

Heartbeat International: Making “poor” hearts beat better

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BACKGROUND Heartbeat International is a little-known 501(c)(3) charitable organization, which for the past 25 years has been responsible for the implantation and follow-up of cardiac implantable electronic devices in over 9000 indigent recipients in predominantly developing countries. Although the concept was founded in Guatemala over 30 years ago, it took the vision and drive of Dr. Henry D. McIntosh, M.D., M.A.C.C., to create Heartbeat International in 1984.

DISCUSSION The organization works through Pacemaker Banks established by local Rotary International chapters and other civic organizations in 24 countries over four continents and is dependent on the generosity of the implantable device manufacturers and teams of dedicated physicians and hospital personnel in the countries of operation. Since the vast majority of personnel are voluntary, 90 cents of every donated dollar directly supports the provision, implantation of devices, and follow-up care. Each

US\$500 provides a pacemaker to one needy patient. The organization's co-mission is also to educate and train implanting physicians in pacing and implantable cardioverter-defibrillator technology. The program remains dependent on the pacemaker manufacturers, who work in an environment of regulatory constraint and economic imperatives. With an ever growing demand for these devices, Heartbeat International will in the future need to increase its operating budget to purchase implantable inventory.

KEYWORDS Pacemaker; ICD; donations

ABBREVIATIONS ACC = American College of Cardiology; FDA = Food and Drug Administration

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Introduction

On December 26, 2008, Dr. Henry D. McIntosh, M.D., M.A.C.C., passed away in Lakeland Florida after a long illness (Figure 1). A distinguished and much beloved physician and administrator, Dr. McIntosh served on numerous cardiology committees and boards, including the presidency of the American College of Cardiology (ACC) in 1974–75.¹ His professorial positions included Duke University School of Medicine (1962–70), University of Florida School of Medicine (1977–2000), University of South Florida School of Medicine (1993–98), and in particular professor and chairman of the Department of Medicine at Baylor College of Medicine in Houston (1970–77). A humble man and forever a humanitarian and champion of the poor, Dr. McIntosh is best known internationally as founder of Heartbeat International, a charitable 501(c)(3) organization, which through its strategic alliances with Rotary International and other civic organizations, pacemaker manufacturers, and an army of medical and nonmedical volunteers is responsible for providing and implanting cardiac implantable electronic devices in indigent and needy patients in 24 countries over four continents. His creed, “The service we give to our

fellow man is the rent we pay for the right to live” is a testimony to his lifetime service in helping the poor. Despite Dr. McIntosh's pioneering endeavors, little is known of Heartbeat International's important humanitarian work. This manuscript aims to help fill that void and provide ongoing support for an organization whose sole goal is to help save the lives of those who, because of financial constraints, cannot afford the cost of an implantable cardiac electronic device.

History

The genesis of Heartbeat International occurred over 30 years ago in Guatemala, Central America, when a local physician, Dr. Federico Alfaro, was referred a profoundly symptomatic 19-year-old with complete heart block. The family was unable to afford the cost of a potentially “curative” pacemaker. Dr. Alfaro tried unsuccessfully to obtain financial assistance, but in the end all he could do was watch the boy die. He vowed that in the future his countrymen would not die because they could not afford a pacemaker.

With the help of the local Rotary group, Club Rotario de la Asuncion, Guatemala City, Dr. Alfaro organized the first Pacemaker Bank in 1977. A board of directors of nonmedical Rotarians, a medical director, and cooperating cardiologists and surgeons were responsible for organizing and operating the bank. Within a short period of time, the bank had acquired over 50 predominantly refurbished pulse gen-

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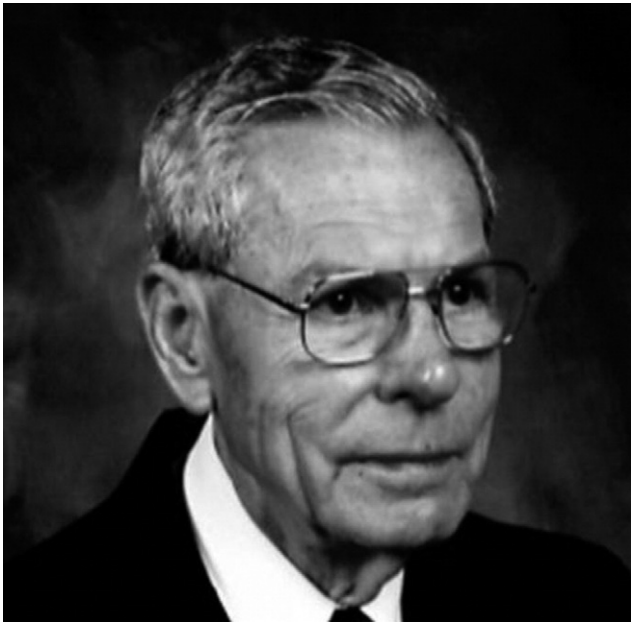


Figure 1 Dr. Henry D McIntosh, M.D., M.A.C.C.

erators from a variety of sources. At that time, refurbishing of pulse generators was a common practice worldwide,² although restricted in the United States by legal concerns and the Food and Drug Administration (FDA). The Central American recipients were indigent, and the implants were provided free of charge without regard to the inevitable need for a replacement should the patient live long enough. Pacemakers donated to the Guatemala bank were not limited to their own populace but were also distributed in Nicaragua, Costa Rica, El Salvador, Honduras, and the Dominican Republic.

In 1983, Dr. McIntosh learned of the program while on a visit to his former student, Federico Alfaro, in Guatemala (Figure 2). Dr McIntosh was so impressed with the beneficial and humanitarian potential of the program that he felt obligated to help in developing a similar international program. After a period of communication, Intermedics (Boston Scientific, St. Paul, MN) agreed to donate 486 new pulse generators and some leads to Dr. McIntosh. The president of Rotary International at the time, Carlos Consecro, M.D., pledged support for the program and subsequently arranged a grant of US\$250,000 for the purchase of sufficient endocardial pacing leads, allowing implantation of the donated devices.

One of Dr. McIntosh's early concerns was continuing education for participating Pacemaker Bank physicians, and thus he requested and received educational support from the ACC, which continues today at an annual workshop held in conjunction with the Annual Scientific Sessions of the ACC.

On October 18, 1984, Heartbeat International was born at the Watson Clinic in Lakeland, Florida, where Dr. McIntosh was a staff member. It was a cooperative effort of the clinic, Rotary International of Evanston, Illinois, representatives of the United States pacemaker industry, and consultative sup-

port of the ACC. By 1986, 16 Pacemaker Banks had been established. In addition to the one in Guatemala, other banks were established in Trinidad, Honduras, Jamaica, Nicaragua, El Salvador, Panama, Barbados, the Dominican Republic, Colombia, Ecuador, Philippines, Thailand, India, Venezuela, and mainland China. The same year, Heartbeat International was awarded a U.S. Presidential Citation for its international humanitarian work. By 1991, the number of Pacemaker Banks had expanded to 25 centers worldwide. During this period, Dr. McIntosh retired from the Watson Clinic and established Heartbeat International at the St. Joseph's Heart Institute in Tampa, Florida. Later, Dr. Peter Alagona served as president for several years, and Wil Mick, the executive director of the St. Joseph's Heart Institute, was appointed executive director of Heartbeat International and continues today to serve as the president and chief operating officer.

With the ever increasing demand for more pacemakers in the early 1990s, industry donations failed to supply sufficient implantable devices. Pacemaker pulse generators that exceeded "use before" dates were distributed from the Mount Alvernia Convent in Montego Bay, Jamaica, and the board of directors discussed the concept of collecting used devices and refurbishing them for use outside the United States. However, the regulatory obstacles were overwhelming. Thankfully, soon after, inventory donations once again

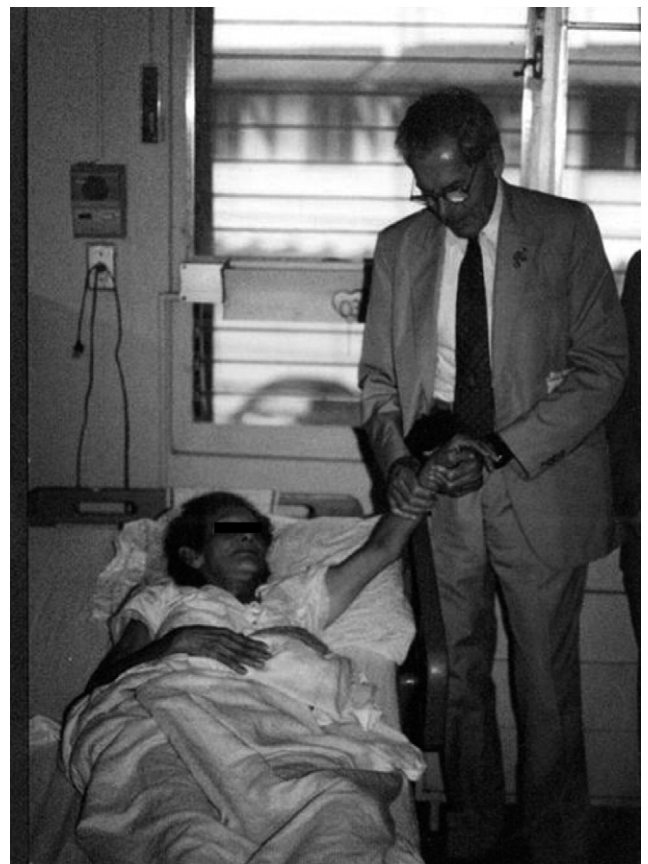


Figure 2 Henry McIntosh doing ward rounds in Guatemala.

increased to workable levels, and the concept of refurbishment was not implemented.

The year 1993 was an active and productive year for Heartbeat International. The organization's co-mission to educate and train implanting physicians was ably assisted by Medtronic (Medtronic Inc., Minneapolis) and the opening of the Arnold Zohn Pacemaker Bank in Chengdu, China, as a training center in Sichuan province. There were now 34 Pacemaker Banks in 23 countries, and at 2 days of age, Jose Alirio Perez of Medellin, Colombia, became the youngest recipient to receive a donated pacemaker. Heartbeat International was accepted as a member of the Independent Charities of America and in August 1995 took the important step of earning 501(c)(3) tax exempt status from the Internal Revenue Service. Financial constraints led to the requirement that each Pacemaker Bank be sponsored for 3 years at \$2000 per year. In 2004, an additional annual fee per Pacemaker Bank of \$4200 was established.

In 1999, Heartbeat International became the first recipient of the North American Society of Pacing and Electrophysiology (now Heart Rhythm Society, Washington, D.C.) benevolent fund. The organization celebrated its 5000th pacemaker implant, and new Pacemaker Banks were established in the Eastern European bloc—Lithuania, Romania, and Russia—giving a total of 41 pacemaker banks in 27 countries. After many years as its founding champion, Dr. Henry McIntosh retired, and Dr. Maniscalco took on the leadership role as chairman and chief executive and continues to serve in this capacity.

Although Heartbeat International is accountable for the correct selection of medically and financially appropriate recipients, the actual work is done locally under the auspices of the board of directors for each Pacemaker Bank. Once implanted, the appropriate paperwork and follow-up reports are sent to Heartbeat International and entered into a database for future reference. In this way, every patient and the implanted device are tracked. Recalls and other issues can be easily addressed.

Recognizing the need to provide greater economies of scale, ensure leadership succession, create local stakeholder participation and governance, and deal with legislative and governmental issues, management began a restructuring of the Pacemaker Banks in the early 2000s. With this came a stricter compliance on patient reports from the Pacemaker Banks back to Heartbeat International. One important change was the concept of one Pacemaker Bank with multiple implantation centers. For instance, Heartbeat International of Mexico and Venezuela were each reduced to one Pacemaker Bank, but with a total of six and three implant centers, respectively. New Pacemaker Banks were established in Pakistan, Honduras, Benin, and the Ivory Coast. Today, there are 24 participating countries over four continents.

Over a time span of 25 years, Heartbeat International has been responsible for the implantation and follow-up of cardiac implantable electronic devices in over 9000 indigent recipients in predominantly developing countries. The organization employs few staff, and its success is dependent

on the members of Rotary International, the incredible generosity of the implantable device manufactures, and the dedicated physicians and hospital personnel in the countries of operation. Since the vast majority of personnel are voluntary, a remarkable 90 cents of every donated dollar directly supports the provision, implantation of devices, and the patient's follow-up care. Each US\$500 provides a pacemaker and ongoing care to one needy patient, in comparison with an average estimated cost of US\$50,000 in the United States.

Future endeavors

There can be only one objective for Heartbeat International: to save and improve the quality of life of those who cannot afford to do so themselves, thus making "poor" hearts beat better. Although remarkable, the saving of 9000 lives is but the tip of an iceberg in regard to the numbers of indigent patients actually requiring implantable devices. A conservative estimate of need may exceed one million per annum worldwide. The program is dependent on the continued generosity of the pacemaker manufacturers. Yet these companies have their own limitations and concerns and work in an environment of continued regulatory constraint and economic imperatives. Thus, into the foreseeable future, significant limitations exist on the volume of donations and the ultimate reach of Heartbeat International. Donated implantable electronic devices are usually shipped urgently to Pacemaker Banks requesting devices for appropriately screened recipients. Many of these devices are approaching end of shelf life, and by FDA rulings, devices must be shipped outside the continental United States before the "use before" date.

Under the current system, it is unlikely that the number of donated devices will meet the need worldwide in the next few years. Pacemaker manufacturing companies may not be able to increase their donations substantially. To grow, Heartbeat International needs to become a bulk purchaser of devices, even at a local level, to cope with the increasing demand for this life-saving product. Obviously, its operating budget needs to be increased substantially. This may come from many different sources including government, charities, philanthropists, and private endowments not only in the United States but also in other generous developed countries and of course in the recipient nations. Heartbeat International has received recognition from the Internal Revenue Service as a public foundation under the name Heartbeat International Foundation. This critical designation allows Heartbeat International to accept funds from all potential donors.

To watch a child with a potentially fatal cardiac bradyarrhythmia receive a simple implantable device and walk briskly from a hospital is a joy to behold. To quote Dr. Henry D. McIntosh once again, "The service we give to our fellow man is the rent we pay for the right to live." Let us not fail him.

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