GLOBAL VOICES

A model for the development of cardiac implantable electronic device services in countries lacking such services

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Introduction

Pacemakers and other implantable devices have been one of the best treatments developed in medical history. Pacemakers save many lives and improve the quality of life of many others. Pacemakers are extremely cost-effective solutions for patients whose intrinsic heart rhythm has failed them. It is hard to imagine a world without these devices, but sadly, there are countries in the world where there are no services provided for implanting pacemakers and other devices.

The Pacific islands (Figure 1) are a region in the world where such services are completely absent. Islands such as Fiji, Samoa, Tonga, and Vanuatu have no pacemaker services. This means that not only do they not have the capability to implant the devices, but there is also no capability to check or follow up patients who have devices. Pacific island peoples have shorter life expectancies than people in the developed world due to lack of healthcare facilities and specialists. The life expectancy in Fiji is 70.4 years for women and 66.6 years for men.[1] By comparison, the life expectancy in New Zealand, which has a mixture of different ethnicities including Pacific Islanders, is 83.5 years for women and 80 years for men.[2] None of the Pacific islands offer their own cardiac surgical service in a region with a high prevalence of rheumatic valvular disease.

Challenges faced in the developing world

The biggest problem that developing countries face is of course one of smaller economies with a lack of funds to develop such facilities and services. This problem is compounded by a lack of people trained to do work such as pacemaker implantation and programming. There is a lack of cardiac procedural facilities. Fiji now has a cardiac procedural facility, but none of the other islands do. In such a vacuum of finances, facilities, and staff, it is extremely difficult for a developing country to develop such a service.

KEY FINDINGS

- The Pacific islands, including Fiji, Tonga, Samoa, and Vanuatu, have no implantable cardiac device services and are reliant on mission trips by voluntary organizations.
- Pacific Islands Pacemaker Services is a voluntary organization performing cardiac device implantation services in this region.
- A model is being developed to progress from reliance on mission trips to the development of local services.
- Development of local services in this region will require collaboration with other countries and institutions to enable training of Pacific island personnel, particularly in the area of device interrogation and programming.

Evolution of Pacific Islands Pacemaker Services

Pacific islands expatriates living in New Zealand and Australia recognized the lack of cardiology and cardiac surgical services in their homelands and developed an organization to address this. The Friends of Fiji Heart Foundation (FOFHF) was initiated in 2006 by a Fijian cardiac surgeon living in New Zealand. FOFHF developed a volunteer organization that sent missions of cardiac surgical teams to Fiji to perform valve replacement surgery on patients with underlying rheumatic valvular disease. Some patients post–valve replacement required pacemakers, and these were implanted by the surgeons. The need for support with pacing was evident. The 2-person volunteer pacemaker service team, which had been working with the Open Heart Fiji Team, was incorporated into the FOFHF cardiac surgical team.

From that initial service, the Pacific Islands Pacemaker Services (PIPS) team grew into what it is now. The need

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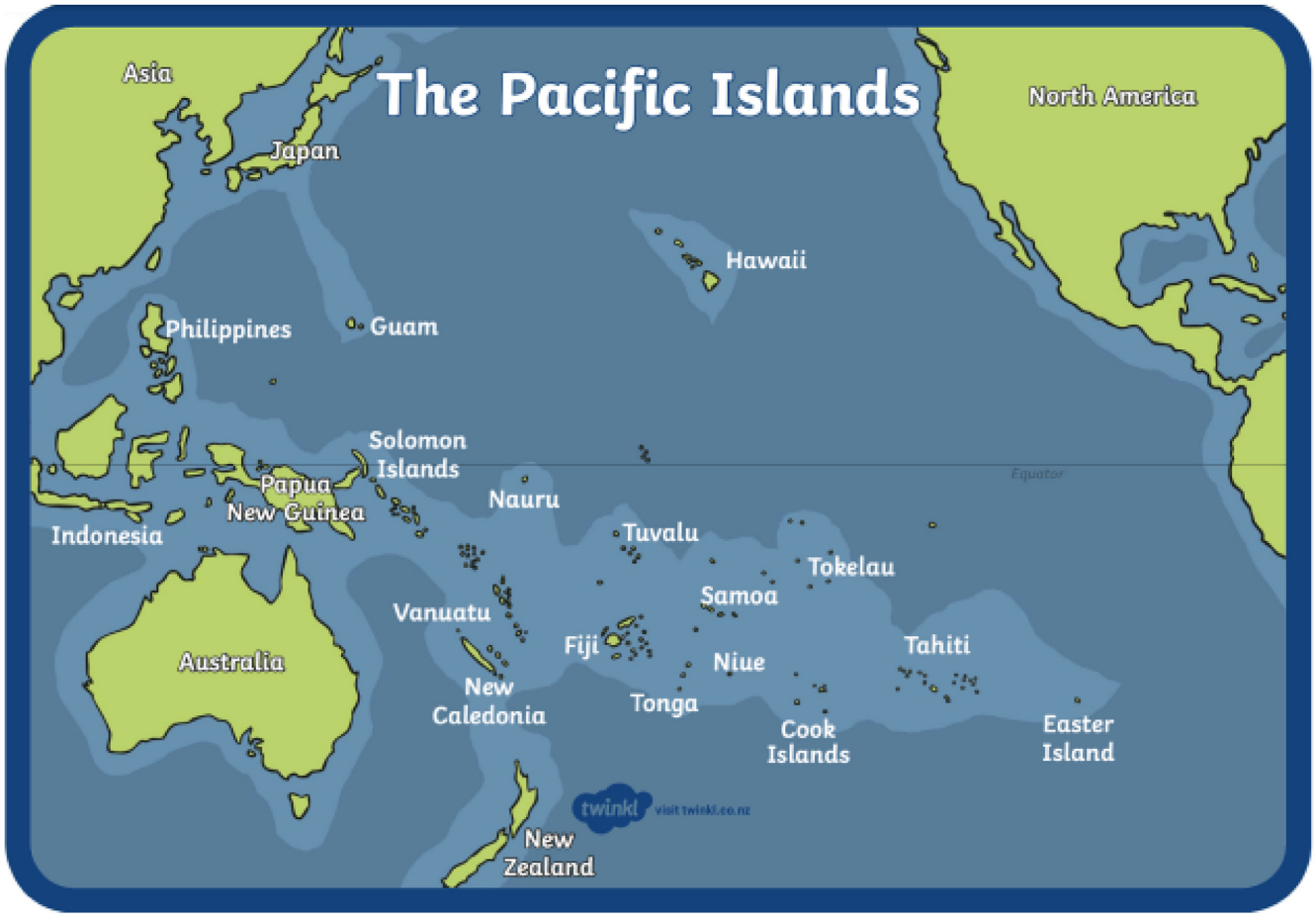

Figure 1 Map of Oceania showing Pacific Islands.

for other patients not having cardiac surgery to have pacemakers implanted for heart block was overwhelming and obvious. A team was then put together to send a mission that included an electrophysiologist to implant the pacemakers, a cardiac theater nurse to assist with the procedures, and 3 cardiac physiologists to perform programming of the devices and also to check all of the patients with devices. PIPS was born in 2009 (Figure 2).

The early years of missions had the pacemaker procedures performed in the local general surgical operating theater in Lautoka, on the north west coast of Fiji, using portable x-ray equipment. The temperature in the operating theatre was around 30 °C (86 °F), as there was no air conditioning. The portable x-ray was an old machine from the previous century with poor images. Conditions were challenging, but we proved that even in arduous conditions we could still safely perform pacemaker implantation procedures. When a center in Australia decommissioned their cardiac cath lab x-ray equipment, it was donated to Fiji and installed in the hospital in Suva, on the south east coast of Fiji. Since then, the procedures have been performed in the cath lab.

Figure 2 PIPS logo.

It soon became clear that a single trip per year only met a fraction of the need. Fiji has a population of just under 1 million people, so implanting on average 15 pacemakers in a year was better than nothing but still way behind implant rates in developed countries. In Australia, the new implant rate for pacemakers is 755 per million population and in New Zealand is 446 per million population.[3] The PIPS team then developed a second trip to Fiji each year. By doing a second trip each year, we doubled our new implant rate in Fiji to around 30 pacemakers per million population per year: better, but still considerably underserviced. In New Zealand people of Pacific Islands ethnicity have the highest rate of pacemaker implantation.[4] Extrapolating therefore from New Zealand data, there would be an expected need for pacemaker implantation of 420 pacemakers per year in Fiji.

Again, extrapolating from data of Pacific Islands people in New Zealand, there would be an expectation of around 160 patients with second- or third-degree atrioventricular block in Fiji per year.[5,6]

Clearly, there are impediments to patients being referred for a pacemaker in addition to the lack of pacemaker services. Access to primary healthcare is very limited. Consequently, patients only seek medical attention when they are very ill. The lack of primary care services is the major stumbling block. Some of the patients referred to our service have never had an electrocardiogram (ECG) performed prior to seeing us. Patients are referred purely on a slow pulse that has been detected clinically in locations where there is no access to basic services such as an ECG. We diagnose heart block with their first-ever ECG.

An unofficial wait list is kept by the local Fijian cardiologists between trips. Sadly, every time we arrive there are patients on the list who have died between trips. These patients could not survive with complete heart block until the next mission. Patients may have to wait around 6 months until the next mission from the time of diagnosis of heart block. The natural history of heart block without a pacemaker is clear. In the Africa-Pace program, 50% of patients died while waiting for a pacemaker, with a median wait time of 18.4 months.[7] Having completed successful missions to Fiji, the service expanded to other Pacific islands including Tonga, Vanuatu, and Samoa. Fiji will remain the hub of the region, as it has the best facilities and has 2 cardiologists that are having ongoing training with pacemaker implantation.

Current model of PIPS

PIPS is a voluntary organization, consisting of cardiac electrophysiologists, cardiac nurses, and cardiac physiologists. In New Zealand, cardiac physiologists are registered and certified practitioners. They usually have degrees in science and then undergo specific training in cardiac physiology. They are not doctors or nurses, but rather are their own professional group. Their role is to perform all the cardiac device checks and also to be present at device implantation. Cardiac physiologists make the vast majority of programming decisions independently and consult with electrophysiologists only when required in complex cases. All of these volunteers donate their time and expertise to go and do the work in the Pacific islands. There is a lot of planning done prior to each trip to ensure that all necessary equipment gets there and that everything runs smoothly. The team leader is the person doing most of the planning and coordinating.

We have deliberately chosen a strategy of making a cardiac physiologist, not the electrophysiologist, the team leader. There are a number of reasons for this decision. We wanted to recognize the fact that the cardiac physiologists started the service and were already active in this space before the original electrophysiologist got involved. The cardiac physiologists go ahead of the rest of the team and perform most of the device checks prior to arrival of the cardiac nurse and electrophysiologist. In New Zealand, the cardiac physiologists sort all the logistics around ensuring that all necessary equipment is available for procedures. They are therefore better equipped to deal with the considerable logistics of ensuring that all necessary equipment gets to Fiji. Finally, having a cardiac physiologist as team leader gives the cardiac physiologists the ability to choose the team members that they think will work together most effectively.

The original cardiac physiologist that went on the first trips became the chairperson of the PIPS charitable trust when it came into being. She is still the chairperson and is helped by a committee of volunteers including electrophysiologists, nurses, and cardiac physiologists.

It is essential when performing this work that there is a low complication rate. The local cardiologists, physicians, and patients need to have confidence that the procedures will be as safe as possible. This is always foremost in our minds. The electrophysiologists selected are experienced, high-volume operators with proven track records. In New Zealand, all institutions performing cardiac device implantation are obliged by the ministry of health to have all procedure data captured into the national database. The purpose of the database is to not only achieve equity in access, but also improve quality of service and monitor complication rates with the aim of reducing complication rates. The database includes all procedural complications out to 6 weeks postprocedure. This database information is open to public access and scrutiny. The Ministry of Health can obtain the complication rate for every cardiac device implanter within New Zealand. Complication rates from the database have been published, with low overall complication rates.[6] Our complication rates in Fiji are very similar to what they are in New Zealand. The hematoma rate is slightly higher because diathermy is not always available, and some procedures are performed without diathermy. There have been no pneumothoraces. Cephalic vein access is used routinely for all leads and axillary vein puncture only in those patients that do not have a useable cephalic vein. There have been no cardiac perforations or tamponade. Lead repositioning is around 2%. The infection rate is difficult to establish, as we are only present for a week at the time of implantation. We do rely on patients reporting back to the local cardiologists if they have issues postprocedure. The infections that we have been made aware of give us an infection rate of around 1%.

Each team is sent for 1 to 2 weeks, and during that period, all of the patients on the islands with devices are checked. The establishment of regular device follow-ups is crucial in extending the lives of these patients and to the success of this service. In Fiji, this now means performing more than 200 device checks per trip. Any patients that are found to require device replacement will then have their device replaced. In addition, all patients that have been referred for a pacemaker will get a new pacemaker implanted. The vast majority of these patients have complete heart block. The majority of patients therefore have standard dual-chamber pacemakers implanted. Patients with slow atrial fibrillation have single-chamber devices. Lead positioning depends on the electrophysiologist. The majority of right ventricular

leads have been positioned in a right ventricular outflow tract septal position. The remainder have been positioned midseptal or apical. Most trips now will have an average of around 20 pacemakers implanted during the second week of the trip. Each patient has a file and data is captured into a Paceart database. At the end of each trip, there is a debrief to go through all that was done and to consider any possible changes that may make future trips more efficient. The trips are intense, with long days in order to get through all the work.

Development of a sustainable volunteer workforce

Each of the members of PIPS use a week or two of their annual leave in order to go on the mission trips. With a handful of trips done each year, this requires a group of volunteers in order to be able to sustain the service. A team has been developed across NZ of volunteers from all the disciplines required including electrophysiologists, nurses, and cardiac physiologists. Most of the volunteers do 1 trip per year or alternative years, but some members have done multiple trips in a year. Recruiting people to do this work has, in fact, been very easy. Everybody who goes on a trip goes back to their usual workplace and feeds back to all of the people around them how enriching and rewarding this work is. Consequently, we get more volunteers.

Donated pacemakers

In the early days, the pacemakers, leads, and sheaths used were donated by various pacemaker manufacturing companies. Pacemaker interrogator/programmers are taken with the team and are borrowed from New Zealand public hospitals or industry for use in Fiji and then returned afterward. The pacemakers were usually pacemakers that had passed their use-by shelf date. There were limited numbers of devices available for each trip, and decisions had to be made around which patients had the greatest need and would derive the greatest benefit. Difficult decisions when almost all of the patients had complete heart block. As the service got up and running and established, Medtronic came alongside us and decided to generously commit to donate as many pacemakers as there were patients lined up for each trip. This was with the view to development of local services. The expectation was that once there is some local service, Fiji would purchase pacemakers as they required them, and so it has transpired. Medtronic representatives also join the teams during the trips and are embraced as part of the team.

Pacemaker reuse programs are used in other parts of the world, but we have not needed to use this approach. Devices that manufacturers can no longer sell or are unlikely to sell due to short shelf-life dates or have been superseded by newer models are our choice. We have managed to persuade manufacturers to donate such devices, so we have no need to reuse devices. It is our experience that device longevity for these devices is very similar to what we get with our devices implanted in New Zealand.

Transitioning to development of local services

One of the visions of PIPS is to be able to train the local people in Fiji to be able to provide the services themselves. There are 2 cardiologists in Fiji, and both join us with these missions; we are in the process of training them up to be able to perform pacemaker implantations. In addition, the cardiac nurses are also trained. This training has reached the point where the local team are now able to implant some pacemakers on their own when our team is not there. This is very challenging because patients in the Pacific islands are often only referred very late, when they have severe bradycardia related to complete heart block. These are often challenging and unstable patients. During pacemaker procedures, for the local team providing the service, there is no anesthetic support, surgical backup, or resuscitation team.

The PIPS team has built up a relationship with the local community. With a proven track record of safety and reliability, we have gained a position of trust, not only with the local cardiac team, but also with hospital management. Supporters of PIPS were able to meet with members from the Fijian health ministry. These connections have been made through personal connections. There are no formal processes or certifications in place. Eventually, the point has been reached where the Fijian health ministry has recognized the service that was being established and decided to support it. The Fijian health ministry then, for the first time, purchased pacemakers from Medtronic with the understanding that our team would continue to support the fledgling pacemaker service in Fiji. Long-term processes and certifications still need to be established.

Continued support

Thanks to the generosity of Medtronic selling the pacemakers at a reduced price, Fiji is now able to source the devices. The local team is developing, but is not yet at a stage in which they are able to run a service by themselves. We do envisage a need for continued support with teams sent from New Zealand. We envisage that in time the local service will become independent, but we are prepared to keep sending teams for continued support for as long as is required. The local Fijian cardiologists will over time reach the point in which they are able to perform the procedures independently. Our support will still be needed, mostly with teams going to check all the patients with pacemakers and other devices. Developing systems in the Pacific islands to be able to check devices is particularly problematic and challenging. Cardiologists and nurses exist, but the role of pacemaker programming does not exist. With development of the service, such roles will need to be established. Remote monitoring of devices is not currently feasible, given that many of the patients have no Internet connection or access to such facilities.

Independence and collaboration

The final step of the PIPS model is for the Pacific islands to ultimately reach independence with their own cardiac device services. That will require collaboration with people from

other countries. In order to train up local people to get involved with device programming, it will probably require bursaries or fellowships to send people to developed countries for intense periods of training. This would not be something that the Pacific islands can afford to do and will probably rely on institutions in the developed countries providing salaried fellowships. At present, most fellowships are for doctors advancing their training into specialized services. International fellowships are needed to train cardiac physiologists/device programmers.

Conclusion

There is an obligation on all of us to strive toward equity of access to healthcare services for all of humanity. There is gross inequity at present between developing countries and developed countries. Sharif and Ptaszek[8] highlighted the global disparities in arrhythmia care and outlined the challenges and potential opportunities for improvement in access. This is something that we as heart rhythm workers can help to improve by doing voluntary work. PIPS has developed a model that appears to be working not only in providing services in the Oceania region, but also in training countries without such services to develop their own service. The challenges are still enormous and ultimately beyond the control of healthcare workers. We can, however, do our part. The work is hard, but meeting so many wonderful people and knowing that you are making a difference is an enormous reward.

It is a privilege and a pleasure to be able to assist our island neighbors in the development of a pacemaker service. This model of development relies on the following. Trust has to be earned. Relationships have to forged and nurtured. Procedures must be performed at the same level of competency as we expect in the developed world. Working in places lacking resources requires a high level of skill to ensure safety and a low complication rate. Teams have to be dedicated and committed to the long haul. Hospital hierarchical models are best put aside in a team that spends almost all waking moments of the trip together. All members of the team are equally essential and valuable.

Progress is being made in the establishment of a pacemaker/CIED service establishment in the Pacific islands. Fiji is the logical hub for this, as it has the largest population and best infrastructure of the Pacific islands. PIPS will continue to support the development of this service for as long as it takes. Private enterprise has joined in the form of Medtronic coming alongside. The Fijian health ministry has recognized the service and purchased pacemakers. Public awareness through social media is being developed but needs support from people who know how to get the most out of it. Publication will help connect with other people in the heart rhythm healthcare sector who may be able to lobby with private institutions and government organizations. Fiji and the Pacific islands will not be able to develop this service on their own. Together, we can make it happen!

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