving detection, diagnosis, and management of bradycardias, influencing healthcare policies and driving changes within healthcare systems to overcome roadblocks. Campaigns may be conducted to raise awareness and educate the public on the role of pacemakers in the management of

symptomatic bradycardias. It removes the stigma associated with the condition and/or pacemaker implantation and empowers patients to take charge of their decisions and treatment plans. Advocacy also brings the voice of these patients and their families to the table in close collaboration with physicians, professional societies, and even policymakers.

Advocating for those who are unable to speak for themselves is also important, this is especially true for paediatric patients in LMICs. While adults in LMICs in need of pacemaker therapy often do not have access to care, the problem is exacerbated for children with CHDs. Nearly half of children with a CHD will need medical intervention, which includes pacemakers, and it has become the leading cause of death for neonates in LMICs. Yet 9 of 10 children in LMICs have no access to the necessary cardiac care, causing life-long debilitation.²⁴ While more advocacy is needed for all pacemaker-indicated patients in LMICs with no access to proper care, a special focus should be made to advocate for children with CHDs who require pacemakers.

Role of industry

Research and development

Medical device manufacturers have the primary responsibility of developing and advancing pacemaker technology. They must continue to invest in research and development to improve the design, functionality, and longevity of pacemakers making them more suitable for the specific needs of patients, while at the same time searching for ways to make their devices more affordable. As the technology progresses, medical device companies could continue production of older pacemaker models and offer them to patients in underserved countries at more feasible prices or donate inventory for older models that are no longer part of their portfolio.

Affordability and accessibility

Industry players can help bridge the gap of bradycardia therapy access in several ways, most notably by working on cost reduction strategies and development of affordable pacemaker models specifically targeted to the needs of developing countries. They can also work with local governments to establish distribution networks and supply chains to ensure the availability of pacemakers in remote areas.

As previously mentioned, recycling of CIEDs for use in LMICs has gained steam in recent years and has been shown to be medically feasible. In 2018, Sinha *et al.*²⁵ performed a meta-analysis on the safety of pacemaker and implantable cardioverter-defibrillator reuse that included nine (five with control groups) observational studies. The rates of infection, device malfunction, and premature battery depletion were not significantly different than the controls. In 2020, Khairy *et al.* reported on the safety and efficacy of CIED reuse. This study analysed the outcomes of recycled CIEDs implanted in LMICs in Latin America by experienced providers (>5 years' experience) in comparison to a control group receiving new CIEDs in Canada. The results demonstrated a low 2-year infection rate (2.0% vs. 1.2% in controls, $P=0.06$) and no difference in device-related deaths.²⁶

Though there are ethical concerns raised about the potential risks of implanting recycled CIEDs, these concerns must be weighed against the ethics of failing to prevent significant morbidity and mortality related to poor access to CIEDs in these LMICs. The industry should collaborate with NGOs and the local LMIC regulatory bodies to ensure proper CIED sterilization, supply the pacing leads at cost, establish standards, ensure quality assurance, and help create a registry of these recycled CIEDs. While most, if not all, of the programs for CIED reuse have been started by non-profit organizations, industry, and original manufacturers of the devices could play a bigger role in facilitating the proper preparation and distribution of second-hand devices in LMICs.

Training and support

Industry can provide training programs to healthcare professionals on the implantation, maintenance, and troubleshooting of pacemakers. They can also offer technical support and guidance to hospitals and clinics in LMICs to ensure effective implementation of training programs. In 2011, industry partners, in association with an EP team from Fortis Hospital in India, took the initiative to train physicians and anaesthetists from nearby rural areas for temporary pacing under C arm, which is used for orthopaedic procedures and is widely available. Placing these patients on temporary pacemakers bridged the gap until they were able to get to larger hospitals where they could get permanent treatments. Industry can also facilitate proctorship programs which are instrumental in training new implanters who can then provide direct services to the community. A well-organized proctorship program in sub-Saharan Africa from 1996 to 2018 led to an increase in the percentage of people receiving needed pacemaker therapy from 3 to 98%.²⁷ With virtual learning becoming more common and internet more accessible, industry manufacturers, in concert with local governments and NGOs, can develop online courses for physicians in underserved countries to train proper implant techniques with their instruments and devices.

Role of medical societies

Professional guidelines

Medical societies play a crucial role in developing guidelines and standards of practice for pacemaker therapy. Guidelines help healthcare professionals in developing countries to understand the indications, implantation techniques, and follow-up care related to pacemakers. However, due to the lack of data from LMICs, the guidelines are mostly created based on experiences from developed countries, and it is unclear how this impacts cardiac arrhythmic care in developing regions. Thus, it is imperative that societies perform due diligence to ensure that guideline-recommended care can be applied to LMICs for the most effective therapy plan. This can be aided by the expansion of region-specific societies (for example AFHRA, APHRS) in developing areas of the world that can focus on gathering data from their regions to help inform therapy guidelines. Region-specific societies can then collaborate with government health officials to ensure that guideline-directed education and training is delivered to those who need it most.

Knowledge exchange

Medical societies facilitate knowledge sharing among healthcare professionals, both nationally and internationally. They organize conferences, seminars, and scientific publications, enabling doctors in developing countries to stay updated with the advancements and best practices in pacemaker therapy. Continued virtual access to these conferences is important so that physicians from LMICs can benefit from these educational activities without the need for travel. Along these lines, holding regional conferences makes it easier for physicians to attend and learn or exchange information with professionals in their field who serve similar patient populations. The Africa Heart Rhythm Association (AFHRA) held its inaugural Cardiorhythm Africa conference in January of 2020 in Nairobi. It was attended by an international multidisciplinary network (including clinicians, and industry and allied health professionals) being established for the first time.²⁸ To develop capacity, the ARHRA launched a 30-week online modular course covering arrhythmia management and basics on interventional cardiac EP.²⁹ Subsequently, advanced courses and live teaching cases were added to the module. Such initiatives bring much needed training and education activities to the physicians in underserved regions and thus an effort must be made to mirror such societies in other underserved regions.

Training of physicians and paramedics

Multiple fellowship and training programs are run by medical societies which are instrumental in training professionals who can provide pacemaker therapy. The coordination between local and international societies can prove very important to disseminate the latest technologies and improve quality of implants. In India and Bangladesh, the Improve Brady study implemented patient and physician education around the diagnosis of SND in hopes of increasing the number of implants for guideline-recommended patients. In phase I of the study patients with symptomatic bradycardia were treated by physicians as per standard care. Phase II began after implementing educational material for patients and physicians. The diagnosis of SND and implantation of permanent pacemakers increased significantly from Phase I to Phase II (72% vs. 87% and 17% vs. 32%, respectively).³⁰

Also important is ensuring that physicians from LMICs who train in EP specialties abroad return to their home countries. In Lebanon, the Lebanese Society of Cardiology Arrhythmia and Pacing, which includes 20 cardiac electrophysiologists who trained in the USA or Europe, was formed to help improve access to EP services in Lebanon. They have made several strides including the formation of a National registry in Lebanon for tracking cardiac implantable electronic device infections.^{31,32}

Conclusion

The phrase, 'it takes a village to raise a child' is an African proverb which conveys the message that nothing of great importance can be accomplished alone and that it requires not just many people, but many people working together. Similarly, the implementation of pacemaker therapy in LMICs requires the collaborative efforts of government,

NGOs, industry, and medical societies in conjunction with patients and local physicians. These agencies must coordinate their efforts to ensure the successful development and implementation of pacemaker therapy in developing countries. By combining their expertise, resources, and advocacy, they can make significant strides in improving the quality of cardiac care and enhancing the lives of patients residing in developing nations.

The framework of geographic accessibility, availability of CIED service, financial affordability, and acceptance of the therapy identifies important barriers. Many of these factors are specific to or more prominent in certain LMICs, and depend on local context and how policies are implemented. As such, while each type of organization can contribute to improving access to pacemaker therapy, success will depend heavily on their understanding of the barriers within each region and identifying strategies that complement the unique issues each LMIC faces.

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