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Cardiac Pacing and Implantable Cardioverter-Defibrillator Surveys: Long-Term Australian and International Experience

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Forward:

This thesis represents work conducted over 40-years initially with Australian surveys on cardiac pacing and later ICDs. During the late 1990's, the author took on the responsibility of also organizing the world surveys, which are conducted each four years. The last two Australian and World (2005 and 2009) surveys were conducted and published under the banner of the Department of Epidemiology and Preventive Medicine, Faculty of Medicine, Nursing and Health Sciences, Monash University, Melbourne, Victoria, Australia and forms the nucleus of the dissertation.

The thesis has been prepared as an epidemiological work that can be readily understood by both medical and non-medical readers. All medical terminology has been carefully explained in simple English in Chapter 1. This was originally the Appendix, but the author felt that this represented a vital link in the development of the thesis and was promoted to the beginning. Although, probably too simple for the examiners, it nevertheless will be important to readers who are involved in taking on the arduous task of developing sophisticated pacemaker and ICD registries. Finally, each chapter has been written as a single entity with its own references. Consequently, there are areas of repetition in the text.

Preface and Acknowledgements:

The first implantable cardiac pacemaker was inserted in Sweden in 1958 using epicardial leads.[1] Within three years, a pacemaker was implanted at the Royal Melbourne Hospital in Australia.[2] During the first decade, world-wide cardiac pacemaker implant numbers were very low as the units were unreliable and short-lived.[3] However, by the mid 1960's, physicians commenced implanting permanent pacemakers using transvenous endocardial leads. Those early cases were technically long and difficult and the complication rates excessive.[2] Gradually with time, the implant procedures improved as did the incidence of complications and by the early 1970's, the number of fully implanted pacemakers implanted rose significantly.

In April 1973, the fourth International Symposium on Cardiac Pacing was held in Groningen, The Netherlands.[4] There were 1148 participants from 41 countries. At his opening address, His Royal Highness Prince Claus of the Netherlands reported that at that time, 2,500 patients scattered throughout the world, had received permanent artificial cardiac pacemakers. Previous pacemaker meetings in New York and Monaco had been very small and essentially local. A feature of the Dutch meeting was the presentation of the first pacemaker survey from 30 countries including Australia and New Zealand. It was the second time, I had presented at an international meeting and the first meeting to include virtually all the pioneers of cardiac pacing. The meeting had one lecture room and 16 invited speakers presented data on surveys from 31 countries, generally spread over a number of

years, but almost all included the calendar year 1972. Such was the importance of the world survey, that it covered 40 pages of the published proceedings.[4]

The 1972 Australian and New Zealand data was collected by me and presented by Dr Graeme Sloman.[4] During that year, 341 new pacemakers and 335 replacements were implanted in 20 Australian centres. Being such a small survey, outcome data including deaths before and after 30-days and clinical improvement were also collected. At this and subsequent symposia, the surveys were collected, presented and published in the style of the individual country coordinators, which was often incomplete, may have involved more or less than one-year and frequently the data was extrapolated to hopefully encompass the whole country.

Since those early pioneering days, there have been significant changes in the way survey data has been collected. The first attempts were made through the International Cardiac Pacing and Electrophysiology Society (ICPES) of which I have been a Board member for more than 20-years. This organization, now called the World Society of Arrhythmias (WSA), encouraged quadrennial world surveys to be presented at the Pacing World Symposia, but left it to the host country to organize. Consequently, there was little structure or organization with the presented data. For the 1997 survey, I took on the responsibility of creating a single survey format for future use. Apart from the United States of America contribution, this was successful. For the 2001, 2005 and 2009 world surveys however, the format was the same for all countries including the United States of America. Implantable cardioverter defibrillators (ICDs) were included in the survey for the first time in 1993.

For Europe, there has always been an organization to collect survey data. The collection of survey data outside Europe, however, is dependent on a group of devoted survey coordinators who each four years send me the required data for their individual countries. The whole system is internet-based with no costs incurred. Where such surveys are not possible because of the size of the country, cardiac implantable electronic device (CIED) manufacturers are asked to assist in the collection of data.

This thesis is dedicated to all those survey coordinators and manufacturers who made the world survey of pacing and ICDs happen. For the 2009 World Survey of Cardiac Pacing and ICDs, to be able to present 61 countries with a combined population over 5 billion and more than 80% of the world's CIED implants, takes thousands of emails, persistence and a smattering of chutzpah. I had to overcome legal hurdles from CIED manufacturers, failure of contacts to acknowledge my requests and in one instance a coordinator's life was threatened if he provided certain local information.

In the end, my contacts were very obliging and most reports were on time. In particular, my deep-felt thanks to Dr Alessandro Proclemer, the Director of Cardiology Unit. Cardiothoracic Department, Azienda Ospedaliero-Universitaria in Undine, Italy, who being responsible for the European pacing and ICD survey was harassed daily by me with email requests.

Finally, thanks to Professor Andrew Tonkin and Associate Professor Rory Wolfe of the Department of Epidemiology and Preventive Medicine, Faculty of Medicine, Nursing and Health Sciences, Monash University for their guidance, reading the draft and making wise and helpful comments.

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General Declaration

Monash University
Monash Research Graduate School

Declaration for thesis based or partially based on conjointly published or unpublished work

In accordance with Monash University Doctorate Regulation 17/ Doctor of Philosophy and Master of Philosophy (M Phil) regulations the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes six original papers published in peer reviewed journals and no unpublished publications. The core theme of the thesis is *Australian and International Cardiac Pacing and Implantable Cardioverter-Defibrillator Surveys*. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of me, the candidate, working within the Department of Epidemiology and Preventive Medicine, Faculty of Medicine, Nursing and Health Sciences under the supervision of Dr Rory Wolfe.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

There are no conflicts or financial interest involved in this survey work.

In the case of chapters 2 and 3, my contribution to the work involved the following:

Thesis chapter	Publication title	Publication status	Nature and extent of candidate's contribution
2	Australian and New Zealand Surveys	Two papers published	Sole contributor of Australian survey.
3	World Surveys	Three papers published	Co-authors provided European/Canadian data

In the published manuscripts are a number of co-authors who assisted me in collecting survey data:

Ralph ML Whitlock, Auckland, New Zealand, assisted the candidate in collecting the New Zealand data for the 2005 and 2009 Australian and New Zealand surveys. Dr Whitlock was not involved in the Australian survey component, but prepared and proof read the New Zealand contribution in the manuscript prior to publication. Deceased October 2011.
Drs Hugo Ector, Belgium and **Dr Alessandro Proclemer**, Italy were involved in collection of the European data for the 2001, 2005 and 2009 World surveys and proof read the European contribution in the manuscript prior to publication.
Miss Marleen Irwin provided the Canadian component for the 2005 World survey and proof read her contribution in the manuscript prior to publication.
Dr Carlos Morillo proof read the 2001 World Survey.

Prior to publication all survey coordinators were asked to proof read their contribution to confirm accuracy.

I have not renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

Signed: .....[redacted]

Date: .....5/9/13.....

Abbreviations and Acronyms:

AV	Atrio-Ventricular
APHRS	Asia Pacific Heart Rhythm Society
Bi V ICD	Implantable cardioverter defibrillator with both dual chamber and biventricular pacing capabilities.
CD	Single chamber implantable cardioverter defibrillator
CIED	Cardiac Implantable Electronic Device
CRT	Cardiac Resynchronization Therapy
DCCD	Implantable cardioverter defibrillator with dual chamber pacing capabilities
ICD(s)	Implantable Cardioverter-Defibrillator(s)
ICPES	International Cardiac Pacing and Electrophysiology Society
WSA	World Society of Arrhythmias

Curriculum Vitae:

Harry George Mond

OAM	Medal of the Order of Australia, 2010
MBBS	Bachelor of Medicine and Surgery, University of Melbourne, 1966
MD	Doctorate of Medicine by thesis, University of Melbourne, 1975
FRACP	Fellow of the Royal Australasian College of Physicians, 1976
FACC	Fellow of the American College of Cardiology, 1979
FCSANZ	Fellow of the Cardiac Society of Australia and New Zealand, 2004
FHRS	Fellow of the Heart Rhythm Society, USA, 2006
CCDS	Certified Cardiac Device Specialist, USA by examination, 1986
DDU	Diploma of Diagnostic Ultrasound, 1979

Principal Fellow with title of Associate Professor, Department of Medicine, Royal Melbourne and Western Hospital, University of Melbourne, 2000.

Adjunct Associate Professor, Department of Epidemiology and Preventive Medicine, Faculty of Medicine, Nursing and Health Sciences, Monash University. 2006.

- Resident, Registrar, Fellow in Cardiology at the Royal Melbourne 1967 to 1973.
- Completed cardiac fellowship in 1974 at Emory University in Atlanta, Georgia and has been practicing since 1975 at the Royal Melbourne

Hospital in Victoria, Australia and at Cato Cardiology, 12 Cato St, Hawthorn East.

- First author three books, numerous book chapters and over 250 published manuscripts.
- Foundation committee member of NASPeXAM (IBHRE), the foremost international examination authority for competency in cardiac pacing.
- Board member of World Society of Arrhythmia (WSA), formerly the International Pacing and Electrophysiology Society (ICPES).
- Board member and medical director of Heartbeat International, an organization dedicated to providing CIEDs to indigent populations around the world.
- Associate editor "Pacing and Clinical Electrophysiology" the foremost and oldest monthly journal on pacing, ICDs and electrophysiology.
- 2012 Pioneer in Pacing and Electrophysiology award, Heart Rhythm Society.
- 2013 Honorary Fellowship of the Hong Kong College of Cardiology.

Current research interests include right ventricular septal pacing, minimizing CIED infections and the World Survey of Cardiac Pacing and ICDs.

Introduction:

An ongoing responsibility of the World Society of Arrhythmias (WSA), formerly the International Cardiac Pacing and Electrophysiology Society (ICPES), is a worldwide quadrennial survey of cardiac pacing and implantable cardioverter defibrillator (ICD) practices. This survey is conducted two years prior to the World Symposium on Cardiac Pacing and Electrophysiology. The World Survey on Cardiac Pacing and ICD practices was first conducted in 1972 (Groningen, Holland).[1] Since then, surveys have been conducted for calendar years 1975 (Tokyo, Japan),[2] 1978 (Montreal, Canada),[3,4] 1981 (Vienna, Austria),[5] 1985 (Jerusalem, Israel),[6,7] 1989 (Washington, USA),[8] 1993 (Buenos Aires, Argentina),[9] 1997 (Berlin, Germany),[10,11,12] 2001 (Hong Kong),[13] 2005 (Rome, Italy)[14] and 2009 (Athens Greece). ICDs were included in the survey for the first time in 1993.

These surveys were initially small, involving only a few interested countries and were presented in a way that comparisons were not possible as the data were incomplete for many countries and the survey periods very variable. Some countries surveyed only a limited number of centres, whereas others completed less or more than a calendar year. As the pacemaker implant numbers grew, so did the problems associated with conducting comprehensive implant surveys. Unless there were only a few major implant centres within a country, it became almost impossible to obtain the cooperation of all the physicians in all the implanting hospitals. The failure of just one major implanter to provide appropriate data makes the overall country's data meaningless.

Another issue encountered was the enthusiasm of the nation hosting the World Symposium. The role of survey coordinator was usually delegated, with limited or no funding, to the most junior member of the organizing committee who had no infrastructure to work with and in most instances was unaware of who had performed the previous surveys. At least initially, there was no template or guidelines on what information was required and thus all countries provided their own survey.

The 1985 VIIIth World Symposium on Cardiac Pacing and Electrophysiology held in Jerusalem, Israel was a typical example of poor survey organization. Because of a number of local issues, no survey was contemplated and thus a European and American group took over this section and although there were eventually 26 countries involved, the presentations were poor with minimal meaningful data published.[7] Australia was not involved for the first and only time. The 1989 (Washington, USA)[8] and particularly the 1993 (Buenos Aires, Argentina)[9] meetings were equally disappointing as far as the surveys were concerned. By the late 1990's, as a member of the WSA board which coordinates the World Symposia, the author was asked to take on the onerous task to coordinate future World Surveys. At the time, the WSA was eager to continue ongoing surveys in a format that allows the evolving trends in cardiac pacemaker and ICD usage to be readily available to government health administrators, hospital administrators, implanting physicians and cardiac implantable electronic device (CIED) manufacturers and distributors.

There were many major challenges. Firstly the author needed to recruit new countries and establish an ongoing network of interested and cooperating survey coordinators outside Europe without funds being available. The second major challenge was to develop a simple standardized format that could be universally used in all countries and provide ongoing data to compare both changes within a country and the rest of the world. Initial resistance came from the American coordinators who had consistently provided data from a select group of implanters with limited information; very different from the rest of the world. These coordinators insisted on continuing this format and not take up the proposed survey model. Thus for the 1997 World Survey, all participating countries under my direction produced similar surveys with the exception of the United States of America. This lack of coordination resulted in three separate publications; Europe,[12] the United States of America[11] and the rest of the world.[10]

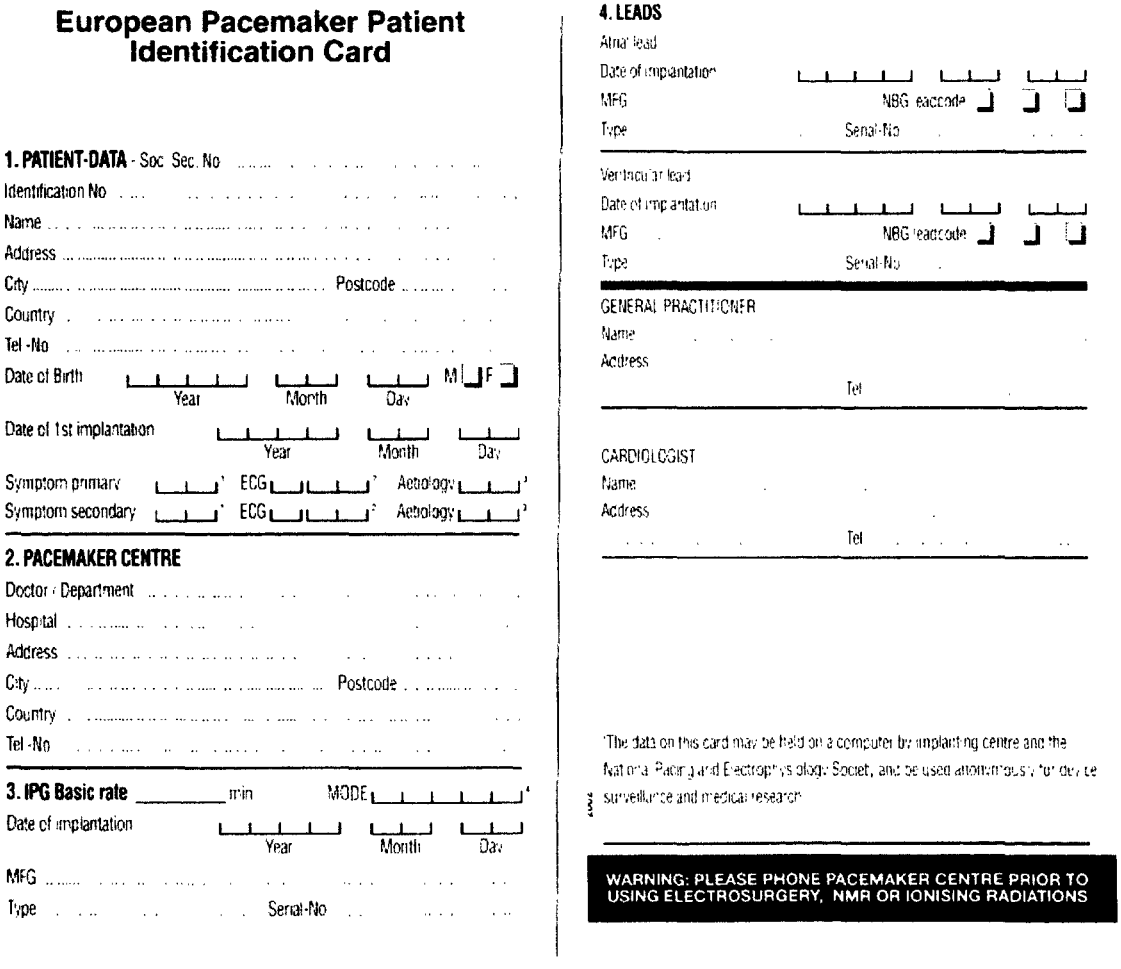
For the 2001 world survey, the Americans insisted on survey funding which was not forthcoming. As a result the American coordinators became disinterested and unable to recruit a local coordinator; the author took on the task of personally performing the United States of America survey with the aid of all the manufacturers and distributors of CIEDs. Once this obstacle was resolved, a common format was quickly developed, loosely based on the evolving European model. Therefore, since and including the 2001 survey, all countries have performed near identical pacing and ICD surveys, allowing true meaningful comparisons of world pacing and ICD practices between countries and between surveys. For the first time, a single publication was possible.[13]

The original European survey data evolved from the European pacemaker registry which was founded in 1978 by the late Drs. Bert Thalen, Giorgio Feruglio and Tony Rickards [16,17,18] They developed the European pacemaker patient identification card (Figure Introduction 1). Details from these cards are registered with national registration centres that send aggregated annual data to the European Working Group on Cardiac Pacing. The simple form has four components: Firstly, a formal registration section which includes demographics, relevant clinical details and pacemaker details which is in the hospital file. The second copy accompanies the implanted CIED warranty details to the manufacturers and the third to the local national registry centre. Lastly there is the actual identification card given to the patient. These forms will be detailed in the Methods section. The data is comprehensive, meaningful, and new European countries are recruited each year.

For all countries outside Europe, a system similar to the European model needed to be designed. For the survey coordination, a central office was created around my home computer with reliable support from my internet provider. Many hundreds of hours were spent recruiting new countries and local survey coordinators and convincing them to provide reports. Apart from Australia and the United States of America, all local coordinators, once recruited, were required, without funding; to conduct their own surveys either using hospital data or local information from pacemaker companies or distributors. A survey form, including clinical data such as age, gender and indications was provided and completed as much as possible. This will be detailed in the Methods section. Similar European details were received from the European coordinator, Dr Alessandro Proclemer, the director of Cardiology Unit, Cardiothoracic Department, Azienda Ospedaliero-Universitaria,

Udine, Italy. Once received, the data was collated by the author and the final report prepared and published.

Figure Introduction 1 European pacemaker patient identification card.



European Pacemaker Patient Identification Card

1. PATIENT-DATA - Soc Sec. No
Identification No
Name
Address
City Postcode
Country
Tel -No
Date of Birth Year Month Day M F
Date of 1st implantation Year Month Day
Symptom primary ECG Aetiology
Symptom secondary ECG Aetiology

2. PACEMAKER CENTRE
Doctor / Department
Hospital
Address
City Postcode
Country
Tel -No

3. IPG Basic rate min MODE
Date of implantation Year Month Day
MFG
Type Serial-No

4. LEADS
Atrial lead
Date of implantation
MFG NBG eadcode
Type Serial-No
Ventricular lead
Date of implantation
MFG NBG eadcode
Type Serial-No

GENERAL PRACTITIONER
Name
Address
Tel

CARDIOLOGIST
Name
Address
Tel

The data on this card may be held on a computer by implanting centre and the National Pacing and Electrophysiology Society, and be used anonymously for device surveillance and medical research

WARNING: PLEASE PHONE PACEMAKER CENTRE PRIOR TO USING ELECTROSURGERY, NMR OR IONISING RADIATIONS

Why bother with such an onerous task? My initial objective was to develop a survey format that all countries could take up and provide comparative data. To a great extent, this has been successful. With persistence, the Asia Pacific region surveys were almost complete for 2009. Survey data from Europe has continued to grow with the recruitment of new countries although much work needs to be done in developing a universal format so as to get the same information from each country as in the Asia Pacific region. There has been variable progress in the Americas. Some countries such as Mexico are impossible to survey. Others will provide for one survey and not the next. An active local region coordinator or committee needs to be established. Previously this has failed. Africa and the Middle East need a lot of work to recruit and provide reports. This is hampered to some extent by unstable governments, fragile CIED services and hostilities.

What then is the next step? It is useful to have basic CIED implant data available to compare between surveys and countries, but much more is needed in the future. Apart from implant numbers and types of hardware used, we need to know if expensive CIED implants work, are they cost effective, are the complications acceptable, do they improve mortality and better outcomes and above all if the current indication guidelines for implantation are being adhered to. To obtain such data, sophisticated expensive registries are necessary. Software CIED follow-up programs are becoming available that can provide much of this data and will be discussed later in this dissertation.

Who then can lead this development? Over the last two decades, the World Symposium of Pacing and Electrophysiology has become a very small and insignificant meeting and the WSA organization has currently no interest in the world survey. The original symposia each four years were the world's premier pacing meetings. With the establishment of sophisticated electrophysiology services, individual country or regional societies have now become prominent. These include the Heart Rhythm Society in the United States, Europace in Europe and the rapidly developing Asia Pacific Heart Rhythm Society (APHRS) in Asia. These organizations, at this stage, have limited interest in surveys and registries.

The development of a sophisticated CIED registry with outcomes is a complex undertaking and must be initiated at a local level such as in Victoria, Australia. With developing experience, the work can then be extended nationally and eventually internationally with the support of organizations such as the APHRS which are now beginning to show interest.

In 2006, at the invitation of Professors Andrew Tonkin and John McNeil, I was invited to join the Department of Epidemiology and Preventive Medicine, Faculty of Medicine, Nursing and Health Sciences, Monash University as an Adjunct Associate Professor to continue my work in pacemaker and ICD surveys under the Monash University banner. This provides the perfect environment to commence future work. It is hoped that the development of such a registry will provide health care providers; Government health bureaucrats, hospital administrators, private health fund administrators and even CIED hardware distributors and manufacturers, valuable information on how such expensive equipment is utilized.

The question remains as to who is prepared to pay for this information? Australia is an ideal continent to initiate such a registry. It is a relatively large user of CIEDs and there are sophisticated implanting and follow-up services available. The population is stable with little movement between States and few patients are lost to follow-up. With appropriate funding, the outcomes of a vast majority of CIED recipients can be documented, although there may be some physician resistance.

Because I was associated with Department of Epidemiology and Preventive Medicine, the 2005 and 2009 Australian and New Zealand as well as the World Survey have been attributed to the department. Five surveys; four attributed to the Department of Epidemiology and Preventive Medicine and one to the University of Melbourne and a general review manuscript on the "lessons learnt" form the basis of this thesis. Earlier surveys conducted by me will be referred to in the text, particularly in regard to growth in the usage of CIED devices as well as the evolutionally trends in device development.

The thesis encompasses both the Australian and World surveys. As principal coordinator, the European data is also included, although this material has been collected by Dr Alessandro Proclemer. I was responsible for Malta and all the countries outside Europe and personally performed the surveys for Australia and the United States of America.

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Chapter 1: Cardiac Implantable Electronic Devices

In order to appreciate the importance of CIEDs in the management of slow or fast heart rhythms, it is necessary to enter the world of the electrophysiologist or cardiac electrical specialist who defines those patients that require the devices and the methods by which they are implanted. To understand this, there must be a basic understanding of the anatomy and physiology of the heart.

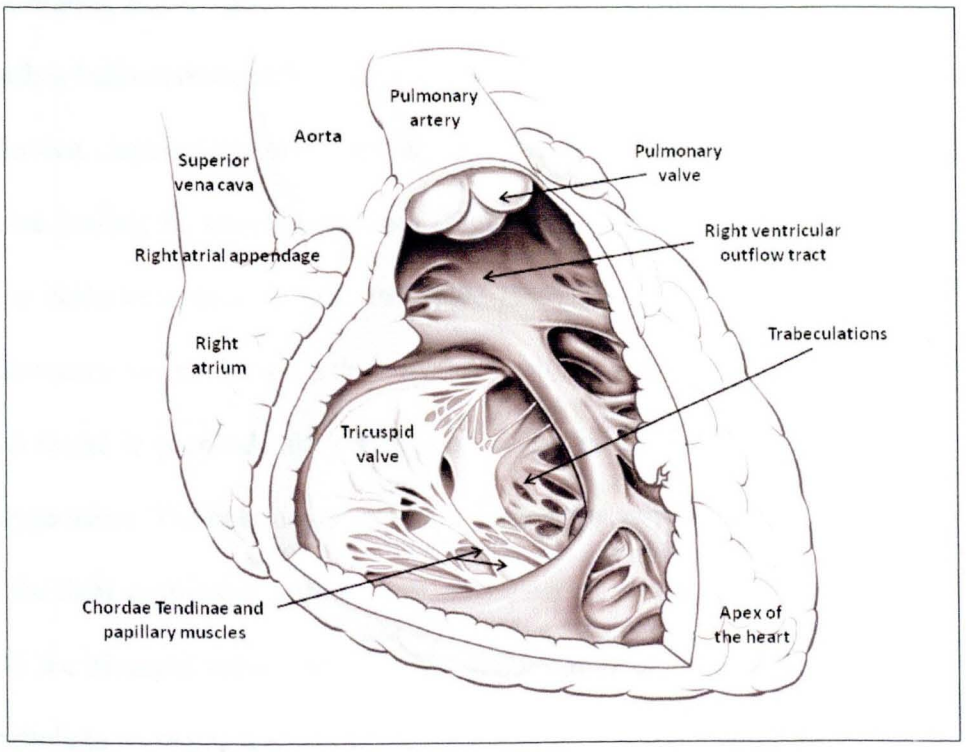
Cardiac Implantable Electronic Devices is a recently defined term with the acronym CIED to describe those electronic devices that cardiologists implant in the heart. They are indicated for cardiac electrical disturbances called arrhythmias which can be slow (bradycardias or bradyarrhythmias) or fast (tachycardias or tachyarrhythmias). These arrhythmias in the worst case scenario, may be lethal without the protection from an implanted CIED and in the best case scenario, the CIED may not only save the recipient's life, but also may markedly improve the patient's quality of life. More recently, a non arrhythmic indication for a CIED has been described which is a technique for electrically "rebooting" a poorly contracting heart is called "cardiac resynchronization therapy (CRT)"

Very specific hardware is necessary to pace or shock the heart. CIEDs include a low voltage pulse generator for cardiac pacing and a high voltage shock box for defibrillation. These interface with the heart muscle by insulated wires called leads which require careful implantation in specific areas of the heart.

1.1 Anatomy and Physiology of the Heart:

By engineering criteria, the heart is a highly efficient pump which lies in the central part of the chest called the mediastinum. It is composed of four chambers; an upper set called the atria which are essentially filling chambers and a lower set, the ventricles or pumping chambers. There are a set of atria and ventricles on both the right and left sides. The right sided chambers lie not only on the right, but also in front or anterior. Via the superior (top) and inferior (bottom) venae cavae, which are the large collecting veins, deoxygenated blood from the periphery is emptied into the right atrium. The right side of the heart is important for the implantation of CIEDs, because of their connection with the low pressure venous system through which leads can be passed "transvenously" under fluoroscopic or x-ray control (Figure 1.1.1).

Figure 1.1.1 Anatomy of the heart with emphasis given to the right heart.



High on the right atrium, lying forwards is a cul-de-sac; the right atrial appendage, which has no known anatomical function, but is important for attachment of right atrial pacing leads. Once in the right atrium, blood passes to the right ventricular chamber via an open tricuspid valve. This ventricular resting part of the cardiac cycle is called diastole or the filling phase. The right atrium does contract (atrial systole) at the latter part of diastole and thus emptying the right atrium. This is important as the right ventricle must be primed with as much blood as possible prior to ventricular contraction in order to achieve the optimal cardiac output. The inner surface of the heart is called the endocardium and has a rough or trabeculated surface particularly in the ventricle (Figure 1.1.1).

At the commencement of ventricular systole which is the contracting phase of the cardiac cycle, the right ventricle commences contraction with a rise in cavity pressure. As a consequence, the tricuspid valve closes. The tricuspid or atrioventricular valve is a complex active valve, which is composed of three leaflets; hence the name. The leaflets balloon retrograde towards the right atrium and are prevented from prolapsing into that chamber by three papillary muscles which are attached to the cusps of the valve leaflets by chordae tendinae (Figure 1.1.1). These papillary muscles contract very early in systole holding the valve closed. Soon after systole commences, the pulmonary valve which is a three leaflet semilunar passive valve opens under pressure and blood is pumped into the pulmonary artery and from there into the lungs for oxygenation. The pulmonary valve lies high in the ventricle and immediately below it is the right ventricular outflow tract. At the end of systole, the pulmonary valve closes and the tricuspid valve opens as the ventricle relaxes and the pressure falls to allow diastole to recommence.

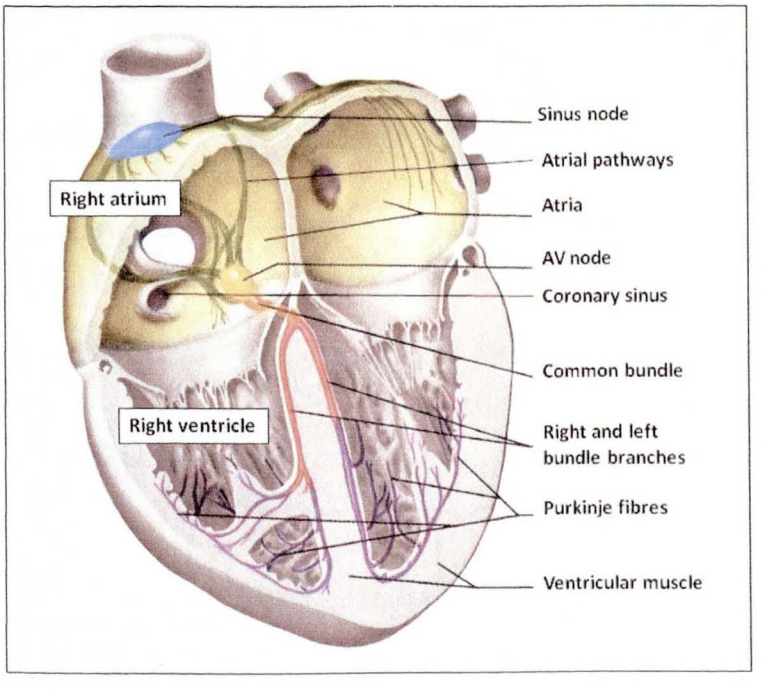
The left chambers lie behind the right chambers and their anatomy and function mimics the right side. Oxygenated blood returns from the lungs via four pulmonary veins and enters the left atrium. It then passes into the left ventricle via the bicuspid mitral valve. With systole, the mitral valve closes to prevent blood regurgitating into the left atrium and the aortic valve opens to allow blood to be pumped into the aorta and from there to all parts of the body. The pressures on the left side of the heart are considerably higher by about five fold compared to the pressures on the right.

The left and right sides of the heart are separated by walls called the atrial septum and the ventricular septum. The blood supply to the heart is via the coronary arteries which are the first branches of the aorta immediately above the aortic valve. The venous return is via the cardiac veins which drain into a large channel; the coronary sinus lying on the back wall of the heart. This in turn, drains into the low pressure deoxygenated chamber; the right atrium. Seeing the cardiac veins traverse the outer wall or epicardial surface of the heart, they are suitable for placement of pacing leads onto the left ventricle via the coronary sinus.

Cardiac pacemakers and ICDs are used in patients with electrical rhythm disturbances. In order to understand such disturbances, it is important to understand the anatomy of the cardiac conducting system. The heart can be likened to a house. It has rooms, walls, doors or valves and as described, a circulation of coronary arteries and cardiac veins which is the plumbing service. The cardiac conducting system is the electrical supply to the heart, which like in a house is subject to breakdowns and short circuits. The conducting system is composed of specialized heart muscle cells which act or rather conduct like nerve cells. The junction box or sinus node (sino-atrial node)

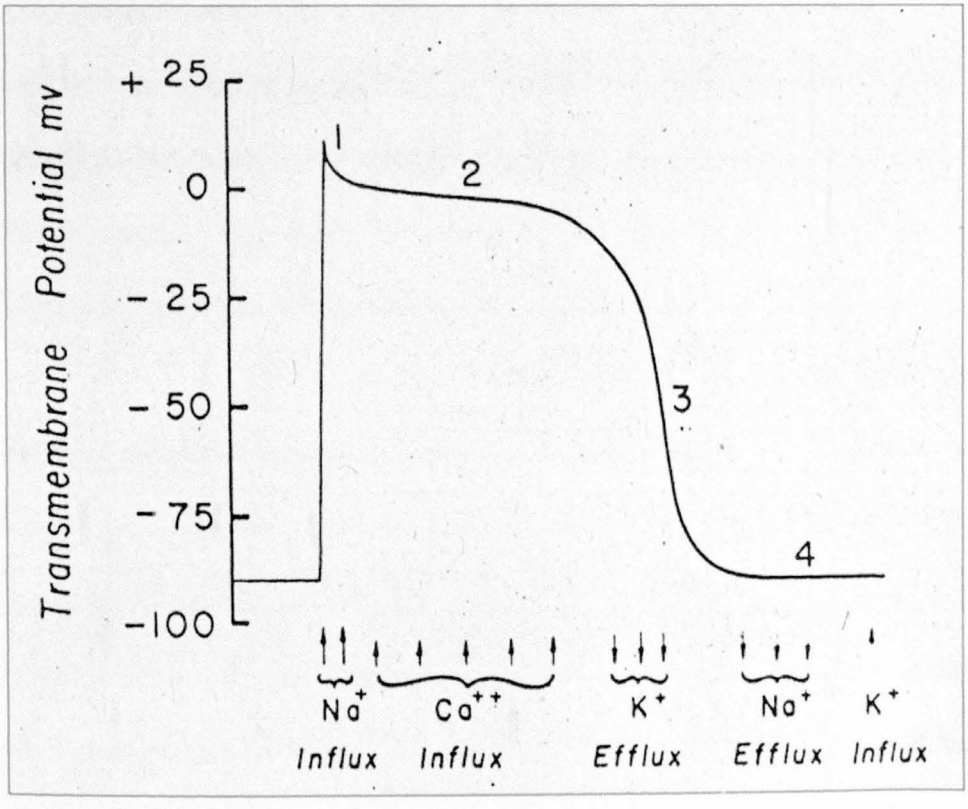
lies very high in the right atrium immediately below the superior vena cava (Figure 1.1.2). The cells of the sinus node like all cardiac muscle will contract spontaneously in response to electrical changes which occur on the surface of the cell called depolarization. Unlike ventricular myocardial cells, the cells of the sinus node depolarize at a much faster rate which is about 50 to 60 times per minute and thus under normal circumstances act as the instigator for cardiac depolarization and contraction. It is thus the normal heart pacemaker. The node is influenced by external nerves of the autonomic nervous system called the vagus or parasympathetic nerves, which slow the heart rate (sinus bradycardia if <60 pulses per minute) or the adrenergic or sympathetic nervous system which increase the rate (sinus tachycardia if >100 pulses per minute).

Figure 1.1.2 Cardiac conducting system. Note the coronary sinus ostium or opening in the right atrium. The pathways in green between the sinus node and the AV node are ill-defined and are not discrete pathways as shown.



In order to understand depolarization, one must visualise, the intense electrical activity occurring in and on the cell membrane of myocardial cells. All myocardial cells are able to spontaneously depolarize and conduct the impulse to neighbouring cells, which in turn depolarize and act as the stimulus for normal cardiac cells to contract. This ability to depolarize spontaneously is related to the movement of ions such as potassium (K+), sodium (Na+) and calcium (Ca++) across the cell membrane. The changes of depolarization are referred to as the action potential (Figure 1.1.3).

Figure 1.1.3 The myocardial cell action potential. These are the electrical changes that occur across the cell membrane during depolarization. See text for details.



During the resting phase or diastole, there is a potential of about -80 to -90 millivolts across the cell membrane in normal cardiac cells and less in the sinoatrial node. When depolarization commences, there is a very rapid change in the potential to close to 0 millivolts, which is mainly sodium ions and later calcium ions entering the cell. Repolarization, which is mainly potassium ions leaving the cell, then follows. Ionic adjustments to re-establish the electrical potential occurs during the resting phase. The specialized conducting cells are electrically designed to conduct the fastest, whereas the cells of the sinoatrial node commence depolarization most frequently and hence are the natural cardiac pacemaker.

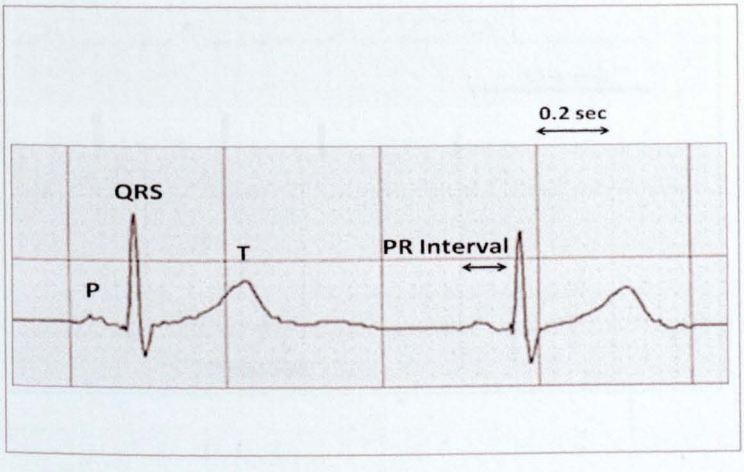
From the sinoatrial node, the impulse is rapidly conducted via ill-defined conduction pathways to the whole right and left atria in about 0.04 seconds. The impulse then traverses down the atrial septum to another node which lies close to the upper border of the tricuspid valve. This is the atrio-ventricular (AV) node which acts essentially as a barrier to conduction (Figure 1.1.2). Here the impulse is blocked for 0.12 to 0.20 seconds to allow the atria to contract and fill the ventricles in late diastole to optimize the next systole. In order for this to occur, there can be no muscle or nerve bridges between the atria and ventricles apart from the specialized conducting system.

Once the impulse is released from the AV node, it enters the His bundle and from there to the common trunk which immediately divides into the discrete right bundle branch and a fan-like left bundle branch which has anterior and posterior divisions (Figure 1.1.2). As the names suggest, these bundle branches traverse the corresponding ventricles dividing into very small divisions called purkinje fibres. Conduction along the bundles branches and purkinje fibres is extremely fast, so that

every ventricular cell is depolarized within 0.10 seconds. The subsequent contraction pattern is very organized and coordinated as sheets of cells shorten and pump the blood from the apex below to the base lying adjacent to the aortic and pulmonary valves. Like the sinus node, the cells of the AV node and the bundle branches will depolarize spontaneously if not depolarized from above. The AV node rate, however, is usually less than 60 pulses per minute and the bundle branches slower again.

Electrical conduction though the described components of the conducting system can be identified on the surface electrocardiograph. The sinus node is anatomically a very small structure with relatively few cells, so that the sum total of the depolarization potentials are insufficient to register on the surface electrocardiograph. Atrial muscle depolarization is registered as a small P wave (Figure 1.1.4). There is a pause after the P wave before ventricular depolarization or the QRS occurs, called the PR interval. This is the summation of atrial depolarization and the slowing down of the impulse at the AV node. The QRS represents the depolarization of every ventricular cell and usually is completed in <0.1 second.

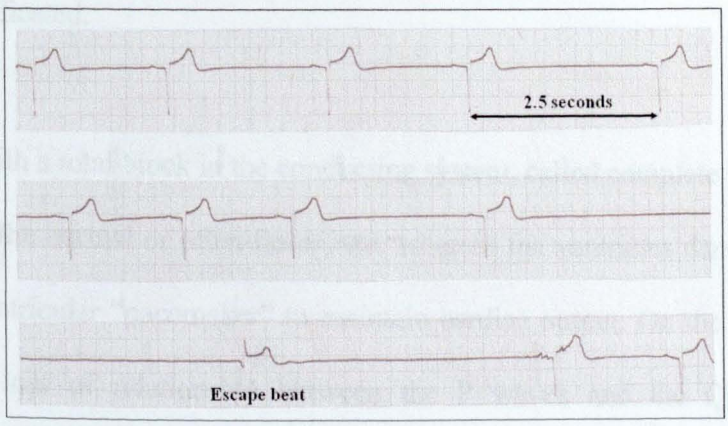
Figure 1.1.4 Surface electrocardiograph, lead II.



1.2 Cardiac Arrhythmias and Indications for a CIED

A standard cardiac pacemaker is usually indicated for a slow heart rate or bradycardia resultant from disease of the conducting system. Degenerative disease in the sinus node leads to a bradycardia and often pauses where there is a failure of impulse generation in the sinus node and these abnormalities are collectively called the sick sinus syndrome. Most patients with sick sinus syndrome are elderly and present with tiredness and shortness of breath on exertion. When significant pauses occur, there may be dizziness, pre-syncope and syncope (loss of consciousness). Pacing the atrium alleviates the symptoms. On occasion with profound pauses, a pacemaker may be essential for life. Patients with sick sinus syndrome frequently have fast atrial arrhythmias such as atrial fibrillation; the so called "tachycardia – bradycardia" syndrome, which is very difficult syndrome to treat without a pacemaker.

Figure 1.2.1 Sick sinus syndrome. The pulse rate is about 30 beats per minute. There is a sinus pause for about 10-seconds with one escape beat from the AV node.



A block in the conducting system at or below the AV node is a more serious abnormality often resulting in a slow debilitating or sudden death. Again patients are usually elderly and the causes degenerative, although congenital causes or heart block post cardiac surgery may occur. A block, usually at the AV node, although occasionally more distal, is called first degree AV block and patients are usually asymptomatic. A higher degree of block may also occur here with pauses called second degree or Wenckebach AV block. Again this usually does not require cardiac pacing. When a block occurs in the bundle branches, the QRS widens to demonstrate a delay in conduction to either the left or right bundle branches. Such patients are usually asymptomatic from the block. However, combinations of blocks frequently occur, giving rise to decreasing levels of AV synchrony or break in the relationship between the P wave and the QRS.

The conduction disturbances may occur gradually with a lengthening PR interval (first degree AV block) followed by a dropped QRS (second degree Wenckebach block) or with a fixed relationship between the P waves and the QRS such as a 2:1 AV block. The resultant pauses or slow ventricular rate may be very symptomatic and generally denotes a more serious block is inevitable, so that cardiac pacing is indicated.

With a total block in the conducting system, called complete heart block, the atria beat at the normal or often faster rate, whereas the ventricles depend on a local very slow ventricular "pacemaker" to maintain cardiac output. On the electrocardiograph there is loss of relationship between the P waves and the QRS (Figure 1.2.2). The symptoms are usually profound and syncope due to the heart ceasing to depolarize

(asystole) may be fatal (Figure 1.2.3). With a pacemaker, the prognosis is equivalent to not having the heart block. Symptomatic patients with AV block frequently change from one level to another upwards or downwards, thus potentiating or alleviating symptoms such as shortness of breath or syncope. When the electrocardiograph patterns alter, the patients are said to have "high degree AV block".

Because of the advanced age of the patients and the level of cardiac degeneration present, it is not uncommon to see electrocardiographic evidence of both the sick sinus syndrome and AV block in the same patient; the so called "pan conduction syndrome".

Figure 1.2.2 Complete heart block. No relationship between P waves and the QRS. The atrial rate is >100 beats per minute and ventricular rate 35 beats per minute.

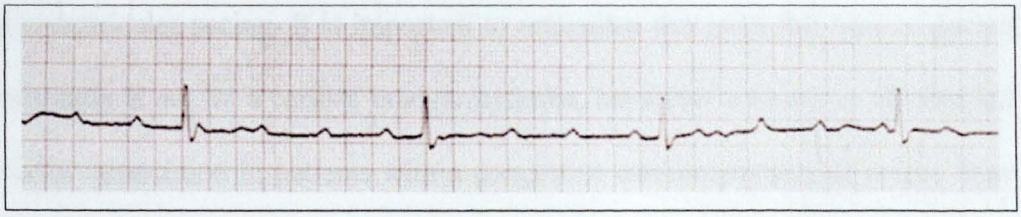
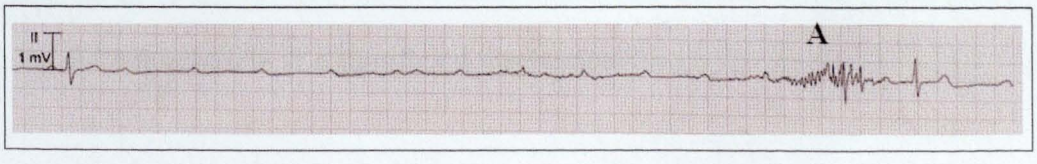


Figure 1.2.3 Complete heart block with ventricular asystole. There are frequent P waves, but only two QRS complexes. The artefact (A) is due to patient collapsing.



Over the years, a number of indications for cardiac pacing in patients without a bradycardia have evolved. In the hereditary syndrome, hypertrophic obstructive cardiomyopathy, there is marked left ventricular hypertrophy or muscle thickening, particularly in the interventricular septum resulting in obstruction of blood flow into the aorta. Pacing the right ventricle from the apex will result in an abnormal pattern of depolarization and hence a dysynchronous (abnormal) contraction which may partially alleviate this obstruction. However, pacing from the right ventricular apex although popular some years ago, has now been superseded by other forms of treatment, including implantation of an ICD. Similarly, pacing the heart faster than normal in patients with hereditary long QT syndrome may prevent sudden death although today such patients receive an ICD with pacing to treat potentially fatal arrhythmias.

A recent major advance in cardiac pacing is cardiac resynchronizing therapy (CRT) using biventricular pacing. It is important to remember that with this type of pacing the indication is not for a cardiac bradyarrhythmia, but rather a means of altering left ventricular contraction in patients with a congestive cardiomyopathy or severe heart muscle disease. Patients with a congestive cardiomyopathy frequently have a left bundle branch block on the electrocardiograph. Conventional pharmacological regimes for congestive cardiac failure with a left bundle branch block are limited because of the dysynchronous or abnormal contraction pattern of the left ventricle, placing the left ventricle at a significant mechanical disadvantage during systole.

To overcome this, biventricular pacing can be used to resynchronize ventricular contraction in order to hopefully improve left ventricular performance and thus

symptoms and mortality. This is achieved by pacing the right and left ventricles almost simultaneously in a manner hopefully similar to the normal heart depolarization and contraction and the procedure is referred to as CRT. Unlike standard pacing where there is one (right atrium or ventricle) or two (right atrium and right ventricle) leads, with CRT a third lead is positioned to pace the left ventricle simultaneously with the right ventricle. This is

achieved by implanting a specialized pacing lead from the right atrium into the coronary sinus and then retrograde into a small venous channel on the epicardial surface of the left ventricle. The procedure can be technically very difficult, with significant surgical and postoperative complications such as lead dislodgement, high energy requirements for left ventricular pacing and pacing of the phrenic nerve which in turn stimulates the diaphragm. As well, there is a substantial non-responder rate, where the patient does not experience any improvement. The procedure is most frequently used together with an ICD, although biventricular pacemakers are also available.

1.3 The Artificial Implantable Cardiac Pacemaker

1.3.1 Pacemaker hardware:

The artificial cardiac pacemaker is an integrated electrical system comprising a pulse generator and one or more leads (Figure 1.3.1). The remainder of the circuit is composed of living tissue, particularly myocardium and thoracic structures. The modern pulse generator has three major components: a hermetically sealed encapsulating can, an extremely reliable lithium power source and sophisticated microprocessor based electronic circuitry (Figure 1.3.2).

Figure 1.3.1 Implanted pacemaker system

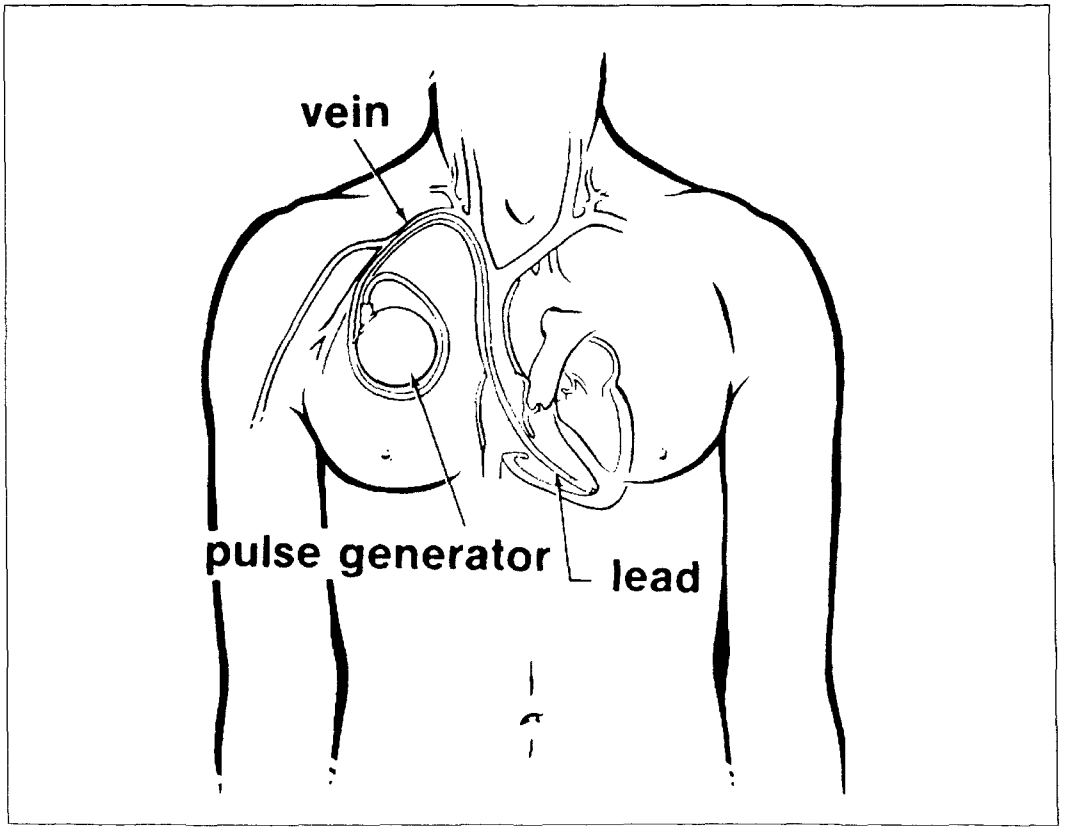
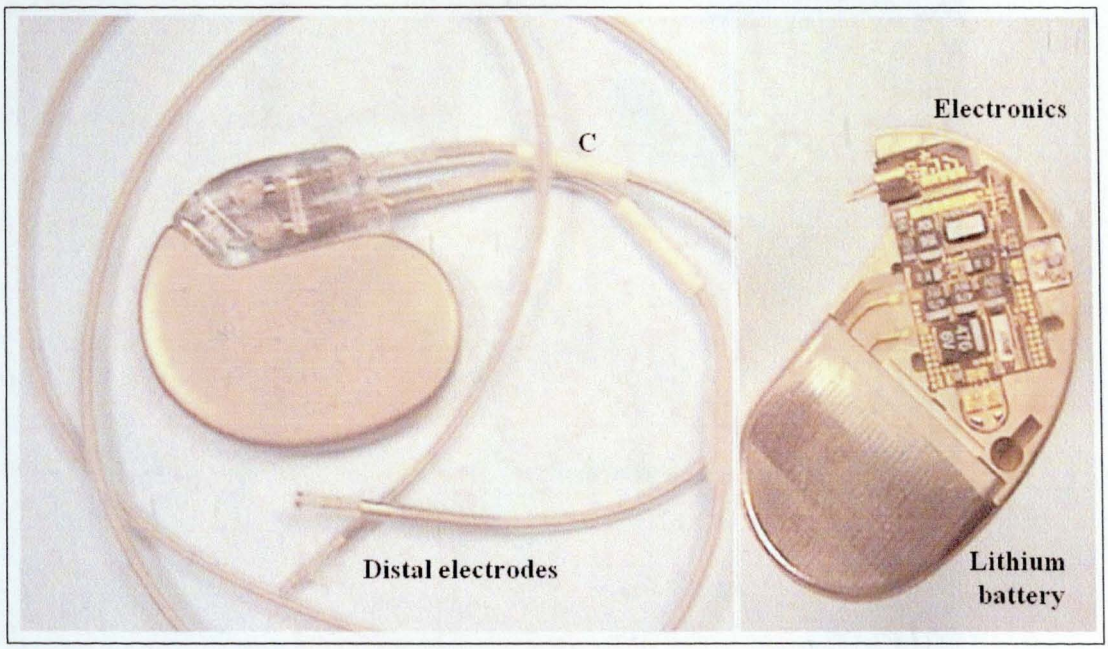


Figure 1.3.2 Dual chamber transvenous pacemaker system.

Left: **Two leads; atrial and ventricular are connected to the pulse generator. "C" are white plastic collars used to attach the lead to the surrounding tissues at the venous insertion site. The distal bipolar electrodes are shown.**

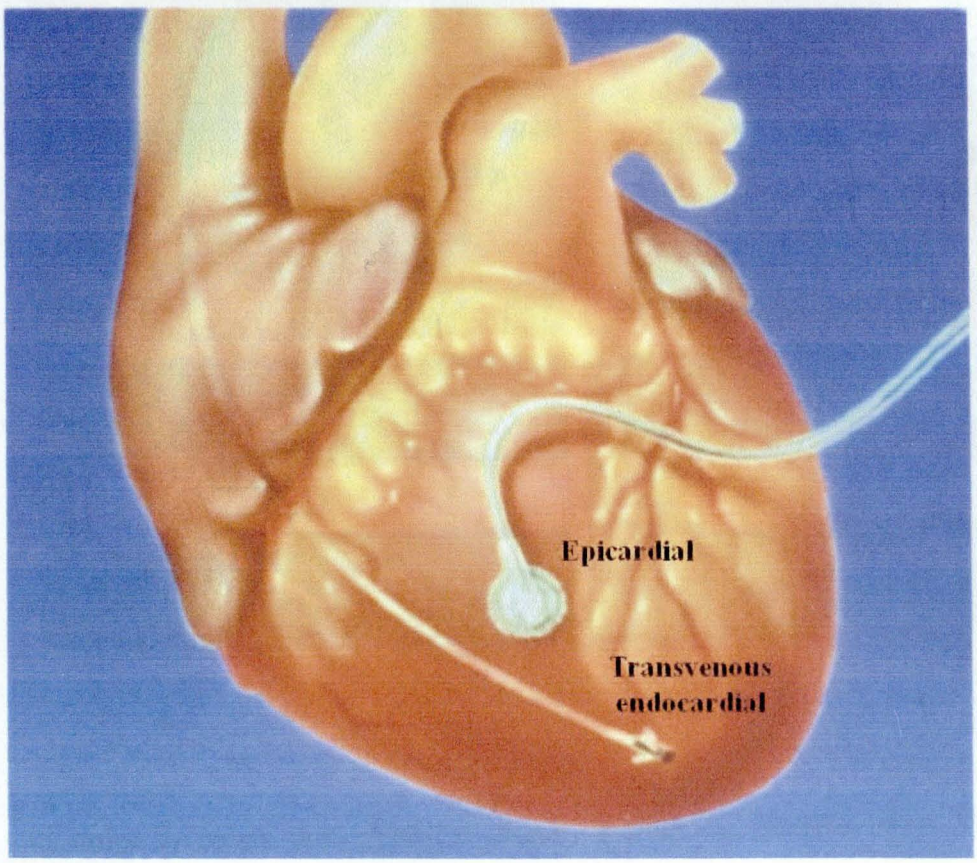
Right: **The encapsulating can of the pulse generator has been removed to demonstrate the electronics and lithium power source.**



The other major component of a pacemaker is the lead connecting the pulse generator to the heart (Figure 1.3.2). A pacemaker lead is composed of an insulated metal conductor coil with a universal connector that joins the lead to the pulse generator. At the distal or heart end is the electrode; a small area of bare metal such as platinum or titanium which is connected to the conductor responsible for transmission of the pacing stimulus to the heart.

Most pacemaker leads are implanted via the transvenous route and make contact with the inner or endocardial surface. On occasion, the leads are attached directly by a cardiac or thoracic surgeon to the outer or epicardial surface of the heart (Figure 1.3.3).

Figure 1.3.3 Lead attachment to the heart.

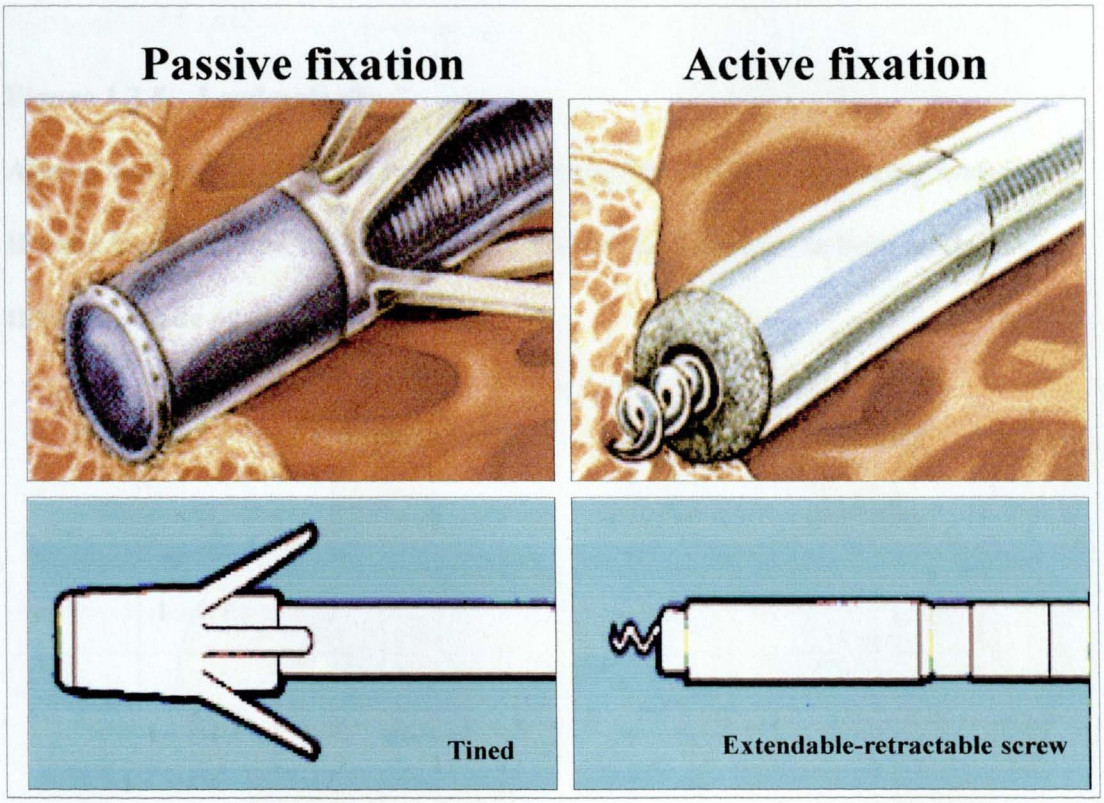


With transvenous pacing, there must be a lead fixation device to prevent dislodgment. A simple passive fixation device such as tines behind the electrode, which become anchored beneath or between trabeculae, are very effective. The other method of lead attachment is active fixation such as an extendable-retractable endocardial screw (Figure 1.3.4).

Figure 1.3.4 Lead fixation.

Left: Passive fixation leads rest against the endocardium with the external soft tines lying beneath trabeculae.

Right: Active fixation leads penetrate the endocardium with a screw.

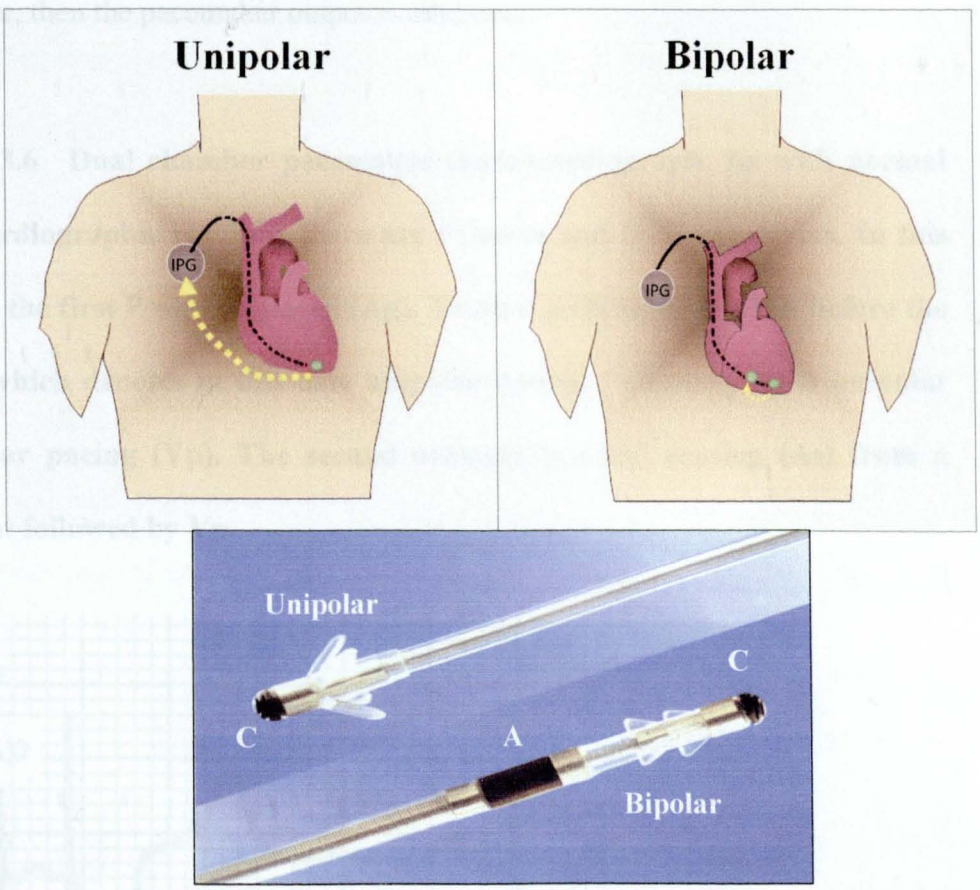


In order to create any electrical circuit, there must be two poles. Current or electricity flows from the negative pole or cathode via body tissues to the positive pole or anode. Pacing leads may be unipolar or bipolar (Figure 1.3.5). With a unipolar system, only one electrode, the cathode lies on the lead at its distal end. The anode lies on the surface of the implanted pulse generator and is usually the entire metal can of the pulse generator. Because the dipole or distance between the two poles is wide, there will be a wide sensing window and therefore, such pacing systems are prone to electromagnetic interference or inappropriate sensing. Hence,

unipolar leads are rarely used today. In contrast, a bipolar system has both poles on a single lead and lying a short distance behind the cathode is a ring anode. (Figure 1.3.5).

Figure 1.3.5 Lead polarity

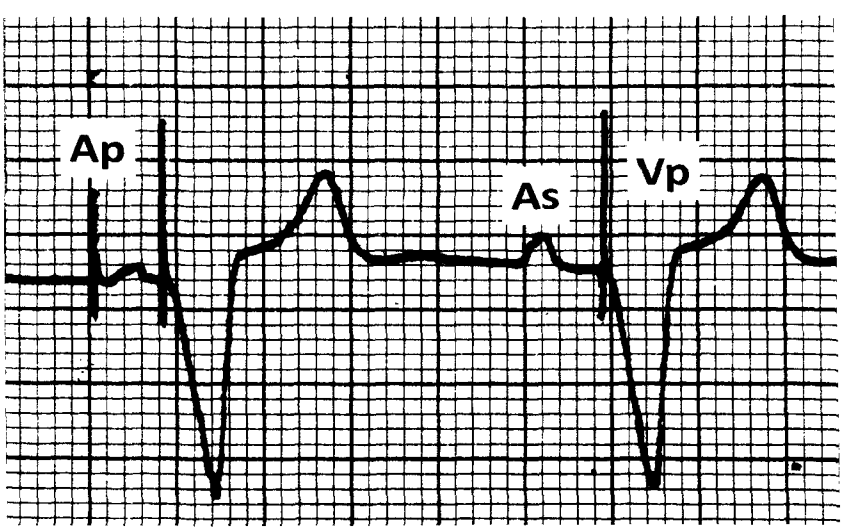
Above: Schematic diagram to illustrate unipolar and bipolar pacing systems. Below: Unipolar and bipolar leads. "C" is the tip cathode on both leads. "A" is the ring anode on the bipolar lead.



1.3.2 Pacemaker electrocardiography:

A pacemaker system must pace the heart and be also able to sense spontaneous intracardiac electrical potentials, which once recognised as electrical activity from the heart will inhibit pacing. When the pacemaker discharges its energy into the myocardium, a voltage deflection occurs on the electrocardiograph, which is either a large deflection with unipolar pacing or small or absent with bipolar pacing. Depending on the chamber being paced, a P or QRS wave immediately follows (Figure 1.3.6). If, however, the patient's spontaneous rhythm is faster than the pacemaker, then the pacemaker output is inhibited.

Figure 1.3.6 Dual chamber pacemaker electrocardiograph. As with normal electrocardiographic rhythms there are P waves and QRS complexes. In this example, the first P wave is paced (Ap). There is a stimulus artefact before the P wave which denotes in this case unipolar pacing. Following Ap is unipolar ventricular pacing (Vp). The second example is atrial sensing (As) from a sinus beat followed by Vp.



1.3.3 Types of pacing systems:

Table 1.3.1 details the identification code for cardiac pacemakers. The first and second letters define the chamber paced and sensed and the third letter, the response to sensing. A fourth letter is used if there is rate adaptive pacing which is a means of increasing the pacing rate using a sensor.

Table 1.3.1

The Four Letter Pacemaker Identification Code

To identify the type of pacemaker or the pacing mode programmed, a three letter identification code has been developed with a fourth letter 'R' to identify a rate adaptive function.

First letter (chamber being paced),

A— atrium

V—ventricle

D—atrium and ventricle

O—no pacing or sensing

Second letter (chamber being sensed)

A— atrium

V—ventricle

D—atrium and ventricle

O—no pacing or sensing

Third letter (response to sensing).

I—inhibited

T—triggered

D— dual chamber, inhibited and triggered

O—no (response to) sensing

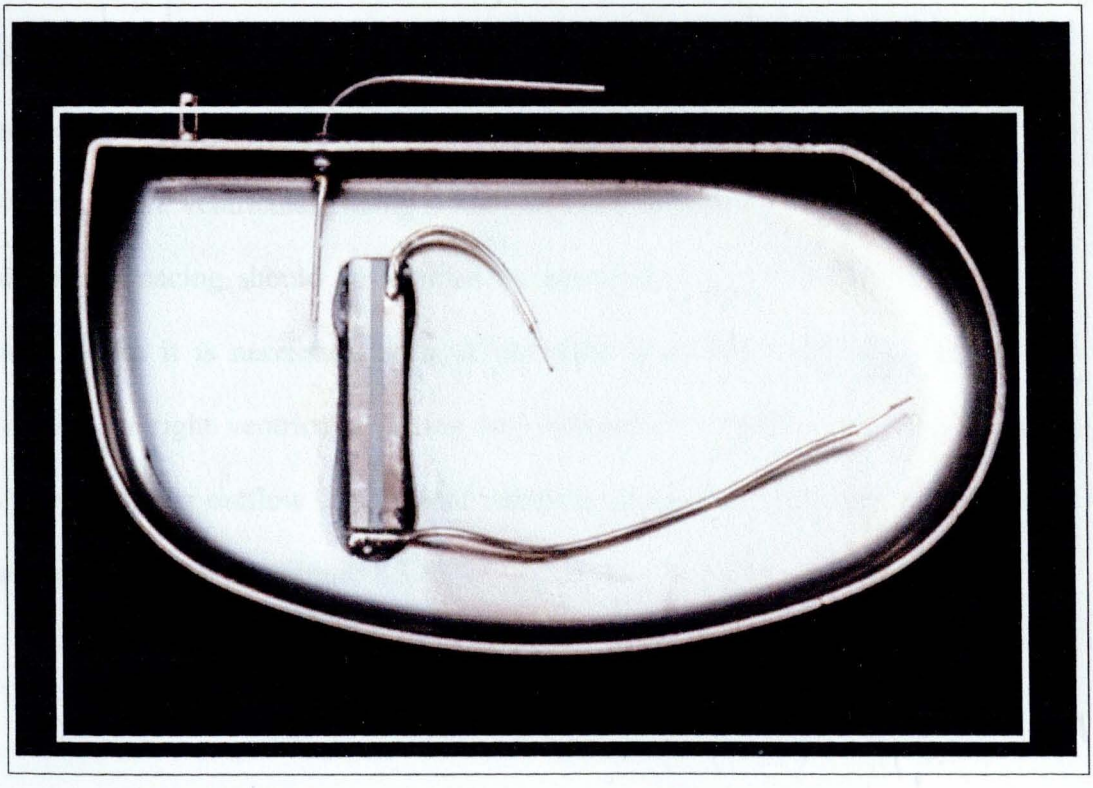
A pacemaker that delivers an electrical impulse at a set repetition rate irrespective of the underlying rhythm is a fixed rate or asynchronous system and may be atrial (AOO), ventricular (VOO) or dual chamber (DOO). Such pacemakers are unavailable today as spontaneous intracardiac potentials, such as sinus beats or ectopics need to be recognized and the pacemaker responds appropriately. However, all implanted pulse generators can be programmed to asynchronous pacing and this may be occasionally required if there is concern with electromagnetic interference in a pacemaker dependent patient.

With modern pacing systems, both the atria and ventricles can be used for pacing and sensing. The simplest systems are the single chamber ventricular inhibited system (VVI) or the rarely used single chamber atrial inhibited pacing (AAI). Another form of sensing is a triggered response (AAT, VVT) which on sensing the spontaneous cardiac rhythm delivers all the energy of the pacemaker output into the depolarized chamber. Such pacing is very rarely used today, because delivering energy for every paced or sensed beat shortens the life of the power source.

Because the atrial contribution is not included, single chamber ventricular pacing (VVI) is unphysiologic. Another disadvantage of ventricular pacing is the lack of rate responsiveness which is the ability to change the rate of pacing with exercise or stress. Physiologic dual chamber pacing (DDD) uses both atrial and ventricular leads to re-establish or maintain AV synchrony. The P wave can be sensed and after a set AV delay, the ventricle is paced (Figure 1.3.6). With this system, there is a physiologic rate response to changes in sinus rhythm.

However, if the sinus mechanism is slow, then the atrial or ventricular paced heart rate remains fixed even with exercise. To allow pacing rates to increase with physiologic demand, all modern pacemakers use sensors to detect activity or stress. This is referred to as *rate adaptive pacing,* with the most popular sensor being an accelerometer within the pulse generator which detects vibration or patient movement (Figure 1.3.7). On the identification code a 4th letter "R" is used to denote rate adaptive pacing.

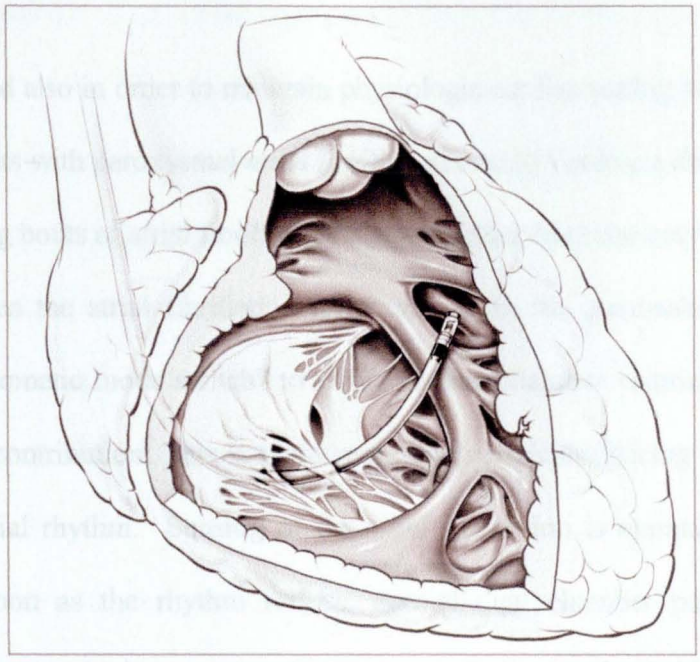
Figure 1.3.7 Early model, "activity" rate adaptive pacemaker. There is a piezo-electric crystal welded to the interior of the pulse generator can which detects movement and sends a very small electric signal to the pacemaker circuitry. Once detected the pacemaker alters its pacing rate in response to physiologic demand.



An Australian designed pacemaker sensor is minute ventilation, which measures the resistance of a tiny current across the chest wall between a standard bipolar lead and the pulse generator can. These changes in resistance and respiratory rate correlate closely with minute ventilation. Although the sensor is useful for the very fit pacemaker recipient, it is only occasionally used today. Another available sensor is the closed loop system. The implanted device uses an intracardiac impedance signal (measurement of electrical resistance inside the heart), which can be used to monitor myocardial contraction dynamics due to the heart's inotropic response to exertion and emotion. All of these sensors have been incorporated into single and dual chamber models (AAIR, VVIR and DDDR) and today all pacemakers have a sensor for rate adaptive pacing, although this can be programmed OFF, if not required.

In recent years it has been recognised that patients with continual right ventricular pacing, particularly from the apex may develop left ventricular dysfunction or reduced pumping efficiency and consequent heart failure. For this reason, in patients where ventricular pacing is not necessary such as the sick sinus syndrome, ventricular pacing should be avoided by appropriate programming. However, in cases where it is necessary, such as complete heart block, the apex should be avoided for right ventricular pacing and consideration given to pacing from the right ventricular outflow tract or mid ventricle, although to date, this has not been proven to be superior (Figure 1.3.8).

Figure 1.3.8 Ventricular pacing with the lead on the right ventricular outflow tract septum.



In general, patients receive a pacemaker tailored to their needs although in many countries, cost is an important limitation. With sick sinus syndrome only an atrial pacemaker is usually required (AAIR). With the fear of AV block developing, almost all patients receive a dual chamber pacemaker with the capability of pacing both the atria and the ventricles and controlling the PR interval or more accurately the AV delay. Patients with AV block usually require a dual chamber pacemaker for physiologic pacing.

Frequently patients with conduction tissue disease also have atrial arrhythmias such as atrial fibrillation. Patients with persistent atrial fibrillation cannot be paced in the atrium and thus only ventricular pacing is used. Chronic or intermittent (paroxysmal)

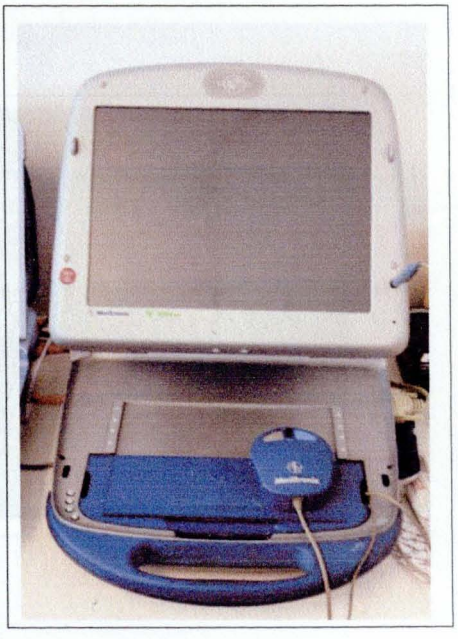
atrial fibrillation is in itself a common indication for cardiac pacing as significant pauses may occur or intensive drug therapy to control atrial fibrillation with a rapid ventricular response may result in bradycardias.

For this reason and also in order to maintain physiologic cardiac pacing when free of arrhythmia, patients with paroxysmal atrial fibrillation usually receive a dual chamber pacemaker. During bouts of atrial fibrillation, the ventricular response may be rapid or slow. If slow, then the atrial fibrillation is recognised by the pacemaker, cleverly triggering an "automatic mode switch" to single or dual chamber ventricular pacing without an atrial contribution. This is to prevent rapid ventricular pacing in response to the chaotic atrial rhythm. Sensing of the atrial fibrillation is maintained in the atrium and as soon as the rhythm reverts, normal dual chamber pacing is re-established. If the ventricular response to the atrial fibrillation is rapid, then drug treatment is required to slow the heart rate and there is no fear of a bradycardia as the pacemaker will "kick" in with ventricular pacing at a programmed lower rate such as 60 or 70 beats per minute.

1.3.4 Pacemaker testing and programming:

Testing of an implanted pacemaker system is a complicated procedure simplified by the use of a sophisticated, company specific, programming computer, which communicates with the implanted device by radio-frequency telemetry. All pacemakers available today are multi-programmable with memory capability to collect vast amounts of information which includes pacemaker usage, arrhythmia documentation, automatic testing and battery status. This patient information is now available to the physician via the telephone network from anywhere in the world, allowing for continual home monitoring of pacemaker function.

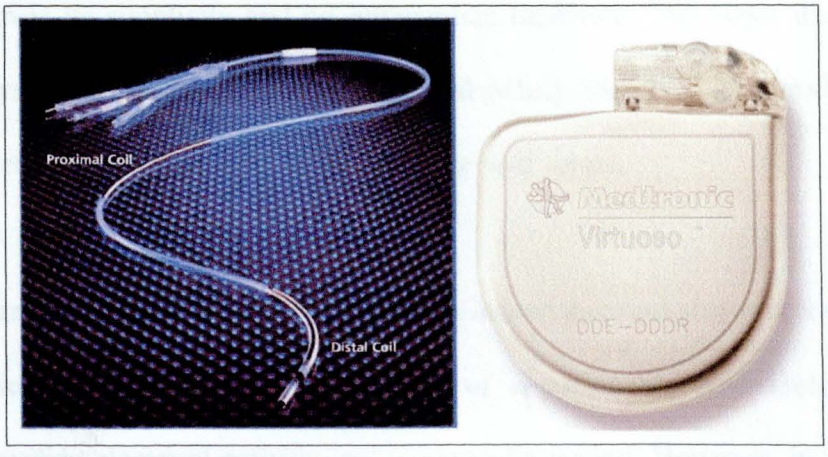
Figure 1.3.9 CIED programmer (Medtronic, Minneapolis, MN, USA). The programmer wand communicates with the implanted CIED allowing it to alter the operating parameters of the CIED. Stored information can also be retrieved.



1.4 The ICD.

Like a cardiac pacemaker, an ICD is also an integrated electrical system comprising a pulse generator or shock box and one or more leads. Like its pacemaker counterpart, the shock box also has three major components: a larger hermetically sealed encapsulating can, an extremely reliable lithium power source and sophisticated microprocessor based electronic circuitry. There are also cardiac pacing capabilities built into an ICD. This is, however, where the similarity to a pacemaker ends. Whereas a pacemaker paces regularly, when required, using about 10 to 20 micro joules (2.5 volts for 0.5 milliseconds) per output, an ICD when activated delivers 10 to 30 joules into the heart or one million times the energy of the pacemaker.

Figure 1.4.1 Implantable Cardioverter-Defibrillator. Left: lead with two shock coils. The tip of the lead is a conventional active-fixation pacing electrode for sensing ventricular arrhythmias. Right: shock box.



Currently, there are three types of implantable ICDs:

- The first is a single chamber cardioverter defibrillator (CD) with ventricular pacing capability.
- The second is a dual chamber cardioverter defibrillator (DCCD), which also acts as a dual chamber pacemaker.
- The third is a biventricular cardioverter defibrillator (BiVCD), which is a fully functional ICD with both dual chamber and biventricular pacing capability, which will be discussed later in this chapter.

A fourth type of ICD, currently under clinical evaluation and not yet available for implantation in Australia is the subcutaneous defibrillator manufactured by Cameron Health (Cameron Health Inc, San Clemente CA, USA) which is now a wholly owned subsidiary of Boston Medical. Unlike all other CIEDs, there is no intracardiac or epicardial hardware. Rather, there is a subcutaneous left parasternal (lying next to the sternum) lead and an implanted axillary high voltage generator. The implantation of the hardware requires no fluoroscopy (xray) control and can be inserted by any trained surgeon or cardiologist. The obvious advantage of this system is its simplicity and no intracardiac hardware. The major disadvantage of this system is that there is no conventional pacing available. The product should be registered and available in Australia in the near future.

The transvenous endocardial ICD lead is indeed a remarkable medical device. It is required to perform all the functions of a pacemaker lead including sensing intracardiac electrical activity and bradycardia pacing. However, in addition there are one or two shock electrodes (Figure 1.4.1) and the accompanying cables and

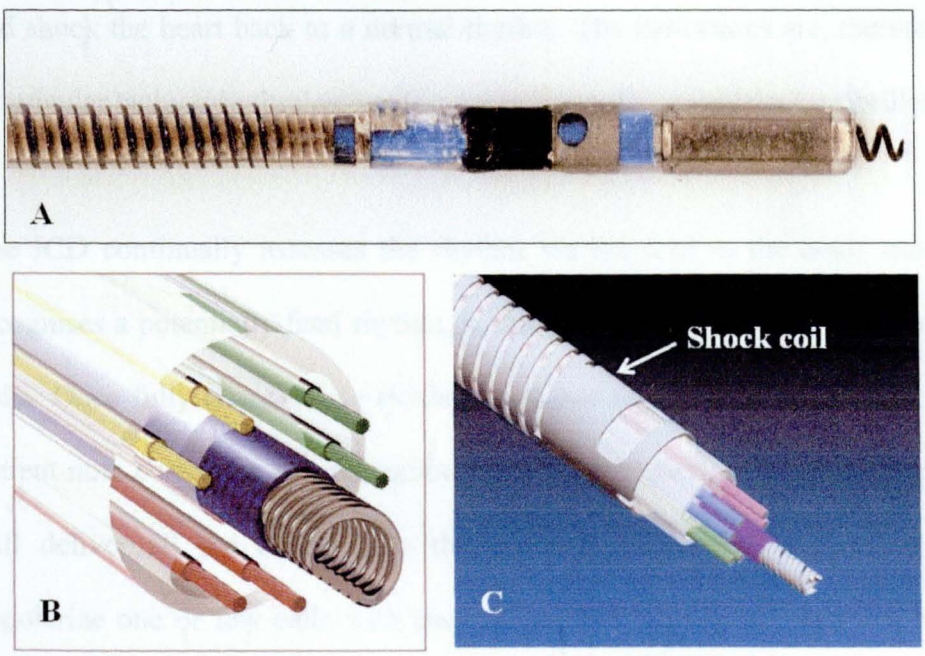
insulation materials all packed into a small diameter lead (Figure 1.4.2). These shock electrodes must be able to deliver high-voltage, high-current discharges from the ICD to the heart in order to allow successful defibrillation.

Figure 1.4.2 Implantable Cardioverter-Defibrillator Lead.

A: the cardiac (distal) end of the lead. On the left is the shock coil and on the right is the active fixation screw.

B: The cross section of the lead to show the two shock cables (yellow and green, two each for redundancy) and the two pacing/sensing conductors (red anode and blue multifilar coil cathode with an internal lumen to allow a stiff stylet for lead positioning at implantation).

C: Cross section at the level of the shock coil which in this model is a plate.



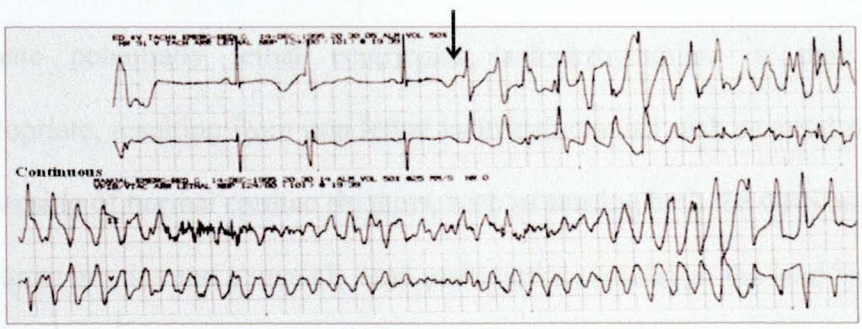
Apart from the massive electrical and thermal stress that these shocks place on the electrodes, there is also the constant mechanical stress of cardiac contraction, which results in torsional bending and compression forces being applied to the lead with each heart beat which occurs around 37 million times per year. Additionally, there are the extra-thoracic stresses of arm and chest movements, which also apply mechanical forces. Finally, there is the chemical and oxidative stress of being implanted within the hostile and destructive environment of the human body. In light of these demands, it is indeed an engineering masterpiece, but sadly and not surprisingly, the lead is the Achilles heel of the ICD as far as long-term complications are concerned.

Clearly the indications for an ICD will differ from a pacemaker. The role of the ICD is to sit quietly on the chest wall, pacing the heart if required and when a potentially fatal rapid heart arrhythmia occurs, the ICD must reliably detect this and shock the heart back to a normal rhythm. The indications are, therefore, rapid ventricular tachyarrhythmias; ventricular tachycardia or ventricular fibrillation.

The ICD continually assesses the rhythm via the lead in the heart and when it recognises a potentially fatal rhythm, it charges its capacitors to many hundreds of volts. Once fully charged, the rhythm must one again be confirmed and with the patient now conveniently unconscious (syncope) because of a low cardiac output, will deliver all the energy into the heart. A pacemaker is required to only depolarize one or few cells with each output and then by propagation, the whole chamber depolarizes and contracts. In contrast, an ICD will depolarize all the cells of the ventricle simultaneously and in this way abort the fatal tachyarrhythmia

which is being continually propagated along intraventricular networks or coming from an aberrant malignant source. Once fully depolarized, the heart has the opportunity to resume its normal sinus conduction pattern. If unsuccessful, then this is recognised by the ICD and more shocks can occur or if the electrical rhythm is silent (ventricular asystole), pacing commences.

Figure 1.4.3 Ventricular Fibrillation. The rhythm degrades from sinus rhythm to a chaotic ventricular rhythm (black arrow) which results in no cardiac output and syncope. This rhythm is rapidly fatal unless corrected.



An ICD is indicated in two clinical settings:

- *Primary indication* is when potential fatal arrhythmias are likely to occur, but as yet have never been identified in that patient. In clinical trials, the prognostic benefit of an implanted ICD in ischaemic and dilated cardiomyopathy patients has been well established.
- S*econdary indication* is when the patient has survived an "in hospital" or "out of hospital" cardiac arrest due to a potentially lethal tachyarrhythmia.

Though the evidence will never be as strong, the devices are also used in the setting of other substrates that are similarly characterized by a significant risk of sudden cardiac death, such as hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia, and the ion channelopathies such as long QT interval.

Despite the proven benefits of ICD therapy in saving lives, there are the sobering limitations of this therapy when considering the known complications including bleeding, infection, can erosion through the skin, lead dislodgement from its implanted position, perforation of the lead through the right ventricular wall and psychological morbidity from shocks. Such shocks may be appropriate and terminate potentially lethal ventricular tachyarrhythmias, or they may be inappropriate, resulting from non lethal tachyarrhythmias such as atrial fibrillation, over sensing of normal cardiac rhythms, such as sensing both the QRS and T waves as separate entities and above all, lead malfunction. As stated, the lead has been the Achilles heel of the ICD hardware. Because of its complexity, it is prone to insulation breaches and conductor fracture, which in turn creates "false" signals being detected resulting in inappropriate false shocks being delivered.

1.5 Implantation Techniques:

The implantation of a CIED has evolved from a time-consuming procedure with a high complication rate to the rapid, highly sophisticated and relatively uncomplicated routine practiced today. The pacemaker and ICD implantation procedures are remarkably similar. A pacemaker can be implanted from the either the left or right, whereas an ICD is usually implanted on the left side. The procedures are usually performed under local anaesthesia by trained cardiologists in an electrophysiology cardiac catheterization laboratory.

The operator wears appropriate "scrubs", mask, head covering, an irradiation protection lead apron and thyroid collar. Following hand scrubbing, an operating gown and gloves are worn. The patient lies on the operating table, sedation given and the operation area is sterilized with antiseptic solution. The operating drapes are applied and the operating area anaesthetized with local anaesthetic. An incision is made under the clavicle (Figure 1.5.1) and the cephalic vein isolated (Figure 1.5.2) or the subclavian vein punctured. Through this venous access, the ventricular pacing or ICD lead is passed to the right ventricle using fluoroscopy (X-ray imaging) and a site chosen. A passive fixation lead is attached using the tines positioned between or beneath trabeculae (Figure 1.5.3) or with an active-fixation lead, the screw is deployed (Figure 1.3.4). If indicated, an atrial lead is then inserted and positioned in the right atrial appendage area (Figure 1.5.4).

Figure 1.5.1 Incision site for pacemaker implantation. A pacemaker can be inserted from the left or right sides whereas an ICD is usually inserted from the left side.

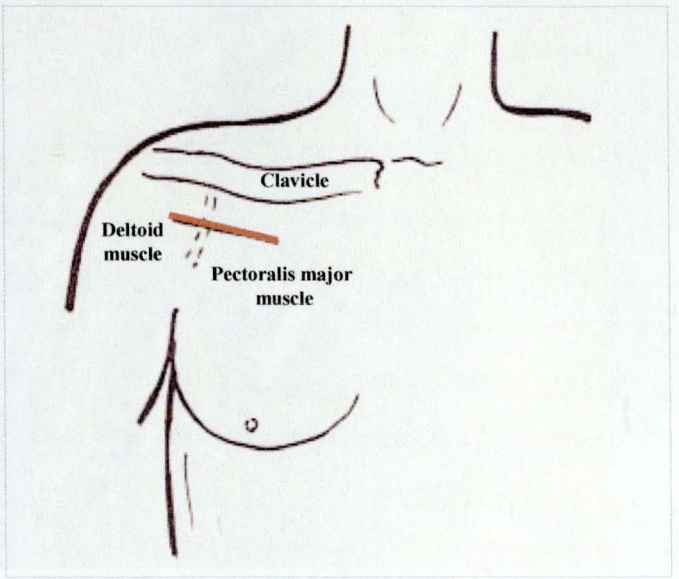


Figure 1.5.2 Lead insertion through the cephalic vein.

A: The cephalic vein is isolated and opened. The leads are then inserted.

B: The atrial and ventricular leads in the vein.

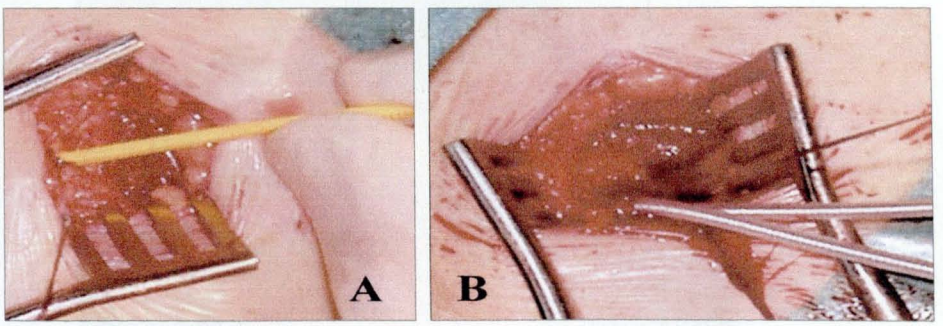


Figure 1.5.3 Tined lead positioned beneath trabeculae at the apex of the right ventricle.

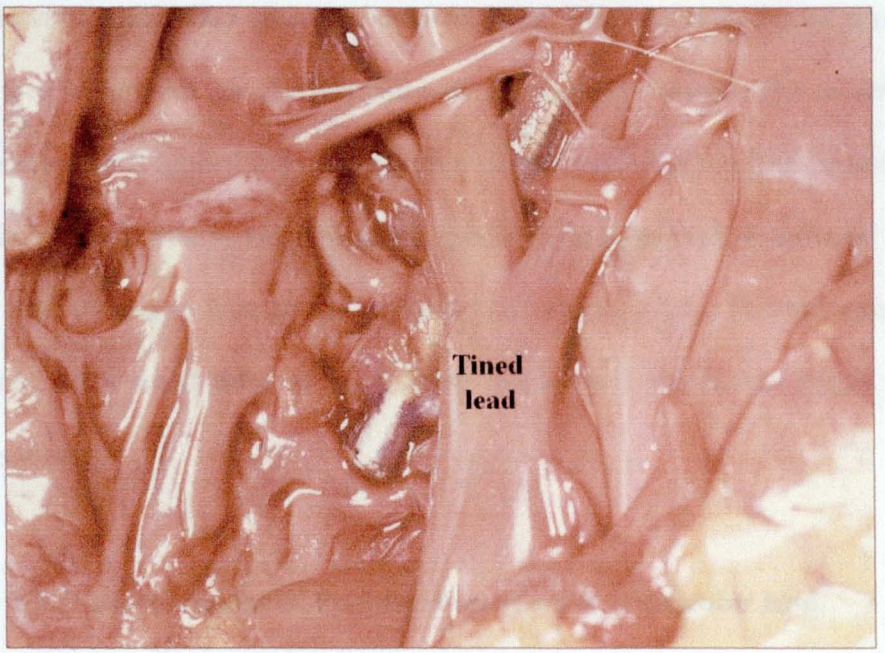
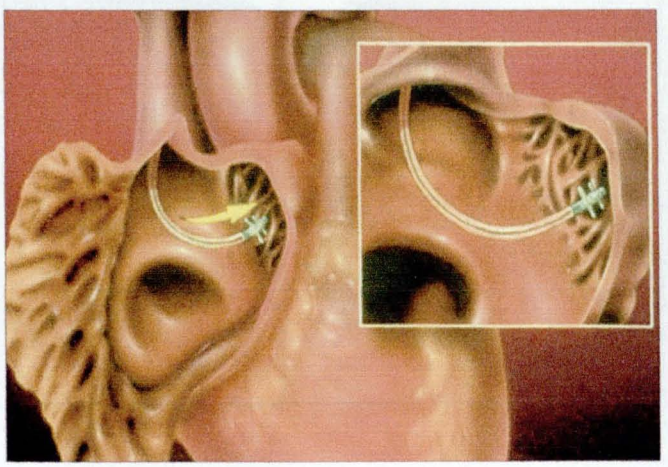


Figure 1.5.4 Positioning of a tined lead in the right atrial appendage.



For cardiac resynchronization therapy, biventricular pacing is required and a second ventricular lead implanted usually onto the epicardial surface of the left ventricle via the coronary sinus and cardiac veins. This is a complicated procedure requiring a venogram or contrast xray of the cardiac venous tree to select an appropriate vein (Figure 1.5.5). A very thin floppy guide wire is then passed along this vein until the site is reached and a specially designed left ventricular lead is passed over the guide wire to the selected site (Figure 1.5.6). The left ventricular leads may have small tines or no fixation mechanism which may result in lead dislodgement.

Figure 1.5.5 Biventricular ICD. Insertion of a left ventricular lead.

Left: Once the coronary sinus is cannulated, a venogram is performed and an appropriate vein chosen.

Right: A floppy guide wire is passed to the vein and over the guide wire a lead with an open lumen is guided into the vein and wedged there.

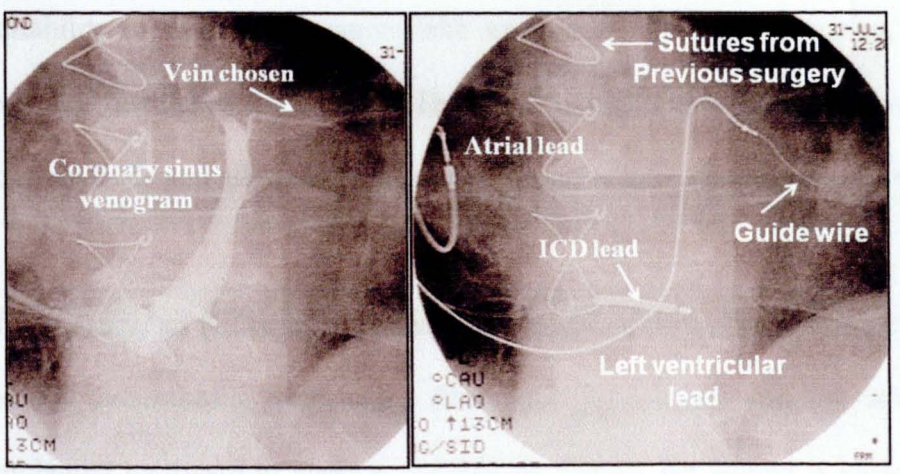
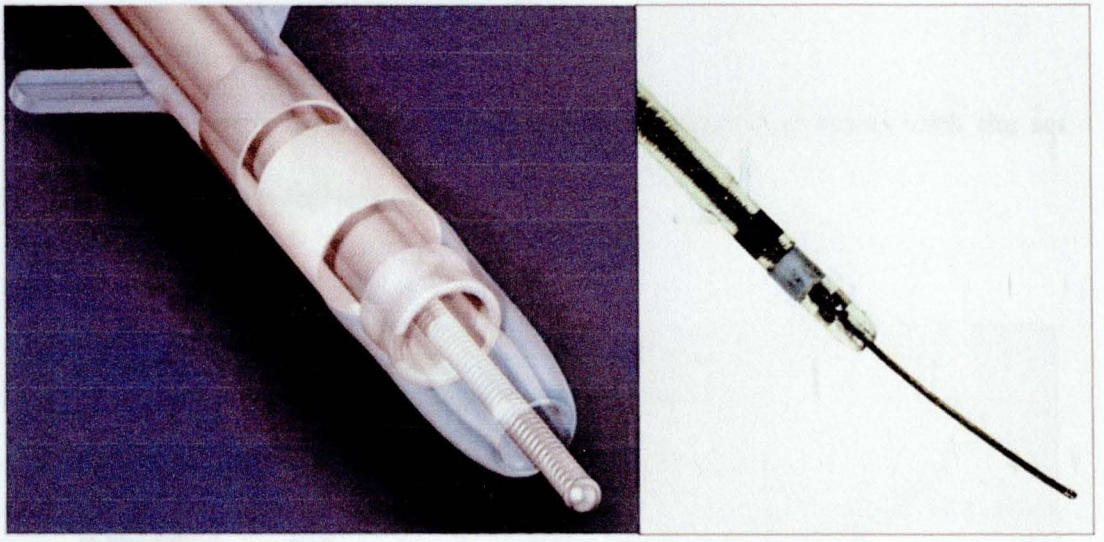


Figure 1.5.6 Left ventricular lead. There is an open lumen through which the lead can be passed over a floppy guide wire into a cardiac vein. This lead has small tines to anchor it in the vein to prevent dislodgement.



Once the leads have been implanted, lead testing is performed to assess the suitability of the area for pacing and sensing. Following lead testing, a pocket is prepared just below the clavicle. The pulse generator or ICD shock box is attached to these leads and all the exposed hardware is placed in the prepared pocket.

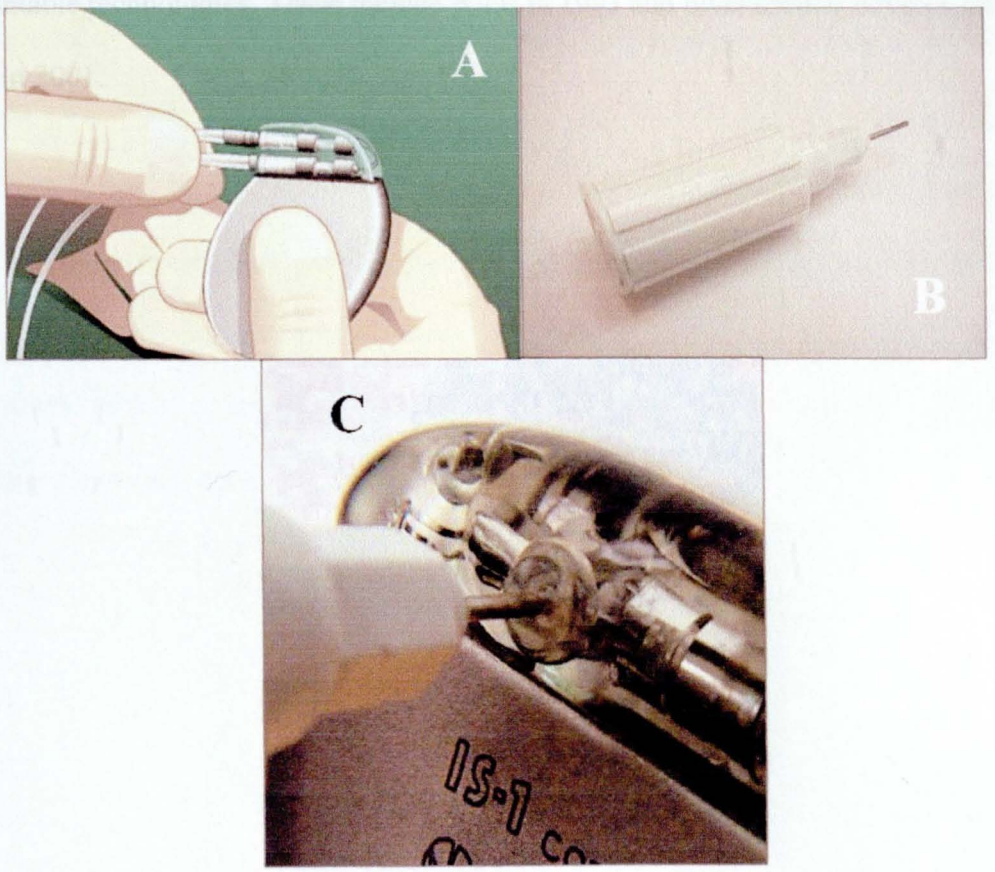
If necessary, an ICD can be tested at this point. Following appropriate sedation or general anaesthesia, ventricular fibrillation is induced and the ability of the implanted hardware to abort it, confirmed. Finally the wound is closed in layers, and a dressing applied.

Figure 1.5.7 Attachment of the CIED to the implanted leads.

A: The lead connectors are inserted into the appropriate connector port of the pulse generator.

B: The screw driver or "Allen key" used to secure the lead connector to the pulse generator.

C: The Allen key is inserted through the rubber port and mates with the set screw, which is then tightened.



Following return to the ward, the patient's electrocardiograph is monitored and the wound inspected for bleeding or bruising. Patients are usually discharged the next day and attend a clinic annually for follow-up testing.

Chapter 2: Methods

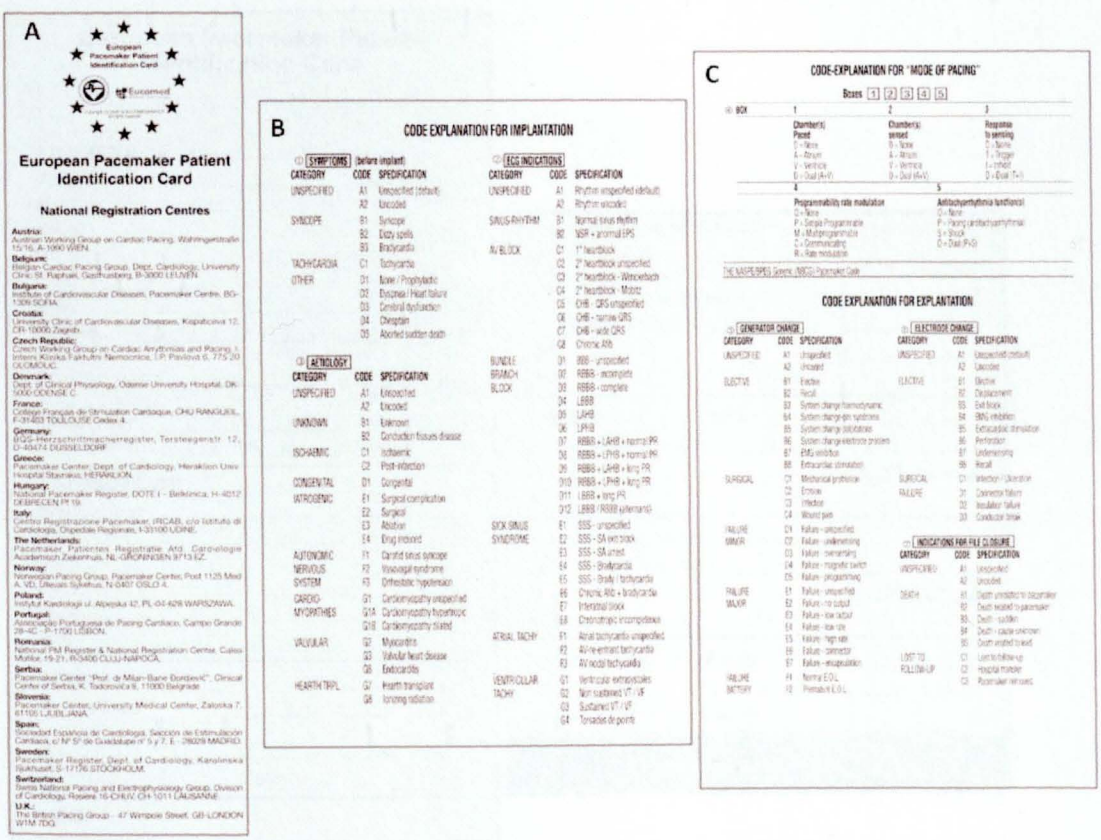
The core of this thesis is the presentation of two Australian Cardiac Pacing and ICD Surveys: Calendar Years 2005 and 2009 and three World Pacemaker and ICD Surveys: Calendar Years 2001, 2005 and 2009. Although the author has been involved in pacemaker surveys since 1972, the actual format for these surveys has evolved over the last 20-years particularly with the addition of relevant new implantable technologies. These include ICDs in 1993 and biventricular devices for CRT in 2001.

2.1 The European Pacemaker Registry

Although the data sets for the Australian and World surveys evolved independently they, nevertheless, correspond well with the European model based on the European pacemaker registry founded in 1978.[1] The basis of the registry is the completion of a "European pacemaker patient identification card" for every pacemaker recipient in each of 22 participating European countries. The card is actually a slim form completed in quadruplicate at the implanting hospital and acts not only as a patient identification card, but also as a hospital file identification, manufacturer warranty form and registration in the national registry centre. The card is sponsored by Eucomed which is an organisation representing the designers, manufacturers and suppliers of medical technology in Europe.[2] The organisation is involved in many aspects of CIED usage including market data collection, health economics, ethical codes of business practice, local regulatory affairs and global regulatory harmonization

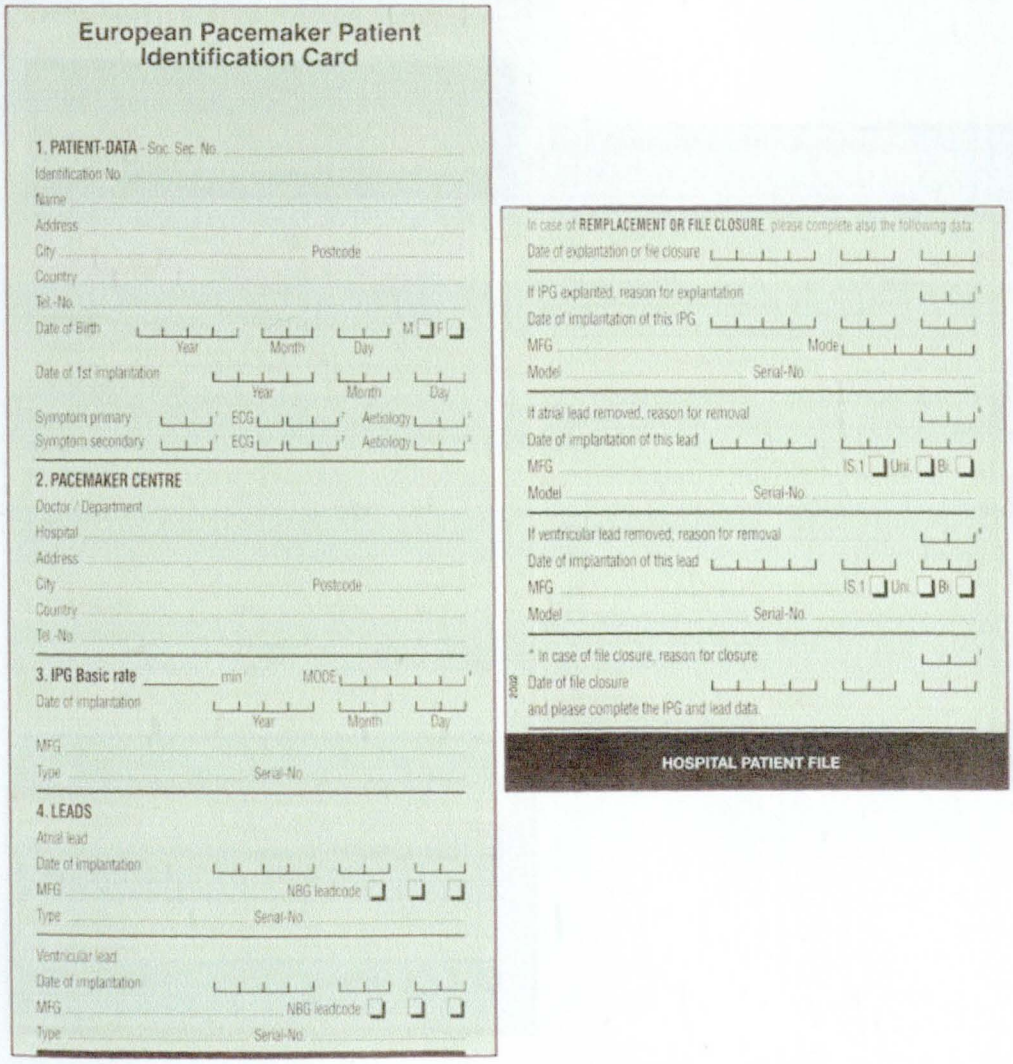
The front page of the form lists the participating countries and their addresses (Figure 2.1.1). On the reverse side is the explanation of the codes used for completion of the form. These codes are specific to the European registry.

Figure 2.1.1 The European pacemaker patient identification card. A is the front page which highlights the Eucomed sponsorship and lists the 22 European National Registration Centres. B and C are the reverse side of the front page and list the code explanation for implantation and the code explanation for mode of pacing.



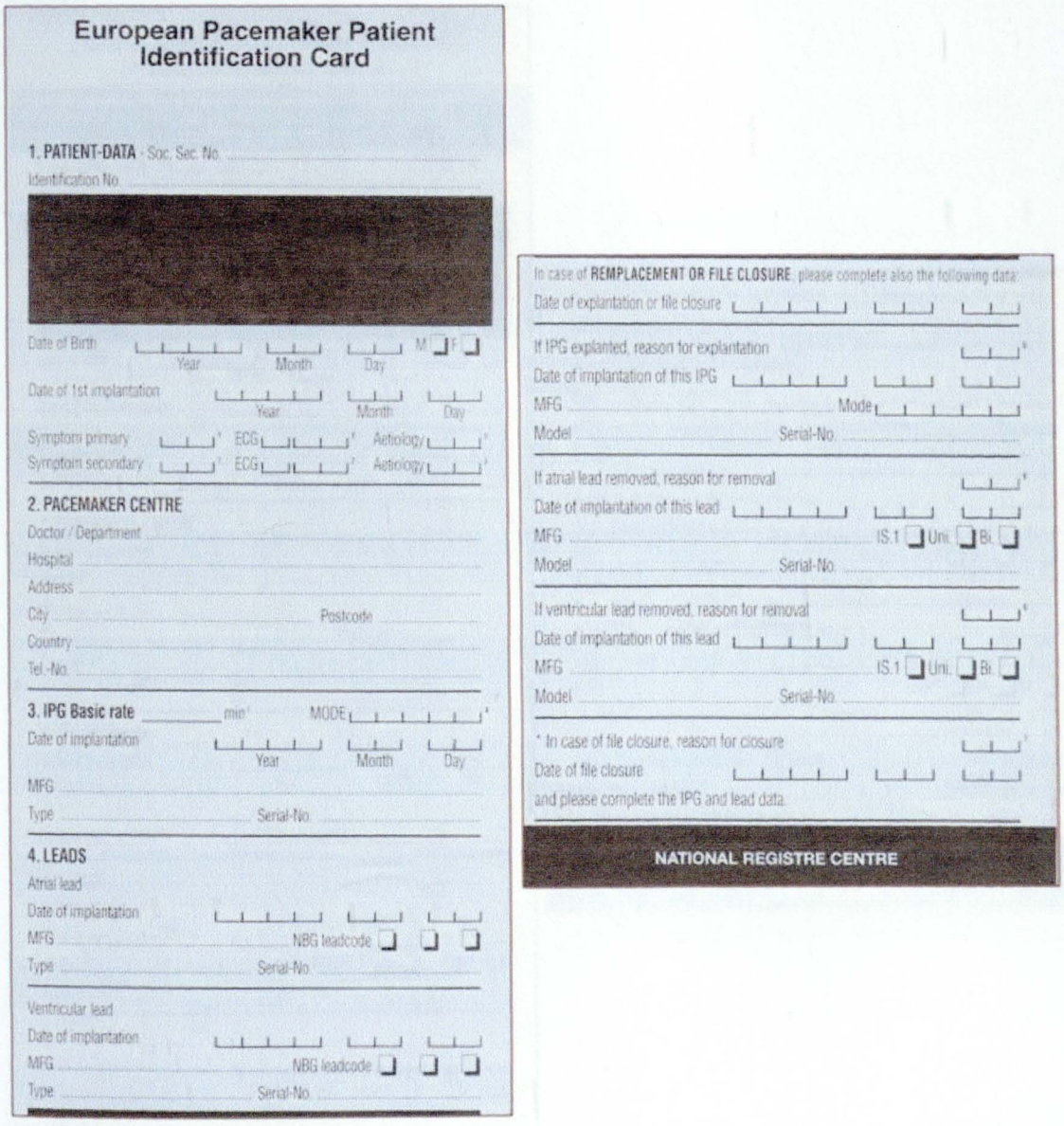
The second page is green and is the front page of the form to be completed (Figure 2.1.2). It is placed in the hospital patient file. The top section of the form is the patient and pacemaker data including the social security number, hospital identification number, surgical dates, clinical information, pacemaker or implant centre and lead and pulse generator models and serial numbers. The bottom section is only completed in the event of a system replacement or file closure.

Figure 2.1.2 Hospital patient file copy of the European pacemaker patient identification card.



The third page is blue and is the national registry centre copy. The social security number and identification number are included, but not the name and address of the recipient (Figure 2.1.3).

Figure 2.1.3 National registry centre copy of the European pacemaker patient identification card. Note that the name and address of the pacemaker recipient are blocked out.


European Pacemaker Patient Identification Card

1. PATIENT-DATA Soc. Sec. No.
Identification No.
[redacted]
Date of Birth Year Month Day M F
Date of 1st implantation Year Month Day
Symptom primary ECG Aetiology
Symptom secondary ECG Aetiology

2. PACEMAKER CENTRE
Doctor / Department
Hospital
Address
City Postcode
Country
Tel.-No.

3. IPG Basic rate min MODE
Date of implantation Year Month Day
MFG
Type Serial-No.

4. LEADS
Atrial lead
Date of implantation
MFG NBG leadcode
Type Serial-No.

Ventricular lead
Date of implantation
MFG NBG leadcode
Type Serial-No.

In case of REMPLACEMENT OR FILE CLOSURE, please complete also the following data:
Date of explantation or file closure
If IPG explanted, reason for explantation
Date of implantation of this IPG
MFG Mode
Model Serial-No.

If atrial lead removed, reason for removal
Date of implantation of this lead
MFG IS.1 Uni. Bi.
Model Serial-No.

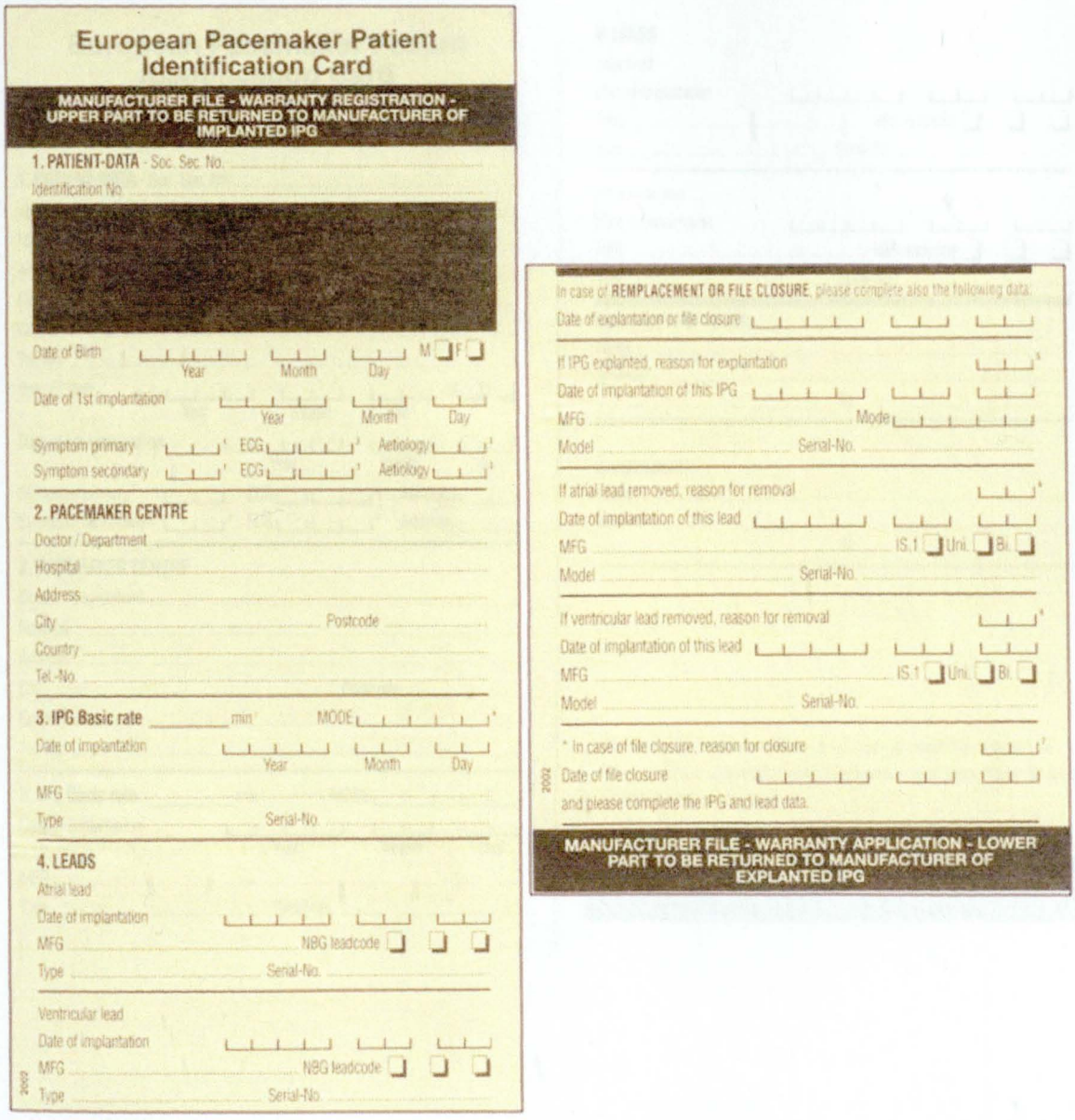
If ventricular lead removed, reason for removal
Date of implantation of this lead
MFG IS.1 Uni. Bi.
Model Serial-No.

* In case of file closure, reason for closure
Date of file closure
and please complete the IPG and lead data.

NATIONAL REGISTRE CENTRE

The fourth page is yellow and is the manufacturer's warranty application form. Once again the social security number and identification number are included, but not the name and address of the recipient (Figure 2.1.4).

Figure 2.1.4 Manufacturers warranty application form of the European pacemaker patient identification card. Note that the name and address of the pacemaker recipient are blocked out.



European Pacemaker Patient Identification Card

MANUFACTURER FILE - WARRANTY REGISTRATION - UPPER PART TO BE RETURNED TO MANUFACTURER OF IMPLANTED IPG

1. PATIENT-DATA - Soc. Sec. No.
Identification No.
[redacted]
Date of Birth Year Month Day M F
Date of 1st implantation Year Month Day
Symptom primary ECG Aetiology
Symptom secondary ECG Aetiology

2. PACEMAKER CENTRE
Doctor / Department
Hospital
Address
City Postcode
Country
Tel.-No.

3. IPG Basic rate min MODE
Date of implantation Year Month Day
MFG
Type Serial-No.

4. LEADS
Atrial lead
Date of implantation
MFG NBG leadcode
Type Serial-No.
Ventricular lead
Date of implantation
MFG NBG leadcode
Type Serial-No.

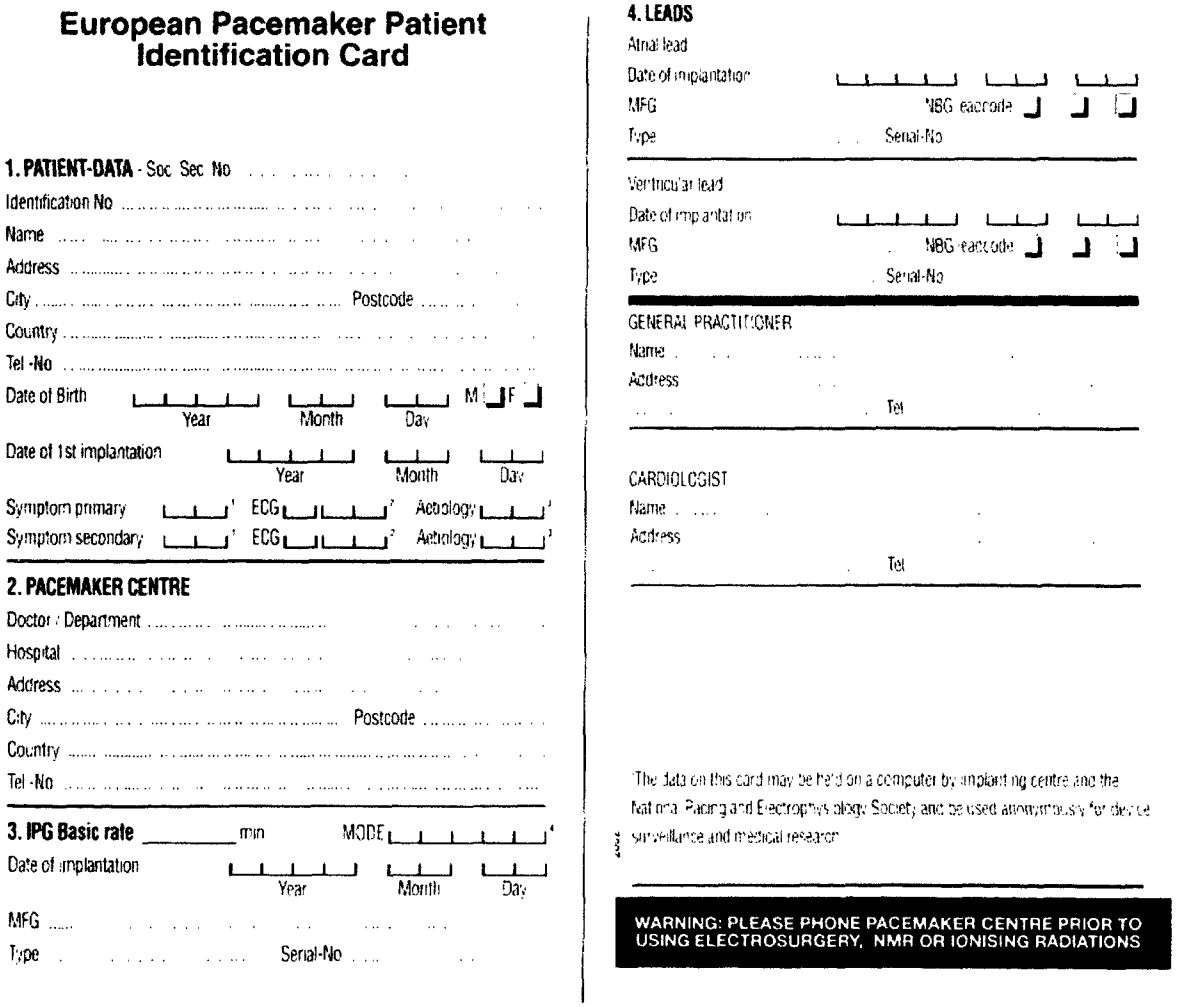
2002

In case of REMPLACEMENT OR FILE CLOSURE, please complete also the following data:
Date of explantation or file closure
If IPG explanted, reason for explantation
Date of implantation of this IPG
MFG Mode
Model Serial-No.
If atrial lead removed, reason for removal
Date of implantation of this lead
MFG IS.1 Uni. Bi.
Model Serial-No.
If ventricular lead removed, reason for removal
Date of implantation of this lead
MFG IS.1 Uni. Bi.
Model Serial-No.
* In case of file closure, reason for closure
Date of file closure
and please complete the IPG and lead data.

MANUFACTURER FILE - WARRANTY APPLICATION - LOWER PART TO BE RETURNED TO MANUFACTURER OF EXPLANTED IPG

The back page is white and composed of cardboard (Figure 2.1.5). This is the pacemaker patient identification card, which is similar to the above forms, but now once again carries the name and address as well as the clinical indications, follow-up centre, lead and pulse generator information and follow-up primary physician and cardiologist.

Figure 2.1.5. European pacemaker patient identification card.



European Pacemaker Patient Identification Card

1. PATIENT-DATA - Soc Sec No
Identification No
Name
Address
City Postcode
Country
Tel -No
Date of Birth Year Month Day M F
Date of 1st implantation Year Month Day
Symptom primary ECG Aetiology
Symptom secondary ECG Aetiology

2. PACEMAKER CENTRE
Doctor / Department
Hospital
Address
City Postcode
Country
Tel -No

3. IPG Basic rate min MODE
Date of implantation Year Month Day
MFG
Type Serial-No

4. LEADS
Atrial lead
Date of implantation
MFG NBG-eacrode
Type Serial-No
Ventricular lead
Date of implantation
MFG NBG-eacrode
Type Serial-No

GENERAL PRACTITIONER
Name
Address
Tel

CARDIOLOGIST
Name
Address
Tel

The data on this card may be held on a computer by implanting centre and the National Pacing and Electrophysiology Society and be used anonymously for device surveillance and medical research

WARNING: PLEASE PHONE PACEMAKER CENTRE PRIOR TO USING ELECTROSURGERY, NMR OR IONISING RADIATIONS

On the reverse of the back page is a table to document relevant clinic findings or programming changes (Figure 2.1.6). The completed patient card can then be stored in a plastic pocket.

Figure 2.1.6. Reverse side of the European Pacemaker Patient Identification Card to illustrate the prepared table to document clinical or programming changes.

European
Pacemaker Patient
Identification Card

Date														
Spontaneous heart rate	bpm													
IPG magnet rate	bpm													
Programmed parameters														
Maximum pacing rate	min⁻¹													
Minimum pacing rate	min⁻¹													
		A	V	A	V	A	V	A	V	A	V	A	V	
Pulse width	ms													
Sensitivity	mV													
Refractory period	ms													
Hysteresis	min⁻¹													
Mode														
Comments														

The European pacemaker patient identification card, although simple in design is essentially a clever multifunctional method of providing pacemaker recipient details to many administrative levels including the patient record, national registry centre, manufacturer's warranty and also provides a copy for the recipient to carry. Such a card system overcomes the necessity of the hospital or clinic staff to complete three or four separate forms. Once completed, it is likely that the national registry and manufacturers will receive their copies and thus be provided with accurate ongoing data.

The same cannot be said for the outcomes data regarding lead or pulse generator reoperations or file closure. This would be very dependent on the structure of the follow-up clinic and the enthusiasm of its staff. A sophisticated computer software package linked to every participating hospital would probably improve the efficiency and reliability of the reporting system, particularly if there was financial incentive for appropriate usage. Be that as it may, this is an excellent attempt by Eucomed to systematically improve data collection on pacemaker implantation in Europe.

2.2 Australian Pacemaker and ICD Surveys.

Cardiac pacemakers have been implanted in Australia and New Zealand since 1961 with the first Australian survey undertaken by the author in 1972. The survey questionnaire was designed by a steering committee and 20 centres contributed data from a total of 22 implanting cardiovascular hospitals.[3] Being such a small survey, outcomes data including deaths before and after 30-days, complications and clinical improvement were also collected.[3,4] Following the 1972 survey, comprehensive pacemaker surveys have been conducted in Australia for calendar years 1975,[5,6] 1978,[7] 1989, 1993,[8] 1997,[9] 2001,[10] 2005[11] and 2009.[12] ICD usage was first included in the 1993 Australian survey.[8]

With significant increases in the number of Australia implanting centres over the last 20-years; it became obvious that the collection of separate data from each implanting institution had become impossible. Consequently, it was decided that for surveys after 1993, all implanted Australian pacemaker and ICD hardware information would be obtained through pacing companies each four years. The companies were sent a simple questionnaire on pulse generators, leads and ICDs sold and registered in Australian States during the designated calendar year. The list of questions was identical to the eventual tables in the reports. No attempt was made to determine individual hospital implant numbers.

The individual company data were received in plain sealed envelopes, transcribed to a working sheet and individual forms destroyed after the data were collated and

transferred to a separate sheet without individual pacing company figures. All pacing companies cooperated with the survey. For each survey, an accurate number of implants, or at least pacemakers and ICDs sold, were obligatory. This needed to be divided into new implants, replacements and leads used. As well as this, the number of pacemaker implanting institutions in each country was required.

There are a number of major limitations and concerns in conducting a CIED manufacturer's survey. The security arrangements, as described, were strictly adhered to and the original sheets shredded on completion of data collation. Only the author saw the individual raw figures for a few minutes only, but had no idea which company they were from. As custodian of proprietary information, this aspect of security was vital so as to maintain credibility with the manufacturers.

All companies needed to cooperate in providing their data. The absence of any one company's figures, however small, completely invalidates the whole survey. The data needs to be as accurate as possible and in particular, the companies need to know what happens to their hardware. The survey numbers provided were sales to implanting hospitals rather than implants themselves. The surveys cover a calendar year and at the end of the year, non-implanted inventory which has been sold rather than on consignment may remain on the shelves and be included as implants. However, this is compensated by invoiced inventory on the shelves at the beginning of the year and therefore the sold hardware numbers should be very close to the implanted numbers.

One major concern was differentiation between new pulse generator and replacement sales. Not all companies have accurate data on this differentiation. This was apparent in the 2005 Australian and New Zealand survey, but by the 2009 survey, the author was assured that the figures were more accurate. Similarly, the manufactures are not always sure whether a pacemaker lead is implanted in the atrium or ventricle. The data on lead implantation has also improved but, it was felt best to report lead sales as a percentage of type and where possible differentiate it into atrial and ventricular implants.

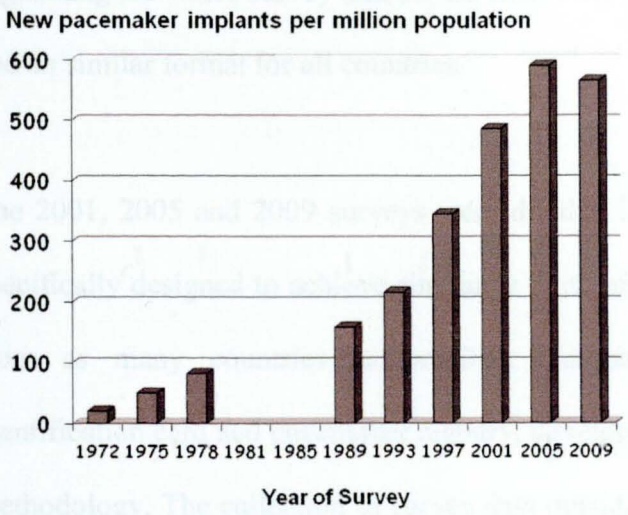
The most serious limitation of such a survey is the inability to collect demographic, clinical and outcomes data from such a simple survey. This of course could be achieved with a hospital survey. In 2009, there were 111 hospital implanting pacemakers in Australia. This breakup was included in the original tables, but removed at the request of the reviewer. Some were large private or public hospitals, whereas others were small with no staff responsible for the pacing services. Care was taken in trying to exclude those hospitals that only provided follow-up services, but no implants. To attempt to surveys all of these hospitals would be a massive and expensive undertaking with little chance of obtaining meaningful accurate data. Most Australian hospitals have some record of implants, but usually no staff available to collate the data and poor access to outcomes information.

There have been attempts to obtain comprehensive pacemaker implant survey data. Figure 2.2.1 is a summary of all the Australian new pacemaker implants per million population, since the first survey in 1972. That original survey included 20 centres out of 22.[3,4] The 1975 survey included only eight major Australian hospitals,[5,6] and

the number of participating centres for the 1978 and 1981surveys were unreported although the actual numbers of hospitals providing reports was low.[7] The author was not involved with the 1985 survey which did not provide any meaningful data and thus was not published. By 1993, with 46 hospitals implanting pacemakers in Australia, it was obvious that a pure hospital based survey would fail and thus from the outset, pacemaker manufacturers and distributors were recruited to try and fill in the void with total implant data for each state.[8] Since 1993, the results have been more meaningful and data between different surveys can be compared.

Another way of obtaining meaningful outcomes data involves the establishment of formal registries. Such registries require a complex expensive infrastructure and it would be anticipated that a small pilot study over an extensive period of time would need to be completed to determine the value of outcomes data before attempts were made to develop a state wide or national structure. This will be discussed in detail in chapter 6.

Figure 2.2.1 Australian new pacemaker implants per million population.



2.3 World Pacemaker and ICD Surveys

The first world survey of cardiac pacemakers was held at the fourth International Symposium on Cardiac Pacing in Groningen, The Netherlands in April 1973.[13] Since 1973, a worldwide survey of cardiac pacing and ICD practices has been conducted every four years and includes calendar years 1975,[14] 1978,[15,16] 1981,[17] 1985,[18,19] 1989,[20] 1993,[21] 1997,[22-24] 2001,[25] 2005,[26] and 2009.[27] ICDs were included in the survey for the first time in 1993.[21]

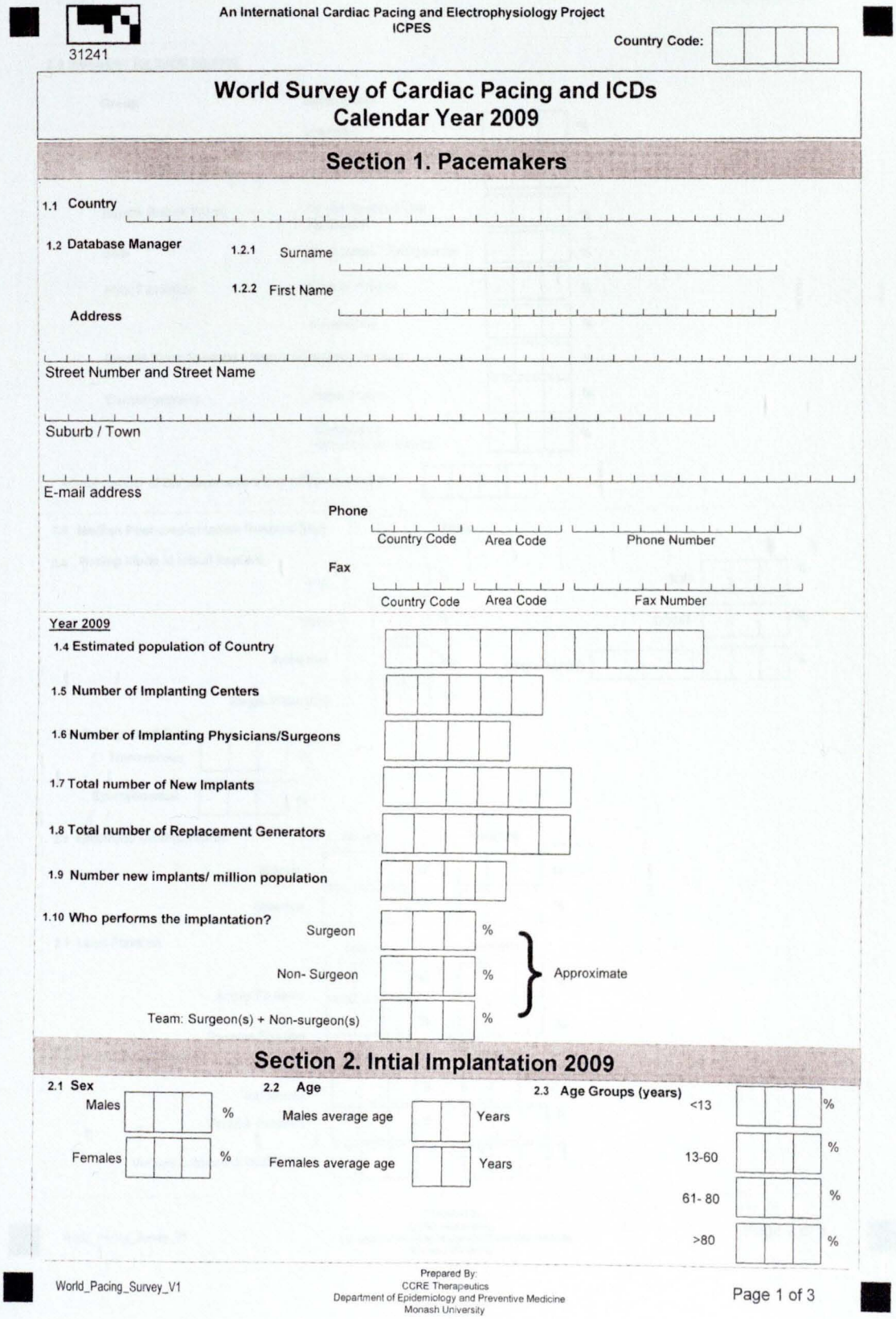
Since those early pioneering days, there have been significant changes in the way survey data has been collected. The first attempts were made through the International Cardiac Pacing and Electrophysiology Society (ICPES) of which I have been a Board member for more than 20-years. This organization, now called the World Society of Arrhythmias (WSA), encouraged quadrennial world surveys to be presented at the Pacing World Symposia, but left it to the host country to organize. Consequently, there was little structure or organization with the presented data, which had no uniformity. For the 1997 survey, I took on the responsibility of organizing the world survey and for the first time, the 2001, 2005 and 2009 surveys had an similar format for all countries.

The 2001, 2005 and 2009 surveys were divided into two major groups and were specifically designed to achieve similarity in reporting and the maximum response from as many countries as possible. Europe, via the pacemaker patient identification card and pacemaker registry, developed its own format and collection methodology. The collection of survey data outside Europe, however, is dependent

on a group of recruited devoted survey coordinators who each four years are requested to send the author the required data for their individual countries. The whole system is internet-based with no costs incurred and involves both pacemakers and ICDs. The forms used are prepared by the Department of Epidemiology and Preventive Medicine of Monash University and the three pages of the survey form have been reproduced in figure 2.3.1. The tables to be published are only prepared once all the country forms have been obtained, although there is occasional country data submitted late whilst the manuscripts are being prepared.

The survey format is kept simple to encourage the coordinators to complete as much as possible. Only a small number of absolute figures are required for both pacemakers and ICDs. These include the population of the country, number of implanting centres, total number of initial implants and replacements. From this, the number of initial CIED implants per million population is calculated. Demographic material is also requested in the survey, which includes mean age, gender, mean hospital stay and diagnosis. The remainder of the study is predominantly percentage based and involves the pulse generator or ICD generator type and the leads used. There is a short section on lead extraction method which has been very poorly answered and therefore not used in the results, but can be collated at a later time to show changes in the methods used.

Figure 2.3.1 World Survey country survey form



An International Cardiac Pacing and Electrophysiology Project
ICPES

31241

Country Code:

World Survey of Cardiac Pacing and ICDs
Calendar Year 2009

Section 1. Pacemakers

1.1 Country

1.2 Database Manager

1.2.1 Surname

1.2.2 First Name

Address

Street Number and Street Name

Suburb / Town

E-mail address

Phone

Country Code | Area Code | Phone Number

Fax

Country Code | Area Code | Fax Number

Year 2009

1.4 Estimated population of Country

1.5 Number of Implanting Centers

1.6 Number of Implanting Physicians/Surgeons

1.7 Total number of New Implants

1.8 Total number of Replacement Generators

1.9 Number new implants/ million population

1.10 Who performs the implantation?

Surgeon %

Non- Surgeon %

Team: Surgeon(s) + Non-surgeon(s) %

} Approximate

Section 2. Intial Implantation 2009

2.1 Sex

Males %

Females %

2.2 Age

Males average age Years

Females average age Years

2.3 Age Groups (years)

<13 %

13-60 %

61- 80 %

>80 %

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2.4 Indication for Initial Implant

Group	Description	
Unspecified	Unknown	[ ][ ][ ] %
High Degree AV Block	All combinations	[ ][ ][ ] %
Bundle Branch Block	All combinations (No AV Block)	[ ][ ][ ] %
SSS	Bradycardia / Tachycardia	[ ][ ][ ] %
Atrial Fibrillation	Slow or Pauses	[ ][ ][ ] %
	AV Ablation	[ ][ ][ ] %
Carotid Sinus Syncope / Neurocardiogenic syncope		[ ][ ][ ] %
Cardiomyopathy	Hypertrophic	[ ][ ][ ] %
	Congestive (Biventricular Pacing)	[ ][ ][ ] %

Actual number of BiV pacemakers (not ICDs) implanted [ ][ ][ ][ ]

2.5 Median Post- implantation Hospital Stay [ ][ ][ ] Days

2.6 Pacing Mode at Initial Implant

VVI [ ][ ][ ] %
VVIR [ ][ ][ ] %
AAI/AAIR [ ][ ][ ] %
Single Pass VDD [ ][ ][ ] %
DDD [ ][ ][ ] %
DDDR [ ][ ][ ] %
Other, specify [ ][ ][ ] %

2.7 Pacing Lead Type

Transvenous [ ][ ][ ] %
Epi-myocardial [ ][ ][ ] %

2.8 Electrode Configuration

	Atrium	Ventricle
Bipolar	[ ][ ][ ] %	[ ][ ][ ] %
Unipolar	[ ][ ][ ] %	[ ][ ][ ] %

2.9 Lead Fixation

	Atrium	Ventricle
Active Fixation	[ ][ ][ ] %	[ ][ ][ ] %
Passive Fixation	[ ][ ][ ] %	[ ][ ][ ] %

2.10 Lead Insertion

	Atrium	Ventricle
Introducer	[ ][ ][ ] %	[ ][ ][ ]
Venous cutdown	[ ][ ][ ] %	[ ][ ][ ] %
Venous cutdown & Introducer	[ ][ ][ ]	[ ][ ][ ] %

Section 3. Lead Extraction

3.1 **Is Lead Extraction Performed** ☐ Yes ☐ No

3.2 **Lead Extraction Method**

Traction		%	
Lead Extraction Kit		%	
Laser		%	
Diathermy		%	
Open Heart Surgery		%	
Other, specify		%	

Section 4. Implantable Cardioverter Defibrillator

4.1 **Total number of intial implants**

4.2 **Total number replacements**

4.3 **Cardioverter Defibrillator (initial implants)**

Single chamber ICD		%
Dual chamber ICD		%
Biventricular ICD		%
Actual number of BiV ICDs implanted		

The United States of America is by far the largest implanter of CIEDs in the world and without data from that country; the whole world survey would be meaningless. Following the withdrawal of the traditional coordinators in 2001, the author was unable to recruit anyone to undertake this potentially massive project, particularly without ongoing funding. Having close contacts with all the manufacturers, the author elected to perform the same company survey as in Australia. Following intense and protracted lobbying, all companies eventually agreed to provide appropriate data on individual company figures on the condition that such data remained confidential nor distributed.

Once again, security measures were paramount in the companies reaching this decision. Apart from minor delays and a number of legal impediments, the surveys were successfully completed and like the Australian company survey, all data were destroyed by shredding, once the final figures were collated. To the best of the knowledge of the author, the United States of America information received from the manufacturers was believed to be accurate.

In general, the amount of information obtained from each country is adequate and no country's report has ever been omitted from the final results. Only countries providing hospital survey data are able to provide demographic and clinical results. This is not possible with CIED manufacturer or distributor data, but coordinators are encouraged to seek help from these companies if the hospital surveys are incomplete. As far as can be determined, no data has ever been lost or corrupted.

The final tables are checked by each of the country coordinators and there are always a number of changes made, some of which are transcription errors and others are errors or updates from the submitted reports. The published proofs are also checked by the coordinators, although because of the very short turn around, not all coordinator reviews are obtained. Pleasingly, there have been no reported errors in the published manuscripts.

Of some concern is the validity of the data obtained. There is no way of verifying the accuracy of the information and the whole survey format is based on trust. There has only been one instance, where the 2001 data from a Middle Eastern country was questioned by a physician. Although there were only a few large implanting centres, the physician believed that the whole country was not surveyed, but rather only the hospitals in the largest city. He agreed to coordinate the 2005 and 2009 surveys for that country.

In the international surveys, privacy issues have never been discussed. Any country where proprietary information is obtained using commercial data and then used by the coordinator is the responsibility of that coordinator. The completed country data is eventually transcribed to the final report form and although not regarded as confidential, nevertheless, the author being the primary custodian of all the data has the responsibility of not distributing this material until the final report is published. Following this the raw data is permanently filed and not destroyed. It is not regarded as confidential and can be used in the future if necessary.

The limitations of such a survey methodology are similar to the Australian survey already discussed. Security arrangements, apart from the United States of America are not as stringent as with the Australian survey but, nevertheless, the coordinators expect that their data not be distributed prior to publication and the author expects that the data is essentially correct. Once a decision is made to use manufacturers or distributors data all companies are required to provide the data. The lack of data from one company makes the survey meaningless. The most serious limitation of such a survey, however, is the inability to collect demographic, clinical and outcomes data. The solutions will be discussed in detail in chapter 6.

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Chapter 3: Australian Pacemaker and ICD Surveys

Cardiac pacemakers have been implanted in Australia and New Zealand since 1961. The first Australian survey was undertaken by the author in 1972 and presented at the fourth International Symposium on Cardiac Pacing held in Groningen, The Netherlands in April 1973. Such was the importance of this first world survey, that it was chapter one of the published proceedings and covered 40 pages with the Australian and New Zealand contribution seven pages.[1] During that year, 676 pulse generators were implanted; 341 new systems and 335 replacements covering 16-million people. The survey questionnaire was designed by a steering committee and 20 centres contributed data from a total of 22 implanting cardiovascular hospitals. Because these were early years in pacemaker implantation and technology, it was felt that the number of patients who had a pacemaker implanted, represented only a fraction of those that could have potentially benefitted.

There were 59% males in the survey, 70% were over 70-years of age and the overwhelming indication was high degree AV block (87%) with only 10 recipients having sick sinus syndrome, which had only been described by Irene Ferrer a few years earlier.[2] A transvenous system was implanted in 89% and 81% of leads were unipolar.

Being such a small survey, outcome data including deaths before and after 30-days and clinical improvement were also collected. Five patients (1.5%) died within 30-days and a further 12 patients died after 30-days with only one from a known

pacemaker complication. Lead dislodgement occurred in 14% of patients and overall lead complications occurred in 22% of new pacemaker recipients. Of importance, 95% of patients were improved by the implantation of a pacemaker. The results were also published in the Medical Journal of Australia.[3]

Following the 1972 survey, comprehensive pacemaker pacemaker surveys have been conducted in Australia for calendar years 1975,[4,5] 1978,[6] 1989, 1993,[7] 1997,[8] 2001,[9] 2005[10] and 2009.[11] With significant increases in the number of Australia implanting centres over the last 20-years; the collection of separate data from each implanting institution would have been a significant undertaking. It would have been unlikely that all centres would have cooperated in the survey and in particular smaller private hospitals without a database on the numbers of CIEDs implanted. Consequently, it was decided that for surveys after 1993, all implanted Australian pacemaker and ICD hardware information would be obtained through pacing companies. The companies were sent a simple questionnaire on pulse generators, leads and ICDs sold and registered in Australian States during calendar year 2009. No attempt was made to determine individual hospital implant numbers.

The individual company data were received in plain sealed envelopes, transcribed to a working sheet and individual forms destroyed after the data were collated and transferred to a separate sheet without individual pacing company figures. All pacing companies cooperated with the survey. For each survey, an accurate number of implants, or at least pacemakers and ICDs sold, were obligatory. This needed to be divided into new implants, replacements and leads used. As well as this, the number of pacemaker implanting institutions in each country was required. A

major limitation of the surveys was the inability to collect clinical and outcomes data such as indications, mean age, hospital stay and postoperative complications.

The early development of ICD technology and usage underwent a slow evolution. Following the untimely cardiac electrical death of a friend and colleague in 1966, Dr Michel Mirowski whilst in Israel became obsessed in the development of an automatic defibrillator that could be reduced to a small size and implanted in the body. Eventually he moved to Baltimore in the United States of America to pursue his dream. There, over 12-years and despite considerable opposition from reputable cardiologists, he developed an automatic implantable defibrillator with the first implant in February 1980. Because the first models were crude and for a period required epicardial patches, the uptake was slow. There were many complications and frequent inappropriate shocks. Also clear indications for this expensive therapy needed to be proven in clinical trials.

The first use of an implantable defibrillator in Australia was in 1984 at the Royal Melbourne hospital with the transvenous shock coil being implanted by the author. By the 1990's, pacing algorithms were developed so that with ventricular tachycardia an attempt at overdrive pacing (bursts of asynchronous pacing faster than the tachycardia) was instituted in order to try and revert the tachycardia and thus prevent the need for a shock. Thus was born the "cardioverter" component of the ICD. As ICD implantation became more common in Australia, their use was included in the Australian and International surveys in 1993.[7]

This chapter will look in detail at the published Australian pacing and ICD surveys for calendar years 2005 and 2009. They will also be compared to previous surveys

to demonstrate the development in pacing services in Australia. In order to compare the Australian experience with the International scene, a selection of countries has been chosen. The selection is across the spectrum and not necessarily with similar health systems to Australia. Hopefully this will allow a clearer perspective of the Australian experience. They have been chosen from Europe, the Asia-Pacific region, the Americas and Israel.

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Contributions to the work involved the following:

Name	% Contribution	Nature of Contribution
Mond Harry G	90%	Principal author, responsible for design of study, liaison with Australian pacemaker and ICD distributors, collection and preparation of Australian data, literature review, writing of manuscript and submission of final draft. Overall responsibility for the whole project
Whitlock Ralph ML	10%	Collection of New Zealand data. Proof reading of manuscript.

Candidate's signature	Date

Declaration by co-authors:

The undersigned hereby certify that:

1) They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication *in their field of expertise*

2) They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication

3) There are no other authors of the publication according to the criteria

4) Potential conflicts of interest have been disclosed to granting bodies, the editor/publisher of the journal and the head of the responsible academic unit

5) The original data are stored at the following location and will be held for at least five years from the date of publication

Location: Department Cardiology, The Royal Melbourne Hospital, Victoria 3050.

Signature: [redacted]

Name [illegible] **Signature** [redacted] **Date** 11-8-11

Original Article

The Australian and New Zealand Cardiac Pacing and Implantable Cardioverter–Defibrillator Survey: Calendar Year 2005

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Background: **A pacemaker (PM) and implantable cardioverter–defibrillator (ICD) survey was undertaken in Australia (Au) and New Zealand (NZ) for 2005.**

Results and Conclusions: **Compared to the 2001 survey, significant increases in implantation numbers were recorded. For 2005, the total new PMs implanted was 11,850 in Au (9498 in 2001) and 1134 in NZ (914 in 2001). The number of new PM implants per million population was 590 in Au (486 in 2001) and 275 in NZ (245 in 2001). Biventricular PMs were documented for the first time with 461 implants in Au and 16 in NZ. Pulse generator types were predominantly dual chamber with 73% in Au (70% in 2001) and 51% in NZ (54% in 2001). Pacing leads were overwhelmingly transvenous and bipolar with an increase in the use of active fixation leads in preference to tined leads. There was a marked increase in the use of ICDs with 2864 new implants in Au (956 in 2001) and 134 in NZ (86 in 2001). The new ICD implants per million population were 142 in Au (49 in 2001) and 33 in NZ (23 in 2001). ICDs were 35% biventricular in Au and 10% in NZ. The Au Northern Territory is included for the first time.**

(Heart, Lung and Circulation 2008;17:85–89)

Keywords. Australia and New Zealand survey; Artificial cardiac pacemakers; Implantable cardioverter–defibrillators

Introduction

Cardiac pacemakers (PMs) have been implanted in Australia (Au) and New Zealand (NZ) since 1961. Implantable cardioverter–defibrillators (ICD) were first used in Au in 1984 and in NZ in 1988 with more recently biventricular models for cardiac resynchronisation being introduced. As an ongoing responsibility of the International Cardiac Pacing and Electrophysiology Society (ICPES), a world wide survey on cardiac pacing and ICD practices has been conducted each four years prior to the World Symposium on Cardiac Pacing and Electrophysiology to which both Au and NZ regularly contribute. To coordinate with previous surveys, the calendar year 2005 was selected as the survey period for the XIIIth World Symposium to be held in Rome in December 2007.

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Methods

Survey Questionnaire

Previous comprehensive PM surveys have been conducted in Au for calendar years 1972,[1,2] 1975,[3,4] 1978,[5] 1989, 1993,[6] 1997[7] and 2001.[8] NZ conducted surveys in 1972,[1,2] 1978,[5] 1981, 1993,[6] 1997[7] and 2001.[8] Implantable cardioverter-defibrillators were included in the survey for the first time in 1993.[6] With a significant increase in the number of Au implanting centres over the last decade, it became obvious that the collection of separate data from each implanting institution had become impossible. Consequently, it was decided that for the surveys after 1993, all implanted Australian PM and ICD hardware information would be obtained through pacing companies. The companies were sent a questionnaire on pulse generators, leads and ICDs sold and registered in the Au states during calendar year 2005. No attempt was made to determine individual hospital implant numbers. The individual company data was received in plain, sealed envelopes, transcribed to a working sheet and individual forms destroyed after the data was collated and transferred to a separate sheet without individual pacing company figures. All pacing companies cooperated with the survey and are listed in the acknowl-

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edgements. For the much smaller NZ survey, the more traditional individual hospital approach was undertaken with assistance from pacing companies if necessary.

For each survey, an accurate number of implants, or at least PMs and ICDs sold, were obligatory. This needed to be divided into new implants and replacements. As well as this, the number of implanting institutions in each country was required. The pacing lead information was obtained through pacing companies for Au and via hospital records in NZ. Unlike previous surveys, no attempt was made to obtain Au clinical information such as indications, mean age, implanter and hospital stay. Such information is presented for NZ.

Results

During 2005, there were 123 Au and 7 NZ centres implanting PMs and 68 Au and 4 NZ centres implanting ICDs. The breakdown of pacing centres in each Au state and the Northern Territory and the corresponding 2001 results for both Au and NZ are listed in Table 1. All Australian Capital Territory implantation data was included with New South Wales. In comparison with the 2001 survey, there has been a 20% increase in Au and a 19% increase in NZ of initial PM implants. All Au States had increases in new PM implants with New South Wales again having the largest number of implants. Victoria, however, with 714 new implants per million population had the highest implant rate. The number of new implants per million population with 590 for Au and 275 for NZ, showed marked increases compared to previous surveys (Fig. 1). For the first time, figures for biventricular PMs for cardiac resynchronisation therapy are included as a separate PM group with 461 implants in Au and 16 in NZ. In Au, the figures for PM replacement (1140) are lower than the 2001 survey (1536). This is likely to be due to inaccurate documentation by the pacemaker companies which often cannot differentiate between new implants and replacements, particularly in public hospitals. Consequently, the actual new implant numbers may be slightly inflated. New Zealand, however, showed a 38% increase in pulse generator replacements compared to the previous survey.

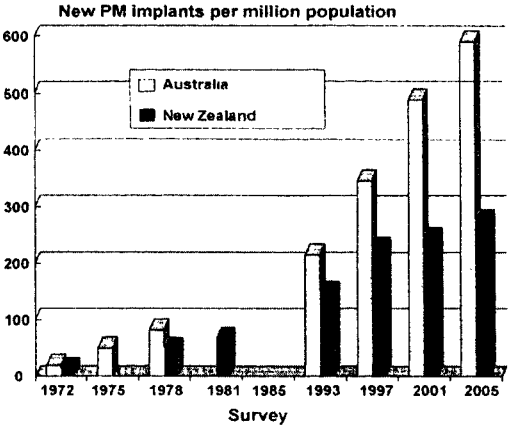

Fig. 1. *Number of new PM implants per million population from all the international PM surveys that Australia and New Zealand have contributed to. There has been an increase with each survey with the greatest changes occurring over the last four surveys.*

For the Au survey, there was no clinical information available However, the much smaller NZ survey (seven implanting centres) did collect clinical information. In particular, the indications for pacemaker implantation were atrioventricular block 49%, sinus node disease 28%, all indications for atrial fibrillation 18%, neurocardiogenic and carotid sinus syncope 2%, all forms of cardiomyopa-

Table 1. *Pacemaker Sales (Au) and Implants (NZ), 2005*

	Total Sales	New	BIVP	Replacement	Popn	NIMP
Australia						
New South Wales (40 centres in 2005) /38 in 2001/	4317	3840 /3340 in 2001/	153	477	6.8	565 /479 in 2001/
Victoria (37) /31/	3917	3568 /2946/	164	349	5.0	714 /607/
Queensland (20) /15/	2241	2130 /1629/	66	111	4.0	560 /444/
South Australia (10) /9/	1097	1032 /869/	30	65	1.6	645 /506/
Western Australia (10) /7/	1182	1063 /648/	48	119	2.0	532 /338/
Tasmania (4) /5/	196	177 /66/	0	19	0.5	354 /140/
Northern Territory (2)	40	40	0	0	0.2	200
Total 2005 (123 centres)	**12990**	**11850**	**461**	**1140 (9%)**	**20.1**	**590**
Total 2001 (105 centres)	11034	9498		1536 (14%)	19.6	486
New Zealand						
Total 2005 (seven centres)	**1450**	**1134**	**16**	**316 (12%)**	**4.1**	**275**
Total 2005 (eight centres)	1109	914		195 (18%)	3.7	245

BIVP, biventricular pacing; Popn, estimated population in millions, December 31st, 2001; NIMP, new implants per million population. New South Wales includes the Australian Capital Territory

Table 2. *Pulse Generator Type (% Sold or Implanted), 2005*

	SSI	SSIR	VDD	DDD	DDDR	BiVent
Australia						
New South Wales	0.1	26	0.7	0	72	1
Victoria	0.1	25	0.1	0	72	2
Queensland	1	22	0.2	0	74	2
South Australia	0.3	20	7	0	69	3
Western Australia	0.2	26	0.3	0	72	1
Tasmania	0	28	0	0	72	0
Northern Territory	0	32	0	0	68	0
Total 2005	**0.3**	**24**	**1**	**0**	**72**	**2**
Total 2001	3	26	1	0	69	1
New Zealand						
Total 2005	**18**	**29**	**0.1**	**29**	**22**	**2**
Total 2001	10	34	4	30	20	2

SSI/SSIR, atrial or ventricular single chamber/rate adaptive (few atrial); VDD, single lead atrial sensing, ventricular pacing, DDD/DDDR, dual chamber/rate adaptive; BiVent, biventricular pacing. <1% given to one decimal place.

thy 2% and unknown 1%. The median hospital stay was 1.2 days and 55% of patients were male. The average age for males was 72 years and for females 74 years. Thirty-three percent of patients were >80 years. For NZ, 98.5% of implants were performed by physicians.

There is a continuing drop in the use of single-chamber pacemaker usage in Au: 24% in 2005 compared with 29% in 2001 with <1% VVI (Table 2). In NZ, however, there was a slight rise between the two surveys from 44 to 47% with 18% VVI. For dual-chamber pacemakers, there were no DDD models implanted compared with 29% in NZ. There were marked differences in DDDR usage between Au (72%) and NZ (22%). Biventricular pacemaker usage was 2% for both countries. In both Au and NZ, the preferred transvenous lead system for standard PM implantation was overwhelmingly bipolar in both the atrium and ventricle (Table 3). In both countries there was an increase in the sale of transvenous screw-in leads with 43% in Au (17% atrium and 10% ventricle in 2001) and 58% in NZ (28% atrium and 16% ventricle in 2001). For this survey, companies were unable to break down the usage to the atrium and ventricle. The marked increase in the use of steroid-eluting screw-in leads in the ventricle reflects the concern that chronic right ventricular apical pacing may result in left ventricular dysfunction. Consequently, these active-fixation leads are being used for right ventricular outflow tract pacing.

As anticipated, there was a marked increase in ICD usage in both Au and NZ compared with the 2001 survey (Table 4). There were 2864 new ICDs (142 per million population) implanted in Au and 134 ICDs in NZ (33 per million population). For this survey, 35% of the ICDs were biventricular in Au (5% in 2001) and 10% in NZ (0% in 2001). Of the remaining ICDs there was a near-equal mix of single- and dual-chamber models.

Discussion

With ongoing hospital budget constraints, surveys of medical procedures are becoming increasingly important to hospital administrators. When compared to previous surveys, this 2005 cardiac PM and ICD survey demonstrates a marked increase in the numbers of implanted devices and, in particular, expensive biventricular models. Coupled with this increased usage has been a significant increase in the number of implanting centres in the larger Au States. This reflects increasing implant numbers in private hospitals, more trained PM and ICD implanters, an aging

Table 3. *Lead Type (% Sold or Implanted), 2005*

	Polarity		Fixation	
	Bipolar	Unipolar	Active	Passive
Australia				
New South Wales	99	<1	47	53
Victoria	99	<1	77	33
Queensland	99	<1	63	37
South Australia	99	<1	34	66
Western Australia	99	<1	46	54
Tasmania	99	<1	48	52
Northern Territory	100	0	6	94
Total 2005	**99**	**<1**	**43**	**57**
Total 2001	100 (A) 98 (V)	0 (A) 2 (V)	17 (A) 10 (V)	83 (A) 90 (V)
New Zealand				
Total 2005	**100**	**0**	**44 (A) 40 (V)**	**56 (A) 60 (V)**
Total 2001	96 (A) 97 (V)	4 (A) 3 (V)	28 (A) 16 (V)	72 (A) 84 (V)

A, atrium; V, ventricle.

Table 4. *ICD Implants, 2005*

	Total	New	Rep	NIMP	Type (%) CD	DCCD	BiVent CD
Australia							
New South Wales (23 centres) /20 in 2001/	1153	1003 /379 in 2001/	150	148	43	33	24
Victoria (21) /16/	768	663 /236/	105	133	22	36	42
Queensland (11) /6/	716	624 /200/	92	156	33	29	38
South Australia (5) /6/	384	344 /91/	40	215	33	19	48
Western Australia (6)/5/	245 /49/	215	30	108	47	16	37
Tasmania (1) /3/	9	6 /1/	3	12	50	38	12
Northern Territory (1)	9	9	0	45	67	22	11
Total 2005 (68)	**3284**	**2864**	**420 (13%)**	**142**	**35**	**30**	**35**
Total 2001 (56)	1115	956	199 (18%)	49	51	44	5
New Zealand							
Total 2005 (4)	**179**	**134**	**45 (25%)**	**33**	**55**	**35**	**10**
Total 2001 (4)	114	86	28 (33%)	23	58	42	0

Rep, replacements; NIMP, new implants per million population; CD, cardioverter-defibrillator; DCCD, dual chamber cardioverter-defibrillator; BiVent CD, biventricular cardioverter-defibrillator.

population and more clearly defined indications for cardiac resynchronisation therapy. As with previous surveys, the current trends in clinical usage of these implanted devices have been highlighted.

One of the limitations of such surveys, particularly in Au, is the inability to recruit physicians or associated professionals to help in collating hospital implant data. PM companies are well placed to assist in the completion of sales figures for each Au State. Following collation of data, these companies also confirmed the accuracy of the results against their own in-house surveys of total Au pacing and ICD trends. Recently with tendering processes, these companies have had difficulties in determining whether the pacemaker has been used as a new implant or replacement. The result of this lack of hospital data was that important clinical information and, in particular, clinical indications were not addressed. The NZ survey, however, was performed using hospital implant data and thus accurate clinical data were available for pacemaker implantation. The results show that the implanter was almost always an electrophysiologist and that the indications were standard with about half the implants resultant from high-degree atrioventricular block and the remainder mainly sinus node disease and atrial fibrillation. Two percent of patients had cardiac resynchronisation therapy without an ICD. Although this information cannot be extrapolated to the Au experience, nevertheless, the results would be expected to be similar.

Pacing complications were not surveyed in either Au or NZ. This is primarily an in-hospital responsibility, rarely performed and more rarely reported. It generally reflects physician or surgeon education and training, and although extremely important, is, nevertheless, well outside the scope of this survey.

Another important limitation of the study was the lack of clinical data regarding the expensive ICD and cardiac resynchronisation therapy. Little is known of the Au experience and in particular the indications and complications. Such a survey would need to be comprehensive and consequently very expensive. An alternative, which is currently being undertaken, is to collect data from a number of large implanting centres. However, it is unlikely that these centres will include private hospitals where the indications and complications may be very different. Only a concerted Federal Government initiative with enthusiastic and cooperative physicians would allow a comprehensive survey to be successful.

This survey presents valuable information on the usage of pacemakers and ICDs in Au and NZ. However, of particular concern was the important clinical information not collected? It behoves us as physicians to thoroughly review this expensive therapy, particularly in regard to clinical indications and complications, so that we have a clear understanding of its usefulness and limitations. The information collected in this survey will be presented at the XIIIth World Symposium to be held in December 2007 in Rome, Italy.

Conclusions

A pacemaker and implantable cardioverter–defibrillator survey was undertaken in Au and NZ for 2005. In comparison to a similar survey in 2001, there were marked increases for both PM and ICD implants and, in particular, biventricular ICD therapy for cardiac resynchronisation. Both Au and NZ use bipolar leads with a growing preference for active fixation.

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Contributions to the work involved the following:

Name	% Contribution	Nature of Contribution
Mond Harry G	90%	Principal author, responsible for design of study, liaison with Australian pacemaker and ICD distributors, collection and preparation of Australian data, literature review, writing of manuscript and submission of final draft. Overall responsibility for the whole project
Whitlock Ralph ML	10%	Collection of New Zealand data. Proof reading of manuscript.

Candidate's signature	Date

Declaration by co-authors:

The undersigned hereby certify that:

1) They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise.
2) They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication.
3) There are no other authors of the publication according to the criteria.
4) Potential conflicts of interest have been disclosed to granting bodies, the editor/publisher of the journal and the head of the responsible academic unit.
5) The original data are stored at the following location and will be held for at least five years from the date of publication.

Location: Department Cardiology, The Royal Melbourne Hospital, Victoria 3050.

Signature: [redacted]

Name R.M.L. WHITLOCK	Signature [redacted]	Date 11-9-11

ORIGINAL ARTICLE

Original Article

The Australian and New Zealand Cardiac Pacing and Implantable Cardioverter-Defibrillator Survey: Calendar year 2009

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Background: **A pacemaker (PM) and Implantable Cardioverter-Defibrillator (ICD) Survey was undertaken in Australia and New Zealand for the calendar year 2009.** *Results and conclusions*: **For 2009, the number of new implants for Australia was 12,523 (11,850 in 2005) and 1277 for New Zealand (1134 in 2005). The number of new PM implants per million population was 565 for Australia (590 in 2005) and 299 for New Zealand (275 in 2005). Both countries had substantial increases in PM replacements. There were 446 biventricular PMs implanted in Australia (461 in 2005) and 45 in New Zealand (16 in 2005). Pulse generator types were predominantly dual chamber with 71% for Australia (72% in 2005) and 54% for New Zealand (51% in 2005). Transvenous pacing leads were overwhelmingly bipolar with marked increases in the use of active fixation leads; Australia 80% atrium, 75% ventricle and New Zealand 65% atrium, 62% ventricle. There was also a marked increase in the number of new ICDs implanted; Australia 3555 (2864 in 2005) and New Zealand 329 (134 in 2005). The new ICD implants per million population were 160 for Australia (142 in 2005) and 77 for New Zealand (33 in 2005). The usage of biventricular ICDs was 33% for Australia and 13% for New Zealand.**

(Heart, Lung and Circulation 2011;20:99–104)

Keywords. Australia and New Zealand Survey; Artificial cardiac pacemakers; Implantable cardioverter-defibrillators

Introduction

Cardiac pacemakers (PM) have been implanted in Australia and New Zealand since 1961. Implantable cardioverter-defibrillators (ICD) were first used in Australia in 1984 and in New Zealand in 1988 with, more recently, biventricular models for cardiac resynchronisation being introduced. As an ongoing responsibility of the International Cardiac Pacing and Electrophysiology Society (ICPES), a world wide survey on cardiac pacing and ICD practices has been conducted each four years prior to the World Symposium on Cardiac Pacing and Electrophysiology to which both Australia and New Zealand regularly contribute. To coordinate with previous surveys, the calendar year 2009 was selected as the survey period for the XIV World Symposium to be held in Athens, Greece in 2011.

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Methods

Survey Questionnaire

Previous comprehensive PM surveys have been conducted in Australia for calendar years 1972 [1,2], 1975 [3,4], 1978 [5], 1989, 1993 [6], 1997 [7], 2001 [8] and 2005 [9]. New Zealand conducted surveys in 1972 [1,2], 1978 [5], 1981, 1993 [6], 1997 [7], 2001 [8] and 2005 [9]. Implantable cardioverter-defibrillators were included in the survey for the first time in 1993 [6]. With significant increases in the number of Australia implanting centres over the last 16 years, it became obvious that the collection of separate data from each implanting institution had become impossible. Consequently, it was decided that for the surveys after 1993, all implanted Australian PM and ICD hardware information would be obtained through pacing companies. The companies were sent a questionnaire on pulse generators, leads and ICDs sold and registered in Australian states during calendar year 2009. No attempt was made to determine individual hospital implant numbers. The individual company data were received in plain sealed envelopes, transcribed to a working sheet and individual forms destroyed after the data were collated and transferred to a separate sheet without individual pacing

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company figures. All pacing companies cooperated with the survey and are listed in the acknowledgements. The data collection and analysis was performed without influence from any of the companies involved and all companies provided all the information asked in the survey form. For the smaller New Zealand survey, the more traditional individual hospital approach was undertaken with assistance from pacing companies when necessary.

For each survey, an accurate number of implants, or at least PMs and ICDs sold, were obligatory. This needed to be divided into new implants and replacements. As well as this, the number of implanting institutions in each country was required. Unlike earlier surveys, no attempt was made to obtain clinical information in Australia such as indications, mean age, implanter and hospital stay. Such information was available for New Zealand and will be published as part of the World Survey.

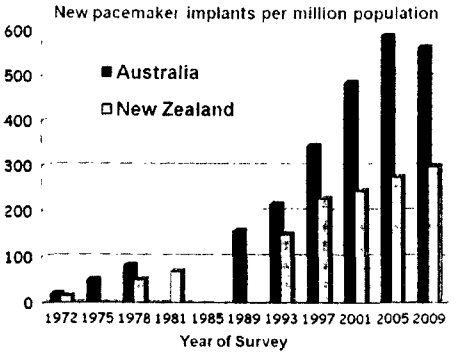

Figure 1. *Number of new PM implants per million population from all the Australian and New Zealand surveys since 1972*

Results

During 2009, there were 111 Australia and 10 New Zealand centres implanting PMs. The breakdown of pacing details in each Australia State and Northern Territory and the corresponding 2005 results for both Australia and New Zealand are listed in Table 1. All Australian Capital Territory implantation data were included with New South Wales. In comparison with the 2005 survey, there was a significant rise in the total PM sales in Australia or actual implants in New Zealand. Despite this, there were only small rises in the number of new PM implants in Australia; 12,523 (11,850 in 2005) and New Zealand; 1277 (1134 in 2005). New South Wales had the largest number of PM implants, closely followed by Victoria.

The number of new implants per million population in 2009 was 565 for Australia which was marginally lower than in 2005 (590) and 299 for New Zealand which was marginally higher (275). With 710 new implants per million population, Victoria had the highest implant rate closely followed by South Australia with 706. The changes in the Australia and New Zealand market since the first PM survey in 1972 are tabulated in Fig. 1. Note that surveys were not conducted in Australia for 1981 and 1985 and in New Zealand in 1985 and 1989.

Compared with the 2005 survey, the number of new biventricular PMs for cardiac resynchronisation therapy fell marginally in Australia from 461 to 446 units compared to a rise in New Zealand from 16 to 45. The figures for both countries are small, because of the preference particularly in Australia for implanting a biventricular ICD in appropriate recipients.

For both Australia and New Zealand, the figures for PM replacement are higher than the 2005 survey. For Australia, this was 25% of all the PMs purchased (9% in 2005) and for New Zealand 25% of the PMs implanted (22% in 2005).

For the Australia survey, there was no clinical information available. However, the smaller New Zealand survey

Table 1. *Pacemaker Sales in Australia and Implants in New Zealand, 2009.*

	Total Sales	New	BiVP	Replacement	Popn	NIMP
Australia						
New South Wales	5290	4054 {3840}	145	1236	7.54	538 {567}
Victoria	5170	3906 {3568}	183	1264	5.50	710 {734}
Queensland	3455	2686 {2130}	62	769	4.47	601 {560}
South Australia	1440	1152 {1032}	30	288	1.63	706 {645}
Western Australia	1445	1049 {1063}	65	396	2.27	462 {532}
Tasmania	256	202 {177}	0	54	0.51	396 {354}
Northern Territory	35	28 {40}	0	7	0.23	122 {200}
Total 2009	**16,265**	**12,523**	**446**	**3742 (23%)**	**22.16**	**565**
{Total 2005	*12,990*	*11,850*	*461*	*1140 (9%)*	*20.10*	*590}*
New Zealand						
Total 2009	**1695**	**1277**	**45**	**418 (25%)**	**4.27**	**299**
{Total 2005	*1450*	*1134*	*16*	*316 (22%)*	*4.1*	*275}*

( ) = %.
{ } = 2005 Survey.
BiVP = Biventricular pacing.
Popn = Estimated population in millions, December 31st 2009.
NIMP = New Implants per million population.
New South Wales includes the Australian Capital Territory.

Table 2. *Pulse Generator Type 2009 (All %).*

	SSI	SSIR	VDD	DDD	DDDR	BiVent
Australia						
New South Wales	0	27	<1	0	70	3
Victoria	0	26	0	0	71	3
Queensland	0	24	<1	0	74	2
South Australia	0	24	<1	0	72	2
Western Australia	0	27	<1	0	68	5
Tasmania	0	25	0	0	75	0
Northern Territory	0	17	0	0	83	0
Total 2009	**0**	**26**	**<1**	**0**	**71**	**3**
{*Total 2005*	*0*	*24*	*1*	*0*	*72*	*3*}
New Zealand (programmed mode at implantation)						
Total 2009	**10**	**33**	**0**	**26**	**28**	**3**
{*Total 2005*	*18*	*29*	*<1*	*29*	*22*	*2*}

{ } = 2005 survey.
SSI/SSIR = Atrial or Ventricular Single Chamber/Rate Adaptive (Few Atrial).
VDD = Single Lead Atrial Sensing, Ventricular Pacing.
DDD/DDDR = Dual Chamber/Rate Adaptive.
BiVent = Biventricular Pacing.

with10 implanting centres did collect clinical information. In particular, the indications for pacemaker implantation were atrioventricular block 49%, sinus node disease 27%, all indications for atrial fibrillation including His bundle ablation 19%, neurocardiogenic and carotid sinus syncope 1% and all forms of cardiomyopathy 4%. The median hospital stay was one day and 61% of patients were male. The average age for both males and females was 72 years. Thirty-five percent (35%) of patients were >80 years. Physicians were involved in 99% of all implants.

There were no SSI PMs sold or implanted in Australia or New Zealand in 2009. Rather all single chamber PMs were rate adaptive SSIR and represent 26% of those sold in Australia and 31% of those implanted in New Zealand (Table 2). These figures are similar to the 2005 survey with the vast majority of units being used for ventricular pacing. The occasional VDD model implanted was probably for the replacement market. For dual chamber pacemakers, there were no DDD models sold in Australia or implanted in New Zealand. There were marked differences in DDDR usage between Australia (71%) and New Zealand (54%). For New Zealand, the programmed mode of pacing following PM implantation was available (Table 2). Although all pulse generators implanted in New Zealand were VVIR and DDDR, the actual percentage programmed to the rate adaptive and non-rate adaptive modes have been documented: 10% VVI, 33% VVIR, 26% DDD and 28% DDDR. Biventricular PM implantation was 3% for both countries.

In both Australia and New Zealand, the preferred transvenous lead system for standard PM implantation was overwhelmingly bipolar in both the atrium and ventricle (Table 3). In both countries, there was a marked increase in the sale of transvenous screw-in leads; 80% atrium and 75% ventricle for Australia and 65% atrium and 62% ventricle for New Zealand. The increased usage

Table 3. *Lead Type Sold or Implanted 2009 (All %).*

	Polarity		Atrial Fixation		Ventricular Fixation	
	Bipolar	Unipolar	Active	Passive	Active	Passive
Australia						
New South Wales	99	<1	65	35	56	44
Victoria	99	<1	85	15	85	15
Queensland	99	<1	83	17	75	25
South Australia	100	0	75	25	75	25
Western Australia	99	<1	42	58	60	40
Tasmania	100	0	90	10	98	2
Northern Territory	100	0	35	65	35	65
Total 2009	**99**	**<1**	**80**	**20**	**75**	**25**
{*Total 2005*	*99*	*<1*	*43 active fixation*		*57 passive fixation*}	
New Zealand						
Total 2009	**99**	**<1**	**65**	**35**	**62**	**38**
{*Total 2005*	*100*	*0*	*44*	*56*	*40*	*60*}

{ } = 2005 survey
<1% = Very small numbers used.
2005 Australian survey – no breakdown between atrial and ventricular fixation.

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Table 4. *ICD Implants 2009.*

	Total	New	Rep	NIMP	Type (%)		
					CD	DCCD	Bi V CD
Australia							
New South Wales	1508	1209 {1003}	299	160 {148}	585 (39)	519 (34)	404 (27)
Victoria	1215	863 {663}	352	157 {105}	389 (32)	383 (32)	443 (36)
Queensland	1001	747 {624}	254	167 {156}	273 (27)	390 (39)	338 (34)
South Australia	506	399 {344}	107	245 {215}	185 (36)	140 (28)	181 (36)
Western Australia	403	308 {245}	95	135 {108}	146 (36)	107 (27)	150 (37)
Tasmania	8	7 {6}	1	14 {12}	0 (0)	6 (75)	2 (25)
Northern Territory	25	22 {9}	3	109 {45}	13 (52)	11 (44)	1 (4)
Total 2009 [101]	**4666**	**3555**	**1111**	**160**	**1591 (34%)**	**1556 (33%)**	**1519 (33%)**
{Total 2005 [68]	*3284*	*2864*	*420*	*142*	*(35%)*	*(30%)*	*(35%)*
New Zealand							
Total 2009 [5]	**414**	**329**	**85**	**77**	**188 (57%)**	**98 (30%)**	**43 (13%)**
{Total 2005 [4]	*179*	*134*	*45*	*33*	*98 (55%)*	*63 (35%)*	*18 (10%)*

( ) = %.
{ } = 2005 survey.
Rep = Replacements.
NIMP = New Implants per Million Population.
CD = Cardioverter-Defibrillator.
DCCD = Dual chamber Cardioverter-Defibrillator.
Bi V CD = Biventricular Cardioverter-Defibrillator.

of active fixation leads in the right ventricle may partially reflect the growing preference for septal pacing.

The ICD market continues to grow in both Australia and New Zealand (Table 4). There were 3,555 new ICDs implants in Australia (2,864 in 2005) and 329 new ICDs in New Zealand (134 in 2005). The number per million population was 160 for Australia (142 in 2005) and 77 for New Zealand (33 in 2005). In both countries, the mix between single chamber, dual chamber and biventricular ICDs was similar to the 2005 survey, although Australia implanted a much higher proportion of biventricular ICDs; 33% in comparison to 13%. Fig. 2 illustrates the number of new ICD implants per million population since the first survey in 1993. Unlike PM implants, ICDs are more likely to be registered by the pacing companies and thus the ICDs sold are those actually implanted and the mix between new implants and replacements very accurate. Not surprisingly, in both countries, the number of ICD replacements has increased markedly since the 2005 survey.

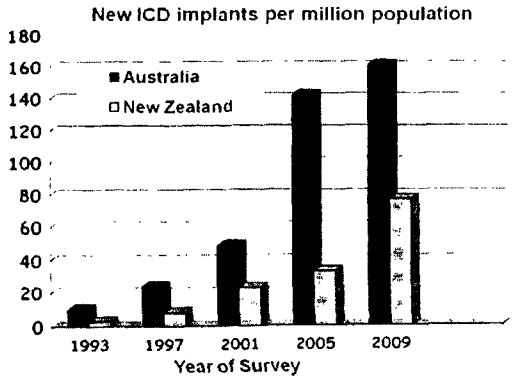

Figure 2. *Number of new ICD implants per million population from all the Australian and New Zealand surveys since 1993.*

Discussion

With ongoing hospital budget constraints, surveys of medical procedures are becoming increasingly important to hospital administrators and government bureaucrats. When compared to previous surveys, this 2009 cardiac PM and ICD survey demonstrates a marked increase in the numbers of implanted devices. Although new PM implants in Australia appears to have plateaued, there has been a significant rise in ICD implants reflecting a better understanding and more clearly defined indications for this mode of treatment and in particular, cardiac resynchronisation therapy [10]. Coupled to this has been a marked rise in the number of ICD implanting centres, more trained electrophysiologists and an aging population.

The major change between this and the 2005 PM survey has been the apparent increase in replacements from 9 to 23% for Australia and from 22 to 25% for New Zealand. The Australian increase may be partially due to the inability of PM companies to always distinguish between new and replacement units sold, particularly to public hospitals when the registration may not be completed. This was of particular concern with the 2005 survey and suggests that the number of replacements in that survey may have been underestimated and the number of new implants overestimated. However, PM registrations have improved over the last four years making the replacement figures more accurate. Of course, a pulse generator sold or on consignment to a hospital may not have been implanted at the completion of the survey. However, it is assumed that the number of units awaiting implantation at the commence-

Table 5. *Comparative Implant Data [10].*

	New PM		ICDs	
	Sales/Implanted	*NIMP*	*Sales/Implanted*	*NIMP*
2009				
Australia	16,265	565	4666	160
New Zealand	1695	299	414	77
2005				
Australia	11,850	590	2864	142
New Zealand	1134	275	134	33
United States	223,425	752	119,121	401
Canada	17,600	550	3000	91
Argentina	10,876	294	672	18
Belgium	8122	789	846	82
France	44,915	738		
Italy	44,000	765	7439	129
China	16,595	13	186	1
Japan	30,817	245	2360	19
Israel	2334	333	683	98

ment of the year is similar to the number at the end of the year and thus any errors in assumed implant numbers are very small.

Be that as it may, the numbers of PM replacements is reflective of the large increases in PM usage earlier this decade in both Australia and New Zealand with implanted pulse generators now reaching end of service life (Fig. 1). This also holds true for the much more expensive ICD replacements as well (Fig. 2). For future planning, a much higher proportion of budget allocation will be required for replacement units.

How does Australian and New Zealand usage of cardiac implantable electronic devices compare with other countries? No data is as yet available for the 2009 world survey and thus the Australian and New Zealand results must be compared to the 2005 survey [11]. Even accounting for growth in implant numbers, both Australia and New Zealand have high implant rates compared to the rest of the world. A selection of countries is shown in Table 5. For PM, the highest new implants per million population in 2005 was Belgium (789) closely followed by Italy (765), the United States (752) and France (738). Germany has previously been recognised as a large implanter, but did not contribute to the 2005 survey. Australia with 565 new implants per million population follows this group. The usage of ICDs in both Australia and New Zealand is even more impressive. The United States was easily the highest implanter with 401 new implants per million population in 2005, but only Australia and Italy were above 100 in 2005 with Australia now at 160.

One of the limitations of such surveys, particularly in Australia, is the inability to recruit physicians or associated professionals to help in collating hospital implant data. The companies selling or manufacturing cardiac implantable electronic devices are well placed to assist in supplying sales figures for each Australia state. Following collation of data, these companies also confirmed the accuracy of the results against their own inhouse surveys of total Australia pacing and ICD trends. The lack of hospital data also meant that clinical indications for the implants were not addressed. The New Zealand survey, however, being much smaller was performed using hospital implant data and thus accurate clinical data was available. The indications for PM implantation were standard with about half the implants required for high degree atrioventricular block and the remainder mainly sinus node disease and atrial fibrillation.

Another limitation of both the Australia and New Zealand surveys was the inability to follow outcomes such as operative and post-operative complications, device power source longevity and lead failures. Such clinical and outcomes data are very important in allocating future resources particularly for the rapidly growing and extremely expensive biventricular ICD models. However, such comprehensive surveys and registries are complicated, require public and private hospital cooperation and are extremely expensive to conduct. They require a concerted state or federal government initiative, possibly linked to legislation allowing public hospital or private health benefit funding to be dependent on registry information. In the meantime, the responsibilities for use of this expensive therapy lie with the individual cardiology department and implanter. High standards of care are paramount with appropriate indication guidelines followed and complications minimised.

Conclusions

A PM and ICD survey was undertaken in Australia and New Zealand for calendar year 2009. In comparison to a similar survey in 2005, there were marked increases for both PM and ICD implants and in particular PM replacements and all types of ICDs. Both Australia and New Zealand use bipolar leads with a preference for active-fixation.

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- Sorin Group, West End, Queensland.
- Medtronic Australasia, North Ryde, NSW.
- St. Jude Medical, Lane Cove, New South Wales.

New Zealand
- Biotronik, Auckland.
- Boston Scientific Australia and New Zealand, Auckland.
- Medtel New Zealand, Auckland.
- Medtronic New Zealand Limited, Auckland.

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3.3 Australian Cardiac Pacing Surveys: A Review.

The first Australian pacemaker survey was conducted in 1972.[1] In 1975,[2,3] 1978[4] and 1989 further surveys were conducted, but because they were performed using hospital data, they were not necessarily accurate as it was almost impossible to receive information from all implanting Australian institutions. In 1993, after much frustration trying to collect hospital data, pacemaker companies were asked to assist in obtaining implant data numbers from hospitals which failed to return the questionnaire.[5] As a result, accurate implant numbers were obtained, but now there were no clinical data, including demographics.

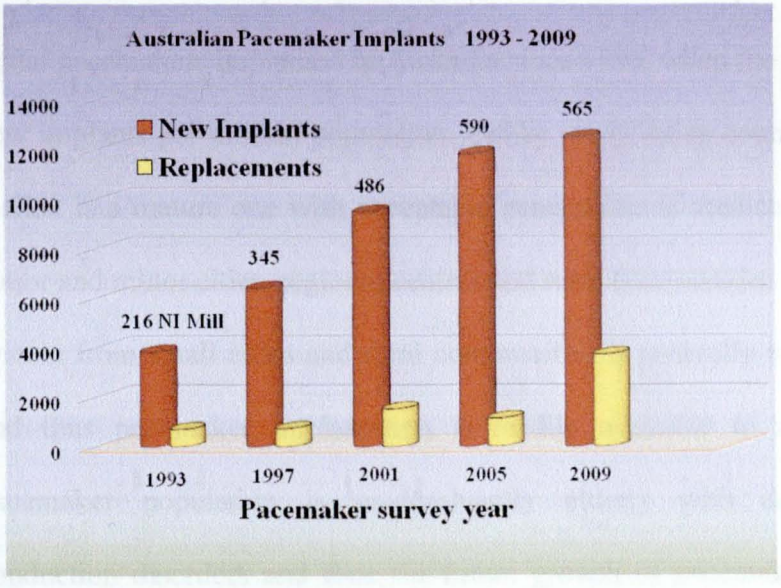
For the 1997,[6] 2001,[7] 2005[8] and 2009[9] Australian pacing surveys, no attempt was made to obtain hospital data and the surveys were conducted using only pacemaker company registration data. It is believed that overall, the pacemaker company data is accurate although, earlier on, there were concerns regarding the breakdown between initial pacemaker implants and replacements, but at least for the 2009 survey, the breakdown is probably accurate. It is now possible to compare the last five conducted surveys (1993 to 2009).

This thesis covers the last two surveys; calendar years 2005 and 2009 when the author became involved with the Department of Epidemiology and Preventive Medicine at Monash University Faculty of Medicine, Nursing and Health Sciences. However, the evolution in pacing and ICD practices are best demonstrated through changes that have occurred over the last two decades.

3.3.1 Pacemakers sold in Australia for initial implantation

The figures for pacemakers sold in Australia for initial implantation increased with each survey with 12,523 new implants in 2009 (Figure 3.3.1). Although the figure is higher than in 2005 (11,850), the number of new implants per million population actually fell between the two surveys from 590 to 565. There are probably a number of explanations for this. As will be discussed in the international surveys, initial implant numbers in the developed countries with long standing mature pacemaker services have generally plateaued and even in some cases fallen. For Australia, the services provided have not altered between surveys and it is unlikely that there have been significant budgetary restrictions. Rather the numbers of potential pacemaker recipients have remained stable.

Figure 3.3.1 Australian pacemaker implants 1993 – 2009.



NI Mill = New pacemaker implants per million population

Despite this, there has been a substantial rise in the Australian population from 20.10 million in 2005 to 22.16 million in 2009. A substantial proportion of this rise in population can be attributed to newborns or young immigrants who rarely require cardiac pacing and although this does not affect the numbers of new pacemaker implants, it does dilute the numbers of new pacemaker implants per million population. The effects of a population shift will be reinforced later in this chapter, when implant data for the individual states are presented.

A third factor to consider is the ability of the pacemaker companies to always distinguish between new implants and replacements units sold, particularly to public hospitals where registration details may not be completed or accurate. It is believed that for the 2005 pacing survey, the number of initial implants may have been overestimated.

Despite this minor implant plateau, there has been a steady rise in the number of initial pacemakers implanted in Australia since 1993, when the figure was only 216 new implants per million population. Unlike many Asian countries, the Australian market is a mature one with acceptable penetration of medical services within all major and minor cities, regional centres and rural communities. The cardiac referral system from small cities and rural communities is generally regarded as excellent and thus pacemaker implantation is readily available to all. In general, the pacemaker population is predominantly elderly with degenerative cardiac conduction disorders and thus the future growth of pacemaker implants will be limited and dependent on an increasing geriatric community, who are now living longer.

How do these figures compare with other countries? Table 3.3.1 lists the 2009 world pacing survey results of other major implanting countries.[10] The largest implanter of pacemakers is the United States of America with 235,567 new implants, although Germany has the highest number of new implants per million population with 927. Australia with 565 new pacemaker implants per million population sits about midway in the European figures and the highest in the Asia Pacific region.

Like Australia, countries with high values for new pacemaker implants per million population, particularly in Europe and North America have well established pacemaker services, their referral systems are both mature with broad country penetration and as a result most patients who require a pacemaker receive one. Countries with smaller numbers are generally poorer, have limited referral avenues and inadequate funding for the indigent population. As a new middle class emerges then the numbers of new implants will increase. It could therefore be inferred that a figure close to 500 new pacemakers per million population would be consistent with a mature service and a modest geriatric population.

Why then do some countries have much higher values? There is no ready or simple explanation for this. Are we missing patients in Australia who require permanent pacing? There may be rural or low socioeconomic areas in Australia where the basic medical facilities such as Holter monitoring are limited and symptomatic patients go undiagnosed, but this would hardly explain significant differences in implant numbers.

Table 3.3.1 Pacemaker implantation 2009 World Survey

Country	Population (Million)	New Implants	New Implants 10^6 Population	Replacements (% of Total)
Australia	22	12,523	565	3742 (23)
United States	307	235,567	767	101,042 (30)
Germany	82	~76,046	927	~25,349 (25)
France	62	~48,487	782	~16,162 (25)
Italy	60	44,653	744	17,974 (29)
Sweden	9	6,320	702	2,817 (31)
Netherlands	17	9,048	532	~4,826 (35)
UK	62	32,135	518	10,176 (24)
Russia	142	22,516	159	3,859 (15)
New Zealand	4	1,277	299	418 (25)
Japan	128	34,813	272	23,532 (40)
Taiwan	23	3,952	172	868 (18)
China	1,300	40,728	31	7,187 (15)
India	1,200	20,000	17	400 (2)
Israel	7	3,000	429	1,200 (29)
Puerto Rico	4	2,423	605	
Uruguay	3	1,084	324	851 (44)
Argentina	40	11,478	287	3,800 (25)
Chile	17	3,045	216	455 (13)
Brazil	184	24,966	136	9,981 (29)

10^6 = million UK = United Kingdom

Is there over-servicing in other countries? Are the indications for implantation more flexible in these countries? These are unknown factors and beyond the limits of this thesis. Probably a more reasonable explanation for differences in implant numbers in these countries lies in the country demographics with an elderly population, the affluence of the community and the availability of similar health services to all the population irrespective of the socioeconomic circumstances. Again although important, these variables were beyond the boundaries of this thesis.

3.3.2 Pacemakers sold in Australia for replacement

Pacemakers sold in Australia for replacement have also risen over the last five pacing surveys with 700 in 1993 (14% of all implants) to 3742 (23%) in 2009. There was a substantial fall in pulse generator replacements in the 2005 survey (9%), but this as discussed, may be due to some inaccuracy on behalf of the manufacturers' figures.

Pacemaker replacements are an important budgetary item that must be considered in overall funding of Australian CIED services. The ideal situation is that once a pacemaker is implanted, then there should be no need for further surgical or hardware costs particularly in elderly recipients. Although over the years, the projected longevity of most implanted pulse generators have increased to almost a decade, the longevity of pacemaker recipients have also improved, necessitating eventual hardware replacements. However, the projected longevity of biventricular pacemakers is often much shorter than single or dual chamber models, because of the increased energy requirements to pace the left ventricle. At this stage, the numbers used are low, because of the preference to implant a biventricular ICD rather than a pacemaker and thus will have little impact on the percentage of replacements compared with total implants.

The percentage of replacements compared with total implants varies significantly with other implanting countries (Table 3.3.1). Most countries with mature pacing services, particularly in Europe, have high percentages of replacements with values ranging from 20 to 40% and a mean level of about 25%. Other countries,

particularly in Asia, have only recently commenced large scale pacemaker implantation services and thus only small numbers of these recipients have required replacements; China 15%, India 2% and Russia 15%. This will rise sharply in the future.

Other factors must be taken into consideration when analysing the percentage of replacements compared with total implants. Although the longevity of an implanted pulse generator has improved in recent years, it is still very dependent on the battery capacity and the programmed voltages. Modern pacemaker are able to measure the stimulation threshold or amount of energy required to depolarize the heart and in this way automatically adjust the voltage output for pacing with an adequate energy safety margin. Programmable algorithms are now available to reduce the amount of unnecessary pacing and thus modern implanted pulse generators when programmed responsibly can achieve a longer service life than their predecessors.

There must also be an understanding as to when to replace a pulse generator. As our experience with power source depletion characteristics increases, we are able to follow patients longer, rather than replace pulse generators prematurely. All these factors must be considered when evaluating the percentage of replacements compared with total implants. It would be reasonable to expect that for budgetary purposes, the figure for pulse generator replacements in Australia will always be at least 20% of new implants.

3.3.3 Initial pacemaker implants for individual Australian States.

For the 2009 Australian pacing survey, New South Wales had the largest number of initial implants at 4054 (Figure 3.3.2), but Victoria had the largest new implants per million population at 710 (Figure 3.3.3). When compared to the 2005 pacing survey, there were only modest rises in initial pacemaker implant numbers in most States, with only small changes in new implants per million population, explained by the population changes in Australian states over the period 2005 to 2009.

For example, implant numbers for Western Australia remained steady over the two surveys, but because of the increase in the young population moving west for better job opportunities, the actual number of new implants per million population fell between the two surveys. In contrast, Queensland had a significant rise in both initial pacemaker implants and new pacemaker implants per million population, which is explained by the large numbers of retirees moving to that state.

When compared to the rest of the world, the 2009 individual new pacemaker implants per million population figures for the larger Australian States are generally high and comparable to the larger European countries and the United States. This is particularly so for Victoria (710) and South Australia (706) and reflects the widespread availability of pacing and ICD services not only in those States but also in the rest of Australia. It must also be remembered that in the Territories and smaller States such as Tasmania, patients are occasionally referred to the larger States for specialized pacing and ICD services not readily available locally.

Figure 3.3.2 Australian pacing survey 2009. New pacemaker implants for each State and Territory are shown with the 2005 survey figures in brackets. Australian Capital Territory figures are included with New South Wales.

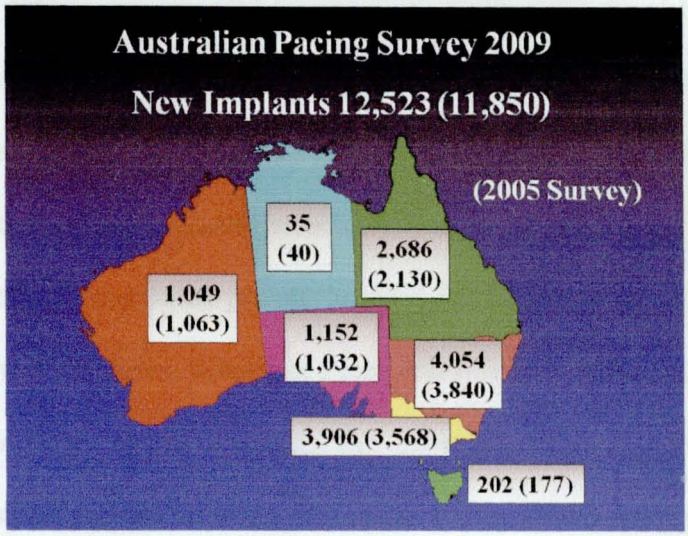
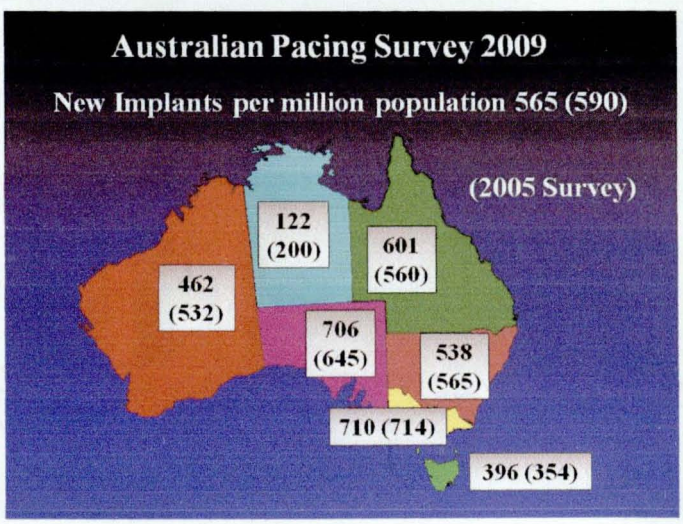


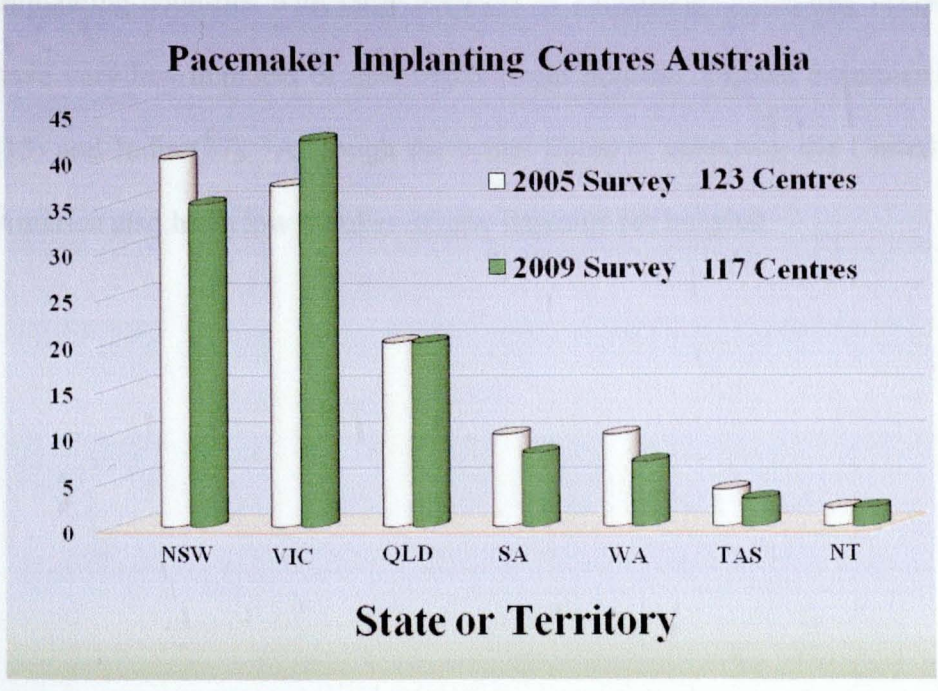
Figure 3.3.3 Australian pacing survey 2009. New pacemaker implants per million population for each State and Territory are shown with the 2005 survey in brackets. Australian Capital Territory figures included in New South Wales.



3.3.4 Pacemaker implanting centres in Australia

In 2009, there were 117 pacemaker implanting centres in Australia. This was lower than the 123 centres documented for the 2005 survey. The most likely reason for this apparent fall was a more accurate collection of data by pacing companies. There were a number of centres listed that only tested pacemakers, but did not implant devices and also a small number where two adjoining hospitals such as a public hospital and the local private hospital implanted pacemakers. Because of rationalization of facilities, it became more economic to implant all pacemakers in the public facility. There was also the situation where a single cardiologist implanted a small number in a small hospital and later because of limited facilities ceased implanting pacemakers at that hospital.

Figure 3.3.4 Pacemaker implanting centres in Australia for surveys 2005 and 2009.



For the 2005 survey, New South Wales had the largest number of pacemaker implantation centres (40), whereas Victoria had the most for the 2009 survey (42). A new derived statistic for the 2009 world pacing survey was the number of new implants per centre. For Australia, this was 113 new implants per centre per year. This suggests that Australia has a reasonable number of implants per centre and that these centres are appropriately utilized. There is cost and staff implications as well, suggesting, particularly in the major cities, that larger centres be encouraged. Although actual figures are not available, centres with large numbers of pacemaker implantations generally have a dedicated well trained staff familiar and comfortable with the procedures and able to handle complex cases. It is also believed that larger implanting centres will usually have lower overall implant complications.

Most countries in Europe have similar high number of implants per centre, particularly in countries with high levels of centralized medical facilities such as Lithuania (454), Hungary (266), Denmark (221) and Spain (221). Conversely, large implanting countries with large numbers of pacemaker implanting hospitals often have very low numbers of new implants per hospital. Typical examples are Japan (15) and India (27). Although the actual figure is unknown, the United States of America also has a low number of new implants per hospital.

3.3.5 Pulse generator types sold in Australia

All pulse generators sold in Australia are programmable, have intracardiac sensing capabilities and an incorporated sensor or sensors to allow rate adaptive pacing (R). Single chamber pulse generators; designated SSI(R) which can be used for ventricular and rarely atrial pacing, represent 26% of all implants (24% in 2005). Dual chamber or DDD(R) pulse generators were 71% (72% in 2005). Biventricular pulse generators for CRT were 3% for both the 2005 and 2009 surveys. The absence of a rise in this therapy can be attributed to the fact that the preferred option for severe heart failure is a biventricular ICD rather than a pacemaker.

All States had similar figures for pulse generator types, suggesting uniformity in the prescribing habits of Australian cardiologists and a preference for the most appropriate pacing therapy rather than a cost limitation. The figures are also comparable to the United States and the wealthier European countries, whereas most countries in the Asia Pacific region use significantly more single chamber models. This is usually because of cost, but in some cases, the implanter may not be able to insert an atrial lead.

3.3.6 Pacemaker leads sold in Australia.

The vast majority of pacemaker leads sold in Australia are bipolar. The use of unipolar leads for CRT has also become rare. A similar situation is present throughout the world, although a number of European and Asian countries until recently, preferred unipolar leads particularly in the ventricle.

The main fixation device used for pacing leads in both the atrium and ventricle has been passive tines. More recently, the active fixation, retractable-extendable screw has become popular in the atrium and now in the ventricle, particularly with interest in pacing right ventricular sites outside the apex.

3.3.7 Concluding remarks.

By world standards, Australia has a sophisticated medical system and consequently this is seen as high usage of cardiac pacemakers. However, on a per million population basis, in the 2009 survey, 11 European countries implanted more pacemakers than Australia, but only two other countries outside Europe; Puerto Rico and The United States of America. Australia had the largest implant numbers in the Asia-Pacific region. Although Australia on a population basis does not implant as many pacemakers as many of the affluent Western and Northern European nations, this may reflect an older population in Europe as the war and post war births now enter the mean age range for pacemaker implants. Australia, in turn, has had a steady and large young immigrant population since the war.

The question can be asked is whether Australians may be missing out on potential life saving pacemakers. This appears unlikely. Medical and hospital services in Australia are mature and sophisticated. The indications for pacemakers are well established and the investigations required for diagnosis widely available. In general, any patient urgently requiring a pacemaker is likely to receive one within an acceptable time and the waiting lists for elective cases are not excessive or unreasonable. It is likely, therefore, that the pacing services in Australia are acceptable and that the figures per million population satisfactory. It would be interesting to know whether over the years, there has been a significant change in the mix of public hospital and private hospital patients. This could only be determined in a more formal registry.

Although pacemaker implants continue to rise in Australia, there has been a trend toward a plateau, similar to many of the other large implanting countries, including the United States of America and much of Europe. Belgium, which has traditionally been one of the largest implanters, has actually shown a modest fall from 789 new implants per million population in 2005 to 627 in 2009. There may be many reasons for this including possible correction of over-servicing and more scrutiny, a changing population with young immigrants or even a tightening of hospital budgets.

The Australian States have also showed a plateau in implant numbers between the 2005 and 2009 Australian pacemaker surveys with Western Australia showing a modest reduction in new pacemaker implants per million population from 532 in 2005 to 462 in 2009. This probably reflects the marked influx of young workers and their families moving westward because of the mining boom, confirming that the reduction reflects demographic shifts rather than tightening hospital budgets.

Another interesting question is the influence of the number of Cardiologists and in particular Electrophysiologists have on the pacemaker implantation numbers. In order to answer this, a differentiation is required between those electrophysiologists who implant and those that don't. It could be argued that the more implanters, the more implants. However, the plateau in implant numbers at a time during which there was an increase in trained implanters entering the Cardiology work force suggests that the impact of more electrophysiologists has not been excessive. Similarly there was no increase in the number of implanting hospitals between the surveys. The influence of implanting electrophysiologists on implant numbers is

outside the boundaries of the Australian surveys, but is an important question which should be answered in an ongoing registry.

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3.4 Australian ICD Surveys: A Review.

The first use of an implantable defibrillator in Australia was in 1984 at the Royal Melbourne hospital. This was a very simple and crude device, which upon recognition of a potentially fatal ventricular tachyarrhythmia would shock the heart. Only some years later, were the implantable devices able to attempt overdrive ventricular pacing and thus the concept of a cardioverter defibrillator or ICD, as we understand it today, was born. For many reasons, the uptake of this therapy was slow and thus their use and documentation was not considered until the 1993 Australian survey.[1]

Subsequent to the 1993 survey, further Australian ICD surveys were conducted for calendar years 1997,[2] 2001,[3] 2005[4] and 2009.[5] Only ICD company registration was used. Because an ICD company representative is almost always present at the initial implant or replacement, formal registration is always undertaken for these expensive implantable devices and thus the company data obtained for the surveys is very accurate. Consequently, it is possible to compare the last five conducted surveys (1993 to 2009).

Since 1993, vast changes have occurred with both the ICD lead and high output generator, but this cannot always be reflected in a simple company based survey. The original devices were simply a shock box with a floating lead or patches to deliver the energy. In order to sense ventricular fibrillation, a bipolar endocardial or two epicardial leads were also required. With improvements in design, the shock was delivered through endocardial coils on an ICD lead. The next major

evolutionary change was the development of a dual chamber pacing device incorporated into the ICD and more recently biventricular pacing. Such changes can be easily incorporated into a company based survey. However, with such new expensive technology with a high incidence of potentially serious and life threatening complications, it is important to be able to survey clinical indications, demographics and above all outcomes and complications.

The Australian survey of ICDs gives valuable information on the evolution of device usage and the numbers used. It is, however, only a glimpse into a complex important technology, whose usage is expected to rise exponentially with time resulting in a significant drain on Australia's health budget.

3.4.1 ICDs sold in Australia for initial implantation

For ICDs, the number of units sold accurately reflects the number of units implanted. At ICD implantation, there is always a company representative to provide the most appropriate hardware and to test the implanted device. ICD hardware purchased is then automatically registered and the company figures reflect those that are actually implanted. In contrast, single and dual chamber pacemakers are often delivered or sold on consignment and are "stored on the shelf" ready for implantation. Thus the company figures for pacemakers may reflect a certain percentage sold, but waiting implantation. Biventricular pacemakers are more likely to be handled like ICDs.

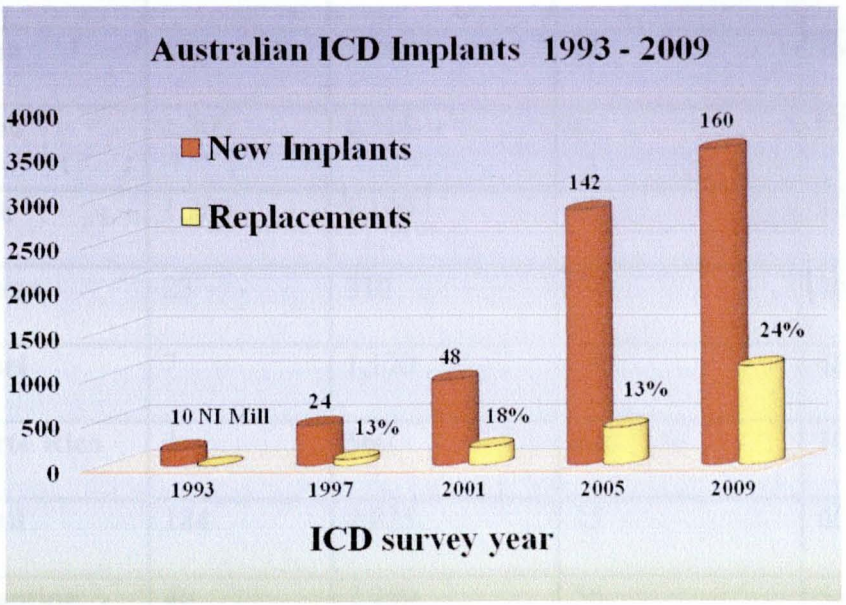
Initial Australian ICD implants increased significantly for each survey conducted from 1993 to 2009. For the first ICD survey, there were only 180 ICDs implanted in Australia with the vast majority being initial implants. In contrast, there were 3,555 new ICDs implanted in 2009 (Figure 3.4.1). The largest implanting nation, the United States of America had 133,262 initial ICD implants and only Japan in the Asia Pacific region with 5341 units had more initial ICD implants than Australia (Table 3.4.1).

The number of new implants per million population in Australia also rose significantly with each survey. In 1993, it was only 10 new implants per million population, whereas it had risen to 160 new implants per million population by the 2009 ICD survey. How does this compare with other ICD implanting nations? Table 3.4.1 lists a representative group of 20 countries. The United States of

America has by far the largest number with 434 new ICD implants per million population. Germany (290), The Netherlands (220), Italy (174) and Israel (167) were the only other countries ahead of Australia (160).

In comparison with the rest of the world, Australia implants significant numbers of ICDs. It must be remembered that the ICD market is maturing and the indications are still evolving. There is also a gradual wider physician acceptance of ICDs although this is tempered by ongoing concerns about ICD recalls and inappropriate shocks. It is expected that the usage of ICDs will increase in the years ahead.

Figure 3.4.1 Australian ICD implants 1993 – 2009.



NI Mill = New ICD implants per million population

Table 3.4.1 ICD implantation 2009 World Survey

Country	Population (Million)	New Implants	New Implants 10^6 Population	Replacements (% of Total)
Australia	22	3,555	160	1,111 (24)
United States	307	133,262	434	73,217 (35)
Germany	82	~23,752	290	~10,180
Italy	60	10,434	174	4,438 (30)
France	62	~6,720	108	~2,880
UK	62	~5990	97	~2567
Netherlands	17	~3,736	220	~1601
Sweden	9	1,013	108	317 (24)
Russia	142	550	4	64 (10)
New Zealand	4	329	77	85 (21)
Japan	128	5,341	42	1,447 (22)
China	1,300	1,316	1	116 (8)
India	1,200	1,100	1	100 (8)
Taiwan	23	310	13	45 (13)
Israel	7	1,170	167	480 (29)
Puerto Rico	4	560	140	10 (2)
Brazil	184	2,825	15	603 (18)
Argentina	40	2,250	56	560 (20)
Chile	17	245	14	
Uruguay	3	116	39	38 (25)

10^6 = million UK = United Kingdom

3.4.2 ICDs sold in Australia for replacement

The replacement number of ICDs implanted in Australia increased significantly for each survey. Because the service life of ICDs is shorter, compared to pacemakers, it is not surprising that the percentage of replacements compared to initial implants has gradually risen and in 2009, this was 24% (Figure 3.4.1). The replacement figure is also dependent on ICD high voltage usage and with time it is expected that the percentage of replacements compared to initial implants will continue to rise. This is an important consideration when planning hospital budgets as at least a quarter of this money must be allocated to ICD replacements. Another factor which must be considered is the replacement burden for ICD recall as a result of faulty hardware. This will be discussed in Chapter 4.

3.4.3 Initial ICD implants for individual Australian States.

For the 2009 Australian ICD survey, New South Wales had the largest number of initial implants at 1,209 (Figure 3.4.2), whereas South Australia had the highest new implants per million population at 245 (Figure 3.4.3). On a 2009 world survey country comparison, South Australia has one of the highest rates of initial ICD implantation in the world, exceeded only by the United States of America (434) and Germany (290). There are probably a number of reasons for this high implant rate. The services in South Australia are very well established with sophisticated training facilities and high numbers of well trained electrophysiologists resulting in high referral rates. South Australian hospitals probably implant most of the ICDs from Northern Territory and because of their reputation also receive referrals from other States and particularly from Asia. Because the ICD implant figures in Australia are small, a modest number of such referrals can have a significant impact on the numbers of new implants per million population.

When compared to the 2005 Australian ICD survey, all States and Territories showed increases in new ICD implants as well as new implants per million population. Unlike the well established pacemaker market, the smaller but much more expensive ICD market is still growing as indications expand and the earlier concerns with ICD lead issues are better understood.

Figure 3.4.2 Australian ICD survey 2009. Initial ICD implants for each State and Territory are shown with the 2005 survey figures in brackets. Australian Capital Territory figures are included with New South Wales

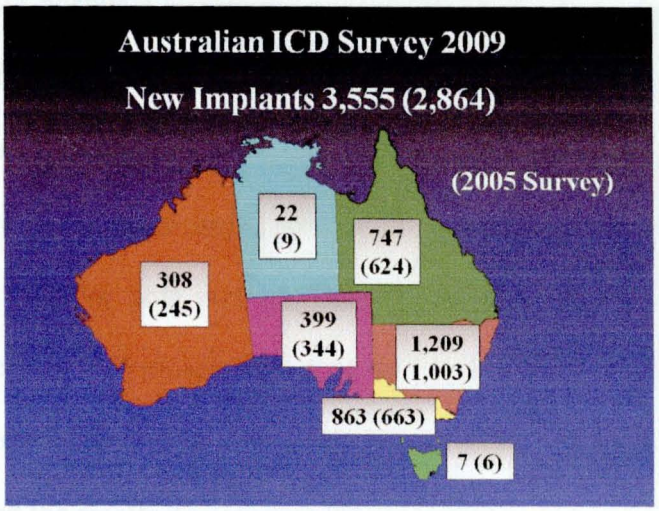
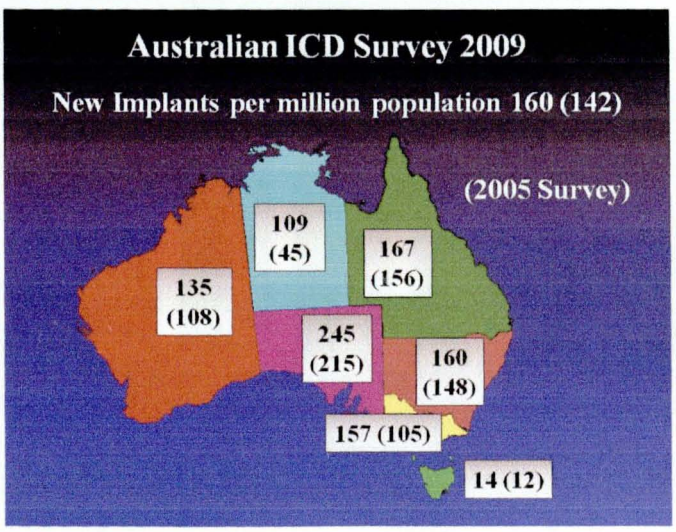


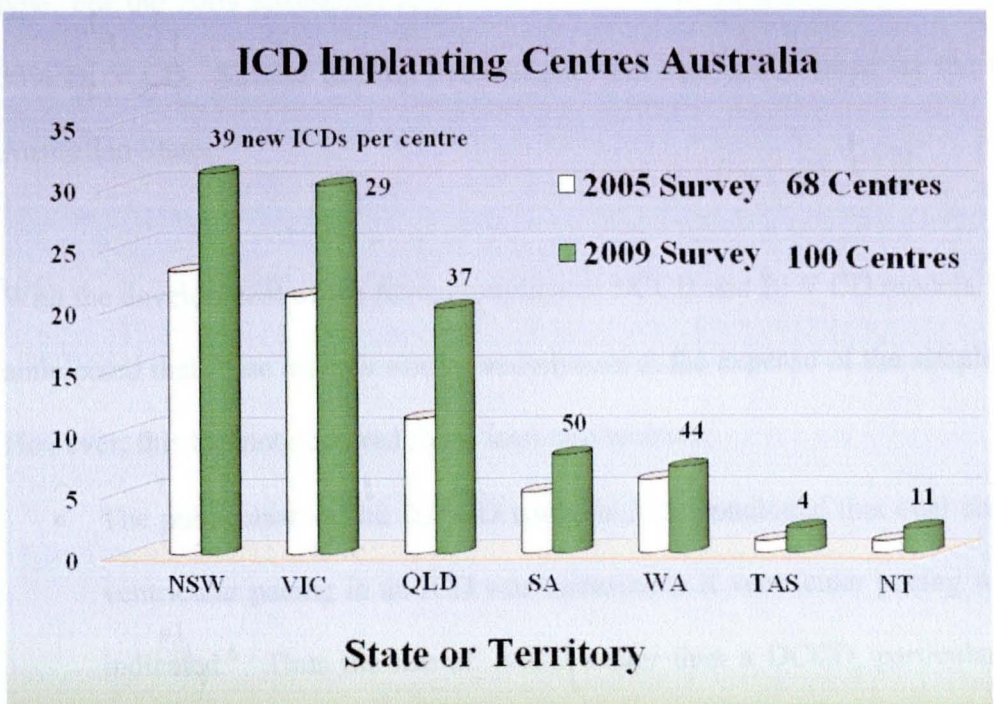
Figure 3.4.3 Australian ICD survey 2009. New ICD implants per million population for each State and Territory are shown with 2005 survey in brackets. Australian Capital Territory figures are included with New South Wales.



3.4.4 ICD implanting centres in Australia.

In 2009, there were 100 hospitals implanting ICDs in Australia compared to the 123 hospitals implanting pacemakers. Not all physicians who implant pacemakers also implant ICDs. Some hospitals that implant only small numbers of pacemakers may not implant ICDs. Between the 2005 and 2009 Australian ICD surveys, there was an increase in the number of centres implanting ICDs from 68 to 100 (Figure 3.4.4). For both surveys, New South Wales had the largest number of implanting centres (30) closely followed by Victoria (29). South Australia, with 50, had the largest number of new implants per centre, whereas of the bigger states, Victoria had the smallest number at 29 new ICD implants per centre.

Figure 3.4.4 Pacemaker implanting centres in the States and Territories in Australia for surveys 2005 and 2009.



3.4.5 ICD types sold in Australia.

As described earlier (page 54), there are three types of ICDs available in Australia:

- CD – This is a simple ICD with only ventricular pacing backup (VVIR). The major indication is for primary prevention of sudden death, where back up dual chamber or biventricular pacing is not required and left ventricular function is satisfactory. It is also used in patients with chronic atrial fibrillation.
- DCCD - This is the combination of an ICD and a DDDR pacemaker, when both modalities are required.
- Bi V CD – An ICD is combined with biventricular pacing for resynchronization therapy in patients with severe left ventricular failure.

Since the introduction of Bi V CDs, there has been about one third usage of each type. For the 2009 Australian ICD survey, there were 34% CD, 33% DCCD and 33% Bi V CD. Similar implant percentages were also documented for the larger Australian States.

With the development of the more complicated DCCD and Bi V CD models, it was anticipated that these models would predominate at the expense of the simpler CD. However, this has not occurred for at least two reasons:

- The publication of the DAVID study in 2002 concluded that dual chamber ventricular pacing in an ICD was undesirable if ventricular pacing was not indicated.[6] Thus the use of a CD rather than a DCCD, particularly for primary prevention of sudden death has remained the usual

recommendation unless atrial pacing and occasionally ventricular pacing were also required.

- The use of Bi V CD pacing for severe heart failure is in theory a very desirable treatment option, but its use is limited by cost, a high incidence of non-responders, operative complications and ICD and left ventricular lead issues.

The ICD market has experienced a rapid evolution of both hardware and software. Most of the changes have occurred with the Bi V CD with improvements in left ventricular lead design resulting in both improvement in stability and reliability of these leads. However, the right ventricular high voltage shock lead remains the Achilles' heel of the ICD and despite marked design improvements over recent years, there are still an inappropriate number of model recalls from all manufacturers as a result lead failures and in particular inappropriate shocks.

3.4.6 Concluding remarks.

Unlike the more mature and well developed pacemaker market, ICD implant numbers have grown significantly over the last decade in Australia. This increase in the usage of ICDs reflects the improvement in implantation techniques, the availability of a range of therapeutic options and the increased numbers of trained electrophysiologists able to implant and understand the complex management protocols.

Unlike pacemaker therapy, the implantation indications are not as clearly defined. The secondary indications for potentially lethal ventricular arrhythmias or survival of out of hospital cardiac arrest are unquestioned. However, the primary indications in patients likely to develop fatal ventricular arrhythmias, although established with clinical trials are not always easily recognised. These patients with congestive, ischaemic or hypertrophic cardiomyopathies or hereditary channelopathies are all at risk, but the clinical circumstances and the potential implantation complications and hardware failure issues makes the therapy questionable for some recipients. We not only need to define relevant subgroups, who are more prone to lethal ventricular arrhythmias, but also determine those that are at low risk and therefore less likely to benefit from an ICD.

The question once again is asked whether Australians may be missing out on potential life saving ICDs. Unlike pacemakers, not all patients who may need an ICD actually get one. Because of the costs involved, there may be constraints on the numbers that can be implanted. There remains lingering concern about the

long-term performance of ICD leads and inappropriate shocks. Despite these limitations, Australia with 160 new implants per million population, ranks highly on the world stage in the numbers of ICDs implanted per million population. Only the United States of America, Germany, Italy, the Netherlands, Austria, Denmark, Slovakia and Israel implant more ICDs and almost all these countries apart from the United States of America and Germany have similar figures. These data suggest that Australia at this stage in the therapy development implants about the correct number of ICDs.

The major concern both in Australia and elsewhere in the world is the question of efficacy. ICDs are very expensive, have numerous and troublesome complications and hardware issues and we need to know in Australia whether they are cost effective and save lives. This can only be determined with an appropriate far reaching registry with outcomes.

2.5 The Australian Pacemaker and ICD Market

It is now generally acknowledged that the world's first attempt at successful cardiac pacing occurred in Australia immediately prior to 1929.[7] Mark C. Lidwill a Sydney physician, anaesthetist and inventor described a machine that he had designed and built in an attempt to resuscitate the asystolic heart.[8] He reported the successful use of the machine in a stillborn infant at the Crown Street Women's Hospital.

The first fully implantable pacemaker, however, had to await the invention of the transistor and a small portable battery. Following the implantation of the first artificial cardiac pacemaker in Sweden in 1958, the first pacemaker was implanted in Australia in 1962 at the Royal Melbourne Hospital under the direction of Dr Graeme Sloman.[9] Within a few years a number of commercial companies were marketing pacing systems using epimyocardial leads. Both the world and Australian markets were very small, particularly as surgeons were very reluctant to implant these unreliable devices with very high complication rates in sick patients experiencing very dramatic asystolic episodes. The design of the endocardial transvenous pacemaker lead in the mid to late 1960's, stimulated physicians to undertake pacemaker implants initially with help of surgeons but later by themselves.[5]

In 1965, a small Sydney electronics company, Telectronics Pty Ltd, developed an implantable cardiac pacemaker.[9] For the next 30-years, this company, together with a number of international companies, successfully sold pacemakers in the

developing Australian market. Like many other aspects of cardiology and medicine in general, the practice of cardiac pacing in Australia kept abreast of the hardware advances, rapidly embracing new technologies, whilst maintaining a high standard of patient care.

The early growth of cardiac pacing in the 1970's brought with it a concomitant escalation of about 20 relatively small pacing companies, some independent such as Telectronics, Medtronic or Biotronik, whereas others were separate pacing divisions of larger companies such as General Electric, American Optical and Starr Edwards. The majority of these companies were initially represented by importing agents. Despite this growth, the world pacing market in the 1980's was still too small to sustain all of these companies and as a result, most were absorbed by expanding companies and in particular those with strong international links. With the demise of Telectronics in the early 1990's, the only Australian owned manufacturer disappeared from the world market. Purchased by Pacesetter which was later absorbed by St Jude Medical, Telectronics products, manufactured in Denver Colorado, continued to be sold for a short period of time in Australia.

Since the end of the 20th century, five pacemaker companies have dominated the world's pacemaker market with the three American companies; Medtronic Inc, St Jude Medical and Boston Scientific, all headquartered in Minneapolis-St Paul, controlling the lion's share. As well, there are two smaller European companies; Biotronik and Sorin. All five companies are currently represented in Australia in a proportion similar to their world sales. The actual market share of all these companies is not freely available, but over the years Medtronic Inc has had about

40% of both the world and Australian market share with a peak of 55% in 2008. More recently, however, this share was reported at about 30% and falling.[10, 11] It is hard to be sure what these figures really mean. Are they the pacemaker market, the biventricular market, the ICD market or all of them? Boston Scientific and St Jude Medical have a similar smaller share followed by Biotronik and lastly Sorin. Because of the strict security arrangements put into place by the author for both the Australian and United States of America surveys, it was not possible to determine the actual percentages when conducting the surveys.

The early development of the ICD was also slow with a somewhat reluctant involvement of cardiac surgeons placing unreliable epicardial defibrillator patches via open chest procedures. With the introduction of the transvenous ICD lead, the interest in this complicated technology accelerated particularly with physician implanters. This in turn, stimulated multicentre trials to help define and standardize the emerging, somewhat confusing indications. As the technology advanced, there was a robust growth of this new industry. Although some of the original small manufacturers were independent, this very rapidly changed with the involvement of the large pacing companies, who had the experience, manufacturing facilities and above all, the financial resources to develop and market this expensive implantable hardware. Today, the ICD market is completely controlled by the five pacing companies.

In Australia, the pacemaker and ICD markets are divided into two segments; the public hospital and private hospital components. Within each component, the competition between manufacturers is intense. Pricing for public hospitals has

always been much lower than in private and today bulk purchase by tender has further reduced hardware costs. Hospitals can choose the mix of manufacturers, but negotiated minimal numbers of units must be purchased within the tender price. Within the private hospital system, the choice of manufacturer is at the discretion of the implanter with no input from the hospitals. Unlike some consumables, the private hospitals have to date been unable to negotiate a tender purchasing price in order to resell the product to the recipient or private health fund at a profit.

The pacemaker and ICD cost carries with it a significant implant and postoperative financial burden. Although most large Australian public hospitals employ their own CIED technicians, there is still considerable company involvement at the time of implantation, the running of the pacemaker clinic and after hours testing. In the private market, apart from some of the larger hospitals, there are very few biomedical technologists employed for CIED management and thus the companies are heavily involved in operative and postoperative support. In some circumstances, the CIED companies will also test the implanted devices in the physician's private rooms, although there is now a tendency for physician's to employ technicians to do this for them.

Because of the ongoing concern with ICD leads, there has been a growing interest in a new approach to defibrillation using a totally subcutaneous leadless system (Cameron Health, San Clemente, CA, now a division of Boston Scientific). Having no leads, there is no cardiac pacing possible and hence no true cardioversion, but rather only defibrillation. The defibrillation patches lie outside the ribcage and the

high voltage shock box generator lies in the abdominal wall.[12] Because of the high energy requirements of the generator; this is a larger unit than a conventional ICD.

The implantation of this subcutaneous system is simpler than an ICD and an electrophysiologist is not necessarily required. Although there is a demand for such a defibrillator, the actual indications for implantation over a conventional ICD with pacing have yet to be defined. The system awaits the United States Food and Drug Administration and the Australian Therapeutics Goods Administration approval.

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Chapter 4: World Pacemaker and ICD Surveys

Artificial cardiac pacemakers have been implanted for more than 50-years. During the first decade of use, world-wide cardiac pacemaker implant numbers were very low as the units were unreliable, short-lived and the implant procedures subject to high complication rates.[1] However, by the mid 1960s, physicians commenced implanting permanent pacemakers using transvenous endocardial leads. Those early cases were technically long and difficult with high complication rates.[2,3] Gradually with time, the implant procedures improved as did the incidence of complications and by the early 1970's, the number of fully implanted pacemakers implanted rose exponentially.

The first world survey of cardiac pacemakers was held at the fourth International Symposium on Cardiac Pacing in Groningen, The Netherlands in April 1973.[3] There were pacemaker surveys from 31 countries including Australia. Such was the importance of the world survey, that it covered 40 pages of the published proceedings.[4] Since 1973, a worldwide survey of cardiac pacing and ICD practices has been conducted every four years and includes calendar years 1975,[5] 1978,[6,7] 1981,[8] 1985,[9,10] 1989,[11] 1993,[12] 1997,[13,14,15] 2001,[16] 2005,[17] and 2009[18] ICDs were included in the survey for the first time in 1993.[12]

Since those early pioneering days, there have been significant changes in the way survey data has been collected. The first attempts were made through the International Cardiac Pacing and Electrophysiology Society (ICPES) of which I have been a Board member for more than 20-years. This organization, now called

the World Society of Arrhythmias (WSA), encouraged quadrennial world surveys to be presented at the Pacing World Symposia, but left it to the host country to organize. Consequently, there was little structure or organization with the presented data, which had no uniformity. For the 1997 survey, I took on the responsibility of organizing the world survey and for the 2001, 2005 and 2009 surveys and for the first time the format was the similar for all countries.

For Europe, there has always been an organization to collect survey data. The European Pacemaker registry was founded in 1978 by the late Drs. Bert Thalen, Giorgio Feruglio and Tony Rickards, who developed the European pacemaker patient identification card.[19,20,21] Details from these cards are registered with national registration centers that send aggregated annual data to the European Working Group on Cardiac Pacing. From this information, an annual European pacing and ICD survey is constructed. This data is comprehensive, meaningful, and new European countries are recruited annually. A second data collection group comes from the White Book published by the European Society of Cardiology member countries[22] and Eucomed a joint company based survey group.[23] Details of the European pacemaker patient identification card are in the Methods in Chapter 2.

The collection of survey data outside Europe, however, is dependent on a group of devoted survey coordinators who each four years send me the required data for their individual countries. The whole system is internet-based with no costs incurred and involves both pacemakers and ICDs. The forms used are prepared by

the Department of Epidemiology and Preventive Medicine of Monash University and have been reproduced in the methods in Chapter 2.

The survey is kept as simple as possible to encourage the coordinators to complete it. Only a small number of absolute figures are required for both pacemakers and ICDs. These include the population of the country, number of implanting centres, total number of initial implants and replacements. From this, the number of initial CIED implants per million population is calculated. Demographic material is also requested in the survey, which includes mean age, gender, mean hospital stay and diagnosis. The remainder of the study is predominantly percentage based and involves the pulse generator or shock box type and the leads used. There is a short section on lead extraction method which is not used in the results, but can be collated at a later time to show changes in the methods used.

In larger implanting countries, such as Australia and the United States, a hospital survey is not possible and thus pacemaker countries are asked to provide their sales data. Because the information is proprietary and highly confidential, a system has been set up to ensure that the received data remains secure. This also has been detailed in the Methods in Chapter 2.

All pacing companies cooperated with the survey. For each survey, an accurate number of implants, or at least PMs and ICDs sold, were obligatory. This needed to be divided into new implants, replacements and leads used. As well as this, the number of implanting institutions in each country was required. A major limitation

of the surveys was the inability to collect clinical and outcomes data such as indications, mean age, hospital stay and postoperative complications.

This chapter will look in detail at the International data obtained from three surveys involving calendar years 2001 (published through the Royal Melbourne Hospital), as well as 2005 and 2009 (both published through the Department of Epidemiology and Preventive Medicine, Monash University). It is not possible to discuss every country and thus for comparisons, a selection of countries across the spectrum has been chosen which always includes Australia.

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Publication: Mond Harry G, Irwin Marleen, Morillo Carlos and Ector Hugo: The World Survey of Cardiac Pacing and Cardioverter-Defibrillators: Calendar Year 2001. Pacing and Clinical Electrophysiology 2004; 27: 955-964.

Contributions to the work involved the following:

Name	% Contribution	Nature of Contribution
Mond Harry G	75%	Principal author, responsible for design of study, liaison with manufacturers, recruitment of country coordinators, collection and preparation of data, literature review, writing of manuscript and submission of final draft. Overall responsibility for project.
Irwin Marleen	5%	Collection of Canadian data. Proof reading.
Morillo Carlos	5%	Proof reading.
Ector Hugo	15%	Collection of European data. Proof reading.

Candidate's signature	Date
[redacted]	22 · Sept · 2011

Declaration by co-authors:

The undersigned hereby certify that:

1) They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise.
2) They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication.
3) There are no other authors of the publication according to the criteria.
4) Potential conflicts of interest have been disclosed to granting bodies, the editor/publisher of the journal and the head of the responsible academic unit.
5) The original data are stored at the following location and will be held for at least five years from the date of publication.

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Contributions to the work involved the following:

Name	% Contribution	Nature of Contribution
Mond Harry G	75%	Principal author, responsible for design of study, liaison with manufacturers, recruitment of country coordinators, collection and preparation of data, literature review, writing of manuscript and submission of final draft. Overall responsibility for project.
Irwin Marleen	5%	Collection of Canadian data. Proof reading.
Morillo Carlos	5%	Proof reading.
Ector Hugo	15%	Collection of European data. Proof reading.

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Contributions to the work involved the following:

Name	% Contribution	Nature of Contribution
Mond Harry G	75%	Principal author, responsible for design of study, liaison with manufacturers, recruitment of country coordinators, collection and preparation of data, literature review, writing of manuscript and submission of final draft. Overall responsibility for project.
Irwin Marleen	5%	Collection of Canadian data. Proof reading.
Morillo Carlos	5%	Proof reading.
Ector Hugo	15%	Collection of European data. Proof reading.

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5) The original data are stored at the following location and will be held for at least five years from the date of publication.

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The World Survey of Cardiac Pacing and Cardioverter Defibrillators: Calendar Year 2001

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MOND, H.G., ET AL.: The World Survey of Cardiac Pacing and Cardioverter Defibrillators: Calendar Year 2001. *A worldwide cardiac pacing and ICD survey was undertaken for calendar year 2001. Fifty countries, 22 from Europe, 16 from the Asia Pacific region, 3 from the Middle East and Africa, and 9 from the Americas contributed to the survey. The United States had by far the largest number of cardiac pacemaker implants, although Germany had the highest new implants per million population. Virtually all countries that participated in the 1997 survey showed significant increases in implant numbers over the 4 years. High degree atrioventricular block and sick sinus syndrome remain the major indications for implantation of a cardiac pacemaker with < 2% biventricular pacing in those countries that implanted such systems in 2001. There remains a high percentage of VVIR pacing in the developing countries with only a few countries using substantial numbers of single lead VDD and AAIR systems. There has been an increase in the use of DDDR systems in most countries since the 1997 survey. Pacing leads were predominantly transvenous, bipolar, and passive fixation. There was an increased use of active-fixation leads in the atrium. There was a significant rise in the use of ICDs with the largest usage occurring in the United States. A group of enthusiastic survey coordinators has now been established. Recruitment of new countries will hopefully continue to obtain a fully global experience of cardiac pacing and ICD usage. (PACE 2004; 27:955–964)*

2001 World Survey, pacemaker, ICD

Introduction

An ongoing responsibility of the International Cardiac Pacing and Electrophysiology Society (ICPES) is a worldwide quadrennial survey of cardiac pacing and implantable cardioverter defibrillator (ICD) practices. This survey is conducted 2 years prior to the World Symposium on Cardiac Pacing and Electrophysiology. The World Survey on Cardiac Pacing and ICD Practices was first conducted in 1972 (Groningen).[1] Since then, surveys have been conducted for calendar years 1975 (Tokyo),[2] 1978 (Montreal),[3,4] 1981(Vienna),[5] 1985 (Israel),[6,7] 1989 (Washington),[8] 1993 (Buenos Aires),[9] and 1997 (Berlin)[10–12] ICDs were included in the survey for the first time in 1993.

Once a country has been appointed to host the World Symposium on Cardiac Pacing and Electrophysiology meeting, then the regional organizing committee had traditionally taken on the responsibility for conducting the pacing survey. As such meetings grew in size and complexity, the allocation of resources for the World Survey on Cardiac Pacing and ICD Practices was given low priority. An ongoing network of interested physicians or associated professionals was not established, nor was there an active recruitment of new countries. Despite this, governmental health administrators, hospital administrators, pacemaker companies, and implanting physicians have, in recent years, become increasingly interested in pacemaker and ICD implant statistics. Being aware of this, the ICPES was eager to continue the world surveys and appointed one of its board members to coordinate the 2001 survey presented at the XII[th] World Symposium held in Hong Kong in 2003.

For the first time, the 2001 World Survey is being published as a single manuscript. An ongoing sophisticated and coordinated survey network exists in Europe and this group has been encouraged to continue and expand its activities. Previously, the United States of America conducted its own survey with little similarity to other countries, making comparisons difficult.[11] The "remainder of the world" was divided into Asia Pacific, the Middle East, Africa, Canada, Central America, and South America, which using an identical survey format allowed a single publication.[12] For the 2001 World Survey, the United States for the first time used the remainder of the world survey format. Although the European and the remainder of the world survey styles are different, there are, nevertheless, enough similarities to allow a single presentation format.

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Survey Formats

The European survey is based on the European pacemaker registry and the European Pacemaker Patient Identification Card, first introduced in 1978.[13–15] Details from these cards are registered with national registration centers. Comprehensive questionnaires are sent out annually by the European Working Group on Cardiac Pacing to the registration centers, which in turn, send aggregated data to the working group. From this information, an annual European pacing and ICD survey is constructed.[16,17] All national contributors receive a complete set of data for their own information and correction.

The 2001 survey for most countries outside Europe is based on a questionnaire sent to selected contact physicians or associated professionals. The contact personnel were encouraged to perform a comprehensive hospital survey for their country. An accurate number of pacemaker and ICD implants or at least units sold in the country were obligatory. These data were collected for new cardiac pacing and ICD systems and replacements. The number of implanting institutions in that country was also requested. The remaining information was collected in percentages. It was found that pacemaker and ICD implant centers often kept poor records and in these situations, the contact person found that pacemaker companies were helpful in providing missing information.

In larger implanting countries, like the United States and Australia, hospital surveys were not possible and a separate questionnaire was designed for a cardiac pacing and ICD company survey. This was based on sales and registration figures of pacing and ICD hardware for calendar year 2001. Upon definition and agreement of the security procedures, designed to protect their individual figures, all companies selling pacing and ICD hardware in the United States and Australia readily agreed to cooperate and contribute to the survey. The questionnaire carried no company identification, and when completed it was placed in a plain sealed envelope and sent in an identifiable envelope to the survey coordinator. Once all companies represented in that country had returned the questionnaire, the outer envelope was opened and the plain sealed envelope removed and given a work number. The information was transcribed to a working sheet followed by shredding of the individual forms and all working sheets immediately after the data were collated and placed onto the final data sheet. There remained no evidence of individual company figures.

Results

Fifty countries contributed to the 2001 Cardiac Pacing and ICD Survey compared to 39 countries for the 1997 survey.[10–12] For Europe, there were 22 countries, an increase of 2 compared to the 1997 survey. New contributors included Finland, Georgia, Ireland, and Latvia, whereas for 2001, there were no reports from Greece and Poland.

Sixteen countries in the Asia Pacific region contributed to the survey that included five new countries: Brunei, Indonesia, Myanmar, Philippines, and Thailand. Only two countries reporting in the 1997 survey; Bangladesh and Sri Lanka, failed to provide survey data on this occasion. The remaining two implanting countries in the Asia Pacific region are North Korea and Vietnam. In North Korea, very small numbers of donated units were implanted by foreign doctors and in Vietnam a survey coordinator could not be found. The present 2001 survey covers more than 95% of the cardiac pacing and ICD systems implanted in the Asia Pacific region.

The Middle East and Africa consisted of three countries, Iran, Israel, and for the first time, South Africa. Iranian data from the 1997 survey was not included for comparison as it has been subsequently shown to be inaccurate. Ongoing attempts to recruit survey coordinators in the other Middle Eastern and African countries have been unsuccessful.

For the first time, the United States is included with the Americas, rather than providing a separate report. There were also reports from eight other countries in the Americas with the Dominican Republic, Ecuador, Panama, and Peru participating for the first time. The results of the cardiac pacing survey are presented in Tables I–V and the ICD survey in Table VI.

Table I summarizes new pacing system implants, pulse generator replacements, and the number of implanting centers. The 1997 survey data is shown in parenthesis. The largest implanting nation with 223,226 new implants was the United States followed by Germany (69,823) and France (37,250). Japan, with 26,700, implanted the largest number of new pacemakers in the Asia Pacific region. The new participants in the Asia Pacific region were small implanters.

Germany had the highest new implants per million population at 837 followed by the United States at 786 and Belgium 685. Apart from the Slovak Republic and Uruguay, all countries showed an increase in new implants per million population compared with the 1997 survey. In particular, Italy reported 228 new implants per million population in 1997 and 637 for the 2001 survey.

Table I.

Cardiac Pacemakers

Country	Population (Million)	Number of Centers	New Implants (1997 Survey)	New Implants per Million Population (Compaired with 1997 survey.)	Replacements
Europe					
Austria	8	64	4666 (3840)	583 (435)	1232
Belgium	10	120	7053 (5852)	685 (585)	3086
Croatia	4	11	1049 (774)	238 (161)	157
Czech Republic	11	36	5563 (4914)	530 (468)	
Denmark	5	14	2429 (1637)	467 (309)	967
Finland	5	24	2128 (1582)	411 (307)	
France	59	600	37250 (32350)	628 (552)	5871
Georgia	4	1	108	27	
Germany	83	850	69823 (36550)	837 (440)	
Ireland	4	13	879	228	145
Italy	58	400	36779 (12987)	637 (228)	
Latvia	3	3	528 (320)	210 (125)	127
Lithuania	4	3	953 (364)	272 (104)	
Netherlands	16	106	5016 (4432)	314 (283)	1891
Norway	4	29	1472 (1083)	329 (247)	301
Russia	144	97	10950 (8400)	76 (57)	100
Slovak Rep	5	14	1143 (1598)	212 (286)	
Slovenia	2	2	621 (426)	312 (213)	142
Spain	41	145	16421 (11458)	399 (289)	
Sweden	9	45	4201 (3640)	472 (411)	1485
Switzerland	7	65	3014 (2469)	415 (348)	846
United Kingdom	60	174	17550 (16800)	293 (291)	3823
Asia Pacific					
Australia	20	105	9498 (6405)	486 (345)	1536
Brunei	0.3	1	14	42	2
Hong Kong	7	16	1004 (597)	143 (100)	92
India	1000	329	6725 (5423)	7 (5)	570
Indonesia	220	21	220	1	30
Japan	127	2700	26700 (19855)	210 (158)	11500
Malaysia	22	26	422 (264)	19 (13)	
Myanmar	52	5	24	< 1	2
New Zealand	4	8	914 (823)	245 (228)	195
Pakistan	135	14	910 (770)	7 (6)	60
Peoples Pipublic of China	1300	241	11000 (4500)	8 (4)	855
Philippines	79	10	348	4	12
Singaprore	3	10	281 (184)	92 (61)	20
South Korea	45	65	1162 (854)	26 (19)	322
Taiwan	22	22	2290 (1600)	102 (74)	193
Thailand	62	22	605	10	47
Middle East and Africa					
Iran	60	27	1469	24	211
Israel	6	18	2009 (1700)	335 (293)	663
South Africa	45	39	1814	40	224
The Americas					
Argentina	36	230	9000 (8000)	250 (222)	1000
Brasil	170	243	15167 (7888)	89 (50)	7182
Canada	31	125	18376 (11087)	591 (368)	1218
Dominican Rep	8	22	225	28	42
Ecuador	12	18	180	15	15
Panama	3	4	180	60	95
Peru	25	20	550	22	80
Uruguay	3	12	1160 (1243)	362 (395)	496
United States	284		223226 (152909)	786 (571)	51616

Table II highlights the sex and age of recipients. In smaller countries, these data could be accurately obtained, although in some of the larger implanting countries, accurate data was not possible. The mean age of female recipients was generally older in Europe, the Middle East, and the Americas, but not necessarily so in the Asia Pacific region. An interesting statistic available from most countries was the percentage of recipients > 80 years of age. Countries with sophisticated health systems generally had percentages between 20% and 35%. In developing or poorer countries, these figures were < 15%.

The indications for initial implant are shown in Table III. High-degree atrioventricular block and sick sinus syndrome were almost universally the major indications for pacemaker implantation. Atrial fibrillation with high-degree atrioventricular block was also a significant indication in Europe, but much less so in the developing countries of the Asia Pacific, Middle East, and the Americas. Nonbradyarrhythmic indications for cardiac pacing remain a minor indication for cardiac pacing, but are expected to rise in the future.

Table IV summarizes the pacing mode and highlights the use of dual or single chamber pacing. There was increased use of VVIR pacing in developing countries, although values > 40% were still common in Europe. Of importance, most countries showed a significant increase in the use of DDDR replacing the use of VVIR. Substantial use of single lead VDD pacing systems was scattered throughout the world, whereas AAIR pacing systems were predominantly used in developing or poorer countries. A new pacing mode category was biventricular pacing, and for the 2001 survey only small numbers were implanted, although this is expected to increase dramatically in the future.

Pacing lead details are outlined in Table V. The results of the survey showed a preference for bipolar, passive-fixation leads in the atrium and ventricle. However, there is a growing preference for active-fixation leads in the atrium. As with the 1997 survey, the Peoples Republic of China still prefers unipolar leads.[10]

Table IV summarizes the information obtained on ICDs. The United States is clearly the world's largest implanter with 169 new implants per million population. Second tier implanting nations include Israel (n = 58), Canada (n = 56), Australia (n = 49), and Denmark (n = 47). The implant numbers for the United States were 48,127 followed by Italy with 2,200. During 2001, the single chamber ICD was the most frequently used system, but there is an increasing utilization, particularly in developed countries, of dual chamber ICDs and, more recently, ICD therapy combined with biventricular cardiac pacing systems.

Discussion

The 2001 World Survey is the largest survey of cardiac pacing and ICD practices conducted to date. There were 50 countries surveyed and grouped into four regions: Europe, Asia Pacific, Middle East, and the Americas. The presentation format for the previous two surveys, the Xth in Buenos Aires in 1995[9] and the XIth in Berlin in 1999,[10–12] are similar to the 2001 survey allowing comparisons on growth and trends.

With ongoing hospital budget constraints, surveys of medical procedures are becoming increasingly important to hospital administrators. When compared to previous surveys, this 2001 cardiac pacing and ICD survey demonstrates a worldwide increase in the use of this expensive implantable hardware. The reasons for this growth are not always clear and vary from region to region and country to country. Factors include socioeconomic changes, aging populations, development of appropriate implantation facilities, and physician training including recognition of traditional and emerging indications, together with hardware implantation and follow-up techniques. In particular, ICD implants have increased markedly as indications have become more clearly defined. The 2001 World Survey did not address clinical issues and, thus, a detailed analysis of the reasons for these changes between surveys is beyond the scope of this report. However, the survey does highlight a number of current trends in practice and, in particular, the increasing use of dual chamber systems and the emerging use of biventricular pacing and dual chamber ICD devices. There is also a developing trend to use bipolar, active-fixation leads, particularly in the atrium.

One of the limitations of such a survey, particularly in large implanting countries, is the difficulty in recruiting physicians or associated professionals to collate hospital implant data. Pacemaker companies are well placed to determine sales figures for most countries, however, company-based surveys, although accurate, do not address important demographic and clinical data. In Europe, the pacemaker identification card, national registration centers, and a central coordinating office represent an ideal system to collect pacemaker and ICD data. In contrast, the rest of the world uses a simple questionnaire sent to each country contact person, who then conducts the survey usually using hospital implant data. When this is not possible, a limited survey was performed using pacemaker company sales. If surveys are to continue in the future, clearly the European system needs to be extended to the other international areas with regional coordinating offices reporting to the ICPES.

Table II.

Cardiac Pacemakers

Country	Sex (%)		Age of Recipients		Percentage of Pacemaker Recipients	
	Men	Women	Men (mean)	Women (mean)	> 60 yearsold	> 80 years old
Europe						
Austria	50	50	75	77	92	27
Belgium	56	44	76	78	92	32
Croatia	60	40	70	71		
Czech Rep	49	51	72	74		
Denmark	55	45	73	77	89	36
Finland	45	55			88	30
France	59	41	75	78	94	35
Georgia	60	40	60	47	38	2
Germany	52	48	73	77	93	35
Ireland Italy	56	44	76	79	94	46
Latvia	46	54	68	74	81	14
Lithuania						
Netherlands	54	46	72	75	87	29
Norway	45	55	73	78	88	34
Russia	45	55	63	64	75	19
Slovak Rep	54	46	71	72	82	16
Slovenia			71	72	88	24
Spain	57	43	74	75	91	30
Sweden	54	46				
Switzerland	59	41		83	30	
UK						
Asia Pacific						
Australia Brunei	65	35	57	64	64	0
Hong Kong	44	56	72	72	85	27
India	69	31	60	64	33	5
Indonesia	38	62	63	62	64	10
Japan	47	53	70	73	85	25
Malaysia	46	54	57	50	46	7
Myanmar	50	50	74	65	84	11
New Zealand	58	42	69	72	82	30
Pakistan	65	35	60	70	90	10
PR China	55	45		72		
Philippines	43	57	65	63	64	15
Singapore	40	60	67	69	77	22
South Korea	36	64	62	66	70	7
Taiwan	50	50	74	72	88	24
Thailand	49	51	67	66	85	12
Middle East and Africa						
Iran	56	44	65	66	73	14
Israel	53	47	73	76	87	26
South Africa	55	45	67	69	70	20
The Americas						
Argentina	60	40	65	70		
Brasil	52	48	67	68	70	19
Canada	52	48	71	74	86	28
Dominican Rep	34	66	70	70	79	14
Ecuador	63	37	72	75	74	7
Panama	67	33			85	11
Peru	59	41	44	51	82	26
Uruguay	60	40	74	76	92	33
United States						

> 60 and 80 Y (%) = percintage of pacemaker recipients more than 60 or 80 years of age.

Table III.

Cardiac Pacemakers: Indication for Initial Implant (%)

Country	High-Degree AV Block	BBB	SSS	AF	CSS/NCGS	AV Nodal Ablation	Cardiomyopathy	
Europe								
Austria	32	2	30	21	2		2	
Belgium	36	3	42	15	3	2	4	
Croatia	53	4	21	16	2	2	12	
Czech Rep	34	1	40	20				
Denmark	43	3	35	16	2	1	2	
Finland	40	1	39	14	< 1	< 1	1	
France	39	7	23	10	< 1	< 1	5	
Georgia	44		18	11		37	5	
Germany	37		40	24				
Ireland								
Italy	41	5	22	16	2	1	2	
Italy	41	5	22	16	2	1	2	
Latvia	37	2	38	17	< 1	3	4	
Lithuania								
Netherlands	40	4	30	12	< 1	1	1	
Norway	47	< 1	34	17	< 1	< 1		
Russia	46	6	26	10	1	5	2	
Slovak Rep	54	2	29	13	2	1	1	
Slovenia	50	4	25	19	4	1	17	
Spain	53	6	22	16	1	1	5	
Sweden	38	3	37	17	< 1	< 1	2	
Switzerland	44	4	34	12	2	3		
UK								
							Hpertrophic	Biventricular
Asia Pacific								
Australia								
Brunei	50	0	46	4	0	0	0	0
Hong Kong	39	1	50	7				
India	77		16	2	1	1		1
Indonesia								
Japan	50	1	35	9	1	2	0	2
Malaysia	61		17					
Myanmar								
New Zealand	56	2	20	14	2	3	< 1	< 1
Pakistan	93	5	11	1				
PR China	43		51		1	2	1	
Philippines								
Singapore	53	1	42	1	0	1	2	0
Korea	49	0	37	6	1	0	0	< 1
Taiwan	42	< 1	50	5	< 1	< 1	< 1	0
Thailand	53	5	33	7	0	1	0	< 1
Middle East and Africa								
Iran	71	3	16	5	< 1	1	< 1	< 1
Israel	57	1	40	7	2	2	1	3
South Africa	46	1	19	10	< 1	14	< 1	4
							Hpertrophic	Biventricular
The Americas								
Argentina	56	2	24	11	3	1	1	1
Brasil	60	3	16	10	1	1	< 1	3
Canada	44	0	31	10	1	2	1	3
Dominican Rep	59	0	22	9	0	0	0	0
Ecuardor	43	0	39	4	0	4	1	2
Panama	35	30	36	0	1	2	0	2
Peru	69	< 1	18	2	< 1	6	3	0
Uruguay	55	6	28	15	3	1	2	
United States								

AF = atrial fibrillation; AV = atrioventricular; BBB = bundle branch block, CSS/NCGS = carotid sinus syncope and neurocardiogenic syncope; SSS = sick sinus syndrome.

Table IV.

Cardiac Pacemarkers: Pacing Mode (%)

Country	VVIR (1997 Survey)	AAIR	VDD	DDDR (1997 Survey)	Biventricular
Europe					
Austria	33 (43)	1	7	57 (45)	1
Belgium	22 (29)	< 1	2	68 (68)	2
Croatia	66 (76)	< 1	6	26 (17)	
Czech Rep	49 (52)	1	4	46 (47)	
Denmark	24 (28)	9	3	60 (55)	2
Finland	45	8	10	38 (18)	
France	26 (34)	< 1	7	63 (57)	
Georgia	56	19	7	19 (44)	
Germany	38 (48)	3	3	57 (44)	
Ireland	48	< 1	7	44	
Italy	35 (49)	< 1	12	43 (38)	
Latvia	45	7	4	40 (4)	2
Lithuania	63	24	2	10	
Netherlands	32 (38)	3	5	56 (47)	3
Norway	31 (40)	8	10	51 (27)	
Russia	78	10	< 1	11	0
Slovak Rep	69 (68)	3	7	21 (18)	< 1
Slovenia	50 (50)	2	20	30 (25)	< 1
Spain	40 (55)	2	24	34 (24)	< 1
Sweden	28 (38)	4	< 1	67 (52)	
Switzerland	35 (44)	1	9	56 (47)	
UK	39 (44)	2	< 1	59 (42)	
Asia Pacific					
Australia	29 (34)	< 1	1	69 (62)	1
Brunei	35	0	0	65	0
Hong Kong	40 (62)	0	4	53 (27)	3
India	69 (81)	4	6	20 (12)	1
Indonesia	77	0	5	18	0
Japan	35 (43)	3	13	49 (39)	< 1
Malaysia	46 (46)	0	0	53 (54)	
Myanmar	96	0	0	4	0
New Zealand	41 (44)	2	4	51 (51)	2
Pakistan	85 (90)	0	5	10 (9)	0
PR China	65 (80)			35 (15)	
Philippines	78	< 1	< 1	22	0
Singapore	40 (610)	1	16	43 (39)	< 1
Korea	35 (50)	2	12	51 (29)	1
Taiwan	53 (60)	4	4	39 (25)	0
Thailand	77	1	2	20	< 1
Middle East and Africa					
Iran	55	0	22	23	0
Israel	37 (40)	2	16	42 (42)	3
South Africa	45	2	16	31	6
The Americas					
Argentina	75 (70)		8	17 (20)	
Brasil	46 (67)	1	3	50 (28)	< 1
Canada	51 (62)	2	4	43 (30)	< 1
Dominican Rep	93	0	0	7	0
Ecuador	54	3	2	41	0
Panama					
Peru	88	1	< 1	10	0
Uruguay	42 (44)	1	11	46 (53)	0
United States	23 (32)		< 1	76 (68)	1

Table V.

Cardiac Pacemakers: Pacing Leads (%)

	LEAD POLARITY				ATRIAL		VENTRICULAR	
	BP	UP	BP	UP	Act	Pass	Act	Pass
Europe								
Austria								
Belgium	96	4	74	26	49	51	4	96
Croatia	70	30	57	43	11	89	1	99
Czech Rep	100	0	97	3	43	57	14	86
Denmark	100	0	39	58	61	39	9	91
Finland								
France	94	6	59	41	81	19	9	91
Georgia	37	63	28	72	61	39	2	98
Germany	95	5	62	38				
Ireland	96	4	92	8	54	46	41	59
Italy	80	20	66	34				
Latvia	100	0	81	19	21	79	21	79
Lithuania								
Netherlands			94	6			11	89
Norway	91	9	45	55	48	52	1	99
Russia	50	50	13	87	23	77	2	98
Slovak Rep	100	0	79	21	41	59	1	99
Slovenia	100	0	100	0	19	81	1	99
Spain	100	0	98	2				
Sweden	99	1	41	59				
Switzerland	100	0	94	6	66	34	9	91
UK	89	11	88	12	16	84	6	94
Asia Pacific								
Australia	100	0	98	2	17	83	10	90
Brunei	100	0	100	0	15	85	15	85
Hong Kong	100	0	96	4	10	90	7	93
India	93	7	66	34	35	65	8	92
Indonesia	100	0	53	37	0	100	0	100
Japan	98	2	95	5	12	88	15	85
Malaysia	100	0	94	6	18	82	6	94
Myanmar	100	0	96	4	100	0	4	96
New Zealand	96	4	97	3	28	72	16	84
Pakistan	80	20	80	20	30	70	10	90
PR China	30	70	20	80	6	94	2	98
Philippines	65	35	43	57	14	86	1	99
Singapore	98	2	98	2	39	61	7	93
Korea	96	4	94	6	47	53	53	47
Taiwan	99	1	97	3	5	95	1	99
Thailand	100	0	97	3	96	4	5	95
Middle East and Africa								
Iran	87	13	79	21	13	87	4	96
Israel	100	0	94	6	90	10	2	98
South Africa	100	0	100	< 1	6	94	10	90
The Americas								
Argentina	100	0	95	5	100	0	5	95
Brasil	100	0	94	6	85	15	21	79
Canada	97	3	91	9	39	61	29	71
Dominican Rep	100	0	100	0	100	0	5	95
Ecuador	85	15	85	15	20	80	2	98
Panama	85	15	85	15	5	95	5	95
Peru							1	99
Uruguay								
United States	100	< 1	98	2	73	27	38	62

Act = active fixation; BP = bipolar, Pass = passive fixation, UP = unipolar

Table VI.

Implantable Cardioverter Defibrillators

Country	New Implants (1997 Survey)	New Implants Per Million POP n. (1997 Survey)	Replacements	Type (%)		
				ICD	ICD/DDD	ICD/BiV
Europe						
Austria						
Belgium	437 (235)	42 (24)	169	55	45	< 1
Croatia	14 (3)	3 (1)	2	57	43	
Czech Rep						
Denmark	241 (132)	47 (25)	72	67	29	4
Finland	133 (65)	26 (13)	37			
France	937 (470)	16 (8)	106			
Georgia						
Germany						
Ireland	57	15	5			
Italy	2200 (700)	38 (12)	400	55	32	13
Latvia	9	4	0	55	45	
Lithuania	5	1	0			
Netherlands	590	37	132			
Norway Russia	32	< 1	11	67	33	0
Slovak Rep	77 (30)	14 (5)	16			
Slovenia						
Spain						
Sweden						
Switzerland	288 (132)	40 (19)	92			
UK	1014 (335)	17 (6)	246			
Asia Pacific						
Australia	956 (449)	49 (24)	199	51	44	5
Brunei	0	0	0			
Hong Kong	78 (14)	11 (2)	21	46	48	6
India	73 (21)	< 1 (< 1)	6	75	25	<1
Indonesia	2	< 1	0	50	50	0
Japan	1200 (100)	9 (< 1)	50	35	65	0
Malaysia	19 (15)	1 (< 1)	2	74	21	5
Myanmar	0	0	0			
New Zealand	86 (31)	23 (8)	28	58	42	0
Pakistan	5 (0)	< 1 (0)	0	100	0	0
PR China	63 (23)	< 1 (< 1)	5	84	16	0
Philippines	2	< 1	0	100	0	0
Singapore	30 (12)	9 (4)	8	60	25	15
Korea	63 (3)	1 (< 1)	4	94	6	0
Taiwan	22 (11)	1 (< 1)	0	86	14	0
Thailand	14	< 1	2	86	14	0
Middle East and Africa						
Iran	60	1	0	50	45	5
Israel	349 (297)	58 (50)	105	28	65	7
South Africa	37	< 1	5	93	7	0
The Americas						
Argentina	478 (280)	13 (8)	50	60	36	4
Brasil	565	3	48	54	42	4
Canada	1736 (530)	56 (18)		35	65	
Dominican Rep	0	0	0	0	0	0
Ecuador	0	0	0			
Panama	6	2	0	0	60	40
Peru	3	< 1	0	0	100	0
Uruguay	56 (30)	19 (10)	27			
United States	48127 (35630)	169 (107)	16909	36	62	2

ICD = implantable cardioverter defibrillator, ICD/DDD = ICD with DDD pacing capability; ICD/BiV = biventricular ICD.

One of the anecdotal findings from the survey was the interest and enthusiasm of the designated survey coordinators. These physicians and associated professionals developed many new local contacts and became proficient in the preparation and conduction of their local survey, which they were encouraged to publish locally. It is anticipated that a 2005 survey will be conducted for the XIIIth World Symposium to be held in 2007 in Rome, Italy.

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Contributions to the work involved the following:

Name	% Contribution	Nature of Contribution
Mond Harry G	75%	Principal author, responsible for design of study, liaison with manufacturers, recruitment of country coordinators, collection and preparation of data, literature review, writing of manuscript and submission of final draft. Overall responsibility for project.
Irwin Marleen	5%	Collection of Canadian data. Proof reading.
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Declaration by co-authors:

The undersigned hereby certify that:

1) They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise.
2) They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication.
3) There are no other authors of the publication according to the criteria.
4) Potential conflicts of interest have been disclosed to granting bodies, the editor/publisher of the journal and the head of the responsible academic unit.
5) The original data are stored at the following location and will be held for at least five years from the date of publication.

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The World Survey of Cardiac Pacing and Cardioverter-Defibrillators: Calendar Year 2005

An International Cardiac Pacing and Electrophysiology Society (ICPES) project

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Background: *A worldwide cardiac pacing and implantable cardioverter-defibrillator (ICD) survey was undertaken for calendar year 2005 and compared to a similar survey conducted in 2001.*

Results: *There were contributions from 43 countries: 16 from Europe, 13 from the Asia Pacific region, four from the Middle East and Africa, and 10 from the Americas. The United States had the largest number of cardiac pacemaker implants (223,425). Virtually all countries showed increases in implant numbers over the 4 years. High-degree atrioventricular block and sick sinus syndrome remain the major indications for implantation of a cardiac pacemaker, although indications data were not available for large implanting regions such as Europe, Australia, and the United States. There remains a high percentage of VVI(R) pacing in the developing countries, although compared to the 2001 survey, virtually all countries had increased the percentage of DDDR implants, together with a fall in single-lead VDD implants. Pacing leads were predominantly transvenous, bipolar, and passive fixation. There was, however, an increased use of active fixation leads in both the atrium and ventricle. All countries surveyed showed a significant rise in the use of ICDs with the largest implanter being the United States (119,121) with 401 new implants per million population.*

Conclusions: *Although the numbers of participating countries have fallen, there still remains a group of loyal enthusiastic survey coordinators. Recruitment of new coordinators will hopefully continue in order to obtain a fully global experience of cardiac pacing and ICD usage. (PACE 2008; 31:1202–1212)*

2001 world survey, pacemaker, ICD

Introduction

An ongoing responsibility of the International Cardiac Pacing and Electrophysiology Society (ICPES) is a worldwide quadrennial survey of cardiac pacing and implantable cardioverter-defibrillator (ICD) practices. This survey was conducted 2 years prior to the World Symposium on Cardiac Pacing and Electrophysiology. The World Survey on Cardiac Pacing and ICD practices was first conducted in 1972 (Groningen).[1] Since then, surveys have been conducted for calendar years 1975 (Tokyo),[2] 1978 (Montreal),[3,4] 1981 (Vienna),[5] 1985 (Israel),[6,7] 1989 (Washington),[8] 1993 (Buenos Aires),[9] 1997 (Berlin),[10–12] and Hong Kong 2001.[13] ICDs were included in the survey for the first time in 1993.

Once a country had been appointed to host the World Symposium meeting, the regional organizing committee had traditionally taken on the responsibility for conducting the pacing survey. As such meetings grew in size and complexity, the allocation of resources for the World Survey was given low priority. An ongoing network of interested physicians or associated professionals was not established, nor was there an active recruitment of new countries. Despite this, government health administrators, hospital administrators, pacemaker companies, and implanting physicians have in recent years, become increasingly interested in pacemaker and ICD

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implant statistics. Being aware of this, the ICPES was eager to continue the World Surveys and appointed one of its board members to coordinate the 2005 survey.

For the 2001 and 2005 surveys, the format is similar for all countries. An ongoing survey network exists in Europe and this group has been encouraged to continue and expand its activities. Consequently, Asia Pacific, the Middle East, Africa, Canada, Central America, and South America have used the European format. Previously, the United States had conducted its own survey with little similarity to other countries.[11] The current format now falls into line with the other surveys, allowing a true comparison of world pacing and ICD practices.

Survey Formats

The European survey is based on the European pacemaker registry and the European Pacemaker Patient Identification Card, first introduced in 1978.[14–16] Details from these cards are registered with national registration centers. Comprehensive questionnaires are sent out annually by the European Heart Rhythm Association (formerly the Working Group on Cardiac Pacing) to the registration centers, which in turn send aggregated data to the Association. From this information, an annual European pacing and ICD survey is constructed.[17,18] All national contributors receive a complete set of data for their own information and correction.

The 2005 survey for countries outside Europe was based on a questionnaire sent to selected contact physicians or associated professionals. The contact personnel were encouraged to perform a comprehensive hospital survey for their country. An accurate number of pacemaker and ICD implants or at least units sold in the country were obligatory. These data were collected for new cardiac pacing and ICD systems and replacements. The number of implanting institutions in that country was also requested. The remaining information was collected in percentages. It was found that pacemaker and ICD implant centers often kept poor records and in these situations, the contact person found that pacemaker companies were very helpful in providing missing information.

In larger implanting countries such as the United States and Australia, individual hospital surveys were not possible and therefore a separate questionnaire was designed for a cardiac pacing and ICD company survey. This was based on sales and registration figures of pacing and ICD hardware for calendar year 2005. Upon definition and agreement of the security procedures, designed to protect their individual figures, all companies selling pacing and ICD hardware in the United States and Australia readily agreed to cooperate and contribute to the survey. The questionnaire carried no company identification and when completed was placed in a plain sealed envelope and sent in an identifiable envelope to the survey coordinator. Once all companies represented in that country had returned the questionnaire, the outer envelope was opened and the plain sealed envelope removed and given a work number. The information was transcribed to a working sheet followed by shredding of the individual forms and all working sheets immediately after the data were collated and placed onto the final data sheet. There remained no evidence of individual company figures.

Results

Forty-three countries contributed to the 2005 Cardiac Pacing and ICD Survey compared to 50 countries for the 2001 survey.[13] For Europe, there were 16 countries (22 in 2001). Greece is included again, having missed the 2001 survey. Among the countries failing to provide a report for the 2005 survey was Germany, which in the 2001 survey had the highest number of new implants per million population. Thirteen countries in the Asia Pacific region (16 in 2001) contributed to the survey, which included two new countries: Bangladesh and Nepal. Despite the smaller number of participating countries, the 2005 survey still covered about 80% of the cardiac pacing and ICD systems implanted in the region. The Middle East and Africa consisted of four countries (three in 2001) with the United Arab Emirates participating for the first time. There were 10 countries in the Americas contributing to the survey (nine in 2001) with three new countries: Chile, Puerto Rico, and Trinidad/Tobago. The results of the Cardiac Pacing survey are presented in Tables I to V and the ICD survey in Table VI.

Table I summarizes new pacing system implants, pulse generator replacements, the number of implanting centers, and the mean number of new implants per center. Where relevant, the 2001 survey data are shown in parenthesis. The largest implanting nation with 223,425 new pacemaker implants was the United States. This figure is almost identical to the 2001 figure of 223,226. Other large implanting countries included France (44,915), Italy (44,000), and Japan (30,817). Belgium had the highest new implants per million population at 789 followed by the United States at 752. Only Latvia, Canada, and Peru showed no increase in implant numbers per million population compared to the 2001 survey.

Table I.

Cardiac Pacemakers

Country	Population (Million)	Number of Centers (2001 Survey)	New Implants (2001 Survey)	New Implants per Million Population (2001 Survey)	Mean New Implants per Center	Replacements
Europe						
Belgium	10.4	125 (120)	8,122 (7,053)	789 (685)	65	3,073
Croatia	4.5	11 (11)	1,370 (1,049)	304 (238)	125	388
Czech Rep	10.5	38 (36)	6,191 (5,563)	590 (530)	163	2771
Denmark	5.1	14 (14)	2,857 (2,429)	557 (467)	204	968
France	60.9	575 (600)	44,915 (37,250)	738 (628)	78	14,661
Greece	11.0	65	4,284	389	66	1,348
Italy	57.5	380 (400)	44,000 (36,779)	765 (637)	116	12,000
Latvia	2.4	3 (3)	515 (528)	213 (210)	172	175
Lithuania	3 4	3 (3)	1,354 (953)	397 (272)	451	126
Netherlands	16.3	104 (106)	6,430 (5,016)	394 (314)	62	3,070
Russia	142 8	99 (97)	14,458 (10,950)	101 (76)	146	2,823
Slovak Rep	5.4	14 (14)	1,880 (1,143)	348 (212)	134	634
Spain	44.1	199 (145)	21.505 (16,421)	488 (399)	108	7.219
Sweden	9	44 (45)	5.702 (4,201)	633 (472)	130	1.853
Switzerland	7.46	63 (65)	3,382 (3,014)	453 (415)	54	1,248
United Kingdom	60.2	191 (174)	26,930 (17,550)	447 (293)	141	9,373
Asia Pacific						
Australia	20.1	123 (105)	11,850 (11,034)	590 (486)	96	1,140
Bangladesh	144	12	601	4	50	8
Brunei	0 4	1 (1)	18 (14)	45 (42)	18	4
China	1,300	417 (241)	16.595 (11,000)	13 (8)	40	1,495
Hong Kong	7.5	~20 (16)	1,177 (1,004)	157 (143)	59	277
India	1,100	417 (329)	12,000 (6,725)	7 (7)	29	500
Japan	127	~2,300 (2,700)	30,817 (26,700)	243 (210)	13	18,113
Nepal	20	2	96	5	48	0
New Zealand	4.1	7 (8)	1,134 (914)	275 (245)	162	
Singapore	4	10 (10)	383 (281)	91 (92)	38	95
South Korea	49	100 (65)	1,412 (1,162)	29 (26)	14	386
Taiwan	23	78 (22)	2,704 (2,290)	119 (102)	35	481
Thailand	64	46 (22)	1,434 (605)	22 (10)	31	110
Middle East and Africa						
Emirates	4	6	100	29	17	10
Iran	68	41 (27)	2.529 (1,469)	37 (24)	62	242
Israel	7	21 (18)	2,334 (2,009)	333 (335)	111	658
South Africa	47	47 (39)	2,515 (1,814)	54 (40)	54	444
The Americas						
Argentina	37		10,876 (9,000)	294 (250)		2,175
Brazil	187	252 (252)	19.071 (15.167)	103 (89)	76	7,676
Canada	33	125 (125)	17.600 (18.376)	550 (591)	141	3,600
Chile	16	50	2,455	153	49	435
Panama	3	5 (4)	239 (180)	80 (60)	48	32
Peru	27	14 (20)	366 (550)	14 (22)	26	95
Puerto Rico	4	29	1,754	448	60	
Trinidad/Tobago	1.3	2	51	39	26	7
United States	297		223,425 (223,226)	752 (786)		65,996
Uruguay	3	14 (12)	949	287	68	590

(2001 survey) = comparison with 2001 survey.
Rep = Republic

Of interest is the mean number of new implants per center in each country. Most countries had 30 to 150 implants per center. In Japan, there are a large numbers of implanting centers with generally small numbers per center (mean 13). Countries with predominantly government-funded services, such as Denmark, United Kingdom, New Zealand, and Canada, generally have fewer hospitals implanting pacemakers and hence higher new implant numbers per center.

Table II highlights the gender and age of recipients. In some of the larger implanting countries, accurate data were not possible. The percentage of male implants dominated in most countries, whereas the mean age of female and male recipients were very similar with females marginally older in all the regions surveyed. An interesting statistic was the percentage of recipients greater than 80 years of age. Countries with sophisticated health systems generally had percentages greater than 30%, whereas in developing or poorer countries, this figure was much lower.

The indications for initial implant are shown in Table III. Again in some larger implanting countries, the breakdown is not available. These percentages, as supplied by individual countries, do not always equal 100%. As per previous surveys, high-degree atrioventricular block and sick sinus syndrome were the major indications for pacemaker implantation. Atrial fibrillation with a slow ventricular response was also a significant indication in Europe, but much less so in the developing countries of the Asia Pacific, Middle East, and the Americas. The developing non-bradyarrhythmic indications for cardiac pacing still remain a minor indication, but are expected to increase in the future.

Table IV summarizes the pacing mode and where the figures are significant and compares the changes since the 2001 survey. The percentage of dual-chamber DDDR usage is rising throughout all regions surveyed at the expense of single-chamber VVIR. Most developed countries had more than 50% DDDR usage with 79% in the United States and Belgium. The overall use of single-lead VDD pacing systems fell between surveys, although substantial use still occurred in Italy, Spain, and Japan. Only very small numbers of AAIR pacing systems were used, predominantly in countries with small implant numbers. Although all countries reported an increased usage of biventricular pacing devices, the overall numbers were still small.

Pacing lead details are outlined in Table V. The results of the survey showed a preference for bipolar, passive fixation leads in both atrium and ventricle. There is, however, a growing preference for active fixation leads in both the atrium and ventricle, particularly in the United States.

Table VI summarizes the information obtained on ICDs. The United States remains clearly the world's largest implanter with 401 new implants per million population. Only Australia (142), Italy (128), and Denmark (108) were above 100 new implants per million population. All major implanting countries showed significant rises in the numbers of implants and figures are available for the yearly increases in Italy.[19] A breakdown of the different types, single chamber, dual chamber, and biventricular, showed a significant usage of all types with marked increases in the biventricular models for cardiac resynchronization therapy.

Discussion

Although smaller than the 2001 survey,[13] the 2005 world survey on cardiac pacing and ICDs had 43 countries participating. These countries were grouped into four regions: Europe, Asia Pacific, the Middle East, and the Americas, and common to the 2001 survey was the format, which allowed important comparisons on growth and trends. With ongoing hospital budget constraints, surveys of expensive medical procedures are becoming increasingly important to hospital administrators. When compared to previous surveys, this 2005 cardiac pacing and ICD survey demonstrated a significant worldwide increase in the use of this expensive implantable cardiac hardware. The reasons for this growth vary from country to country. Factors include socioeconomic changes, particularly in India and China, aging populations, and the development of appropriate implantation facilities and physician training. There has also been an increasing recognition of emerging nonbradyarrhythmic indications, together with the availability of appropriate, but expensive, ICD and biventricular hardware.

Apart from indications, the 2005 World Survey did not address clinical issues and thus a detailed clinical analysis of the reasons for these changes between surveys is beyond the scope of this report. The survey, however, did highlight certain trends in practice and in particular, the increasing use of dual-chamber systems and the use of active fixation leads in the ventricle. Active fixation lead usage is expected to rise even further with the acceptance of right ventricular selective site pacing.

One of the limitations of such a survey, particularly in large implanting countries, is the difficulty in recruiting physicians or associated professionals to collate hospital implant data. Pacemaker companies are well placed to determine sales

Table II.

Cardiac Pacemakers

Country	Sex (%)		Age of Recipients				Hospital Stay (Mean)
	Male	Female	Male (Mean)	Female (Mean)	>60 yrs (%)	>80 yrs (%)	
Europe							
Belgium	54	46	75	77	86	32	
Croatia	61	40	72	70	88	21	
Czech Rep	50	50	76	72	87	16	
Denmark	56	44	74	77	88	41	
France	60	40	78	81	93	40	
Greece	59	41	75	75	94	36	
Italy	59	41	76	79	95	40	
Latvia	47	53	69	74	71	22	
Lithuania							
Netherlands	54	46	73	76	88	32	
Russia	46	54	64	66	75	12	
Slovak Rep	62	38	73	74	91	39	
Spain	57	43	75	77	92	35	
Sweden	57	43	75	77	92	43	
Switzerland	57	43			91	36	
United Kingdom	45	55	75	77	90	41	
Asia Pacific							
Australia							
Bangladesh	74	26	63	65	67	13	8
Brunei	55	45	58	63	33	0	3
China	56	44			76		7
Hong Kong	48	52	69	72	82	26	2
India							
Japan	53	47	73	76	89	34	7
Nepal	68	32	65	65	68	11	4
New Zealand	55	45	72	74	86	33	1
Singapore	51	49	70	71	79	22	3
South Korea	39	61	65	67	79	21	5
Taiwan	51	49	71	72	88	34	3
Thailand	45	55	63	67	60	10	3
Middle East and Africa							
Emirates	50	50	65	65	90	2	2
Iran	44	56	61	63	66	15	2
Israel	57	43	72	74	84	40	1
South Africa							
The Americas							
Argentina	57	43	69	66			1
Brazil	52	48	67	69	72	22	2
Canada	54	46	73	76	87	27	2
Chile							
Panama	87	13	78	80	79	12	5
Peru	64	36	73	71	91	26	2
Puerto Rico	57	43	74	70	82	33	2
Trinidad/Tobago	38	62	69	69	76	21	1
United States							
Uruguay	55	45	75	77	93	35	1

~60 and ~80 yrs (%) = percentage of pacemaker recipients over 60 or 80 years

Table III.

Cardiac Pacemakers: Indication for Initial Implant (%)

Country	High Degree AV Block	BBB	SSS	AF	CSS NCGS	AV Node Ablation	Cardiomyopathy	
							Hypertrophic	Congestive
Europe								
Belgium	23	4	40	13	2	1		4
Croatia	36	4	21	22	1	1		12
Czech Rep	20	3	40	22				
Denmark	32	7	32	14	4	1		4
France	25	7	23	9	1	1		5
Greece	14	1	20	6	3	<1		<1
Italy	21	5	21	13	3	<1		1
Latvia	30	2	38	18	2	3		3
Lithuania								
Netherlands	25	7	32	11	1	1		1
Russia	36	3	25	16	1	5		2
Slovak Rep	29	5	33	11	2			1
Spain	38	6	23	17	1	1		4
Sweden	23	4	33	19	1	<1		2
Switzerland	26	2	37	14	2			4
United Kingdom	28	5	26	17	3	1		1
Asia Pacific								
Australia								
Bangladesh	87	<1	13	0	0	0	0	0
Brunei	24	10	24	52	0	0	0	0
China	39		50					
Hong Kong	33	1	46	12	0	1	0	3
India	60	10	25		1	2		2
Japan	46	<1	40	8	<1	1	<1	3
Nepal	84	2	14	0	0	0	0	0
New Zealand	49	1	28	16	2	2	<1	2
Singapore	36	0	44	13	<1	<1	0	1
South Korea	56	0	36	5	2	0	<1	<1
Taiwan	38	1	52	4	0	1	<1	3
Thailand	57	<1	38	2	<1	<1	<1	2
Middle East and Africa								
Emirates	60		30	5				5
Iran	49	3	32	6	<1	3	<1	5
Israel	37	7	35	10	4	2	<1	4
South Africa								
The Americas								
Argentina	68	2	25	5				
Brazil	52	3	13	9	1	<1	<1	4
Canada	38	2	34	18	2	4	1	1
Chile								
Panama	65	<1	35					
Peru	71	2	18	6	0	<1	<1	<1
Puerto Rico	43		44	1		<1		12
Trinidad/Tobago	58	0	26	5	0	5	0	0
Uruguay	60	3	21	10	1	2	<1	<1

AV = atrioventricular; BBB = bundle branch block; SSS = sick sinus syndrome; AF = atrial fibrillation;CSS / NCGS = carotid sinus syncope and neurocardiogenic syncope

Table IV.

Cardiac Pacemakers: Pacing Mode (%)

Country	VVI(R) (2001 Survey)	AAI(R) (2001 Survey)	VDD (2001 Survey)	DDD(R) (2001 Survey)	Biventricular (2001 Survey)
Europe					
Belgium	19 (22)	<1	1	79 (68)	4 (2)
Croatia	66 (66)	0	4	27 (26)	<1
Czech Rep	40 (49)	1	2 (4)	59 (46)	
Denmark	26 (24)	10 (9)	2	56 (60)	7 (2)
France	22 (26)	<1	5 (7)	68 (63)	4
Greece	28		11	61	
Italy	33 (35)	<1	11 (12)	54 (43)	2
Latvia	30 (45)	0	3	59 (40)	2
Lithuania	46 (63)	20 (24)	2	32 (10)	<1
Netherlands	26 (32)	3	2	56 (56)	13 (3)
Russia	72 (78)	8	<1	19 (11)	<1
Slovak Rep	63 (69)	4	5 (7)	26 (21)	2
Spain	40 (40)	1	20 (24)	39 (34)	1
Sweden	27 (28)	4 (4)	<1	64 (67)	6
Switzerland	33 (35)	2	8 (9)	54 (56)	3
United Kingdom	39 (39)	1	<1	55 (59)	4
Asia Pacific					
Australia	24 (29)	<1	1	72 (69)	2 (1)
Bangladesh	86	0	0	14	0
Brunei	10 (35)	0	0	90 (65)	0
China	49 (65)			51 (35)	
Hong Kong	31 (40)	<1	1	62 (53)	4 (3)
India	84 (69)	1	7	10 (20)	
Japan	29 (35)	3 (3)	18 (13)	51 (49)	3 (<1)
Nepal	100	0	0	0	0
New Zealand	41 (41)	6 (2)	<1	51 (51)	2 (2)
Singapore	51 (40)	<1	6 (16)	40 (43)	3 (<1)
South Korea	34 (35)	2	<1	64 (51)	
Taiwan	51 (53)	4 (4)	4 (4)	38 (39)	3 (0)
Thailand	61 (77)	1	1	37 (20)	
Middle East and Africa					
Emirates	50			45	5
Iran	50 (55)	<1	4 (22)	46 (23)	
Israel	31 (37)	<1	8 (16)	56 (42)	4 (3)
South Africa	42 (45)	1	5 (16)	42 (31)	10 (6)
The Americas					
Argentina	65 (75)		1 (8)	34 (17)	
Brazil	34 (46)	<1	9 (3)	53 (50)	4 (<1)
Canada	35 (51)	2 (2)	6 (4)	56 (43)	2 (<1)
Chile					
Panama	77			17	0
Peru	85 (88)	<1	0	14 (10)	
Puerto Rico	33 (50)	0	0	60 (50)	7 (1)
Trinidad/Tobago	30	0	3	67	0
United States	19 (23)		<1	79 (76)	2 (1)
Uruguay	46 (42)	1	3 (11)	48 (46)	<1

Table V.

Cardiac Pacemakers: Pacing Leads (%)

Country	Lead Polarity				Passive Fixation		Active Fixation	
	Atrial		Ventricular					
	BP	UP	BP	UP	Atrium	Ventricle	Atrium	Ventricle
							(2001 Survey)	
Europe								
Belgium	99	1	89	11	66	96	34 (49)	4 (4)
Croatia	99	1	97	3	77	87	23 (11)	13 (1)
Czech Rep	100	<1	99	1	48	80	52	20 (14)
Denmark	100	<1	88	12	0	43	100 (61)	57 (9)
France	100	<1	89	11	14	72	86 (81)	28 (9)
Greece								
Italy	92	8	86	14				
Latvia	100	0	95	5	0	5	100 (21)	95 (21)
Lithuania								
Netherlands	100	<1	98	2	48	77	51	23 (11)
Russia	81	19	67	33	80	96	20 (23)	4 (2)
Slovak Rep	100	0	95	5	45	76	56 (41)	25 (1)
Spain	100	<1	99	1	52	76	48	24
Sweden	100	<1	91	9	5	64	95	36
Switzerland	99	1	97	3	22	78	76 (66)	20 (9)
United Kingdom	99	1	100	<1	85	89	15 (16)	11 (6)
Asia Pacific								
Australia	99	<1	99	<1		57	43 (	12)
Bangladesh	100	0	100	0	0	92	100	8
Brunei	100	0	100	0	90	86	10 (15)	14 (15)
China	60	40	40	60	90	95	10 (6)	5 (2)
Hong Kong	99	1	95	5	83	83	17 (10)	17 (7)
India	100	0	85	15	80	90	20 (35)	10 (8)
Japan	100	<1	98	2	81	82	19 (12)	18 (15)
Nepal	0	0	100	0	0	100	0	0
New Zealand	100	0	100	0	56	60	44 (28)	40 (16)
Singapore	99	1	97	3	9	47	91 (39)	53 (7)
South Korea	94	6	96	4	71	89	29 (47)	11 (53)
Taiwan	97	3	97	3	35	40	65 (5)	60 (1)
Thailand	100	0	99	1	1	72	99 (96)	28 (5)
Middle East and Africa								
Emirates	100	0	100	0				
Iran	100	0	97	3	76	84	24 (13)	16 (4)
Israel	100	0	95	5	30	83	70 (90)	17 (2)
South Africa	100	0	100	0	31	98	43 (6)	2 (10)
The Americas								
Argentina	95	5	90	10	1	98	99 (100)	2 (5)
Brazil	100	0	97	3	13	42	87 (85)	58 (21)
Canada	97	3	97	3	74	77	26 (39)	23 (29)
Chile								
Panama	80	20	80	20	85	85	15 (5)	15 (5)
Peru	79	21	92	8	2	91	98	9
Puerto Rico								
Trinidad/Tobago								
United States	98	2	98	2	15	39	85 (73)	61 (38)
Uruguay								

BP = bipolar, UP = unipolar.

Table VI.

Implantable Cardioverter-Defibrillators

Country	New Implants (2001 Survey)	New Implants per Million Population (2001 Survey)	Replacements	Type (%) ICD	Type (%) ICD/DDD	Type (%) ICD/BiV
Europe						
Belgium	846 (437)	82 (42)	355			
Croatia	32 (14)	7 (3)	5			
Czech Rep						
Denmark	540 (241)	105 (47)	171	45	36	19
France						
Greece	345	31	133			
Italy	7,439 (2,200)	129 (38)	2,968	32	32	36
Latvia	5 (9)	2 (4)	0			
Lithuania	25 (5)	7 (1)	3			
Netherlands	1,555 (590)	95 (37)	737		68	32
Russia	151	2	17	42	40	5
Slovak Rep	180 (77)	33 (15)	32	49	33	18
Spain	1,400	32	593	56	21	24
Sweden	412	46	147			
Switzerland	627 (288)	84 (40)	229		71	29
United Kingdom	2,835 (1,014)	47 (17)	941			
Asia Pacific						
Australia	2,864 (956)	142 (49)	420	35	30	35
Bangladesh	7	<1	0	57	43	0
Brunei	3 (0)	8 (0)	0	33	67	0
China	186 (63)	<1 (<1)	40	70	20	10
Hong Kong	211 (78)	28 (11)	94	33	31	36
India	415 (73)	<1 (<1)	20	66	16	18
Japan	2,360 (1,200)	19 (9)	576	11	89	0
Nepal	0	0	0	0	0	0
New Zealand	179 (114)	33 (23)	45	55	35	10
Singapore	73 (30)	18 (9)	15	81	11	8
South Korea	148 (63)	3 (1)	11	71	31	9
Taiwan	111 (22)	5 (1)	15	47	42	11
Thailand	183 (14)	3 (<1)	20	70	20	10
Middle East and Africa						
Emirates	13	4	1	30	30	40
Iran	314 (60)	5 (1)	16	44	30	26
Israel	683 (349)	98 (58)	194	28	47	25
South Africa	105 (37)	2 (<1)	5	46	17	37
The Americas						
Argentina	672 (478)	18 (13)	109	60	30	10
Brazil	1,413 (565)	8 (3)	446	25	59	16
Canada	~3,000 (1,736)	91 (56)	~1,070	36	36	28
Chile						
Panama	12 (6)	4 (2)	0	50	10	40
Peru	7 (3)	<1 (<1)	1	57	43	0
Puerto Rico	292 (64)	73 (16)		54	10	36
Trinidad/Tobago	0	0	0	0	0	0
United States	119,121 (48,127)	401 (169)	56,065	30	30	40
Uruguay	39	13 (19)	27	74	21	5

ICD/DDD = ICD with DDD pacing capability; ICD/BiV = biventricular ICD

figures for most countries. However, company-based surveys, although accurate, do not address important demographic and clinical data. In Europe, the pacemaker identification card, national registration centers, and a central coordinating office represent an ideal system to collect pacemaker and ICD data. However, not all countries with registration centers, and in particular Germany, which had the highest new implants per million population figure in the 2001 survey, could provide information to the survey prior to publication. In contrast, the rest of the world uses a simple questionnaire sent to each country contact person, who then conducts the survey usually using hospital implant data. When this is not possible, a limited survey is performed using pacemaker company sales. Despite its simplicity, many of the recruited coordinators failed to return a report for their country. If surveys like this are to continue in the future, clearly more work needs to be done with recruitment and assistance. The ICPES has now created a subcommittee whose major goal is to expand the World Survey.

One of the anecdotal findings from the survey was the interest and enthusiasm of the designated survey coordinators who contributed data on their countries. Some of these countries such as India, China, and Japan are extremely difficult to conduct because of the phenomenal growth of pacing and ICD services in those countries. The ICPES is extremely grateful to those and all other coordinators for their tireless work. All physicians and associated professionals developed many new local contacts within their country and became proficient in the preparation and conduction of their local survey, which they were encouraged to publish locally.[20] It is anticipated that a 2009 survey will be conducted for the XIVth World Symposium to be held in 2011 in Greece.

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Name	% Contribution	Nature of Contribution
Mond Harry G	80%	Principal author, responsible for design of study, liaison with manufacturers, recruitment of country coordinators, collection and preparation of data, literature review, writing of manuscript and submission of final draft. Overall responsibility for project.
Proclemer Alessandro	20%	Collection of European data. Proof reading.
Candidate's signature	**Date**	

Declaration by co-author:

The undersigned hereby certify that:

1) They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise.
2) They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication.
3) There are no other authors of the publication according to the criteria.
4) Potential conflicts of interest have been disclosed to granting bodies, the editor/publisher of the journal and the head of the responsible academic unit.
5) The original data are stored at the following location and will be held for at least five years from the date of publication.

Location: Department Cardiology, The Royal Melbourne Hospital, Victoria 3050.

Signature:

	Signature	Date
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WSA

The 11th World Survey of Cardiac Pacing and Implantable Cardioverter-Defibrillators: Calendar Year 2009–A World Society of Arrhythmia's Project

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A worldwide cardiac pacing and implantable cardioverter-defibrillator (ICD) survey was undertaken for calendar year 2009 and compared to a similar survey conducted in 2005. There were contributions from 61 countries: 25 from Europe, 20 from the Asia Pacific region, seven from the Middle East and Africa, and nine from the Americas. The 2009 survey involved 1,002,664 pacemakers, with 737,840 new implants and 264,824 replacements. The United States of America (USA) had the largest number of cardiac pacemaker implants (225,567) and Germany the highest new implants per million population (927). Virtually all countries showed increases in implant numbers over the 4 years between surveys. High-degree atrioventricular block and sick sinus syndrome remain the major indications for implantation of a cardiac pacemaker. There remains a high percentage of VVI(R) pacing in the developing countries, although compared to the 2005 survey, virtually all countries had increased the percentage of DDDR implants. Pacing leads were predominantly transvenous, bipolar, and active fixation. The survey also involved 328,027 ICDs, with 222,407 new implants and 105,620 replacements. Virtually all countries surveyed showed a significant rise in the use of ICDs with the largest implanter being the USA (133,262) with 434 new implants per million population. This was the largest pacing and ICD survey ever performed, because of mainly a group of loyal enthusiastic survey coordinators. It encompasses more than 80% of all the pacemakers and ICDs implanted worldwide during 2009. (PACE 2011; 34:1013–1027)

2009 World Survey Pacemaker, ICD

Introduction

An ongoing responsibility of the World Society of Arrhythmias (WSA), formerly the International Cardiac Pacing and Electrophysiology Society, is a worldwide quadrennial survey of cardiac pacing and implantable cardioverter-defibrillator (ICD) practices. This survey is conducted 2 years prior to the World Symposium on Cardiac Pacing and Electrophysiology. The World Survey on Cardiac Pacing and ICD practices was first conducted in 1972 (Groningen).[1] Since then, surveys have been conducted for calendar years 1975 (Tokyo),[2] 1978 (Montreal),[3,4] 1981(Vienna),[5] 1985 (Israel),[6,7] 1989 (Washington),[8] 1993 (Buenos Aires),[9] 1997 (Berlin),[10–12] 2001 (Hong Kong),[13] and 2005 (Rome).[14] ICDs were included in the survey for the first time in 1993.

Because of the information obtained from the surveys, the WSA has always been eager to continue them in a format that allows the evolving trends in cardiac pacemaker and ICD usage to be readily available to government health administrators, hospital administrators, implanting physicians, and cardiac implantable electronic device (CIED) manufacturers and distributors. For the 2001,[13] 2005,[14] and 2009 surveys, a member of the WSA board was appointed to conduct the surveys using a format similar for all countries. An ongoing survey network exists in Europe and this group has been encouraged to continue and expand its activities. Consequently, Asia Pacific, the Middle East, Africa, Canada, and the Americas have used a format similar to the European model. Previously, the world's largest implanter, the United States of America (USA), had conducted its own limited survey with little similarity to other

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countries.[11] The current format now falls into line with the other surveys, allowing a true comparison of world pacing and ICD practices.

Survey Formats

The European survey is based on the European pacemaker registry and the European Pacemaker Patient Identification Card, first introduced in 1978.[15–17] Details from these cards are registered with national registration centers. Comprehensive questionnaires are sent out annually by the European Heart Rhythm Association (EHRA), formerly the Working Group on Cardiac Pacing, to the registration centers, which in turn, send aggregated data to the working group. From this information, an annual European pacing and ICD survey is constructed.[18,19] All national contributors receive a complete set of data for their own information and correction. For the calendar year 2009 survey, the data collected from the National Pacemaker and ICD registries were integrated with data obtained from the White Book published by EHRA[20] and from EUCOMED,[21] a company-based survey group.

The 2009 survey for countries outside Europe was based on a survey questionnaire sent to selected contact physicians or associated professionals. The contact personnel were encouraged to perform a comprehensive hospital survey for their country. An accurate number of pacemaker and ICD implants or at least units sold in the country was obligatory. These data were collected for new cardiac pacing and ICD systems and replacements. The number of implanting institutions in that country was also requested. Most of the remaining information was collected in percentages. It was found that pacemaker and ICD implant centers often kept poor records and in these situations, pacemaker companies or distributors were very helpful in providing missing information. The population of the individual countries was obtained via the contact physicians or through standard web search engines.

In larger implanting countries such as the USA and Australia, individual hospital surveys were not possible and therefore a separate questionnaire was designed for a CIED company survey. This was based on sales and registration figures of CIED hardware for calendar year 2009. Upon definition and agreement of the security procedures designed to protect their individual figures, all companies selling CIED hardware in the USA and Australia agreed to cooperate and contribute to the survey. The questionnaire carried no company identification and when completed was placed in a plain sealed envelope and sent in an identifiable envelope to the survey coordinator. Once all companies represented in that country had returned the questionnaire, the outer envelope was opened and the plain sealed envelope removed and given a work number. The information was transcribed to a working sheet followed by shredding of the individual forms, and all working sheets immediately after the data were collated and placed onto the final data sheet. There remained no evidence of individual company figures.

Results

Sixty-one countries contributed to the 2009 Cardiac Pacing and ICD Survey compared to 43 countries for the 2005 survey.[14] For Europe, there were 25 countries (16 in 2005) with nine new contributors. Twenty countries in the Asia Pacific region (13 in 2005) contributed to the survey, which included seven new countries. This represents more than 99% of all the cardiac pacemakers and ICDs implanted in the region. Only Macau failed to provide a report. A number of Asia Pacific countries, including Cambodia, Laos, North Korea, and Papua New Guinea, were not believed to implant cardiac pacemakers or ICDs during 2009. The information was obtained through the manufacturers or local distributors. The Middle East and Africa consisted of seven countries (four in 2005) with four new countries participating for the first time. There were nine countries in the Americas contributing to the survey (nine in 2005) with one new country. The results of the cardiac pacing survey are presented in Tables I–V and the ICD survey in Table VI.

New Cardiac Pacing System Implants, Pulse Generator Replacements, Number of Implanting Centers and Mean Number of New Implants per Center (Table I)

Where relevant, the 2005 survey data are shown in parentheses. For seven countries in Europe, only the total number of pacemaker implants was available without a breakdown to new or replacement units. Using previous surveys from those countries, when available, and the data available from other countries, a breakdown formula of 75% new and 25% replacement was used. This has been designated as approximate data (~) in the tables. The main information regarding 2009 CIED implants for four European countries, Hungary, Russia, Slovakia, and Slovenia, was obtained from the EHRA White Book 2010.[20] Country populations are given to the nearest million in the tables, but more exact population data were used to determine the new implants per million population for both pacemakers and ICDs.

The 2009 survey involved 1,002,664 pacemakers, with 737,840 being new implants and 264,824 being replacements (26% of total). As with previous surveys, the largest implanting

Table I.

Cardiac Pacemakers 2009

Country	Population (million)	Number of Centers (2005 survey)	New Implants (2005 survey)	New Implants Per Million Center (2005 survey)	New Implants Per Center	Replacements (% of Total)
Europe						
Austria	8	65	~5,947	743	94	~ 1,982
Belgium	10	125 (125)	6,266 (8,122)	627 (789)	50	2,983 (32)
Croatia	4	13 (11)	1,931 (1,370)	439 (304)	149	440 (19)
Czech Republic	10	39 (38)	6,774 (6,191)	677 (590)	174	2,238 (25)
Denmark	5	14 (14)	3,098 (2,857)	604 (557)	221	1,134 (27)
Finland	5	25	3,133	627	125	1,115 (26)
France	62	550 (575)	~ 48,487 (44,915)	782 (738)	88	~ 16,162
Germany	82	986	~ 76,046	927	77	~25,349
Greece	11	62 (65)	5,369 (4,284)	488 (389)	87	1,522 (22)
Hungary	10	15	~3,996	400	266	~ 1,332
Ireland	5	13	~1,754	351	135	~ 585
Italy	60	400 (380)	44,653 (44,000)	744 (765)	112	17,974 (29)
Lithuania	4	4 (3)	1,816 (1,354)	519 (397)	454	395 (18)
Malta	0.4	2	260	650	130	31 (11)
Netherlands	17	104 (104)	~ 9,048 (6,438)	532 (394)	87	~ 4,826
Norway	5	25	2,348	470	94	712 (23)
Portugal	11	43	7,096	645	165	1,502 (17)
Russia	142	115 (99)	22,516 (14,458)	159 (101)	196	3,859 (15)
Serbia	8	16	2,802	350	175	405 (13)
Slovakia	5	13 (14)	2,400 (1,880)	480 (348)	185	449 (16)
Slovenia	2	4	762	381	191	173 (18)
Spain	45	116 (119)	~ 25,595 (21,505)	569 (488)	221	~ 8,531
Sweden	9	44 (44)	6,320 (5,702)	702 (633)	144	2,817 (31)
Switzerland	8	70 (63)	3,991 (3,382)	419 (453)	57	1,408 (26)
United Kingdom	62	211 (191)	32,135 (26,930)	518 (447)	152	10,176 (24)
Asia Pacific						
Australia	22	111 (123)	12,523 (11,850)	565 (590)	113	3,742 (23)
Bangladesh	160	14 (12)	702 (601)	5 (4)	50	19 (3)
Brunei	0.4	1 (1)	42 (18)	105 (45)	42	4 (9)
China	1,300	783 (417)	40,728 (16,595)	31 (13)	52	7,187 (15)
Hong Kong	7	24 (20)	870 (1,177)	124 (157)	36	322 (21)
India	1,200	738 (417)	20,000 (12,000)	17 (7)	27	400 (2)
Indonesia	230	28	349	2	12	31 (8)
Japan	128	2,300	34,813 (30,817)	272 (243)	15	23,532 (40)
Malaysia	27	28	827	30	30	105 (11)
Myanmar	68	10	130	2	13	3 (2)
Nepal	29	3 (2)	173 (96)	6 (5)	58	9 (5)
New Zealand	4	10 (7)	1,277 (1,134)	299 (275)	128	418 (25)
Pakistan	170	16	728	4	46	72 (9)
Philippines	92	30	629	7	21	110 (15)
Singapore	5	10 (10)	468 (383)	94 (91)	47	133 (22)
South Korea	49	110 (100)	1,691 (1,412)	35 (29)	15	822 (33)
Sri Lanka	20	7	901	45	128	60 (6)
Taiwan	23	85 (78)	3,952 (2,704)	172 (119)	46	868 (18)
Thailand	64	20	1,894 (1,434)	30 (22)	95	64 (3)
Vietnam	88	13	678	8	52	36 (5)

Continued.

Table I.

Continued.

Country	Population (million)	Number of Centers (2005 survey)	New Implants (2005 survey)	New Implants Per Million Center (2005 survey)	New Implants Per Center	Replacements (% of Total)
Africa/Middle East						
Bahrain	1	1	48	48	48	19(28)
Iran	72	54(41)	3,373(2,529)	47(37)	62	375(10)
Israel	7	20(21)	3,000(2,334)	429(333)	150	1,200(29)
Oman	3	1	92	31	92	16(15)
Qatar	2	1	57	36	57	11(16)
South Africa	49	(47)	2,939(2,515)	60(54)		735(20)
Sudan	39	4	180	5	45	11(6)
The Americas						
Argentina	40	600	11,478(10,876)	287(294)	19	3,800(25)
Bolivia	10	<20	639	65	<2	9(1)
Brazil	184	317(252)	24,966(19,071)	136(103)	79	9,981(29)
Chile	17	67(50)	3,045(2,455)	216(153)	45	455(13)
Peru	30	11(14)	904(366)	30(14)	82	262(22)
Puerto Rico	4	27(29)	2,423(1,754)	605(448)	90	
Trinidad/Tobago	1	2(2)	127(51)	127(39)	64	20(14)
Uruguay	3	14(14)	1,084(949)	324(287)	77	851(44)
USA	307	3,400	235,567(223,425)	767(752)	69	101,042(30)

(2005 survey) = comparison with 2005 survey; (% of total) = % replacements for total number of units implanted or sold

nation with 235,567 new pacemaker implants in 2009 was the USA. This figure is similar to the 2005 survey figure of 223,425 implants. Other large implanting countries included Germany (76,046 new implants), France (48,487), Italy (44,653), and for the first time China (40,728). Germany had the highest new pacemaker implants per million population at 927 followed by France (782), the USA (767), and Italy (744). Only Belgium, Argentina, Italy, and Australia showed no increase in pacemaker implant numbers per million population compared to the 2005 survey, although the reduction was very small and for the latter three countries probably reflects a greater rise in population over the previous 4 years compared to implant numbers.

Of interest is the mean number of new implants per center in each country. Most countries had 30–150 implants per center with generally larger numbers in Europe and smaller numbers throughout the rest of the world. The largest number per implant center were in countries such as Lithuania (454), Denmark (221),[22] and Spain (221), where the relatively small number of implanting centers remains static and large established regional government centers were responsible for implanting pacing hardware. In Japan, there are large numbers of implanting centers with generally small numbers per center (15).

In most countries with established pacing services, the number of replacements has grown significantly as patients with implanted pacemaker hardware require elective replacement for end-of-service life. It was decided to present these data as absolute figures and the percentage of the total implant numbers in parentheses. As stated previously, the mean percentage of total implants for pacemaker replacements was about 26%, although higher in Uruguay (44%), Japan (40%), and South Korea (33%). Not surprisingly, countries such as China (15%) and India (2%), with the recent exponential growth of pacing services, had small replacement percentages. It is anticipated that in these two countries over the next decade the numbers of pacemaker replacements will rise dramatically and this will need to be taken into account with budgetary planning.

Gender and Age of Recipients. Mean Hospital Stay (Table II)

Demographics remain the weakest part of the survey, because in larger implanting countries, accurate data were not possible, unless there was a government-initiated endeavor to obtain such information such as in China. In general, patients are elderly and males dominated in most regions. The mean age of female and male recipients was

Table II.

Cardiac Pacemakers 2009: Demographics

Country	Sex (%)		Age of Recipients				Hospital Stay (Mean)
	Male	Female	Male (Mean)	Female (Mean)	>60 years (%)	>80 years (%)	
Europe							
Austria							
Belgium	54	46	75	78			
Croatia			66	69			
Czech Republic							
Denmark	55	45	74	77	90	40	
Finland							
France							
Germany							
Greece	63	37	74	77			
Hungary							
Ireland							
Italy	57	43	77	80	95	50	
Lithuania							
Malta	57	43	68	75	60	32	
Netherlands							
Norway	55	45	74	76			
Portugal							
Russia							
Serbia	64	36					
Slovakia							
Slovenia							
Spain							
Sweden	57	43					
Switzerland							
United Kingdom							
Asia Pacific							
Australia							1
Bangladesh	72	28	62	65	80	13	7
Brunei	62	38	58	61	28	6	2
China	52	48	69	67	79	17	
Hong Kong	48	52	73	75	88	36	
India	68	32			63		4
Indonesia	42	58	71	67	71	17	2
Japan	53	47	73	76			
Malaysia							
Myanmar	49	51	60	65	83	15	6
Nepal	64	36	68	64	70	13	5
New Zealand	61	39	72	72	83	35	1
Pakistan	52	48	63	61	61	6	2
Philippines	37	63	60	65	70	15	
Singapore	45	55	68	69	85	26	2
South Korea	40	60	67	69	74	13	4
Sri Lanka	60	40	60	55	35	1	3
Taiwan	51	49	73	73	82	29	3
Thailand	45	55	62	65	59	8	3
Vietnam							

Continued.

Table II.

Continued.

Country	Sex (%)		Age of Recipients				Hospital Stay (Mean)
	Male	Female	Male (Mean)	Female (Mean)	>60 years (%)	>80 years (%)	
Africa/Middle East							
Bahrain	63	37	63	63	68	10	1
Iran	52	48	65	62	66	20	2
Israel							
Oman	54	46	55	56	58	9	
Qatar	67	33	44	47	36	6	2
South Africa							
Sudan	52	48	67	65	73	8	1
The Americas							
Argentina	58	42	71	65	88	28	1
Bolivia	50	50	40	40			
Brazil	54	46	69	70	78	26	3
Chile	60	40	65	70	70	10	
Peru	62	38	72	69	82	27	2
Puerto Rico	59	41	78	76	83	34	2
Trinidad/Tobago	50	50	68	68	73	19	1
Uruguay	59	41	77	76	94	38	2
USA							

>60 and >80 years (%) = percentage of pacemaker recipients over 60 or 80 years.

very similar with females marginally older in all regions except the Americas.

An interesting, but difficult to obtain statistic was the percentage of recipients greater than 80 years of age. Countries with sophisticated health systems would have expected to have a figure greater than 25%. This was seen with Uruguay (38%), Hong Kong (36%), and New Zealand (35%), whereas in developing or poorer countries, this figure was much lower such as Sri Lanka (1%), Pakistan (6%), and Sudan (8%).

In most countries and in particular those with sophisticated pacing services, the mean hospital stay was short and generally only a few days. In developing countries such as Bangladesh (7 days), Myanmar (6 days), and Nepal (5 days), the length of stay was longer.

Indications for Initial Implant (Table III)

Again in many larger implanting countries, the breakdown was not available. The percentages as supplied by individual countries do not always equal 100% because there are significant numbers where the indication remains unknown or did not fit the classification groups. As per previous surveys, high-degree atrioventricular block and sick sinus syndrome were the major indications for pacemaker implantation with atrial fibrillation representing an increasing indication particularly in the Asia Pacific, Africa/Middle East, and the Americas. The evolving nonbradyarrhythmic indications for cardiac pacing still remain a minor indication with 5% or less in most countries.

Pacing Mode (Table IV)

As demonstrated in previous surveys,[13,14] there is an increasing use of dual-chamber pacing throughout the world and in particular, in countries with rapidly developing pacing services, such as Iran (43% increase from 2005), Singapore (24%), and Taiwan (24%). This, of course, is at the expense of single-chamber ventricular pacing (VVI[R]). The usage of single-chamber atrial pacing continues to fall even amongst traditionally large users such as Denmark (4%) and Sweden (2%). Similarly, single pass lead VDD implants continue to fall with many countries having very small implant numbers, which probably reflects the replacement market. There is, however, still substantial usage of VDD systems in Japan (18%), Portugal (12%), Italy (10%), South Korea (10%), and Uruguay (10%). These figures reflect individual physician preferences for single pass leads and may not be a regional phenomenon. For example, there was a 10% usage in Uruguay but only 1% in neighboring Argentina.

Table III.

Cardiac Pacemakers 2009: Indication for Initial Implant (%)

Country	High-Degree AV Block	BBB	SSS	AF	CSS NCGS	AV Node Ablation	Cardiomyopathy	
							Hypertrophic	Congestive
Europe								
Austria								
Belgium	23	4	42	14	2			3
Croatia	26	7	26	20	1			13
Czech Republic								
Denmark	33	6	35	11	3			4
Finland								
France								
Germany								
Greece	15	1	20	5	5			<1
Hungary								
Ireland								
Italy	19	4	19	10	2		<1	1
Lithuania								
Malta								
Netherlands								
Norway	29	3	36	16	<1			2
Portugal	33	5	21	16	3			5
Russia								
Serbia	30	2	19	13	<1			2
Slovakia								
Slovenia								
Spain								
Sweden	23	6	33	16	0			3
Switzerland								
United Kingdom								
Asia Pacific								
Australia								
Bangladesh	77	<1	20		0	<1	0	1
Brunei	24	5	50	14	0	0	0	2
China	38		49	13	<1		<1	<1
Hong Kong	30	<1	40	17	<1	<1	<1	<1
India	58	7	23		2	1		2
Indonesia	55	0	30	5	0	0	0	5
Japan	46	1	40	8	1	1	1	3
Malaysia	54	<1	22	15	0	3	0	1
Myanmar	68		30	2	0	0	0	
Nepal	84	2	13	<1	0	0	0	<1
New Zealand	47	2	27	17	1	2	1	3
Pakistan	70	1	2	1				2
Philippines	51	10	30	2	0	3	1	
Singapore	39	<1	39	7	1	<1	1	1
South Korea	52	2	39	5	5	1	0	<1
Sri Lanka	38		19	42	1	0	0	<1
Taiwan	36	1	49	9	0	<1	<1	3
Thailand	41	0	46	8	<1	1	0	2
Vietnam								

Continued.

Table III.

Continued.

Country	High-Degree AV Block	BBB	SSS	AF	CSS NCGS	AV Node Ablation	Cardiomyopathy	
							Hypertrophic	Congestive
Africa/Middle East								
Bahrain	75	3	15	7	0	0	0	0
Iran	49	3	29	7	<1	1	0	7
Israel								
Oman								
Qatar	52	9	14	4	0	0	2	0
South Africa								
Sudan	95	1	1	1	0	<1	0	3
The Americas								
Argentina	51	1	32	5	<1	3	<1	7
Bolivia								
Brazil	49	4	14	9	1	1	1	7
Chile	60		10	30				
Peru	55	1	25	10	0	3	1	1
Puerto Rico	34		31	4	0	<1	0	30
Trinidad/Tobago	53	2	22	2	2	1	1	13
Uruguay	62	2	15	11	1	1	1	1
USA								

AV = atrioventricular; BBB = bundle branch block; SSS = sick sinus syndrome; AF = atrial fibrillation; CSS / NCGS = carotid sinus syncope and neurocardiogenic syncope.

There is only limited information on the actual numbers of biventricular pulse generators implanted, with the USA (9,650) being by far the largest user. This market may be growing only slower because of the preference for combined cardiac resynchronization therapy and ICDs.

Pacing Leads (Table V)

Little survey information was available for Europe. The vast majority of pacing leads implanted today are bipolar. Compared with previous surveys, the use of active fixation leads has increased significantly, particularly in the right ventricle. This may reflect an increasing interest in pacing this chamber from sites outside the apex.

ICDs (Table VI)

As with pacing systems, the breakdown of new and replacement numbers was not available for 11 countries in Europe (designated ~) and a mean figure of 30% replacements were used. The 2009 survey involved 328,027 ICDs, with 222,407 new implants and 105,620 replacements (32% of total). Not surprisingly, ICD implantation numbers have grown exponentially in almost every surveyed country since 2005. The USA remains clearly the world's largest implanter with 133,262 implants or 434 new implants per million population. This figure may be lower than anticipated, because of concerns regarding ICD lead recalls, which occurred at the time of the survey. Eighteen countries had greater than 100 new implants per million population compared to four countries in the 2005 survey: 14 countries in Europe, one in Asia Pacific, one in Africa/Middle East, and two in the Americas. Apart from the USA, other large ICD implanters per million population included Germany (290), the Netherlands (220), and Italy (174).

There was a great variation in the breakdown of the different types of ICDs: single chamber, dual chamber, and biventricular. There is, however, increasing use of biventricular ICDs as more physicians are trained in the difficult implantation techniques, although cost must also play a significant role. When available, the exact numbers of biventricular ICDs are recorded. When not available, approximate figures can be calculated by dividing the percentage used into the new implant figures. Once again the USA (49,255) was by far the largest user of biventricular ICDs.

Table IV.

Cardiac Pacemakers 2009: Pacing Mode (%)

Country	VVI(R) (2005 Survey)	AAI(R) (2005 Survey)	VDD (2005 Survey)	DDD(R) (2005 Survey)	New Biventricular (Actual Number)
Europe					
Austria					
Belgium	20 (19)	<1 (<1)	< (1)	78 (79)	
Croatia	57 (66)	0 (0)	5 (4)	37 (27)	
Czech Republic					
Denmark	27 (26)	4 (10)	1 (2)	62 (56)	
Finland					
France					
Germany					
Greece	21 (28)	0 (0)	5 (11)	68 (61)	
Hungary					
Ireland					
Italy	30 (33)	1 (<1)	10 (11)	58 (54)	
Lithuania					
Malta	44	0	0	56	0
Netherlands					
Norway	22	2	1	74	
Portugal	38	1	12	44	
Russia					
Serbia	59	<1	4	31	
Slovakia					
Slovenia					
Spain					
Sweden	22 (27)	2 (4)	0 (<1)	70 (64)	
Switzerland					
United Kingdom					
Asia Pacific					
Australia	26 (24)	<1 (<1)	<1 (1)	71 (72)	446
Bangladesh	84 (86)	0	<1 (0)	14 (14)	8
Brunei	26	9	0	55	4
China	41 (49)	1		58 (51)	
Hong Kong	27 (31)	4 (<1)	1 (1)	69 (62)	14
India	63 (84)	0 (1)	7 (7)	30 (10)	450
Indonesia	70	7	2	21	15
Japan	29 (29)	3 (3)	18 (18)	51 (51)	611
Malaysia	50	1	<1	50	29
Myanmar	85			15	0
Nepal	98	0	0	2	1
New Zealand	41 (41)	2 (6)	<1 (1)	54 (51)	45
Pakistan	70	1	1	27	15
Philippines	72	0	<1	26	5
Singapore	32 (51)	1 (<1)	3 (6)	64 (40)	8
South Korea	26 (34)	2 (2)	10 (<1)	61 (64)	9
Sri Lanka	70	2	2	16	3
Taiwan	31 (51)	2 (4)	2 (4)	62 (38)	124
Thailand	55 (61)	<1 (1)	<1 (1)	45 (37)	40
Vietnam	68	5	0	27	

Continued.

Table IV.

Continued.

Country	VVI(R) (2005 Survey)	AAI(R) (2005 Survey)	VDD (2005 Survey)	DDD(R) (2005 Survey)	New Biventricular (Actual Number)
Africa/Middle East					
Bahrain	80	0	0	20	0
Iran	10 (50)	<1(<1)	1 (4)	89 (46)	263
Israel	27 (31)		4 (8)	70 (56)	
Oman	84	1	1	13	
Qatar	43	0	0	57	0
South Africa	45 (42)	0 (1)	0 (5)	55 (42)	387
Sudan	48	0	0	52	6
The Americas					
Argentina	60 (65)	<1	1 (1)	40 (34)	
Bolivia					0
Brazil	23 (34)	<1(<1)	3 (9)	70 (53)	1,318
Chile	73	0	0	27	
Peru	70 (85)	2 (<1)	0 (0)	28 (14)	5
Puerto Rico	20 (33)	0 (0)	0 (0)	80 (67)	506
Trinidad/Tobago	40 (30)	2 (0)	0 (3)	54 (67)	5
Uruguay	36 (46)	1 (1)	10 (3)	52 (48)	20
USA	19 (19)		<1(<1)	81 (79)	9,650

Discussion

The 2009 survey of cardiac pacing and ICDs is the largest ever published and involved 61 countries encompassing a total population of 5.05 billion people or 74% of the total world population (6.78 billion in 2009). Of the significant implanting countries only Canada is not represented, suggesting that over 80% of all the world's pacemakers and ICDs implants are included.

As with recent previous surveys, the countries were grouped into four regions: Europe, Asia Pacific, the Middle East/Africa, and the Americas. There was a common format allowing important comparisons on growth and trends. With ongoing hospital budget constraints, surveys of expensive medical procedures are becoming increasingly important to government bureaucrats, hospital administrators, implanting physicians, and CIED manufacturers. This survey demonstrated a significant worldwide increase in the use of these expensive devices. The reasons for this growth vary from country to country. Factors include socioeconomic changes, particularly in India and China, aging populations and the development of appropriate implantation facilities and physician training. There has also been an increasing recognition of emerging nonbradyarrhythmic indications, together with the availability of appropriate, albeit expensive, ICD and biventricular hardware.

A major deficiency of the survey was the lack of clinical and demographic data for many of the larger implanting countries. Outside Europe, there are no funds allocated for this survey, which is conducted by interested physicians often with the help of CIED companies or their distributors. Consequently, detailed hospital surveys are not often available. Even more important is the lack of outcome data and in particular, operative and postoperative complications, morbidity, and mortality. Such surveys, although helpful, are nevertheless extremely expensive and difficult to conduct at a national or international level. The survey, however, does highlight certain trends in practice and in particular, the increasing use of dual-chamber systems and the use of active fixation leads in the right ventricle.

A major difficulty in conducting such a survey, particularly in large implanting countries is the recruitment of physicians or associated professionals to collate hospital implant data. Pacemaker companies are well placed to determine sales figures for most countries. However, company-based surveys, although accurate, do not address important demographic and clinical data. In Europe, the pacemaker registry, national registration centers, and a central coordinating office

Table V.

Cardiac Pacemakers 2009 Pacing Leads (%)

	Lead Polarity				Passive Fixation		Active Fixation	
	Atrial		Ventricular					
Country	BP	UP	BP	UP	Atrium	Ventricle	Atrium (2005 Survey)	Ventricle
Europe	100	0	100	0				
Austria	100	0	100	0				
Belgium	100	0	100	0				
Croatia	100	0	100	0				
Czech Republic	100	0	100	0				
Denmark	99	1	99	< 1	< 1	15	99	85
Finland	100	0	100	0				
France	100	0	100	0				
Germany	100	0	100	0				
Greece	100	0	100	0				
Hungary	100	0	100	0				
Ireland	100	0	100	0				
Italy	100	0	100	0				
Lithuania	100	0	100	0				
Malta								
Netherlands	100	0	100	0				
Norway	100	0	100	0				
Portugal	100	0	100	0				
Russia	100	0	100	0				
Serbia	100	0	100	0				
Slovakia	100	0	100	0				
Slovenia	100	0	100	0				
Spain	100	0	100	0				
Sweden	100	0	100	0				
Switzerland	100	0	100	0				
United Kingdom	100	0	100	0				
Asia Pacific								
Australia	100	< 1	100	0	20	25	80	75
Bangladesh	100	0	100	0	99	99	< 1	1
Brunei	100	0	100	0	84	96	16	4
China								
Hong Kong	100	0	100	0	81	76	19	24
India	100	0	98	2	70	70	30	30
Indonesia	100	0	100	0	90	90	10	10
Japan	100	0	98	2	81	82	19	18
Malaysia	100	0	100	0	3	4	97	96
Myanmar			98	2	0	72	100	28
Nepal	100	0	100	0	99	99	1	1
New Zealand	100	0	99	1	35	38	65	62
Pakistan	100	0	100	0	3	70	97	30
Philippines	100	0	100	0	61	74	39	26
Singapore	99	1	99	1	7	3	93	97
South Korea	97	3	97	3	68	74	32	26
Sri Lanka	99	1	99	1	1	1	99	99
Taiwan	99	1	98	2	58	50	42	50
Thailand	100	0	100	1	1	17	99	83

Continued

Table V.

Continued.

Country	Lead Polarity				Passive Fixation		Active Fixation	
	Atrial		Ventricular					
	BP	UP	BP	UP	Atrium	Ventricle	Atrium (2005 Survey)	Ventricle
Vietnam	100	0	30	70	0	10	100	90
Bahrain	100	0	100	0	86	100	14	0
Iran	100	0	99	1	8	24	92	76
Israel								
Oman	100	0	100	0	90	56	10	25
Qatar	58	42	100	0	42	0	58	100
South Africa	100	0	100	0	57	69	43	31
Sudan	100	0	100	0	0	95	100	5
The Americas								
Argentina	100	0	100	0	0	20	100	80
Bolivia						33		66
Brazil	100	0	98	2	2	22	98	78
Chile	100	0	100	0	70	90	30	10
Peru	100	0	95	5	0	10	100	90
Puerto Rico	90	10	90	10	100	100	0	0
Trinidad/Tobago	99	1	97	3				
Uruguay					78	72	22	28
USA	99	1	99	1	15	20	85	80

(%) BP = bipolar, UP = unipolar

Table VI.

Implantable Cardioverter Defibrillators 2009

Country	New Implants (2005 Survey)	New Implants Per Million Population (2005 Survey)	Replacements (% of Total)	Type (%)			Number of New BiV Implanted
				ICD	ICD/DDD	ICD/BiV	
Europe							
Austria	~1,376	172	590			52	
Belgium	1,348 (846)	127 (82)	539 (29)			21	
Croatia	124 (32)	28 (7)	8 (6)	48	39	13	
Czech Republic	~1,719	172	737			84	
Denmark	966 (540)	173 (105)	532 (36)	56	21	23	
Finland	~496	99	212			29	
France	~6,720	108	2,880			75	
Germany	23,752	290	10,180			44	
Greece	979 (345)	89 (31)	176 (15)	18	46	36	
Hungary	700	70	188				
Ireland	~606	121	260	30			
Italy	10,434 (7,439)	174 (129)	4,438 (30)	26	33	41	
Lithuania	48 (25)	14 (7)	15 (24)				
Malta	40	100	7	0	30	70	
Netherlands	~3,736 (1,555)	220 (95)	1,601			52	
Norway	499	102	174 (26)	26	44	30	
Portugal	990	93	123	59	10	31	

Continued

Table VI.

Continued.

Country	New Implants (2005 Survey)	New Implants Per Million Population (2005 Survey)	Replacements (% of Total)	Type (%)			Number of New BiV Implanted
				ICD	ICD/DDD	ICD/BiV	
Russia	550 (151)	4 (2)	64 (10)	29	52	19	
Serbia	405	54	14	55	23	22	
Slovakia	818 (180)	164 (33)	71 (20)	35	10	25	
Slovenia	~99	50	~43				
Spain	2,930 (1,400)	65 (32)	1,178 (29)	52	21	27	
Sweden	1,013 (412)	108 (46)	317 (24)	21	44	35	
Switzerland	~926 (627)	122 (84)	~397			59	
United Kingdom	~5,990 (2,835)	97 (47)	~2,567			70	
Asia Pacific							
Australia	3,555 (2,864)	160 (142)	1,111 (24)	35	30	35	1,519
Bangladesh	12 (32)	1 (<1)	0 (0)	17	25	58	7
Brunei	7 (3)	18 (8)	1 (13)	14	29	57	4
China	1,316 (186)	1 (<1)	116 (8)	45	19	36	510
Hong Kong	140 (211)	20 (28)	84 (38)	39	29	32	43
India	1,100 (415)	1 (<1)	100 (8)	70	10	20	250
Indonesia	14	<1	2 (13)	29	29	42	3
Japan	5,341 (2,360)	42 (19)	1,477 (22)	11	52	37	2,009
Malaysia	87	3	37 (30)	25	25	50	49
Myanmar	1	<1	0 (0)	100	0	0	0
Nepal	2 (0)	<1 (0)	0 (0)	50	50	0	0
New Zealand	329 (134)	77 (33)	85 (21)	57	30	13	43
Pakistan	36	<1	4 (10)	17	72	11	4
Philippines	24	<1	4 (14)	67	12	21	5
Singapore	162 (73)	32 (18)	38 (19)	55	19	26	51
South Korea	277 (148)	6 (3)	65 (19)	53	36	11	31
Sri Lanka	17	1	0 (0)	76	18	6	1
Taiwan	310 (111)	13 (5)	45 (13)	29	60	11	35
Thailand	294 (183)	5 (3)	30 (9)	82	4	14	42
Vietnam	29	<1	0 (0)	69	17	14	5
Africa/Middle East							
Bahrain	11	11	4 (27)	83	8	8	1
Iran	1,260 (314)	18 (5)	140 (10)	30	35	35	495
Israel	1,170 (683)	167 (98)	480 (29)	20	31	49	838
Oman	16	5	1 (6)	35	18	47	8
Qatar	14	9	2 (13)	25	40	35	5
South Africa	308 (105)	6 (2)	45 (13)	25	21	54	~155
Sudan	2	<1	0 (0)	0	0	2	2
The Americas							
Argentina	2,250 (672)	56 (18)	560 (20)	60	34	6	196
Bolivia							
Brazil	2,825 (1,413)	15 (8)	603 (18)	16	59	25	840
Chile	245	14		70	30		
Peru	33 (7)	1 (<1)	9 (21)	30	64	6	2
Puerto Rico	560 (292)	140 (73)	10 (2)	55	5	40	220
Trinidad/Tobago	18 (0)	18 (0)	1 (5)	33	45	22	4
Uruguay	116 (39)	39 (13)	38 (25)	73	24	3	
USA	133,262 (119,121)	434 (401)	73,217 (35)	19	40	41	~49,255

(2005 Survey) = comparison with 2005 survey; (% of Total) = % replacements for total number of units implanted or sold; ICD/DDD = ICD with DDD pacing capability; ICD/BiV = biventricular ICD

represent an ideal system to collect pacemaker and ICD data.[22–24] However, not all countries involved with registration centers could provide information to the survey prior to publication. In contrast, the rest of the world uses a simple questionnaire sent to each country contact person, who then conducts the survey usually using hospital implant data. When this is not possible, a limited survey is performed using pacemaker company sales. Despite its simplicity, a number of the recruited coordinators failed to return a report for their country. If surveys like this are to continue in the future, clearly more work needs to be done with recruitment.

One of the anecdotal findings from the survey was the interest and enthusiasm of the designated survey coordinators who contributed data on their countries. Some countries, such as India, China, and Japan, are extremely difficult to conduct because of the exponential growth of pacing and ICD services in those countries. The WSA is extremely grateful to those and all other coordinators for their tireless work. All physicians and associated professionals developed many new local contacts within their country and became proficient in the preparation and conduction of their local survey, which they were encouraged to publish locally. It is anticipated that the next survey will be conducted in 2013.

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4.4 World Cardiac Pacing Surveys: A Review

Three world surveys on cardiac pacemakers are reviewed; calendar years 2001, 2005 and 2009. These surveys were conducted in the same format and thus comparisons can be made. The number and the regions of the contributing countries are documented in Table 4.4.1. The 2009 world survey was the largest ever conducted with 61 contributing countries. Compared to earlier pacing surveys, there were significant increases in the number of countries from Europe, the Asia Pacific and the Middle East/Africa.

Table 4.4.1 Contributing countries 2009 world pacing survey

	2001	2005	2009
Europe	22	16	25
Asia Pacific	16	13	20
Middle East/Africa	3	4	7
Americas	9	10	9
All contributors	**50**	**43**	**61**

For Europe, there were nine new contributing countries in the 2009 pacing survey compared to 2005. The Asia Pacific region had seven new contributing countries and the survey probably accounted for 99% of all implants in the region with only Macau with two implanting centres failing to provide a report. A number of Asian countries including Cambodia, Laos, North Korea and Papua New Guinea were not believed to implant cardiac pacemakers during 2009. There was a fall in the number of participating Asia Pacific countries between the 2001 and 2005 surveys. This reflects the failure of the author to recruit reliable local coordinators, which was corrected for the 2009 survey. The Middle East/Africa had had four new countries and the Americas had one new country.

Outside Europe, most countries and particularly the smaller implanting nations conducted hospital based surveys with demographic information. When an individual country survey involved too many implanting centres or was difficult or impossible to perform, a pacemaker company based survey was undertaken. This was the case for Australia and the United States of America.

4.4.1 Initial pacemaker implants.

The three world pacing surveys; 2001, 2005 and 2009 involved 68 different countries. The largest survey was 2009 with 61 countries. For Europe, 2009 survey details were not available for Georgia (provided in 2001) and Latvia (2001, 2005). For the Middle East, only the Emirates (2005) did not provide information for the 2009 survey. For the Americas, Canada (2001, 2005), Dominican Republic (2001), Ecuador (2001) and Panama (2001, 2005) did not provide information for the 2009 pacing survey. The 2009 Asia Pacific pacing survey was comprehensive with all previous countries participating.

The 2009 survey encompassed a total population of 5.05 billion people or 74% of the total world population (6.78 billion people in 2009). Of all the significant pacemaker implanting countries, only Canada was not represented, suggesting that well over 80% of all the world's pacemaker initial implants were included.

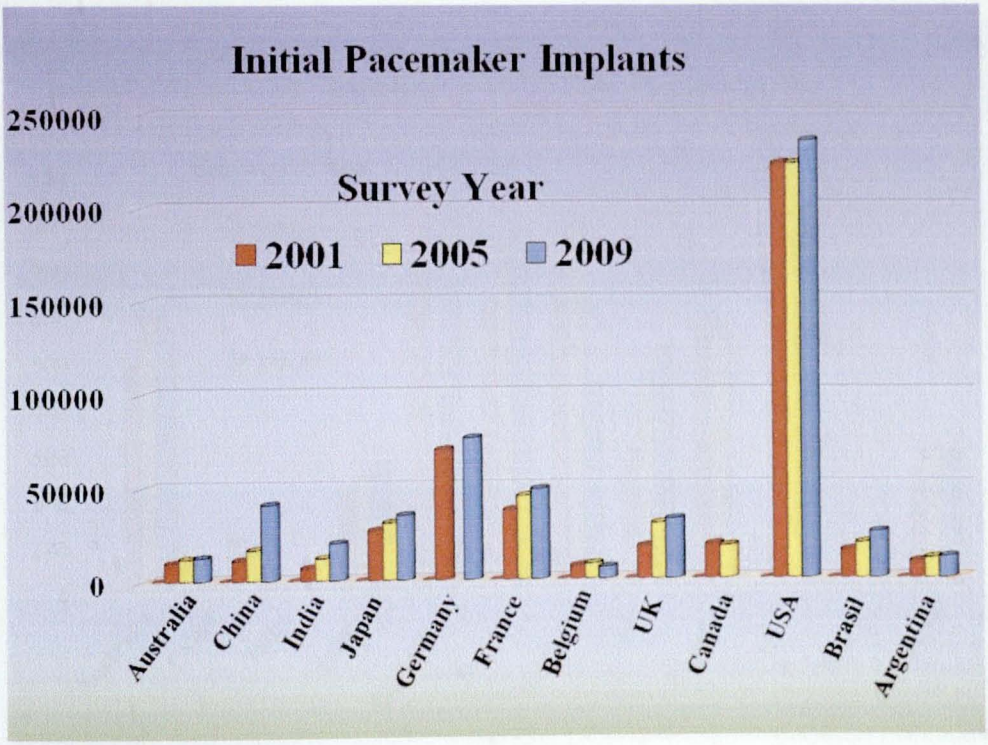
For review of the world's initial pacemaker implants, 12 major implanting countries have been selected from thee zones:

- ***Asia pacific***; Australia, China, India and Japan.
- ***Europe***; Germany, France, Belgium and the United Kingdom (UK).
- ***The Americas***; Canada, United States of America (USA), Brazil and Argentina.

The data has been divided into initial pacemaker implants (Figure 4.4.1) and initial pacemaker implants per million population (Figure 4.4.2).

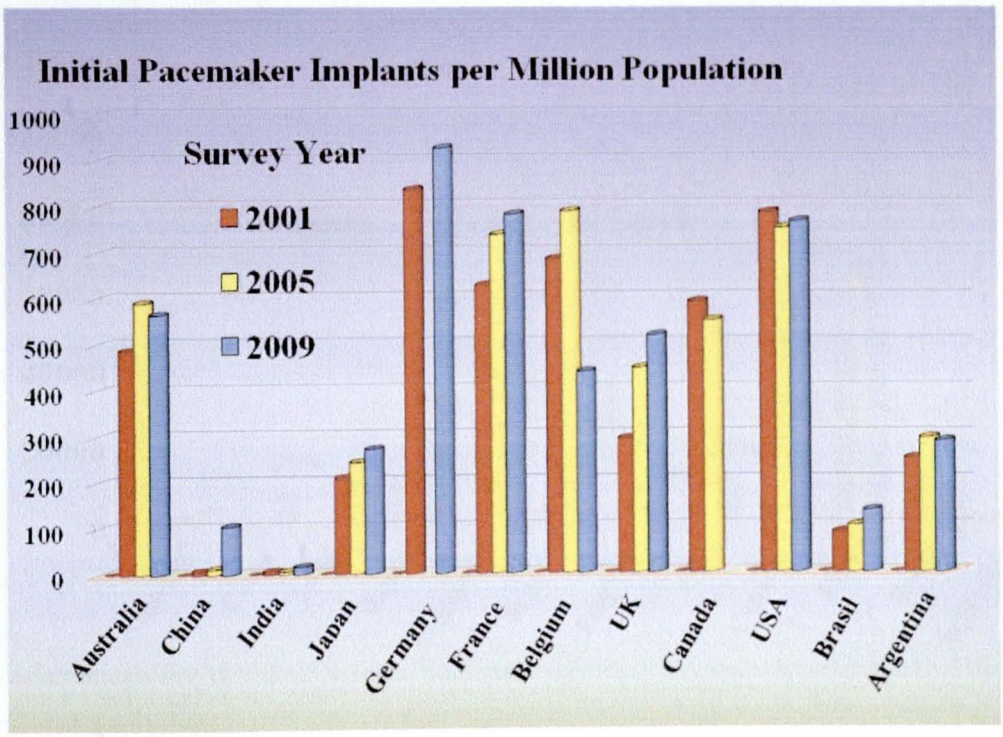
For initial pacemaker implants, there was a modest rise in implants over the three world surveys for most countries, but particularly those with rapidly developing economies such as China, India and Brazil (Figure 4.4.1). The United States of America with 235,567 initial pacemaker implants had by far the largest number of procedures, although there was only a small increase over the three surveys. The second largest implanter was Germany (~76,046) followed by France (~48,487) and Italy (44,653)) with China (40,728) close behind. Japan (34,813) had modest increases in initial implant numbers over the three pacemaker surveys but the overall figures are low for a developed country with such a large elderly population.

Figure 4.4.1 World pacing survey for calendar years 2001, 2005, and 2009: Initial pacemaker implants for 12 major implanting countries.



When the data was corrected for population, Germany had the largest new pacemaker implants per million population for calendar years 2001 (837) and 2009 (927) (Figure 4.4.2). Other countries with high initial implants per million population in the 2009 pacemaker survey were France (782) and the United States of America (767). Australia had 565 new pacemaker implants per million population. Again the Japan implant numbers corrected for population appear to be low with only modest rises over the three surveys (210, 243 and 272). China has had a steady rise in new implants per million population numbers over the three surveys (8, 13 and 31), whereas Belgium had a fall (685, 789 and 627).

Figure 4.4.2 World pacing survey for calendar years 2001, 2005, and 2009: Initial pacemaker implants per million population for 12 major implanting countries.

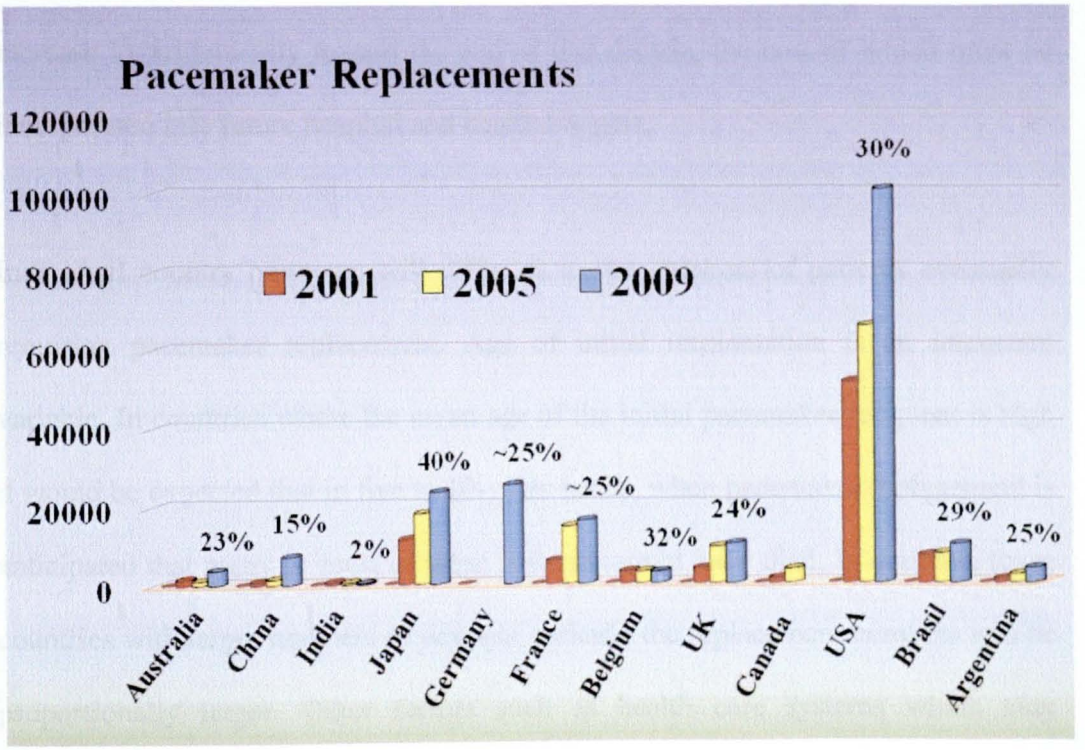


4.4.2 Pacemaker replacements.

Not surprisingly, the country with the largest number of pacemaker replacements in 2009 was the United States of America with 101,042 units. Despite the flat growth in initial implants, the replacement numbers grew exponentially over the three surveys reflecting the significant growth in initial pacemaker implants five to 10-years previously. Almost all countries showed an increase in pacemaker replacements although not as dramatic as the United States (Figure 3.4.3).

Figure 4.4.3 World pacing survey for calendar years 2001, 2005, and 2009: Pacemaker replacements for 12 major implanting countries.

(% = percentage replacements for total pacemaker implants, survey 2009).



In countries with long established and mature pacing services, the average replacement percentage over total implants for the 2009 survey ranged from 25 to 30% (Figure 4.4.3). The exceptions were Japan (40%) and Uruguay (44%) with very high replacement numbers compared to total implants. This may reflect the restrictive introduction of new technologies into Japan earlier last decade resulting in an eventual boost to implants, which is now reflected in the replacement numbers in 2009. Uruguay, however, remains unexplained.

In contrast, the Chinese (15%) and Indian (2%) pacemaker markets have relatively very low replacement figures and reflected the relatively small numbers of initial pacemaker implants earlier last decade reaching replacement now. However, when extrapolated to the more sophisticated markets in Europe, North America and Australia, it would be anticipated that replacement numbers in China and India will increase logarithmically toward the end of this decade, the cost of which must be incorporated into future hospital and health budgets.

Individual country however, will differ as to the numbers of patients eventually requiring pacemaker replacement. Age of initial implantation is an important variable. In countries where the mean age of the initial pacemaker recipient is high it would be expected that in five to 10-years hence, when pacemaker replacement is anticipated that many or most of these patients would have died. In contrast, those countries with larger numbers of younger patients, the replacement numbers will be proportionally larger. Other factors such as health care systems which may determine the care of concomitant illnesses, general wellbeing and other socio-

economic variables will also determine the outlook of the elderly pacemaker recipient at the time of pacemaker replacement.

Another factor which must be considered is pacemaker recall as a result of faulty hardware. In keeping with their complexity, pulse generators are potentially prone to unexpected failure. Because such failures may be life threatening, surgical replacement is usually urgent and even though most recalls are financially the responsibility of the manufacturer, there is considerable stress placed upon the implanting centres, which need to bear this extra surgical load. Coupled to this are potential surgical complications such as infection and lead damage. Fortunately, today, large pacemaker pulse generator recalls, requiring surgical intervention, are rare.

4.4.3 New pacemaker implants per centre.

One of the more interesting figures to be gleaned from the surveys were the number of new implants per centre. The figure, if high, reflects a small number of centres performing most of the implants for that country, which hopefully represents training centres of excellence. When the figure is low, large numbers of centres perform small numbers of pacemaker implants. Table 4.4.1 is a representative list of 15 countries; their number of centres and new implants per centre.

As determined by these world surveys, a mean figure for a country of >80 cases per centre, usually represents a number of centres of excellence. Although not scientifically proven, this figure has been deduced when comparing the new pacemaker implants per centre with the author's knowledge of the pacemaker services in those countries. It is a working number to help in evaluating the significance of the spread of pacemaker centres in an individual country and the quality of the services provided.

This can be seen with the Australian experience. For the 2009 world pacing survey, the new pacemaker implants per centre was 113. Scattered throughout the country are numerous centres of excellence with at least one in most states. These centres are usually training facilities in major public hospitals, occasionally with a large private hospital attached. In contrast, smaller implanting centres are often private hospitals staffed by well trained physicians who may continue to hold teaching sessions in the public domain. Such a system would be expected to provide overall excellent results.

Table 4.4.1 World pacing surveys 2001, 2005, 2009.

Number of "implanting centres (Centres)" and "new implants per centre (NIPC)" in a representative group of countries (15).

Country	2001		2005		2009	
	Centres	NIPC	Centres	NIPC	Centres	NIPC
Australia	105	90	123	96	111	113
Belgium	120	59	125	65	125	50
Denmark	14	174	14	204	14	221
Lithuania	3	318	3	451	4	454
Russia	97	113	99	146	115	196
United Kingdom	174	101	191	141	211	152
China	241	46	417	40	783	52
India	329	20	417	29	738	27
Japan	~2700	10	~2300	13	~2300	15
New Zealand	8	114	7	162	10	128
South Korea	65	18	100	14	110	15
Israel	18	112	21	111	20	150
Argentina	230	39			600	19
Brazil	243	62	252	76	317	79
USA					3400	69

As shown in table 4.4.1, countries with large numbers of implanting centres include Belgium, Russia, United Kingdom, China, India, Japan, South Korea, Argentina and Brazil. Of this group only Russia and the United Kingdom have large numbers of new implants per centre. In contrast, Denmark, Lithuania, New Zealand and Israel have small numbers of implanting centres and large volumes of implants per centre, probably due to strong government control and fewer private hospitals. In contrast, Australia has an equal mix of public and private medicine allowing for both values to be high.

Japan stands out with a huge number of implanting hospitals, the exact figure being unknown and very small mean number of new implants per centre. The United States of America has the most implanting hospitals of any country and like Australia has a mixture of public and private implanting centres. Because many of the smaller hospitals in the United States implant few pacemakers, the mean figure of new implants per centre is relatively low, although it must be remembered that there are many large implanting centres of excellence.

The number of new implanting centres for China and India rose significantly over the three surveys and this is likely to continue in the future. However, the new implants per centre figures remain flat. When there are large numbers of hospitals implanting CIEDs with small numbers per centre, there are always questions raised regarding appropriate indications, operative and post-operative complications and appropriate follow-up. In such countries, health bureaucrats must establish large teaching centres of excellence to ensure that appropriate standards of care are established and maintained.

4.4.4 Patient demographics (2009 survey).

Patient demographics including sex and age of recipients were included in all three world surveys with 38 of the 62 respondents providing data for the 2009 survey. The best responses were from Asia Pacific, the Americas, the Middle East and Africa with only Australia, Malaysia, Vietnam, the United States of America, Israel and South Africa failing to provide data. Only eight out of 25 European countries provided data. Previous surveys from Europe have always provided this data from the European registry and pacemaker patient identification card. This data is collected and determined in the national centres which are not always performed. Large implanting countries like Australia and the United States of America, without centralized registry centres were the least likely to have collected this data.

In almost all countries, men were more likely to receive pacemakers, irrespective of the region surveyed. Females predominated only in the Asia Pacific region which included Hong Kong, Indonesia, Philippines, Singapore and Thailand. In most countries, the mix was almost equal with only Bangladesh (72%) and India (68%) having a marked predominance of male recipients. Male recipients were generally younger, but if the mean age of the males was older, then it was only by a few years.

An attempt was made to determine the percentage of recipients over 60-years and 80-years. The data varied widely in all regions. In Europe, when data was available about 90% of recipients were >60-years and about 30% were >80-years. In other regions, the percentage >80-years were smaller and generally below 30% with a

number of countries having very low figures; Brunei (6%), Pakistan (6%), Sri Lanka (1%) and Qatar (6%).

What do these figures represent? In some countries, cost is such an important factor in the decision making, that there is a preference for younger recipients to receive a pacemaker when indicated. This may be determined by health authorities or when a family is required to pay for the hardware and implantation, preference may be given to a younger fitter family member who may then be able to return to the workforce. A younger patient with symptoms such as syncope may be more likely to be investigated than the elderly, particularly in regions with poor health and investigative facilities. Consequently, in poorer countries such as Pakistan and Sri Lanka the percentage of recipients >80-years is very low.

Another factor is the age distribution. Western and other advanced countries have a growing geriatric population and seeing that most indications for pacemakers are the result of degenerative age dependent disorders, it is not surprising to see large percentages of recipients >80-years. This is so for Italy (50%), Denmark (40%), Hong Kong (36%), New Zealand (35%), Taiwan (29%) and Singapore (26%), whereas South Korea with its aging post-war population has a modest figure of 13%. A potentially interesting figure would be Japan where the post-war population is now elderly and represents a significant percentage of the overall population. The lack of a sophisticated registry in a country with thousands of implanting centres makes this figure impossible to obtain.

4.4.5 Indications for initial pacemaker implant.

The indications for initial pacemaker implantation were included in all three world surveys with data from 43 of 50 respondents from the 2001 survey; 38 of 43 respondents from the 2005 survey and 38 of 62 respondents from the 2009 survey. The reduction in numbers over the three surveys was due to a decreasing response from Europe. Not surprisingly, there were marked variations in the indications from zone to zone, but in general within each country there was a similarity in numbers from survey to survey.

Of concern was the limitation of data from large implanting countries such as Australia and the United States of America. This was obviously because of the method of collecting data using pacemaker manufacturers. It is easier to collect implant indications from countries with small numbers of hospitals performing these services. It was encouraging to receive pacemaker indications data from all Asia Pacific countries apart from Australia and Vietnam. Although the pacemaker indications data is collected in the registration of European pacemaker patient identification card the results of individual countries is not always collated at the regional centres. With proper computerized registries, such data should be immediately available.

By far the two most common indications were all forms of heart block and sick sinus syndrome. Heart block predominated in most countries and particularly so in those with developing pacing services such as Bangladesh, Nepal and Pakistan. In contrast, sick sinus syndrome was the main pacemaker indication in Belgium,

Scandinavia, China, Hong Kong and Taiwan. Once again figures were not available for Australia and the United States of America.

There was a marked variation in the use of pacemakers for atrial fibrillation. For the 2009 survey, usage for Europe ranged from 5% (Greece) to 20% (Croatia). In the Asia Pacific region, there was also a wide variation in usage from <1% (Nepal) to 42% (Sri Lanka) although the usage appeared less than in Europe. In general, there was little usage of pacemakers for atrial fibrillation reported for Africa, the Middle East and the Americas with only Chile having 30% usage. For all surveys, the usage of pacemakers for carotid sinus syncope, neurocardiogenic syncope, AV nodal ablation and hypertrophic obstructive cardiomyopathy was very low.

4.4.6 Types of pacemakers.

In general, the type of pacemakers used can be divided into single chamber or dual chamber. Virtually all pacemakers sold or implanted are now rate adaptive and are single chamber ventricular (VVIR) or dual chamber (DDDR). Once implanted, the pacemakers can then be tailored or programmed to the patient's needs. It is rare to implant a single chamber atrial pacemaker (AAIR) for sick sinus syndrome and intact AV conduction. In virtually all countries, physicians now implant a dual chamber system which can be programmed to AAIR pacing or more likely DDDR with an extended AV delay or an algorithm to minimize ventricular pacing and so prevent the adverse effects of right ventricular pacing on left ventricular function. A small number of countries have continued to use AAIR pacing, but generally within those countries its usage diminished over the three surveys. These include Lithuania, Georgia, Russia, Denmark and Finland. For the 2009 pacemaker survey, only the very small implanting countries, Vietnam and Brunei exceeded 4% and probably reflects the interest of one or two implanting physicians.

Most countries with established pacing services have shown only modest change in VVIR and DDDR pacemakers' usage over the three pacemaker surveys. In general, about $1/3^{rd}$ of the pacemakers are single chamber and $2/3^{rds}$ dual chamber. For the 2009 survey, only Iran (10%) and the United States of America (19%) had <20% VVIR usage with a corresponding >80% DDDR usage. For the 2009 survey, a number of countries in Asia and the Middle East had a low dual chamber (DDDR) usage with Bangladesh (14%), Myanmar (15%), Nepal (2%), Sri Lanka (16%) and

Oman (13%) being <20%. In most countries, there were increases in DDDR usage with sequential surveys.

There is now little usage of single lead VDD pacing, which involves a composite "single pass" lead with atrial sensing and ventricular pacing and sensing, together with a specific pulse generator. Today a standard dual chamber pulse generator can be used and programmed VDD(R) if the connector joining the lead to the pulse generator has two separate connectors rather than an original unique design. The drawback of no atrial pacing limits its use to high degree AV block without chronotrophic incompetence.

The uptake of VDD pacing with a single pass lead has always been limited to a small number of countries often with only small numbers of implanters embracing the technology. Manufacturers have given little research time to further development, particularly as attempts to create a single pass lead with atrial pacing have failed. Because most of the initial development occurred in Italy, there has always been significant interest in that country with 10 to 12% usage over the three pacemaker surveys. For the 2009 pacemaker survey, only Portugal (12%), Japan (18%), South Korea (10%) and Uruguay (10%) used significant numbers of single lead implants, although this is believed to reflect the replacement market, particularly if leads with unique connectors have previously been used.

Dual chamber biventricular pacing for CRT has had a slow uptake worldwide because of difficulties with left ventricular lead insertion, significant lead complications, non-responders and above all high costs. Over the three surveys, the

numbers of pacing systems for congestive cardiac failure remained somewhat static with usually <5% of all pacemaker indications. This is because most patients require ICDs as well which have now been incorporated into CRT hardware. Only three countries reported >10% usage in the 2009 pacemaker survey; Puerto Rico (30%), Croatia (13%) and Trinidad/Tobago.

In order to gain a true picture of biventricular pacemaker usage, the actual number of units implanted was also incorporated into the 2009 pacemaker survey. Not surprisingly, the United States of America implanted the most units (9,650), with Brazil the only other country implanting over a 1000 units (1,318). For the 2009 survey, there was no information from Europe.

4.4.7 Pacing leads: polarity

There is now almost universal usage of bipolar leads in both atrium and ventricle. In the 2001 pacemaker survey, unipolar leads were still frequently used in the ventricle. A representative example of 12 major implanting countries is shown.

Table 4.4.2 World pacing surveys; 2001, 2005, 2009.

Atrial and ventricular bipolar lead polarity (%) in a selection of 12 countries.

Country	Bipolar Atrial Leads			Bipolar Ventricular Leads		
	Survey			Survey		
	2001	2005	2009	2001	2005	2009
Australia	100	99	100	98	99	100
Belgium	96	99	100	74	89	100
Denmark	100	100	99	39	88	99
France	94	100	100	59	89	100
Russia	50	81	100	13	67	100
China	30	60		20	40	
India	93	100	100	66	85	98
Japan	98	100	100	95	98	98
Iran	87	100	100	79	97	99
Argentina	100	95	100	95	90	100
Brazil	100	100	100	94	97	98
USA	100	98	99	98	98	99

There has always been controversy as to which type of pacing lead polarity is superior; unipolar or bipolar.[1] Historically, unipolar pacing in the ventricle was originally very popular as these leads were thinner and because of fewer components, probably more reliable. The original bipolar lead connector was large and cumbersome and required a large receiving port in the pulse generator. However, there were a number of limitations with unipolar pacing and in particular; oversensing.[1] As lead technology improved, the bipolar lead became thinner and probably as reliable. Thus, there was a marked shift to bipolar leads initially and particularly in countries with well-established pacing services such as Australia and the United States of America.

The shift to bipolar leads has been particularly prevalent for atrial pacing, because of superior sensing characteristics. Most countries had almost 100% bipolar atrial lead usage over the three pacemaker surveys (Table 4.4.2). In 2001, only China (70%) and Russia (50%) had significant atrial unipolar lead usage. By 2009, Russia had 100% bipolar atrial lead usage, but polarity usage data are not available for China. Pacemaker companies now manufacture very few unipolar atrial or ventricular leads; although some left ventricular leads remain unipolar.

The uptake to bipolar ventricular lead usage, however, has been slower. The old perceived view that the simpler unipolar lead had fewer complications remained until the end of the 1990's. The almost universal change, to bipolar ventricular pacing can be seen with the three surveys (Table 4.4.2). For the 2001 survey, Denmark (39%), France (59%), Russia (13%) and China (20%) had low bipolar ventricular lead usage, which was converted to almost 100% usage by the 2009

pacemaker survey. A number of countries reported 98 or 99% ventricular lead usage in the 2009 pacemaker survey. This may be due to the small numbers of unipolar coronary sinus leads used for left ventricular pacing.

4.4.8 Pacing leads: Active and passive fixation

Passive "tined" steroid-eluting leads have traditionally been used for atrial and ventricular lead fixation since the 1980's.[2,3] A decade later, with steroid-elution, active fixation leads became popular.[4] This is illustrated in table 4.4.3.

Table 4.4.3 World pacing surveys; 2001, 2005, 2009.

Atrial and ventricular active fixation leads (%) in a selection of 12 countries.

Country	Atrial Active Fixation			Ventricular Active Fixation		
	Survey			Survey		
	2001	2005	2009	2001	2005	2009
Australia	17		80	10		75
Denmark	61	100	99	9	57	85
France	81	86		9	28	
Latvia	21	100		21	95	
China	6	10		2	5	
India	35	20	30	8	10	30
Japan	12	19	19	15	18	18
Iran	13	76	92	4	24	76
South Africa	6	43	43	10	2	31
Argentina	100	99	100	5	2	80
Brazil	85	87	98	21	58	78
USA	73	85	85	38	61	80

There still remains some controversy regarding the use of active fixation leads in the atrium, because of the potential for cardiac perforation, although the incidence of lead dislodgement is probably lower with active fixation. Because of steroid-elution, lead performance in the atrium and ventricle is similar for both types of fixation.

The 2001 pacemaker survey showed a mixed use of active fixation in the atrium with low percentages for Australia (17%), Japan (12%), Iran (13%) and South Africa (6%) (Table 4.4.3). By the 2009 pacemaker survey, the usage had increased significantly to 80% Australia, 19% Japan, 92% Iran and 43% South Africa. Other countries such as France, Argentina, Brazil and the United States of America had higher usage at both surveys. When figures were available, virtually all countries showed an increase in usage of active fixation leads over the three pacemaker surveys.

The use of active fixation leads in the ventricle showed an even more dramatic increase over the three surveys. This probably reflects more confidence in the handling and performance of these leads and above all, the increasing use of alternate pacing sites outside the right ventricular apex. Dramatic increases between the 2001 and 2009 pacemaker surveys were seen with Australia (10% to 75%), Denmark (9% to 85%), Iran (4% to 76%), Argentina (5% to 80%), Brazil (21% to 78%) and the United States of America (38% to 80%).

4.4.9 Concluding remarks.

The 2009 world survey of cardiac pacing, as presented, was comprehensive and covered well over 80% of the world market. Implant numbers in most developed countries had plateaued between surveys, whereas developing countries had significant increases from previous surveys. This was particularly seen in China and India. Clearly these data reflect growing economies in these countries with emerging upper and middle classes. Not only are the new recipients able to afford this expensive therapy, but implant services are now available countywide by health care providers, often trained overseas.

There are many factors affecting the pacemaker implant numbers in a given country. The wealth of the United States of America makes it the largest implanter of pacemakers in the world although the European countries with sophisticated socialized medical services actually implant more pacemakers per million population. The penetration of these services in countries like Germany, France and Sweden suggest that pacemaker usage in these countries is optimal, although there could still be some growth in the biventricular pacemaker market.

In comparison, the Asia Pacific market continues to grow as more recipients benefit from this therapy. Clearly economic growth, hospital facilities and health care provider training plays an ever increasing role. However, limiting factors are the resources available to the indigent population and government hospitals equipped to provide these services. Organizations such as Heartbeat international are able to provide free hardware upon request to third world countries but the

numbers are minimal when compared to the overall needs.[1] Clearly pacemaker implant numbers will increase in developing countries as economic circumstances and medical facilities improve, whereas in developed countries the implant numbers will remain high, but stagnant.

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4.5 World ICD Surveys: A Review

Three world surveys on ICDs are reviewed; calendar years 2001, 2005 and 2009. These surveys were conducted with the same format and thus comparisons can be made. The number and the regions of the contributing countries are documented in Table 4.5.1. The 2009 world survey was the largest ever conducted with 60 contributing countries. In comparison to previous surveys, there were marked increases in the number of countries from Europe, the Asia Pacific and the Middle East/Africa.

Table 4.5.1 Contributing countries 2009 world ICD survey

	2001	2005	2009
Europe	14	14	25
Asia Pacific	16	13	20
Middle East/Africa	3	4	7
Americas	9	9	8
All contributors	**42**	**40**	**60**

For the 2009 ICD survey, Europe had 12 new contributing countries compared to the 2005 survey. The Asia Pacific region had seven new contributing countries and the survey probably accounted for 99% of all implants in the region with only Macau with two implanting centres failing to provide a report. All countries involved in the pacing and ICD surveys implanted ICDs. A number of Asian countries not involved with the 2009 ICD survey, including Cambodia, Laos, North Korea and Papua New Guinea were not believed to implant ICDs during 2009. The Middle East/Africa had four new countries and the Americas one new country. Only Bolivia which provided a pacemaker report, failed to provide information on ICDs.

Outside Europe, most countries and particularly the smaller implanting nations conducted hospital based surveys with demographic information. When an individual country survey involved too many implanting centres or was difficult or impossible to perform, an ICD company based survey was undertaken. This was the case for Australia and the United States of America with both surveys being undertaken by the author.

4.5.1 Initial ICD implants.

The three world ICD surveys; 2001, 2005 and 2009 involved 68 countries. The largest survey was 2009 with 60 countries. For Europe, 2009 survey details were not available for Georgia (provided in 2001) and Latvia (2001, 2005). For the Middle East, only the Emirates (2005) did not provide information for the 2009 survey. For the Americas, Canada (2001, 2005), Dominican Republic (2001), Ecuador (2001) and Panama (2001, 2005) did not provide information for the 2009 survey. The 2009 Asia Pacific survey was comprehensive with all previous countries participating.

The 2009 survey encompassed a total population of 5.05 billion people or 74% of the total world population (6.78 billion people in 2009). Of all the significant ICD implanting countries, only Canada was not represented, suggesting that probably over 90% of all the world's initial ICD implants were included.

For review of the world's initial ICD implants, 12 major implanting countries have been selected from thee zones:

Asia pacific; Australia, China, India and Japan.

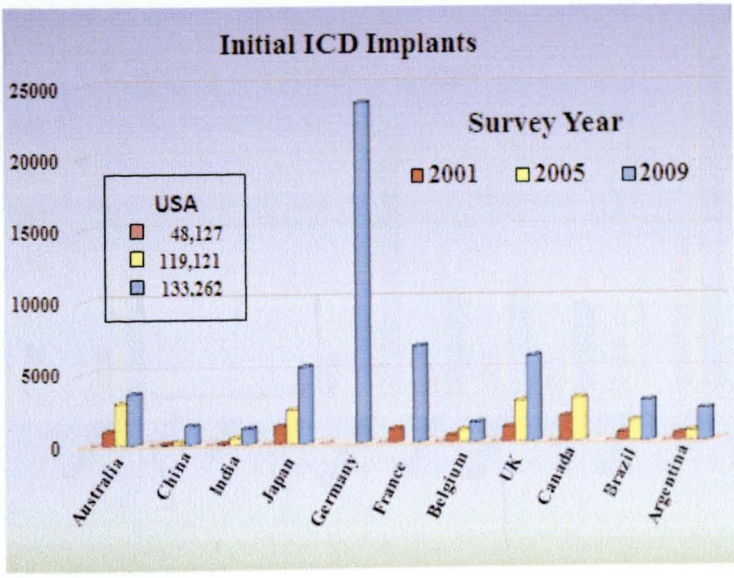
Europe; Germany, France, Belgium and the United Kingdom (UK).

The Americas; Canada, United States of America (USA), Brazil and Argentina.

The data has been divided into initial ICD implants (Figure 4.5.1) and initial ICD implants per million population (Figure 4.5.2).

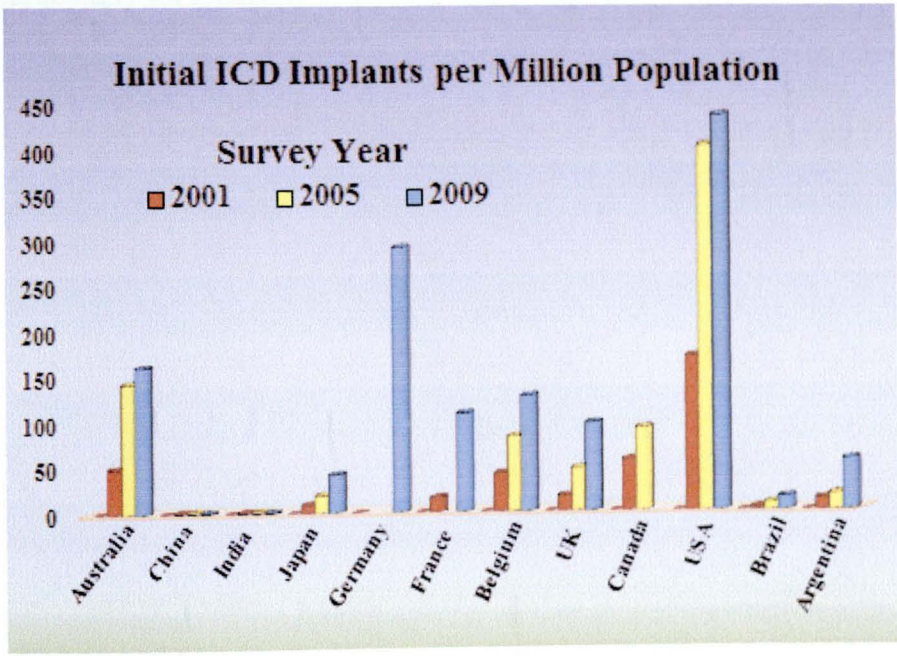
Unlike the more mature pacemaker market, ICDs have generally shown a more marked rise in implant numbers over the three ICD surveys. Not surprisingly, rapidly developing economies such as China, India and Brazil and Argentina have shown the largest relative increases (Figure 4.5.1). Japan also showed marked increases in ICD implant numbers over the three surveys, due to the strong regulatory policies which prevented meaningful implant numbers until midway through the first decade of the 21st century. The relatively slow uptake in ICD initial implants in the United Kingdom until the 2009 survey was probably mainly cost related. France did not provide implant data for the 2005 ICD survey, but the figures suggest there was a significant rise in the 2009 survey as well.

Figure 4.5.1 World ICD survey for calendar years 2001, 2005, and 2009: Initial ICD implants for 12 major implanting countries. Because the USA has such large implant numbers, the data cannot be displayed on the graph without minimizing data from all other countries. USA data is therefore presented in an insert.



For Australia, the initial implant numbers flattened between the 2005 and 2009 ICD surveys partially because of a major recall of the Medtronic Sprint Fidelis® (models 6930/6931/6949/6948) ICD leads between the two surveys due to a significant incidence of unexpected lead failures.[5-7] Failure of these ICD leads may result in inappropriate shocks and possible death. Unlike the high voltage generator, failure of the ICD lead is a serious operative procedure involving implanting a new lead and possible extraction of the old one. The same reason would have limited the USA ICD initial implant numbers, but despite this there was a substantial rise in initial ICD implants between the 2005 and 2009 surveys from 119,121 to 133,262 (Figure 4.5.1).

Figure 4.5.2 World ICD survey for calendar years 2001, 2005, and 2009: Initial ICD implants per million population for 12 major implanting countries.

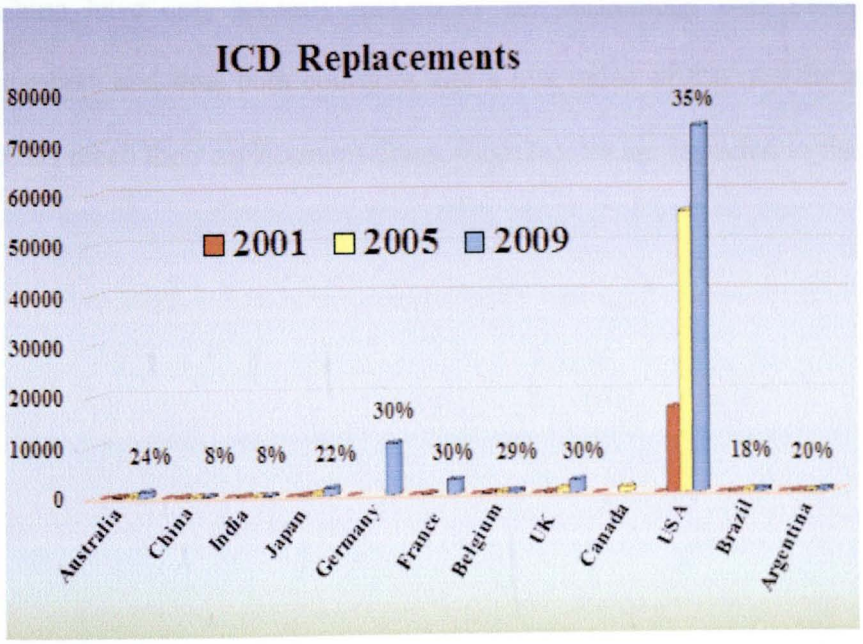


When the data was corrected for population, the USA with 434 new ICD implants per million population in 2009 had by far the highest initial implant ICD numbers, but the rise from the 2005 ICD survey was only modest, again reflecting the impact of the Medtronic Sprint Fidelis® recall (Figure 4.5.2). For the 2009 ICD survey, Germany had the next highest new implants per million population at 290, but the actual change from previous surveys was not possible as data is not available for the 2001 and 2005 ICD surveys. Other major implanters included the Netherlands (220), Italy (174), Denmark (173), Israel (167) followed by Australia (160). Of interest, a number of countries had marked increases of initial ICD implant numbers in the 2009 survey, but the actual initial implants per million population remain low. These include Japan (42), China (1) and India (1). Only Hong Kong had a fall in ICD initial implantations between the 2005 and 2009 surveys. A possible explanation lies with lead recalls that occurred during this period. Hong Kong implants only a small number of ICDs and concern with ICD lead failures could result in a number of implanting physicians reducing their implant numbers, particularly for relatively low risk primary implants.

4.5.2 ICD replacements.

Not surprisingly, the leading ICD replacement country was the United States of America with 73,217 units in 2009 (Figure 4.5.3). This was a rise of more than 17,000 units from the 2005 ICD survey (56,065). Germany had the next highest ICD replacement number (10,180) followed by Italy (4,438), France (2,880), United Kingdom (2,567), Netherlands (1,601), Japan (1,477), Spain (1,178) and Australia (1,111). In comparison, countries with recently established ICD implant services, particularly in Asia, had low replacement numbers; China (116), India (100), South Korea (65), Sri Lanka (0), Vietnam (0) and Bangladesh (0).

Figure 4.5.3 World ICD surveys for calendar years 2001, 2005, and 2009: ICD replacements for 12 major implanting countries.
(% = percentage replacements for total ICD implants, survey 2009).



Whether the rise in ICD replacement rates was small or large, it nevertheless has important economic consequences. Patients with implanted ICDs not only need to be followed regularly for testing, but hospital budgets must take into account that most of these patients will require ICD replacement in about six years or earlier if appropriate or inappropriate high voltage shocks occur. Although the ICD replacement burden in countries such as China and India is currently very low, nevertheless, these costs will rise exponentially as the recently implanted ICDs reach their elective replacement times. This must be taken into consideration when planning future CIED budgets.

One way of gauging the importance of ICD replacements is to calculate the percentage of ICD replacements compared to initial implants. Not surprisingly, the mature United States of America market was 35% and Australia a lower value of 24% with most of the other western countries lying between these two figures. Because of the delayed introduction of ICDs into Japan, the percentage of ICD replacements compared to new implants was relatively low at 22%. Both India and China have only recently introduced this technology with meaningful implant numbers and thus both countries had a low value of 8%. As the early implanted ICDs reach their replacement times, these figures are expected to rise.

4.5.3 ICD types.

There are currently three types of ICDs implanted; single chamber, dual chamber and biventricular. The single chamber models are essentially an ICD with programmable low rate ventricular pacing backup pacing (usually 40 ppm) when required. The dual chamber models are physiologic pacemakers for bradyarrhythmias coupled with an ICD. Biventricular ICDs pace three chambers; the right atrium, the left ventricle usually via the coronary sinus and the right ventricle via the shock lead. The system is used for CRT in patients with severe left ventricular dysfunction.

There is a wide distribution of ICD type usage throughout the world. In countries like Australia, the distribution is about a third of each type. In the United States of America, there are less of the single chamber models implanted and more of the dual chamber and biventricular designs. This is not surprising as the United States of America embraces new technologies very rapidly and is able to offer more complicated implants by rapidly training both established implanters and trainees. Pacemaker manufacturers in turn, are prepared to spend large amounts of money sponsoring symposia and courses to encourage this growth.

Accurate data is not available for many of the major implanting countries in Europe, but figures suggest there is a wide distribution of usage, even in neighboring countries. There are many reasons for this. Major factors include cost, the number of experienced and academic implanting centres and the skill, familiarity and interest of the implanters, particularly with biventricular implants.

Once again, as in the Unites States of America, the larger more affluent countries such as Germany, France and The United Kingdom have high numbers particularly of the biventricular ICDs.

Outside of Europe, the United States of America and Australia, the number of initial ICDs implanted may be so small, that the breakdown is meaningless. In India, Sri Lanka, Thailand, Bahrain and Uruguay the single chamber ICD predominated in the 2009 survey suggesting cost or maybe implanter experience was important. South Korea and Japan are two relatively affluent countries that like the United States of America rapidly embrace new technologies. However, their figures for biventricular ICDs are relatively low. There may be a number of reasons for this such as delayed training and prohibitive hardware costs, but the most likely explanation is the very slow regulatory processes that delay the introduction of new technologies into these countries.

An attempt was made for the first time in the 2009 ICD survey, to document the actual number of initial biventricular ICDs implanted in each country. An approximate figure could also be determined using the total number of initial ICD implants and percentage biventricular usage. Data was not available for Europe, but was available for all other countries except Bolivia. Obviously the United States of America headed the list with 49,255 initial biventricular ICD implants. Because no data were available from Europe, Japan was next with 2,009 implants followed by Australia with 1,519 implants. No other country had more than a thousand implants. Such data will be important in future ICD surveys as more implanters become comfortable with this complicated technology.

As in the Australian ICD survey, the subcutaneous defibrillator has not been considered. During 2009, implants were just commencing in selected centres in Europe and New Zealand. There were no meaningful implant data available, but it is anticipated that small numbers will be available for the 2013 World ICD survey.

4.5.4 Concluding remarks.

The world ICD market is very different to the pacemaker market. Most countries outside Australia, the United States of America and Europe are just commencing ICD programs and where there is appropriate resource allocation and trained implanters, the growth of implants has been exponential. Of the three types of ICDs the single chamber model is only used for antitachycardia overdrive pacing and high voltage shocks, whereas the dual chamber model will also support low voltage pacing in a dual chamber fashion. The biventricular model has all the features of the other two but will also provide cardiac resynchronization therapy. This is the most difficult to implant, is the most expensive and also is most likely to have implant and long-term complications. Initially, there was only the single chamber model, then the dual chamber and lastly the biventricular device.

In the developed world, the indications for each of these modalities have gradually developed, particularly with the assistance of clinical trials. Today, each type has about a 33% market share in most developed countries although the usage does depend on the ability of cardiologists to implant left ventricular leads and resource allocation. It is hard to envisage any significant future changes to this ratio, unless there are significant improvements in biventricular lead implantation and performance.

In the developing world, the ratio of usage is heavily dependent on the implanter training. The figures at times are skewed by the small numbers of implants. For instance in Bangladesh there was 58% usage of biventricular ICDs but only a total

of 12 ICDs were implanted in 2009 for the whole country almost certainly by one cardiologist able to implant left ventricular leads. Asia, South America and maybe Eastern Europe will provide the main growth over the next decade depending on the economic circumstances.

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Chapter 5: The World Survey of Cardiac Pacing and ICDs: Lessons Learnt

Reference:

Mond HG. The world survey of cardiac pacing and cardioverter-defibrillators: Lessons learnt. J Interventional Cardiac Electrophysiology. 2006; 17: 211-214.

The 2009 world survey of cardiac pacing and ICDs was an immense undertaking providing valuable information from 61 countries which encompassed 74% of the world's population and probably more than 80% of the world's initial CIED implants. Apart from Europe, the survey was successfully undertaken using a team of enthusiastic study coordinators both recruited and conducted via the internet. There was no budget and virtually no costs involved.

Such an undertaking presents many difficulties particularly in initial recruitment and reliance on coordinators and highlights the confines of working without funding. This chapter will review the lessons learnt from the surveys including the limitations on the information obtained and suggestions on the steps required to eventually develop a CIED registry.

Declaration for publications to be included in Thesis

Monash University

Declaration for

Mond HG: The world survey of cardiac pacing and cardioverter-defibrillators: Lessons learnt.

J Interventional Cardiac Electrophysiology. 2006; 17: 211-214.

Contributions to the work involved the following:

Name	% Contribution	Nature of Contribution
Mond Harry G	100%	Single author of review manuscript. No contribution by others.

Declaration by Author:

The undersigned hereby certify that:

1) He meets the criteria for authorship having participated in the conception, execution, or interpretation of the complete manuscript.
2) He accepts overall responsibility for the publication.
3) There are no other authors of the publication according to the criteria.
4) Potential conflicts of interest have been disclosed to granting bodies, the editor or publisher of the journal and the head of the responsible academic unit.
5) There is no original stored data.

Name	Signature	Date
Harry G Mond		

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The world survey of cardiac pacing and cardioverter-defibrillators: Lessons learnt

Harry G Mond

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Abstract A world-wide survey of cardiac pacing and implantable cardioverter-defibrillator (ICD) practices is held each 4 years. For the most recent survey held in 2001, 50 countries, 22 from Europe, 16 from the Asia Pacific region, 9 from the Americas and 3 from the Middle East and Africa participated. This was the first survey, where all countries completed a similar format allowing comparisons between countries. The European contribution came from the expanding European pacemaker registry. For countries outside Europe, the survey was based on a questionnaire completed by selected coordinators and conducted predominantly from hospital implants. In some large implanting countries such as the United States of America (USA) and Australia, the surveys were conducted using the sales figures of pacemaker and ICD companies. The major criticism of this method is the limited clinical information obtained. An alternative system would be an ongoing pacemaker and ICD registry in each country similar to the European model, which in the USA would be an expensive and logistical nightmare to organise and administer. With smaller implanting countries, the current system of a dedicated coordinator to conduct the hospital survey works well although there is still much recruiting work to do in Central America, the Middle East, Africa and to a lesser extent, South America.

Keywords Survey pacing ICDs

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1 Introduction

An ongoing responsibility of the International Cardiac Pacing and Electrophysiology Society (ICPES) is a world-wide quadrennial survey of cardiac pacing and implantable cardioverter-defibrillator (ICD) practices. This survey is conducted 2 years prior to the World Symposium on Cardiac Pacing and Electrophysiology. The World Survey on Cardiac Pacing and ICD practices was first conducted in 1972 (meeting in Groningen) [1]. Since then, surveys have been conducted for calendar years 1975 (Tokyo) [2], 1978 (Montreal) [3, 4], 1981(Vienna) [5], 1985 (Jerusalem) [6, 7], 1989 (Washington) [8], 1993 (Buenos Aires) [9], 1997 (Berlin) [10, 11, 12] and 2001 (Hong Kong) [13]. ICDs were included in the survey for the first time in 1993.

Once a country has been appointed to host the World Symposium meeting, the regional organizing committee had traditionally taken on the responsibility for conducting the pacing survey. As such meetings grew in size and complexity, the allocation of resources and time for the world survey was given low priority. There was no ongoing network of interested physicians or associated professionals established, nor was there an active recruitment of new countries. Not surprisingly, the surveys became smaller, with varying information collected from each participating country. The only exception to this was the European pacemaker registry, which was a coordinated effort to develop a patient identification card and from this collate data on pacing practices in participating countries. For all countries outside the European registry, the surveys depended on cooperative individuals who often varied from year to year and provided data whose accuracy could not be confirmed. Because the type and accuracy of data varied from survey to survey, no realistic comparison could be

undertaken. This prevented analysis of important trends such as evolving indications, pacing mode types and changes in hardware usage.

Despite this, government health administrators, hospital administrators, pacemaker manufacturers and implanting physicians have in recent years, become increasingly interested in pacemaker and ICD implant statistics. Being aware of this, the ICPES was eager to continue the World Surveys and appointed one of its board members to coordinate the ongoing surveys. No budget was allocated and the surveys outside the European pacemaker registry were conducted initially by post and fax and later entirely by e-mail. The last survey for the Hong Kong World Symposium held in 2003 was the largest ever undertaken and the results for the first time can be compared with data from the previous one in held in Berlin in 1999.

2 Historical foundations

The first world survey of cardiac pacing was held during the 4th International Symposium on Cardiac Pacing in Groningen, the Netherlands in April 1973 [1]. As a wide-eyed young pacing physician, it was my second international meeting and the first to include virtually all the pioneers of cardiac pacing. The meeting had one lecture room, no concurrent sessions and sixteen invited speakers presented data on surveys from 31 countries, generally spread over a number of years, but almost all included the year 1972. Such was the importance of the world survey, that it covered 40 pages of the published proceedings [1]. At this and subsequent symposia, the surveys have been collected, presented and published in the style of the individual country coordinators, which often was incomplete and frequently the data was extrapolated to hopefully encompass the whole country.

To create some order from this chaos, the European pacemaker registry was founded in 1978 by the late Drs. Bert Thalen, Giorgio Feruglio and Tony Rickards [14, 15, 16]. In close cooperation with the International Association of Medical Prosthesis Manufacturers, they developed the European Pacemaker Patient Identification Card. Details from these cards are registered with national registration centers that send aggregated annual data to the European Working Group on Cardiac Pacing, which in turn, is responsible for providing data for the quadrennial world survey. This data is comprehensive, meaningful, and new countries are recruited each year. For the 2001 World Survey, 22 countries contributed information compared to 18 countries, the survey before.

Until the 2001 survey, the United States of America (USA) conducted its own survey with little similarity to other countries, making comparisons difficult [1–4, 8, 11]. The *Remainder of the World* was divided into Asia Pacific, the Middle East, Africa, Canada, Central America and South America, which using an identical survey format allowed a single publication [10]. This survey was intentionally designed to be similar to the European model, thus for the first time providing a common format. Because of a lack of funding to perform the *old style* USA design, the 2001 survey took on the format identical to the rest of the world.

3 Survey format

During the 12th World Congress of Pacing and Electrophysiology held in Hong Kong in February 2003, the 2001 world survey of cardiac pacing and ICDs provided for the first time, a comprehensive survey of pacing and ICD practices in 50 countries [13].

The 2001 survey for most countries outside Europe was based on a questionnaire sent to coordinators who were selected contact physicians or associated professionals. The coordinators were encouraged to perform a comprehensive hospital survey for their country. An accurate number of pacemaker and ICD implants or at least units sold in the country were obligatory. These data were divided into new pacing and ICD systems and replacements. The number of implanting institutions in that country was also requested. The remaining information was collected in percentages. It was found that pacemaker and ICD implant centers often kept poor records and in these situations, the contact person found that pacemaker companies were very helpful in providing missing information.

In large implanting countries such as the USA and Australia, hospital surveys were not possible and therefore a separate questionnaire was designed for a cardiac pacing and ICD company survey. This was based on sales and registration figures of pacing and ICD hardware for calendar year 2001. Upon definition and agreement of the security procedures, designed to protect their individual figures, all companies selling pacing and ICD hardware in USA and Australia readily agreed to cooperate and contribute to the survey. The questionnaire carried no company identification and when completed was placed in a plain sealed envelope and sent in an identifiable envelope to the survey coordinator. Once all companies represented in that country had returned the questionnaire, the outer envelopes were opened and the plain sealed envelopes removed and given a work number. The information was transcribed to a working sheet followed by shredding of the individual forms and all working sheets immediately after the data were collated and placed onto the final data sheet. There remained no evidence of individual company figures. This style of survey was limited to data that companies

could provide on hardware sales. Thus, it was not the intention to collect data on indications for initial implant, sex and mean age of recipients. Despite this limitation, important and accurate implant data was obtained which could be compared to other countries or further surveys.

4 Survey limitations

The major criticism of the present survey format is the limited information obtained. Clinical information is lacking in a number of large implanting countries, where the survey is conducted with the assistance of pacemaker companies. In Australia and the USA, the total survey was obtained by one person who was totally reliant on all the pacemaker companies to provide the requested information. Although very inexpensive, the system is nevertheless, very fragile as non-cooperation by only one company will result in a failed survey for that country. Although all pacemaker and ICD companies were obliging for the 2001 survey, this may not occur in the future.

An alternative system to the company sales figures would be an ongoing pacemaker and ICD registry in each country similar to that conducted in Europe. In large implanting countries, where implants occur in hundreds and maybe thousands of hospitals, such a system would be expensive and probably impossible to police. It would require full cooperation from pacing companies, implanting physicians and hospitals. Registries, however, would have other important functions such as assisting in hardware recalls or gauging implanting trends within countries to assist in economic planning and budget preparation. The European model was commenced over 25-years ago in a small number of countries, at a time when implant numbers were tiny. As acceptance grew, so did the registry, encouraging other countries to join, particularly those in Eastern Europe. In comparison, a registry in the USA, with about 250,000 new pacemaker implants per year, would be a logistical nightmare to organise and administer. The prohibitive costs of such a registry would necessitate ongoing government funding. In some countries, because of privacy laws, the collection of personal data without appropriate permission may require legislative changes.

With smaller implanting countries, the current system of a dedicated coordinator to conduct the hospital survey works well. However, not all the coordinators provided reports and when this happens; there is usually not enough time to recruit another coordinator. For example, in the Asia Pacific region, 19 countries implanted pacemakers at the time of the 2001 survey. Only three small implanting countries failed to provide a report. Thus, well over 95% of the implants in the region were covered. There is still much work to do in Central America, the Middle East, Africa and to a lesser extent South America. Recruitment of survey coordinators, able to perform national surveys remains a challenge.

Another limitation and criticism of the current survey process is the accuracy of the data presented. On occasion, particularly with earlier surveys, the received published figures were later reported by others to be incorrect and usually only covered the major centers or a region. Hopefully this has now been rectified. However, as individual country implants increase, such surveys will become harder to conduct. In most countries outside Europe, the USA and Australasia, pacing and ICD companies are often represented by agents. Such companies are secretive with their sales and even the parent pacing companies have no knowledge as to the sales in an individual country as the agent may sell in two or more countries. A country coordinator in a specific country trying to obtain information from agents may have influence with only one or maybe two agents and therefore receive confusing and incomplete data.

5 Future challenges

The forthcoming 13th World Congress of Cardiac Pacing and Electrophysiology to be held in Rome, Italy in December 2007 is planned to be the last world congress. Although a world survey is tentatively planned for calendar year 2005, there are no plans to continue the surveys beyond that. There will be no organization to oversee and take responsibility for conducting the surveys, no forum to present the findings, and therefore fewer incentives for coordinators and pacing and ICD companies to cooperate. Apart from Europe, the conduction of the surveys is currently built on a flimsy platform of enthusiasm only.

Despite this, the 2001 survey was the largest undertaken and the first to be published in a single manuscript using a common format. The international response has been good particularly from pacing and ICD companies. The European model remains solid. It behoves us to develop a similar structure for the rest of the world. This will require funding, but most of all, a benevolent sponsor within the pacing and ICD fraternity to support the work and provide credibility.

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5.1 Introduction.

The 2001, 2005 and 2009 world surveys of cardiac pacing and ICDs were massive undertakings performed via emails and at least from the author's perspective, there were no costs involved. For the 2009 survey, 61 countries provided reports. There were 24 countries from Europe using questionnaires sent out by the European Heart Rhythm Association to national registration centres and coordinated by Dr Alessandro Proclemer of Udine Italy. The remaining 37 countries which also included Malta were directly responsible to the author and involved a simple, yet comprehensive survey form (Chapter 2; pages 80-82).

For the non-European surveys, the form could be completed by a comprehensive hospital survey, which included clinical and demographic data. This was the case with most countries in the Asia Pacific region, Africa, the Middle East and the Americas. Exceptions were the United States of America and Australia. In this situation, survey forms were sent by the author to all pacemaker manufacturers/distributors and CIED hardware sold (pacemakers) or implanted (ICDs) were then determined. For both countries, the author was responsible for the creation and distribution or the survey forms and for the collection and collation of data. Where necessary, a combination of hospital and manufacturers was also used. Once completed all the country surveys were emailed to the author.

5.1.1 Lessons learnt: Historical foundations.

The historic foundations of the world survey of cardiac pacing were laid in 1972 in preparation for the 4th International Symposium on Cardiac Pacing, held in Groningen, The Netherlands in 1973.[1] The author was responsible for collecting the Australian data and at that time, there were only small numbers of pacemakers implanted in Australia and even then it was difficult to obtain implant figures from all centres. Subsequent to the Groningen meeting, Australian pacing and later ICD surveys were conducted prior to all World Symposia with the author either being involved or responsible.[2-9] As the World Symposia grew in complexity, the organization of the surveys deteriorated and thus for the 1997 world pacing and ICD survey, the author took on the challenge of organizing a meaningful survey, where data between countries could be compared. The United States of America, however, remained an obstacle preparing a report which was not comparative nor meaningful,[10] whereas Europe and the rest of the world prepared similar reports with the author recruiting by email a team of coordinators outside Europe willing to prepare local pacemaker and ICD surveys.[11,12]

For the 2001 world survey of pacing and ICDs, the organizers of the United States of America survey requested funding which was not forthcoming and thus the author agreed to prepare a United States of America report using the assistance of the pacemaker companies.[13] The aim was to provide sales and registration figures for CIED hardware. This became a formidable challenge as every pacemaker company initially refused to provide such proprietary data. After protracted negotiations and the creation and preparation of strict security arrangements that

had already been put into place for the similar Australian pacing and ICD survey, the companies finally agreed to cooperate. From this initial 2001 report, grew the 2005 and 2009 world surveys.

Over the last 40-years, the world survey of cardiac pacing and ICDs has taken a long protracted course, initially involving small numbers of countries all providing different information to the relatively sophisticated coordinated surveys prepared by Mond and Proclemer. The foundations have now been set and the surveys are ready to advance to the next stage.

5.1.2 Lessons learnt: Survey format.

The format of the international pacing and ICD surveys was created with the intention to obtain the maximum return. There were only a few absolute numbers required and the local coordinators were specifically asked that these be as accurate as possible. These included the number of new and replacement pacemakers and ICDs implanted. Most of the remainder of the surveys required percentage usage such as clinical indications, types of low and high voltage generators and leads used. Age breakdown, when possible, was also required. The result was an insight into important trends both internationally and nationally involving indications, pacing and ICD types and most important changes in CIED hardware usage.

Although all this information is helpful for budget planning, the questions often asked by government health bureaucrats, hospital administrators, pacemaker manufacturers and implanting physicians are outcome results which are clearly outside the boundaries of this type of "internet" survey format.

5.1.3 Lessons learnt: Survey limitations.

A major advance in the pacing and ICD surveys presented in this dissertation has been the development of a single survey format for all countries, thus allowing comparisons between countries and previous surveys. The system developed for the three surveys required no funding outside Europe and there was an almost universal response in the Asia Pacific region. Despite the cost advantages and the simplicity of its structure there are, however, significant limitations and fragility with such a survey format:

- With a CIED company dependent format, there are no clinical and demographic information obtained. Only a single company rejection was required to completely invalidate a country report. Indeed, because of in-house legal opposition, a number of companies refused to provide information for the United States of America survey and only by persistent emailing at higher and higher levels within the companies was permission eventually obtained from all manufacturers. Such objections occurred with different companies for all the surveys, suggesting that it may recur in any future survey.

- Not all CIED companies sell directly in countries. There may be an agent or distributor who sells directly to hospitals, physicians or patients and in general these agents are very reluctant to shares sales information even with the parent company. In some situations as in South America, the agent sells in more than one country and individual country sales may be impossible to

determine. In other situations such as Japan, a single agent may sell two or more different company products to the same hospital. These differences create obstacles to a wider usage of company sales figures.

- Another concern is with the designated survey coordinators. These are predominantly busy implanting physicians recruited to obtain survey data in their country. They require cooperation from their colleagues and thus the results may not always be accurate. There is no way of verifying the accuracy of data from these sources.

- Ideally, a worldwide ongoing CIED registry similar to Europe would be necessary for a comprehensive international survey. This would obviate the need to recruit coordinators to perform the country surveys. Coordinator recruitment can be a very frustrating exercise. In general, the response to emails is poor and unpredictable. Probably 2,000 emails were sent for the 2009 world survey. Despite this, persistence and continual searching for coordinators eventually paid off with a record 61 countries for the 2009 survey. Only in Canada, Macau and a number of Middle Eastern, South American and African countries was recruitment unsuccessful. An enthusiastic coordinator was recruited for Mexico, but a report was not possible after he was threatened with legal action if he incorporated data from a major implanting hospital which only implanted single chamber models.

- Although a worldwide registry is desirable, in many countries such as the United States of America, Japan and India this would be almost impossible to organize and a logistical nightmare to manage. These countries have thousands of implanters with very few interested in surveys and registries. Many would regard this as interference in their implanting practices. On the other hand, China is developing a sophisticated registry model that only a country with tight central control can attempt and this may theoretically be the registry model for other countries to try and adopt in the future. Such a registry has many advantages and in particular assisting CIED hardware recalls and gauging implanting trends to assist in economic planning and budget preparation.

- The cost of a sophisticated registry may well be prohibitive. It would necessitate ongoing funding probably from a Government source or maybe private health funds and in many countries because of privacy laws, the collection of personal data without appropriate permission may well require legislative changes.

- Even the European registry model had its limitations. Although there are a significant number of contributing countries, not all European countries are involved. Once registered, not all countries provided information and many failed to complete all the required questions. Only one country, Denmark, a small CIED implanting nation, conducts a comprehensive survey each year. The largest implanter, Germany, failed to provide a report for the 2005

survey. It was only by the persistence that Dr Alessandro Proclemer was able to obtain 24 reports from Europe.

- Although the costs of a sophisticated registry may be prohibitive, both government and private medical funds remain interested, provided there are also indications and outcomes in the registry to help determine correct CIED usage, complications and device and clinical efficacy. This is particularly so with biventricular devices and ICDs which are very expensive and their correct usage remains controversial, the complications high and in some situations, outcomes are not the same as in the reported literature.

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Chapter 6: The World Survey of Cardiac Pacing and ICDs: Future Considerations.

The world survey of cardiac pacing and ICDs is a major undertaking conducted using the internet and outside Europe is not dependent on funding. By standardizing the survey format, the results are now able to be compared between countries as well as the trends between surveys in individual countries. With the ever increasing demands of Government bureaucrats, hospital administrators and private health fund managers for local, national and international information on trends in CIED usage, such information is invaluable although in its current format is limited. More clinical information is required and above all clinical outcomes, justifying a considerable expenditure in the future.

It is inevitable that changes in surveys will occur to incorporate clinical and outcomes data. The changes, particularly in Australia, will require significant financial investment by interested bodies. An organization and committee(s) must be established to determine the aims, the information required, the impediments to achieving these aims and in particular, the legal obstacles to be encountered, such as privacy issues in collecting data. There will also be hospital and physician resistance as the outcome results may reveal unflattering results or inappropriate usage of devices for unproven indications. Hospital will find it expensive to fund such exercises and will insist on separate funding for staff to undertake and complete the ongoing registry requirements.

6.1 Australian Experiences with Clinical Registries

As of 2009, there were 28 registries in Australia collecting and analysing medical information in order to monitor the quality of care received by patients.[1] They ranged from cancer, burns, organ transplantation, intensive care, bleeding disorders, infections, trauma and a wide range of organ specialties including cardiovascular, gastrointestinal, orthopaedic, rheumatology and neurology. The common goal of the multi-site registries was to monitor clinical outcomes, improve quality of medical care and reduce the frequency of adverse events. Much of this routine quality measurement is new to Australia, but now that the importance of this information has been recognised, there have been recent federal government initiatives and policy changes committed to providing appropriate reporting of performance data.[2,3]

A notable example of a demonstrable impact on improving aspects of service delivery is the data collected by the Australian Joint Replacement Registry. The registry entirely funded by Australian Government, monitors the outcomes of all joint replacement procedures undertaken in Australia. It is an initiative of the Australian Orthopaedic Association and was established in 1999 and fully implemented nationally in 2002. Such a comprehensive registry requires the collaboration between orthopaedic surgeons, government, all private and public hospitals undertaking joint replacement surgery and the orthopaedic industry. Its outcomes objective is to improve the results of all joint replacement surgery. It has been estimated that that the registry has already been responsible for a reduction of

1,200 operative revisions a year with a cost saving of 16 to 32 million dollars a year. The benefits to patients are obvious.[4]

Equally obvious would be the similarities of a registry monitoring the outcomes of all CIED implants in Australia. Whereas the cost of implanted orthopaedic devices represents 35% of total expenditure for the procedure, it would be anticipated that CIEDs are significantly more expensive than their orthopaedic counterparts and therefore a potentially greater cost saving per unit implanted to the Government and private health providers. Both implant groups are predominantly the elderly whose numbers are growing, although the orthopaedic surgical numbers are expected to rise at a greater rate than for CIEDs. The reduction in orthopaedic revision rates is now better than most countries with the exception of Sweden which has had orthopaedic registries for over 30-years.[4] Of interest the orthopaedic registry remains one of the most valued and internationally renowned registries and provides information on a regular basis to international organizations such as the United States Food and Drug Administration under contractual agreements.

What about Australian cardiac procedures and cardiothoracic registries. The first attempt at a cardiac registry was the National Registry of Cardiac Surgical Procedures sponsored by the National Heart Foundation in 1962 at the dawn of this specialty and was a rudimentary attempt to collect surgical data. This initiative was the first of its kind to be established in the world, but it essentially failed as the number of cases increased dramatically and poor submission of annual returns.[5] In 1980, a national register of coronary angioplasty was established and it to suffered the same problems as the cardiac surgical initiative in that there was a poor hospital

response and little worthwhile long-term or outcomes data. The last report was in 2003. In 2001, there was a call for a National Cardiac Procedures Database resulting in an attempt to establish a unified, systematic approach to data collection with both cardiac surgery and interventional cardiology.[6] Two registries were eventually established: The Australian Society of Cardiac and Thoracic Surgeons and the Melbourne Interventional Group.

The impetus for the cardiac surgical database followed identification of major misclassification of outcomes from existing data requiring the development of a standardized data definition set so as to allow appropriate comparison of data for performance indicators locally, nationally and with international benchmarks. Initially a Victorian initiative, it is now national and encompasses public hospitals performing cardiac surgery.

The Melbourne Interventional Group is a percutaneous coronary intervention registry founded in 2004 to again overcome the somewhat fragmented collection of this data.[7] The registry which follows a number of current international databases, has been found to be useful tool in examining short- and long-term success. It was envisaged that these two registries be integrated to create a nationwide cardiac procedures database. In the meantime, two very small pilot studies have been undertaken under the banner of the Australian Cardiac Procedures Registry. The first was to validate and test the proposed technical standards for coronary intervention and the second was for CIEDs; ICDs and biventricular devices.

This ongoing initiative is the Victorian Cardiac Outcomes Registry which is a project of Monash University in conjunction with Victorian Cardiac Clinical Network. It is envisioned that this registry will incorporate coronary intervention, percutaneous valve implantation and CIEDs. There is currently funding from Medibank Private Health Fund and the Victorian Department of Health. The objective is to develop and maintain a secure online data collection tool and storage mechanism to provide the database for related analysis and reporting. The registry will measure the success of relevant treatments and procedures performed on patients in Victorian hospitals. It will do this by capturing data about patient demographics, symptoms, clinical presentation and diagnosis and the treatments they receive and related clinical outcomes. The first module of the Victorian Cardiac Outcomes Registry involves percutaneous coronary intervention with planning underway for the CIED module.

6.2 The Case for a CIED Registry

Unlike many areas of modern medical treatment, pacemaker therapy is not necessarily based on evidence based medicine. The original indications for pacemaker implantation were for profound often fatal cardiac bradyarrhythmias necessitating urgent surgery often under the cover of a temporary pacing wire. The results were outstanding and life saving, but until the late 1970's, the incidence of complications were high. There were no significant trials of pacing efficacy at least for major indications. The few trials undertaken were for minor indications including neurocardiogenic syncope and obstructive cardiomyopathy, but in general these trials were not appropriately designed nor conducted and thus the results were equivocal and without evidence based medicine, the widespread use of pacing for these indications fell into disrepute.[8]

With the development of dual chamber pacing, a number of trials as to the value of dual chamber over single chamber pacing once again provided conflicting results particularly in the elderly.[8] Recently, the somewhat incidental finding that long term right ventricular apical pacing may lead to left ventricular dysfunction because of the dysynchronous depolarization of the ventricles, has lead to the development of methods to either minimize ventricular pacing or pace the right ventricle from alternate sites.[9] Trials to determine if these alternate sites are physiologically superior are currently underway.[10]

Overall therefore, clinical trials to determine the efficacy of cardiac pacing have not been particularly helpful in establishing guidelines for this therapy. Despite this, there are clear international guidelines as to the appropriate use of cardiac pacing in patients with standard indications for this therapy.[8] All the recognised indications are covered and whenever possible, evidence based.

The classification recognises three classes:

- *Class I:* There is evidence and/or general agreement that cardiac pacing is useful and effective.
- *Class II:* There is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of cardiac pacing. Consequently two sub groups are described:

  Class IIa: Weight of evidence/opinion in favour of cardiac pacing.

  Class IIb: Usefulness/efficacy of cardiac pacing less well established.
- *Class III:* Cardiac pacing not useful/effective or may be harmful.

Within each class, there are three levels of evidence:

A) Data derived from multiple randomized large clinical trials.

B) Data derived from a limited number of trials, either small or well designed data analyses of non randomized studies or observational data registries.

C) Consensus of experts.

In practice, the guidelines for cardiac pacing have been very helpful with only minor areas of controversy and thus the implanting physician or surgeon should be comfortable making a decision in the vast majority of patients. Despite these guidelines, there are a number of instances where pacemakers may be are recommended in patients on the basis of electrocardiographic findings in the absence of symptoms or conversely symptoms without electrocardiographic abnormalities. Obviously outcomes data would be very helpful in these instances.

Unlike cardiac pacing, CRT and ICD usage are more modern therapeutic modalities whose acceptance and usage have been dictated by large randomized clinical trials.[1] However, the indications for both CRT and ICD have many grey areas and the value of the therapy remains cloudy in certain instances such as ICD therapy for non-classical forms of Brugada syndrome or CRT in patients without a left bundle branch block.

CIED therapy is expensive and because a proportion of the hardware needs to be implanted intracardiac, the treatment is not without serious complications. A simple survey of its use, albeit helpful, probably raises more questions than the survey answers and therefore a registry with outcomes is a preferable option.

6.3 Remote Follow Up and Monitoring

One of the concerns in the development of a registry with outcomes is patient cooperation and in particular attending or communicating with personnel responsible for collecting the data. With CIED follow-up and testing, there is a well defined protocol usually requiring hospital or physician visits. Provided the registry requirements are in concert with regular follow-up, then the added registry burden can be incorporated into the same visit.

A major advancement in CIED follow-up is the recent development of remote follow-up capabilities, now available from all CIED manufacturers and distributors in Australia. Remote wireless ambulatory follow-up of pacemakers, ICDs and CRT devices can now be automatically obtained at any time outside the pacemaker clinic. The equipment supplied to the patient is used at home to transmit regular follow-up data, normally obtained by visits to the physician's office or pacemaker clinic. This is ideal for patients who live in remote rural areas with poor access to hospitals and also for infirm patients or those that travel frequently either nationally or internationally.

However, a much more important function of such equipment is remote monitoring based on the premise that in order to save lives, we need to be able to immediately diagnose issues in patients with CIEDs that may adversely affect outcomes. Such issues involve:

- *Hardware:* Include lead problems and in particular ICD leads, power source end of life and the occasional isolated electronic circuit failure.

- *Software:* Include inappropriate programming and warnings such as high pacing thresholds and impedances outside the normal range.
- *Clinical:* Include percentage ventricular pacing for CRT and transthoracic impedance measurements for documentation of congestive cardiac failure.
- *Arrhythmias:* Include documentation of atrial fibrillation and ventricular tachyarrhythmias.

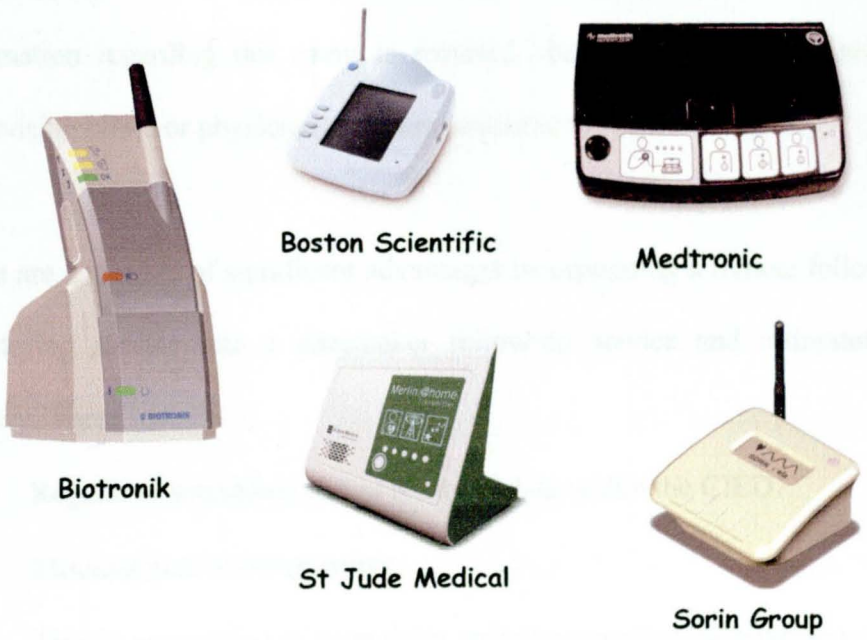
Such remote monitoring is important in the documentation and transmission of critical abnormalities, the correction of which may be life saving. However, once diagnosed, any changes to the programming cannot be performed remotely and the patient will need to attend the physician's rooms or pacemaker clinic for ongoing treatment or intervention. Obviously in urgent situations, there may be need attend or be admitted to a hospital.

The equipment used at the patient end is referred to as a "home monitor" and unique to each company. It must be supplied or purchased from the manufacturers (Figure 6.1). Collection of data by the monitor can be automatic or patient activated. The information collected and stored as memory in the CIED can be downloaded by open wireless technology (Bluetooth) to the monitor often sitting next to the bed and transferred to a central receiving site, which may be a private agency, hospital or physician.

For remote follow-up, this can be on a scheduled regular basis. For remote monitoring, there can also be scheduled transfer of data or if an abnormality is detected outside the preset programmed boundaries, then there is an urgent alert to

the receiving service and then an automatic flagging of alerts to all responsible personnel which may be in the form of a facsimile, email or small message service. The responsible personnel may be alerted even before the patient recognises a problem. In other situations, the patient may trigger the event because of symptoms such as palpitations, syncope or the discharge of an ICD.

Figure 6.1 Home monitors from the five CIED manufacturers which remotely collect data from implanted hardware and transmit the data to a central collection site.



It is now also possible to link appropriate clinical data not directly involved with the CIED into the scheduled or urgent transmission. Ancillary communicating hardware and software has been developed to complement the transmission. This

includes weighing scales and automatic blood pressure recorders which automatically link to the remote monitors by open wireless technology. This ancillary hardware can be used with the implanted CRT device to predict episodes of left ventricular failure prior to the patient developing symptoms.

At this stage it is hard to predict how much of this remotely transmitted CIED memory would be helpful in a registry. Routine follow-up data would indicate that the patient's CIED was functioning satisfactorily. Remote monitoring, however, could detect an abnormal function of the implanted device or a clinical abnormality which could then be recorded in the patient's CIED clinic or physician's file and where appropriate, classified for outcome purposes as an adverse event. If more information regarding this event is required, then this can be obtained by the supervising clinic or physician and communicated to the CIED registry.

There are a number of significant advantages incorporating a remote follow-up and monitoring service into a pacemaker follow-up service and ultimately into a registry. These include:

- Regular or scheduled access to stored data within the CIED.
- Minimal patient involvement.
- Timely recognition of potentially serious asymptomatic adverse events.

Remote monitoring, however, requires company specific and potentially expensive hardware and currently is only used for follow-up and monitoring. The remote equipment is provided to the patient and either the patient or responsible carers need to trained in the correct use and maintenance of the transmitters. Although the

primary purpose is follow up and monitoring, the equipment does have the potential for research and registry purposes.

The question is who pays for this equipment?

This can be summarized as the:

- Implanting hospital (public system) which purchases the implanted hardware and the remote monitors as a package in the State Government health tender for CIEDs.
- Private health insurance which incorporates the remote monitors in the purchase price of the implanted hardware.
- Patient.
- Device manufacturers.
- Research trials or registry requirements.

Currently, the use of remote follow-up is limited to specific situations specifically those patients with limited access to a pacemaker clinic. In reality, the indications for remote monitoring are very broad and defined by the interests of a number of groups including physicians, implanting hospitals, follow-up clinics, CIED companies and patients. Currently, until its usage is better defined, the companies have provided monitors free of charge to selected patients particularly for monitoring of recall implanted hardware such as ICD leads.

At the other end of the transmitted CIED data is the collection or service centre. The structure and function of these centres remains very variable. In order to familiarize physicians and follow-up centres on the value of remote monitoring and

follow-up, most of the CIED manufacturers have taken on the onerous task of establishing these service centres at their expense. However, as the numbers of patients increase the costs of running such centres will escalate to a point where a free service will no longer be financially viable.

The establishment of remote monitoring and follow-up services again reflects the interest of physicians, implanting hospitals, follow-up clinics, CIED companies and private enterprise. Again someone must pay for the running of the clinic. The service must maintain a constant link to the patient, albeit remotely, but also communicate routinely and urgently if necessary. The service centre needs to be responsible for the correct function of the equipment and provide medical advice to the patient when necessary. Collected data must be screened for potentially or obvious abnormalities and be able to forward on the information to the responsible physicians or other staff.

At this stage most of the cost of running a centralized follow-up and monitoring service lies with the CIED companies. With modern cell phone technology, the information can be transmitted instantly anywhere in the world. Eventually, however, pacing clinics or private enterprise will be required to take on the task. Although each company has its own proprietary software and hardware, there is the need for a universal software program to encompass all the companies' data in a common format. This same software program can be in a central office or licensed to a physician's office or pacemaker clinic, where different company's products are tested.

6.4 Storage and Presentation of Data

The storage and presentation of a CIED report to a universal software program represents a mammoth undertaking. The software required must be flexible to collect all the required data. It also must be able to recognise all pacemaker manufacturers' software programming. The objective is to download programmer or remote monitor data from all CIED manufacturers and convert it to a common format.

Currently, CIED clinics collect vast amounts of information which may or may not be transferred to a computer program. In reality, such computer programs are primitive and difficult to manage. They may be company specific allowing only one company's information to be stored appropriately. Despite these limitations, individual CIED testing and remote follow-up can now be transferred to an appropriate computer program for storage and retrieval.

The challenge is to develop a single product which can recognise and store all CIED company's products. This massive undertaking requires the establishment of a single "independent" company to develop appropriate software for information storage in a common format. Once developed, the CIED companies must provide sensitive software information on all their products in order to allow an interface with the designed software. All CIED companies have developed their own "clinic" structures for collection of remotely transmitted information and a number have also developed software for routine CIED clinics which may be able to file all company's testing, but allow their own products to be stored and retrieved more

elegantly. These companies are clearly resistant to sharing sensitive information with an independent company.

It is not difficult to visualize the clinical benefit of a common storage and retrieval format for patient care, product recall notifications, clinical research and above all the development of a common registry system which encompasses all CIED products being implanted.

Such a universal software product to store CIED implantations and follow-up testing and surveillance was released in May of 2011 and is able to work with CIEDs manufactured by St Jude Medical, Boston Scientific, Medtronic and Biotronik with negotiations currently underway to also incorporate the Sorin Group. This is the *ScottCare One View™ CRM*, manufactured by ScottCare in Cleveland Ohio. All CIED products sold and implanted in Australia can potentially interface with the software. It has been designed to consolidate discrete data from all manufacturers including implantation, clinic or physician visits and remote follow-up and monitoring. The application is web-accessible and thus can be accessed from any computer, iPad or Smart phone. It allows for data analysis and is ideal as a tool for a sophisticated CIED registry. It has been designed to act as a local, national or even international database that would allow and assist in collecting registry data as well as outcomes data to assist hospital and Government bureaucrats make informed decisions on better health care and also allow immediate investigation and management of CIED product recalls.

6.5 Development of an Australian Registry

Australia is a perfect country model to develop a sophisticated registry system. In Australia, CIED implantation services are sophisticated with hospitals well equipped and cardiac electrophysiology training programs usually excellent. There are a small number of States with a mixture of wide reaching indirectly federally funded public hospitals and private hospitals. As shown in the 2009 survey, there were 117 pacemaker implanting centres in Australia with a mean of 113 new pacemaker implants per centre. Such numbers are workable within a registry say compared to Japan where there are more than 2,300 pacemaker implanting centres with a mean of 15 new pacemaker implants per centre. The world surveys omitted to request the number of ICD implanting centres, but for Australia this figure is about 101 centres and thus the new ICD implants per centre is 46 which for the smaller ICD market is excellent for registry purposes.

The appropriate software for collection of registry data can reside at a physician or hospital level with automatic download links to a State or National databank. At the Federal Government level, it can also be linked to the National Death Index database maintained by the Australian Institute of Health and Welfare in Canberra. This database is a listing of all the deaths in Australia and is an invaluable tool for such a registry. Another endeavour of the Australian Institute of Health and Welfare is the National Hospital Morbidity Database and is a collection of the electronic summary records for separations in Australia. The database collects hospital admission diagnoses and procedures and once again would be invaluable for the collection of adverse event data.

How could a national universal register be established? It would require the cooperation of every CIED implanting hospital and every implanter in Australia. This is obviously a joint State and Commonwealth Government initiative which would require that all CIED implants be registered before hospital payments are processed. For the private sector, Commonwealth and Health Fund payments to patients, doctors and hospitals would also depend on patient registration. It is even possible that credentialing of implanters could be linked to participation in registries.

The role and responsibility of the CIED hardware manufacturer or distributor must also be defined. As part of their own internal registration, all implanted CIED hardware could be downloaded into the central registry, particularly to confirm the CIED implantation and product used. It would be anticipated that all these options would be highly controversial with intense vocal resistance at all levels. As always, a financial sweetener would be necessary to overcome resistance.

Another important aspect of a comprehensive national registry is who has access to the information? One can envisage all the potential levels of interest including State and Federal Government bodies, private health funds, hospital bureaucrats, physicians, pacemaker companies, researchers, international investors, legal bodies, and maybe patients. How much information will be available to these groups? For instance private health funds will be interested in inappropriate implants, regional differences in Australia and outcomes. If sufficient information is forthcoming, then such bodies may be interested in partnering the project with the Federal Government.

Because of the interest of such diverse groups with their own particular interests, the creation of registry datasets will be a critical issue in the development of the service. The simple part is the creation of key fields common to the surveys already presented. The next step, however, will be critical as it requires a number of difficult, sensitive information

6.6 Development of the Universal Registry

Historically, there has been surprisingly little work on the development of international registries for cardiac pacing and ICDs. Despite this, many countries have attempted to develop a national pacemaker registry, but these have been generally incomplete, short-lived and have provided no more information than the surveys presented in this dissertation.

The first call for a pacemaker registry in the United States of America was in 1974. At the behest and funding of the Food and Drug Administration, three implanting institutions were funded to create a registry of their practices.[11,12] The registry was funded until 1981, but continued later self funded and involving five implanting institutions. Later the registry also included anti-tachycardia pacemakers and ICDs. The data were published initially every month in the journal Pacing and Clinical Electrophysiology and although only five large implanting institutions were involved, it nevertheless represented a window into the pacing and ICD practices in the United States of America and documented the historic and profound developmental changes that were occurring in the industry at that time. Of particular importance were the documentation and publication of pulse generator longevity and premature hardware failure. Its founder and principal driving force, Dr. Michael Bilitch died in 1987 and the core group continued without funding until 1993.[12]

The 1980's also represented a time when implantable anti-tachycardia pulse generators were being marketed and there was concern as to their efficacy and

safety. Although a strong argument was made for a national anti-tachycardia pacemaker registry,[13] it never eventuated as these pacemakers were soon to be replaced by curative ablative electrophysiological procedures and later still, ICDs. The United States of America always provided a report for the World Surveys, but these surveys were the results of questionnaires sent to a select group of physicians. This was the case with the first survey presented at the International Symposium on Cardiac Pacing in Groningen, The Netherlands in 1973. This partially company sponsored survey, which also involved Canada, was sent to 647 physicians with 176 responses (27%). The survey was not year related and involved 87 questions.[14]

Further reports followed for each World Symposium and the surveys remained small and selective with participating physicians mainly in the New Jersey area.[15] The authors commented on how difficult it was to conduct the surveys and many of the findings regarding patient care were disturbing to the authors. The conclusion of the 1985 report was the recommendation that a comprehensive national pacemaker registry be developed in the United States of America.[15]

Taking this on board, the United States Department of Health and Human Services in July 1987, issued a statement on behalf of the Food and Drug Administration and the Health Care Financing Administration regarding the establishment of a national pacemaker registry as required by the Deficit Reduction Act (DEFRA Public Act 98-369) of 1984.[16] The final rule required that certain information be submitted to the Food and Drug Administration by physicians and providers of service requesting or receiving Medicare payments for the implantation, removal or replacement of permanent cardiac pacemaker devices and leads. This information

was then to be included in a registry. Failure to provide this information would result in non-payment for the services. The registry would then be used to track the performance of cardiac pacemakers including leads and to perform studies and analysis regarding the use of the devices. In November 1999, the Act was repealed as unnecessary in order to eliminate duplicative medical device reporting.[17] The responsibility to track implants and collect data was then given to the manufacturers and distributors.

There have been other attempts to create CIED registries in the United States of America. The *Interinstitutional Cardiovascular Center Pacemaker Registry* was founded in Chicago in 1977 to provide an impartial record and tabulation of the reliability and survival rates of CIEDs. By 1991, 15 medical centres were participating, but no further reports could be found in the literature.[18] Its founder, Dr Robert Hauser left the organization in 1987 and went on to create a similar group at the Minneapolis Heart Institute Foundation in Minnesota in 1992.[19]

This new CIED registry had the advantage of being internet based and has developed a significant database.[20] The organisation has also been responsible for a number of significant investigations and product recalls by Medtronic,[21] St Jude[22] and Boston Medical suggesting that manufacturers who all have the intent to produce implantable products with a zero premature failure rate cannot, however, cannot be trusted enough to take early and appropriate action when a product is suspected of having a design or manufacturing problem. These companies do make an attempt to improve postmarket CIED surveillance, but this form of passive reporting generally fails to detect early potentially very serious problems. The

independent Minneapolis Heart Institute Foundation surveys have been successful in the early reporting of ICD lead problems, but its market coverage needs to be expanded to a national role.

In 1987, the American College of Cardiology created a database called the *National Cardiovascular Data Registry*^{TM} to standardize what and how information was collected for patients receiving cardiac catheterizations and angioplasty.[23] In 2004, together with the United States *Heart Rhythm Society,* a working group was set up with the intention of creating a National ICD Registry. In 2008, the centres for Medicare and Medicaid via the Senate Finance Committee in Congress selected the National Cardiovascular Data Registry to implement the program referred to as the *ICD Registry*^{TM}. This is a nationwide program that helps participating hospitals improve care for patients with ICDs. The hospital performance is compared to a national benchmark and it hopes in this way will enhance patient outcomes. The registry delivers information on the morbidity and mortality of a particular disease entity.

In 2009, there were almost 1500 hospitals participating and data had been collected from 550,000 implants in the United States of America.[24] About 10,000 new ICD implants are registered per month and it is believed that approximately 90% of all ICD implants performed in the United States of America are entered into the registry.

The Longitudinal ICD Registry Study was developed by the National ICD Registry Working Group in 2007 and was designed to prospectively follow a cohort of about

3,500 Medicare beneficiaries receiving a primary prevention ICD with a primary end point of the first delivery of appropriate ICD therapy including an ICD shock or anti-tachycardia pacing. Secondary end points include survival at three and five years; death from any cardiovascular cause; total number and rate of device therapies; and ratio of inappropriate to total device therapy. To date, the ICD Registry have provided a number of impressive reports on the national ICD practices.[25-27] Clearly the ICD Registry has been very successful in collecting information on ICD usage in the United States and hopefully with time will provide valuable outcomes information on the use of these complicated and expensive implanted devices.

The REPLACE registry was a single company sponsored safety study, the objective of which was to prospectively estimate at 6-months, the all-cause complication rates for patients undergoing implanted device generator replacement due to power source depletion, advisory or upgrade. All company pacemaker pulse generators and ICDs were included with the trial commencing in July 2007 and completed in June 2009. Seventy two US centres contributed data. The trial was also designed to investigate the complication rates encountered with device replacement as a result of an advisory. Situations, where lead extraction was required were excluded. There were 1744 patients registered, involving all CIED manufacturers with a 4.0% major complication rate, 7.4% minor complication rate and 1.3% infection rate.[28,29] Although this registry was intentionally short-lived and not national, it nevertheless, provided valuable insight into the previously unknown incidence of CIED complications and particularly infection following pulse generator and ICD shock box replacement.

What about the development of registry services in other countries? The annual European registry data which is included in this dissertation, although valuable, does not include outcomes and the clinical information is very limited. Only the Danish Pacemaker and ICD Registry offers comprehensive clinical information and some outcomes.[30,31] Although these outcomes were initially only for 3-months, the registry has now been expanded to cover the life-time of the implanted hardware and the patient.

The pacemaker registry was established in 1982 and because Denmark is a small country of only five million people with a sophisticated and mature national healthcare system providing universal coverage, it is able to collect the necessary information. All public healthcare in Denmark is free, although the private healthcare section is growing. There are only 14 implanting centres and to date, there have been 90,000 pacemaker and ICD recipients registered.

Unlike the Australian and world pacing and ICD surveys presented, the Danish registry also incorporates explants, all complications, the implant procedures, mortality and performance. In order to obtain outcomes information, there is a requirement that all CIED complications are reported to the Danish Pacemaker Registry. Information is also obtained from the Danish National Hospital Discharge Register and because all Danish citizens have a personal identification Civil Registration Number, this can be used to record vital information such as death. There have been published quality assessment reports on the appropriate use of CIEDs and postoperative complications,[32] as well as lead complications[33-35] and even the cancer risk in pacemaker recipients.[36]

Other European countries have also developed CIED registries, but nowhere as sophisticated as the Danish model. These include Austria,[37] Finland,[38] France,[39-42] Germany,[43-46] Greece,[47-48] Italy,[49-51] Norway,[52] Portugal,[53] The Netherlands,[54,55] Spain[56-59] and the United Kingdom.[60] The national registries are based on the original European Pacemaker registry founded in 1978 by the late Drs. Bert Thalen, Giorgio Feruglio and Tony Rickards.[61-63] They developed the European pacemaker patient identification card, still used today. Details from these cards are registered with national registration centres that send aggregated annual data to the European Working Group on Cardiac Pacing. However, not all of the reported country registries are national. A number are retrospective or prospective, single or multi-centre surveys of particular types of hardware or clinical issues have been reported.[38,41,42,46-48,50-53,55] Despite the sophisticated collection of data from the European Working Group, there is surprisingly very little published work outside the World Surveys conducted each four years.[64,65] On occasion, CIED company have sponsored short–term European multicentre registries to test and hopefully prove the beneficial effects of their software algorithms.[66,67]

Eucomed Medical Technology, which represents the European medical technology industry, was founded in 1979 with the stated aim to improve patient and clinician access to modern, innovative and reliable medical technology. Eucomed represents directly or indirectly 4,500 designers, manufacturers and suppliers of medical technology. Since 2004, Eucomed has been collecting statistical information on CIEDs. The data are provided quarterly by manufacturers on a voluntary basis, collated and made public annually. Like a number of the countries' reports analyzed in this dissertation, the data is predominantly from the sales of CIED

hardware and therefore suffers the same limitations as the world surveys. In a 2009 Eucomed review from 2004 to 2008, data from 15 European countries was presented, although there was no more detail than in this dissertation.[68]

In recent years, the European Heart Rhythm Association has embarked on an ambitious project via its national cardiology societies and working groups to document the electrophysiological practices in its member countries. The project is single company sponsored. The collected data includes all CIED implants including loop recorders and lead extractions. The data is published each year in a White Book available over the internet.[69] The fifth edition was published in 2012 and involves 46 of the 54 member countries of the European Society of Cardiology, although the information for some countries is minimal. The data collection is voluntary and in most countries uses established national databases. Countries without registries are encouraged to establish them. A common format of collection and presentation will hopefully eradicate heterogeneous presentations allowing continual refinement and improvement. Each annual edition of the White Book contains the previous year's data with information appropriate updated. There has been a steady annual increase in participating countries. A number of White Book manuscripts have now been published.[70-72] The European Heart Rhythm Association has also been involved with other CIED registry projects including the European CRT Survey in conjunction with the Heart Failure Association.[73]

There has been very little work on national registries outside Europe and the United States of America. However, because of the World Survey of Cardiac

Pacing and ICDs presented in this dissertation, a group of loyal and enthusiastic coordinators have been established and a number of these have expressed interest in taking their local survey to the next step. However, there will be the need for local implanter and national cardiac societal cooperation, government assistance and above all appropriate funding.

A much talked about issue is the reuse of CIEDs. Refurbishment of cardiac pacemakers was initially a popular way of reducing the financial burden on the implanting hospital. The methods by which the devices were selected, tested and resterilized were first reported by the author in 1980.[74] However, mainly for legal concerns, the practice was abolished, particularly in western countries by the early 1990's. There are still eastern European and third world countries implanting refurbished pulse generators usually retrieved from deceased original recipients. Although refurbishing and implanting pulse generators is safe in regard to infections, nevertheless, strict controls on the retrieval process, safe transport to the refurbishing centres and testing for unsuspecting malfunction and satisfactory projected longevity are all vital.

The question is who refurbishes the pulse generator for reuse? The manufacturers are reluctant to do so for many reasons. Once refurbished, is the original manufacturer's warranty still valid? For countries like the United States, the legal and administrative paper work and refurbishing costs may be prohibitive and as expensive as the cost of a new unit. There are also Food and Drug Administration restrictions on the export of such items outside the United States of America, especially exporting medical items with an expired use by date. Once a refurbished

unit is available, must specific consent be obtained from the patient or carer to allow a used pacemaker to be implanted. Despite the overwhelming limitations on the use of refurbished CIEDs, there has been a United States initiative to collect prematurely explanted pulse generators, refurbish them and donate them to third world countries.[68] Of interest, many of the recipient countries charge import duties on the hardware and there may also be bribes to release the CIEDs from customs.

What is particularly important is if the initiative is successful, a comprehensive registry would be vital to document and control every step of the process and document outcomes.[76] This in itself would be an expensive undertaking. Another possible humanitarian effort for impoverished third world countries is the donation of new CIED hardware which has passed its use by date. Such hardware cannot be sold, donated, implanted or even exported to third world countries from the United States of America. Currently, such donated hardware must be exported from the United States of America prior to the expiry date, implanted immediately or in some cases stored in a repository until it can be used in a country with lax expiry date laws on the use of such hardware. Such an undertaking is currently underway with the charitable organization Heartbeat International headquartered in Tampa, Florida of which the author is the Medical Director.[77]

Because CIED company inventory control has markedly improved in recent years, the number of near use by date units has fallen and the organization has become dependent on either the donation or bulk purchase of conventional product. Once again, the importance of a registry is required. Heartbeat International works through local chapters of Rotary International to distribute and document the

implant process. However, in third world countries, follow up may be poor and outcomes not possible.

The ultimate answer to the safe and reliable follow up of all patients with a CIED is a Universal or Worldwide Registry.[78] We now have excellent follow up tools which can make this possible. The two limiting factors are cost and cooperation. With enough interest at both a government and cardiac societal level, such programs can be established. It seems unlikely at this point, that comprehensive CIED registries can or will be widely developed on an international scale. Most of the larger CIED implanting countries have too many implanting centres and physician cooperation would be minimal. However, the success of the ICD Registry™ in the United States of America suggests, that if the correct tools are used, a total CIED registry is possible.

The Asia Pacific region is rapidly growing and there is a wide interest in attempting to create more than that provided by the ongoing surveys. The widely acknowledged organization in the region is the recently formed and rapidly developing, Asia Pacific Heart Rhythm Society (APHRS). The organization has expressed strong interest in creating a registry format to be used, where possible, in the region. With the assistance of the author, a committee will be established to not only develop the registry format, but also create the infrastructure and budget required for such a large undertaking. Once established, a specialized body experienced with registry work, such as the Monash University Faculty of Medicine, Nursing and Health Sciences, Department of Epidemiology and

Preventive Medicine, will be required to coordinate the registry activities in a professional manner.

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Chapter 7: The World Survey of Cardiac Pacing and ICDs: Concluding Remarks

This thesis has presented an ongoing Survey of Cardiac Pacing and ICD practices in Australia and 60 other countries throughout the world. The collation of data is the work of the author and is conducted entirely by the internet with the assistance of an army of loyal enthusiastic survey coordinators, including Dr Alessandro Proclemer of Italy, who was responsible for much of the European information . The 2009 survey encompasses more than 80% of all the pacemakers and ICDs implanted worldwide and provides a comprehensive picture of the CIED practices throughout the world.

Although the thesis presents in detail three Australian and International surveys conducted since the turn of the century, it nevertheless also encompasses both the evolution of the CIED industry since the early 1970's as well as the surveys conducted over that period that the candidate was involved with. From very humble beginnings using simple, unreliable and fragile equipment, CIEDs have developed into a formidable highly competitive billion dollar industry providing reliable, life saving, implantable cardiac hardware. It behoves us as implanting physicians and surgeons to prescribe and implant these devices correctly, responsibly and with minimal complications.

Academic training institutions are necessary for the teaching of the craft to young cardiologists embarking on a career of Electrophysiology. Because of the glamour

of ablating tachyarrhythmias, the training of CIED implantation is often relegated to a sideline with little emphasis on correct technique and minimizing complications.

The surveys presented in this dissertation outline evolutionary changes and represent only numbers and give no insight into how patients were selected for the devices, the success or otherwise of the operative procedure and how the recipients are progressing. This is a major recognized deficiency with such a format and highlights the need for the next step. What are required, therefore, are much more accurate clinical information and clinical outcomes data in a registry format.

CIED hardware is expensive and such data is essential for future budgetary planning in Australia at all levels of responsibility, including Federal and State Health Departments, private healthcare insurance providers and public and private hospital administrators. Thus more information will be necessary in the future and registries need to be designed to provide outcomes data. This is an expensive undertaking requiring co-operation between all of the aforementioned interested parties. There has been remarkable progress in the development of CIED follow-up and monitoring which can interface with a sophisticated software program designed to store and analyze vast quantities of data.

The future is now and there is need for responsible action....