



Review of Implantation Procedures for Permanent Pacemakers in NSW Public Hospitals 2007

Public Report

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This document represents the final report of the Special Review of implantation procedures for permanent pacemakers in NSW public hospitals, which was conducted in 2007. It was prepared by the Special Review Committee and Ms Alex Warner, Manager, Special Reviews.

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Executive Summary

This purpose of this report is to publish within the public domain the results of an enquiry conducted by the Clinical Excellence Commission (CEC) into permanent pacemakers implanted in New South Wales (NSW) Public Hospitals. The inquiry was commissioned by the Director General NSW Health following concerns raised about the safety and quality of care provided to patients who had a permanent cardiac pacemaker implanted in two public hospitals in NSW.

To identify the complication rates occurring in NSW public hospitals where permanent pacemakers are implanted the CEC performed an audit on a sample of cases from hospitals that perform these procedures. In addition, the review revealed inconsistencies in credentialing processes for medical specialists that implant these devices.

Like most other studies in the medical literature (2, 3, 4, 5, and 6) this study examined complication rates that occurred in hospital or caused readmission to hospital. The difference between these studies and this study was that data was collected from multiple implanting facilities rather than single implanting centres. The exception was a study by Møller (1) which studied procedure related complications for all implantations performed in Denmark over a three year period. The main difference between Møller's study and this study was in the method of data collection – Møller's was based on self-reporting from the implanting facilities and this study used file audit data to evaluate complication rates. Møller notes that the information on complications related to modern pacemaker therapy is sparse and with few exceptions is limited to experience in single centres. He concludes that such information is important for quality improvement in single centres but does not probably reflect the complication rate in general.

Most facilities maintained a pacemaker register but this information has not been centrally reported or analysed. Therefore, the results of this study should serve as a baseline from which future practice and outcomes can be evaluated.

Complications following any procedure are a cause for concern but the ongoing measurement of complications and publication of standardised benchmarks will continue to drive practice improvement.

There appeared to be no difference in complication rates between Cardiothoracic Surgeons and Cardiologists who implant pacemakers, volume of procedures performed and where the procedure was performed.

Background

The Clinical Excellence Commission (CEC) is a statutory health corporation established under the Health Services Act 1997. The role of the CEC is to identify issues of a systemic nature that affect patient safety and clinical quality in the New South Wales (NSW) health system and develop and advise on improvement strategies to address these issues. The CEC does not investigate matters of individual performance nor does it deal with individual patient incidents or complaints.

The Minister for Health or the Director General NSW Health, may from time to time, require the CEC to conduct system wide reviews in relation to quality and safety of health care on his or her behalf. The specific nature of any review will be determined by the Director General. The purpose of any review will be to bring about improvements in clinical quality and patient safety within NSW.

This review was instigated by concerns raised in 2005 by a consultant physician and cardiologist, about the quality of care provided to patients he had referred for pacemaker implantation to two hospitals in a particular Area Health Service in NSW. Specifically, the concerns related to the rate of complications and re-operation associated with pacemaker implantation and lead repositioning, which it was asserted was unacceptably high. This assertion was based on a prospective three-year study in a rural cardiology practice which reported a complication rate of 30% related to atrial lead dislodgement. A prospective study in Denmark by Møller (1) et al suggested that a re-operation rate higher than 3% for atrial as well as ventricular leads in individual implanting hospitals should cause the hospital to evaluate carefully the procedure as well as the performance of the individual implanter. However, as noted in the Executive Summary, Møller (1) asserts that results from single centre studies do not probably reflect the overall complication rate in multicentre studies.

In April 2006 the Director General issued a "Certificate of Authority" under the Health Services Act 1997 (2) authorising the CEC to conduct a special review of *Implantation Procedures for Permanent Pacemakers and Related Devices*. The initial Certificate of Authority expired in August 2006 before the review had been completed and a new Certificate was issued in January 2007. The Manager, Special Reviews at the CEC was appointed by the Director General as the Authorised Officer (AO) to conduct the review.

Terms of Reference

- (i) Identify what if any systems or procedures are in place within area health services to determine:
 - (a) At which facilities (and in which departments of such facilities) within the area health service such procedures are and can be performed;
 - (b) By which practitioners such procedures can be performed, including the extent to which and how NSW Health role delineation and credentialing policies are applied to such decisions.
- (ii) Identify what if any systems are in place within facilities of area health services where pacemaker implantation procedures are performed to collect and review information on the outcomes and complications of such procedures and to what extent if at all such information is used as the basis

for system improvement;

- (iii) Benchmark the complication rate for pacemaker implantation procedures undertaken over the period 1 November 2005 to 30 November 2006 at the facilities identified at (i)(a) above;
- (iv) Advise and make recommendations to specific area health services in relation to any areas for improvement to local level systems identified in the course of the inquiry;
- (v) Make such other recommendations as are considered necessary to ensure the safety and quality of care of patients undergoing pacemaker implantation procedures in NSW public hospitals.

Major findings

1. The review identified 18 hospitals in NSW where permanent pacemakers are implanted including principle referral hospitals, major metropolitan hospitals and one major non metropolitan hospital. The procedure is carried out under sterile conditions in either cardiac catheter laboratories or operating theatres.
2. In general, permanent pacemakers are implanted by medical specialists in cardiology and cardiothoracic surgery. The review identified no clear and consistent credentialing process across implanting hospitals with particular reference to documentation of specific clinical privileges for pacemaker procedures.
3. Whilst the majority of implanting facilities had a pacemaker database. The review identified variation in the amount and type of data collected. In particular, these databases were restricted to early surveillance parameters only.
4. The review found no evidence to indicate that pacemaker complication rates in NSW were significantly different from the international experience. Other figures sighted as the reason for the review could not be substantiated.
5. Although there was a large variation in the volume of pacemakers implanted by each of the 18 hospitals, this study found no obvious relationship between hospital volume and complication rates.
6. The analysis found that there was little evidence to suggest that the complication rates and re-operation rates are different for cardiothoracic surgeons who implant pacemakers and cardiologists who implant pacemakers.
7. In the course of conducting the review at one hospital (not previously identified in the original allegation) other matters not within the scope of the Terms of Reference were referred to the appropriate Area Health Service Chief Executive for further action.

Recommendations

Credentialing and performance review

1. The Cardiac Society of Australia and New Zealand in conjunction with the relevant Colleges develops standards relating to credentialing and minimum number of implantations to be performed annually.
2. At the Area Health Service level, all cardiologists and cardiothoracic surgeons should be appropriately credentialed to implant permanent pacemakers. This would include a clear statement of scope of practice associated with their appointment that is documented and provided to the specialist.
3. There should be regular performance review of cardiologists and cardiothoracic surgeons who implant pacemakers.

Surveillance

4. Hospitals conduct regular ongoing surveillance of patients who have had a pacemaker implanted to monitor the incidence of early and late complications. Further, that the results of this surveillance is documented and used to monitor clinical outcomes and make local system improvements as necessary.
5. The Cardiac Society of Australia and New Zealand (CSANZ) in conjunction with the Australian Society of Cardiac and Thoracic Surgeons (ASCATS) develops standardised definitions for both early and late pacemaker complications.

Three month follow-up

6. Hospitals should establish follow-up systems to ensure that all patients are reviewed by a medical specialist at approximately three months after having a pacemaker inserted.

Aggregated data

7. A central pacemaker registry should be established to collect and analyse data including early and late complications. The registry could be operated under the auspices of the appropriate cardiothoracic and cardiac craft groups, and report publicly on aggregated and de-identified data. A central registry could provide a benchmark base for regular performance review of cardiothoracic surgeons and cardiologists who implant permanent pacemakers. Such a registry would require support from the Department of Health, respective Area Health Services, as well as CSANZ and ASCATS.

PART ONE
COMPLICATIONS RELATED TO PACEMAKER
IMPLANTATION

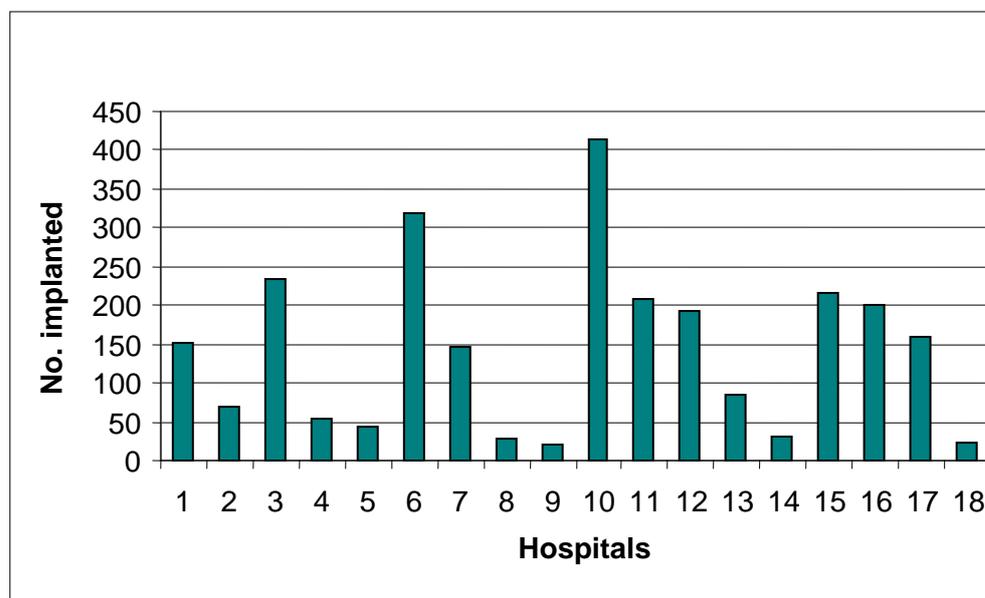
Aim and Introduction

This review examined procedure-related complications performed in implanting hospitals in NSW over a thirteen month period. The aim of the study was to identify, if possible, differences in the quality of pacemaker surgery as reflected by postoperative complications in implanting hospitals. Hospital 6 referred to in the Executive Summary and Hospital 7 were identified as the hospitals with the reported high atrial lead dislodgment rates.

Insertion of pacemakers

The study is based on pacemakers implanted in 18 hospitals (Figure 1) in NSW between 1 November 2005 and 30 November 2006. The data extract for the study period showed that a total of 2,596 patients had a permanent pacemaker implanted. It should be noted that during the file review it became evident that a small number of these patients had in fact had an Automatic Implantable Cardiac Defibrillator (AICD) implanted. Consequently, the numbers shown in Figure 1 also include a small number of AICDs. With one exception, pacemaker insertions were performed by qualified cardiologists and cardiothoracic surgeons or advanced trainees of the speciality. The exception was one hospital where pacemakers are implanted by two medical specialists working as a team comprising a qualified general surgeon and a qualified cardiologist. All pacemakers were implanted under sterile conditions in either operating theatres or cardiac catheter laboratories.

Figure 1 Number of pacemakers implanted by hospital



Types of complications

Types of complications were classified as follows:

- Myocardial perforation

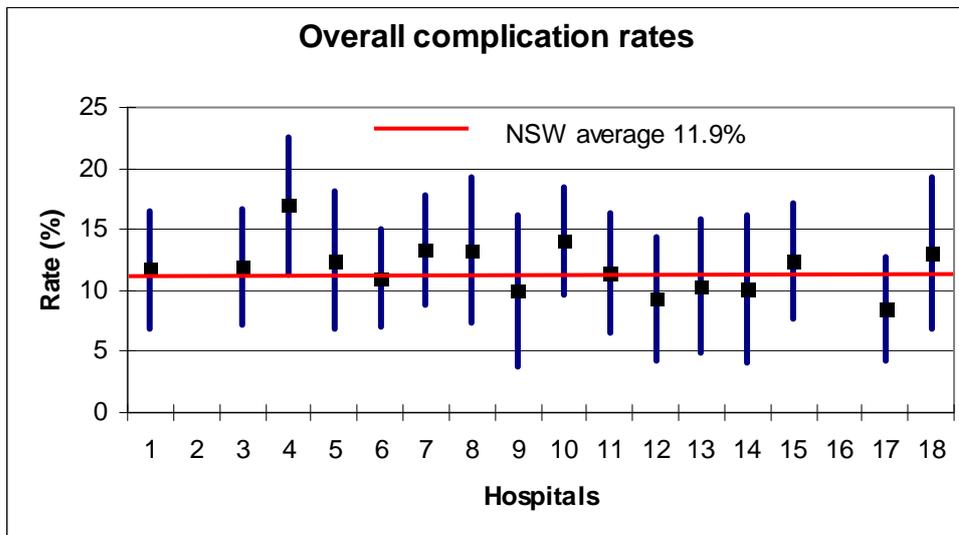
- Wound haematoma requiring re-operation
- Infection requiring re-operation
- Dislodgement or dysfunction of the atrial lead or ventricular lead requiring re-operation
- Pneumothorax or haemothorax requiring chest tube following central line puncture
- Death

File Reviews

A retrospective medical file review was conducted at 16 of the 18 pacemaker implanting hospitals with a total of 1,317 files reviewed equivalent to 51% of total insertions for the study period. File reviews were not conducted at Hospital 2 and Hospital 16 because of time constraints. The same cardiothoracic surgeons who implant pacemakers at Hospital 16 also implant at Hospital 15 which was one of the hospitals reviewed. The file review team worked in pairs for the majority of the reviews to confer and ensure consistency and standardisation of data. A data collection sheet was used for each patient (Appendix A).

Complication Rates

Figure 2 Overall complication rates by hospital



The NSW overall complication rate was 11.9% (Figure 2), with 95% confidence interval (10.6%, 13.2%). Figure 2 shows the complication percentages for the 16 reviewed hospitals. The black square is the observed percentage. The bar is the 95% confidence interval which indicates the uncertainty in the estimate. For example, the highest rate is at Hospital 4 with 17% of patients experiencing a complication but there is 95% probability that the true rate lies between 11.3% and 22.6%. The lowest percentage is at Hospital 17 with 8.5% but rate could be as low as 4.2% or as high as 12.8% at this hospital.

The graph shows that there is no statistically significant difference in complication rates between the implanting hospitals.

The line at 11.9% indicates the NSW average which is consistent with the international literature.

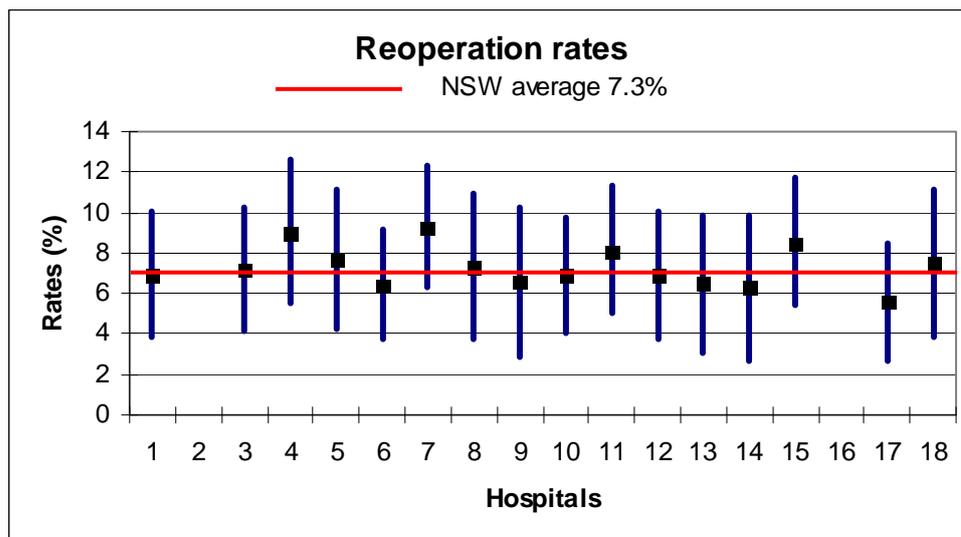
Infections

The most serious and life threatening complication was infection - seven patients developed an infection confirmed by positive blood cultures:

- Two patients had staphylococcus aureus
- One patient had enterococcus faecalis
- Three patients developed an MRSA infection attributable to the pacemaker insertion. One patient died. The second patient with MRSA was being treated with vancomycin and died two months after insertion of the pacemaker. It was unclear from the medical record whether this death was attributable to the pacemaker. The third patient grew MRSA on the lead tip and was treated with antibiotics, removal of leads, and recovered.
- One patient developed a wound infection which tested positive to staphylococcus aureus.

Re-operation rates

Figure 3 Overall re-operation rates by hospital



The NSW re-operation rate was 7.3% (Figure 3) with 95% confidence interval (6.2%, 8.3%). Re-operation rates for all complications ranged from 5.6% (95% CI (2.7%, 8.5%)) at Hospital 17 to 9.0% (95% CI (5.5%, 12.6%)) at Hospital 4.

Wound haematomas were detected in 2.6% (95% CI (1.9%, 3.2%)) of patients with 0.7% (95% CI (0.3%, 1.2%)) requiring operative intervention.

The incidence of pneumothorax requiring a chest tube was 0.4% (95% CI (0.2%, 0.6%)). No patients in the sample experienced a haemothorax requiring a chest tube.

Infection occurred in 1.3% (95% CI (0.3%, 1.0%)) of patients with 0.8% (95% CI (0.2%, 0.7%)) of patients requiring re-operation.

Lead problems (dislodgments and other problems) occurred in 5.7% (95% CI (4.8%, 6.6%)) of patients, with re-operation needed for atrial lead problems in 2.4% (95% CI

(1.8%, 3.1%)) of patients and in 2.2% (95% CI (1.6%, 2.7%)) for ventricular lead problems.

Discussion

This is the first study in NSW to examine complication rates following pacemaker implantation in multiple centres.

The NSW re-operation rate for pneumothorax, infection, and lead problems (Table 1) is within the range reported in the literature (2 – 6). Møller et al (1) provide a guideline for quality (Table 1) that provide a good benchmark to aim for in NSW.

Table 1 NSW re-operation rates compared with the literature and rates suggested by Møller (1)

Type of complication	NSW rate	Range in the literature	Rates in Møller's study
Pneumothorax	0.4% with 95% CI (0.2%, 0.6%)	0.6% -1.5%	0.8%
Infection	0.9% with 95% CI (0.5%, 1.2%)	0.2% - 2.7%	0.3%
Lead problems	5.7% with 95% CI (4.8%, 6.6%)	2.5% – 6.5%	6.5%

Although there was a large variation in the volume of pacemakers implanted by each hospital, this study found no obvious relationship between volume and complication rates.

The analysis found that there was little evidence to suggest that the complication rates and re-operation rates are different for cardiothoracic surgeons who implant pacemakers and cardiologists who implant pacemakers.

Hospital 17 consistently had the lowest complication rates (overall, re-operations and lead problems). Hospital 4 had the highest overall complication rate, highest lead problems and the second highest re-operation rate. Whilst it is possible to identify the hospitals with the highest and lowest complication rates the fact that there is no statistically significant difference indicates that such comparison is meaningless.

The two hospitals reported as having high atrial lead dislodgment rates were Hospital 6 and Hospital 7. Hospital 6 rated below the NSW rate for overall complications, overall re-operations, and lead re-operations. Effective system improvements had been introduced at Hospital 6 which has resulted in complication rates below the NSW rate. Hospital 7 had an overall complication and lead re-operation rate higher than the NSW rate, and the highest overall re-operation rate.

The limitation of this study is that it did not include late complications i.e. three months after insertion. However, as the great majority of complications occur within the first three months after pacemaker insertion (1 and 4) patients should have access to clinical review and treatment from medical specialists. Consequently the NSW overall complication rate of 12.0% should be viewed as a conservative estimate.

During the course of the review it was identified that pacemaker clinics staffed by medical specialists provide an effective method for monitoring patients and early identification of complications.

It should be noted that in some instances the pacemaker was implanted by a cardiothoracic surgeon but follow-up provided by a cardiologist. This highlights the need for good communication to ensure continuity of care, and a feedback mechanism to the implanting surgeon about complications associated with the procedure.

Conclusion

The aim of this study was to identify, if possible, differences in the quality of pacemaker surgery as reflected by postoperative complications in implanting hospitals in NSW.

The NSW re-operation rate for pneumothorax, infection, and lead problems compares favourably with rates reported in the literature (4, 9, 11, 15, and 17).

The review found no obvious explanation as to why Hospital 4 and Hospital 7 have the highest re-operation rates.

No difference in complication rates was found between surgeons and non-surgeons which implies that the implanting location – operating theatre or cardiac catheter laboratory had no significant effect on clinical outcome including infection rates. Notwithstanding, infection remains the most serious and life threatening of all complications following pacemaker insertion and was associated with two deaths in this study.

Follow-up of patients who have had a pacemaker inserted should be viewed as an integral part of the whole treatment process and can be achieved by having systems in place such as pacemaker clinics staffed by medical specialists. It is also very important to have a process for flagging patients to identify those who may have been missed and do not get reviewed.

PART TWO
CREDENTIALING AND DEFINING SCOPE OF
PRACTICE

Aim and Introduction

The rapid increase in the availability of new and complex clinical services, procedures and other interventions, and specialisation by medical practitioners have highlighted the need for a more rigorous process for credentialing and defining scope of practice. Hence, the aim of part two of this review was to describe the current processes of Area Health Services with implanting hospitals and how they align with the requirements of NSW Health's policy on delineation of clinical privileges for visiting practitioners and staff specialists (3), and the appointment process for Visiting Medical Officers and Staff Specialists (4 and 5).

Credentialing and defining scope of practice

Health care facilities are not allowed to appoint specialist medical practitioners without appropriately credentialing and defining their scope of clinical practice (clinical privileges). There are three Department of Health policies in relation to appointment of VMOs and Staff Specialists which cover granting of clinical privileges:

1. Delineation of clinical privileges for visiting practitioners and staff specialists (3)
2. Visiting Practitioner Appointment (4)
3. Staff Specialists Appointment (5)

The purpose of credentialing and defining scope of practice is to maintain and improve the safety and quality of health care. The process of delineating a practitioner's clinical privileges aligns the practitioner's permitted scope of practice within a facility with his/her clinical competencies and the clinical service role of that facility. A public health organisation's Medical and Dental Appointments Advisory Committee (MDAAC) and Credentials (Clinical Privileges) Subcommittee provide expert advice to the governing body on the appointment and credentialing of VMOs and Staff Specialists. Appointment of Visiting Medical Officers occurs every 3 to 5 years and most Staff Specialists are permanent employees.

Data collection

Semi-structured interviews were held with senior clinicians¹ and managers in each of the relevant Area Health Services. An interview guide in Appendix B was used to guide discussion at these interviews. The interviews were conducted by the Authorised Officer and generally took between 30 and 40 minutes to complete.

Findings

VMO appointment cycle

The amalgamation of Area Health Services in 2004 resulted in the *new* AHS having different VMO appointment cycles to manage. Efforts have been made by Areas to align the cycles as the process is lengthy and time consuming. A good example is South Eastern Sydney Illawarra Health where five year appointments are currently being finalised and four year appointments will be offered to VMOs in the 2008 cycle. This will result in alignment of the whole appointment process by 2012.

¹ Consultant Cardiologists and Cardiothoracic Surgeons.

Defining scope of practice and review of clinical privileges

All Area Health Services were aware of the NSW Health policy in relation to the delineation of clinical privileges. Information obtained during the interviews indicated that only a small number of implanting medical specialists had insertion of permanent pacemakers documented as part of their scope of practice.

There was evidence that three Areas are making efforts to be more specific about defining scope of practice. A good example is one Area Health Service using the appointment process as an opportunity to review clinical privileges granted to VMOs *and* Staff Specialists who implant pacemakers to better align with the requirements in the policy. The General Manager of one large principal referral hospital was supportive of greater specificity but commented that agreement about specific privileges would need to occur with the relevant Colleges.

Discussion

There was support for greater specificity in the delineation of clinical privileges for cardiologists, but less support for cardiothoracic surgeons. The Royal Australasian College of Surgeons Guide (6) to credentialing makes a broad statement about delineation of clinical privileges "...being within the scope of the individual's qualifications, training and experience", but offers no further guidance as to how specific these need to be.

The NSW Health policy (18) identifies three categories of clinical privileges to be considered by the Credentials (clinical privileges) Subcommittee - broad, specific, and non-routine as part of the appointment process. Granting of clinical privileges to implant permanent pacemakers could probably fall into the "Broad" or "Specific" categories. The "Broad" category relates to procedures or treatment areas in keeping with the practitioner's qualifications and training, but stipulates that the Credentials Subcommittee should not assume that because a speciality group generally undertakes a specific procedure, that privileges would automatically be granted to all specialists in that group. The "Specific" category relates to procedures that might be a normal part of the practitioner's training but are performed irregularly. These are regarded as procedures and treatments in subspecialties or areas where additional training has been undertaken.

It is worth noting that not all cardiologists and cardiothoracic surgeons implant pacemakers.

Conclusion

With regard to insertion of pacemakers and the NSW policy on delineation of clinical privileges the views of the Cardiac Society of Australia and New Zealand and relevant Colleges should all reflect best practice.

PART THREE

PERFORMANCE REVIEW

Aim and Introduction

The aim of Part Three of the review was to describe the current processes in relation to performance review at the departmental level and individual specialist level, and how these align with existing standards and policies (7 and 8).

There is a close link between credentialing and clinical privileges discussed in Part Two and performance review – one is necessary for the other. The NSW Health Department's policy on delineation of clinical privileges (3) states that public health organisations must undertake annual performance review of practitioners to ensure early identification of matters that may compromise patient care. The Department's policy titled "Visiting Practitioners – Performance Review" (7) provides a useful template for the review process which includes a section on "Clinical review, audit and other quality activities". The Royal Australasian College of Surgeons released a document titled "Surgical Audit and Peer Review in 2005" (8). It provides a guide to the audit process and points out that the audit's purpose is to examine whether what you think is happening really is, and whether current performance meets existing standards.

Data collection

Data about performance review was collected during the semi-structured interviews used in part two.

Findings

During the course of the interviews it was acknowledged that regular performance review is an important part of providing safe high quality patient care. There is support for annual performance review of VMOs and Staff Specialists, and that this would be an appropriate time to review clinical privileges. Should there be a significant change to an individual specialist's privileges, a formal submission would be made to the Medical and Dental Medical Appointments Advisory Committee.

There are formal and informal systems in place to review pacemaker complications in most implanting hospitals including morbidity and mortality meetings and clinical meetings. A good example is the cardiology department at one hospital which uses its weekly interdisciplinary clinical meeting to review adverse events including pacemaker complications. The majority of hospitals had pacemaker databases but not all collect data on complications. It is of interest to note that the specialists who were interviewed were good historians when asked about their complication rates and could generally name the particular patients or list the number and type of complications for the past few years. This verbal information matched fairly closely with the data from the file reviews.

The informal systems relied on what one senior specialist described as the "close knit team" at his hospital to pick up any problems but acknowledged that a more systematic process was desirable.

The use of clinical audit to review complications was not widespread but where it was used, specialists report that the results provided a useful benchmark and more importantly, information about what areas of practice needed to be improved. A good example is one Area Health Service where an annual area wide audit of pacemaker

morbidity and mortality is conducted. This has resulted in some important system improvements being introduced.

Conclusion

There is support for regular performance review for VMOs and Staff Specialists who implant pacemakers in the six Area Health Services.

At the departmental level there was evidence of a range of systems to monitor and report on pacemaker complications including clinical audit and file review. Some of this is rather ad hoc and requires a more systematic approach.

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Abbreviations and Glossary of Terms

Abbreviations

AHS	Area Health Service
AICD	Automatic Implantable Cardioverter Defibrillator
AO	Authorised Officer
ASCATS	Australian Society of Cardiac and Thoracic Surgeons
CEC	Clinical Excellence Commission
CSANZ	Cardiac Society of Australia and New Zealand
MRSA	Methicillin-resistant Staphylococcus aureus
VMO	Visiting Medical Officer

Automatic Implantable Cardioverter Defibrillator

An AICD is a surgically inserted electronic device that constantly monitors the heart rate and rhythm. When it detects a very fast, abnormal heart rhythm, it delivers electrical energy to the heart muscle. This causes the heart to beat in a normal rhythm again.

Cardiac Conduction System

In a normal heart, each beat or contraction is initiated by an electrical impulse originating in the sinoatrial (SA) node and passing through the heart's conduction system. The impulse from the SA node spreads through the atria, causing them to contract and pump blood to the ventricle below. The impulse then passes through the atrioventricular (AV) node (a junction between the atria and ventricles) to the ventricles, causing them to contract and pump blood to the lungs from the right ventricle and to the rest of the body from the left ventricle.

Abnormalities in the conduction system (e.g. Atrioventricular Block) or disease of the Sinoatrial node (known as Sick Sinus Syndrome) result in an irregular or excessively slow heart rate leading to diminished cardiac output. Other dysrhythmias with a fast rate also result in poor cardiac output as the ventricles are unable to fill completely before a contraction. Pacemakers artificially stimulate the heart to correct these rhythm disturbances.

Complication

A complication was defined as *“Any untoward event that required or might have required surgical intervention, such as wound haematoma, pneumothorax, haemothorax, air embolus, infection or electrode malposition”* (6)

Credentials

Documented evidence of a person's formal qualifications, training, experience and clinical competence.

Credentialing

Credentialing refers to the formal process used to verify the qualifications, experience and professional standing and other relevant professional attributes of medical practitioners for the purpose of forming a view about their competence, performance and professional suitability to provide safe, high quality health care services within specific organisational environments.

Pacemaker

A small, lightweight, electronic device that is implanted (inserted) into the body, ready to pace the heart. The pacemaker monitors the heart's electrical activity and delivers electrical pulses when the heart needs them. The devices are powered by batteries that can last 16 years or longer.

Special Reviews and appointment of Authorised Officers

Under the powers of the Health Services Act 1997 the Director General has the authority to initiate a special inquiry into standards of patient care within public hospitals and in relation to other services provided by the public health system. The Director General may appoint any person, or class of persons, as an authorised officer or authorised officers to exercise the functions of Section 125 of the Act which gives the authorised officer/s powers of entry and inspection.

Staff Specialist

A staff specialist is appointed as an employee of the public health organisation in accordance with the salary and conditions set out in the Staff Specialist (State Award).

Visiting Medical Officer

A medical practitioner or dentist who is appointed by the public health organisation otherwise than an employee to practise as a medical practitioner or dentist in accordance with conditions of appointment, at any of its public hospitals or health institutions, or in relation to any health service it provides, specified in the appointment.

Appendix A – File review data collection sheet

PACEMAKER REVIEW

CONFIDENTIAL

REVIEW SHEET FOR RECORDS PPM

HOSPITAL:

SURNAME:

NAME OF REVIEWER:

PRINCIPLE DIAGNOSIS ON DISCHARGE SUMMARY

- | | |
|----|---------------------------------------|
| 1 | Atrial fibrillation and flutter |
| 2 | Sick Sinus Syndrome |
| 3 | Atrioventricular Block, complete |
| 4 | Atrioventricular Block, first degree |
| 5 | Atrioventricular Block, second degree |
| 6 | Bradycardia, unspecified |
| 7 | Other specified heart block |
| 8 | Syncope and collapse |
| 9 | OTHER |
| NC | NOT COLLECTED |

SURNAME OF IMPLANTER ON OPERATION REPORT:

TYPE OF ANAESTHETIC

- | | |
|-----|---------------------|
| GA | General |
| LA | Local |
| LA+ | Local with sedation |

WAS THE PATIENT ON ANTICOAGULANTS?

Yes

No

COMPLICATION

N No complication

Y Complication that **did not** require re-operation

Y+ Complication that **did** require re-operation

TYPE OF COMPLICATION

NA Not applicable

LD Lead dislodgment not specified

ALD Atrial lead dislodgment

VLD Ventricular lead dislodgement

OLP Other lead problem

WH Wound haematoma

LI Local infection

SI Systemic infection

Px Pneumothorax requiring chest drainage

Hx Haemothorax requiring chest drainage

MP Myocardial perforation

DTH Death

OTH Other

SUMMARY (free text box)

Appendix B – Interview guide

CLINICAL EXCELLENCE COMMISSION

PACEMAKER REVIEW INTERVIEW GUIDE

CONFIDENTIAL

DELINEATION OF CLINICAL PRIVILEGES

Q1

Structure of cardiac services and delineated service level

Q2

Re-appointment cycle

Q3

Who is responsible for managing the re-appointment process?

Q4

How are clinician's credentials verified?

Q5

How specific is the delineation of clinical privileges for cardiothoracic surgeons and cardiologists/electrophysiologists in relation to insertion of permanent pacemakers?

Q6

Is there a review of practitioners' privileges within the appointment period?

Q7

How could/should the process be improved?

TRAINING, SUPERVISION, AND ASSESSMENT OF "TRAINEES"

Q1

How many "Trainees" are currently attached to the service (includes Registrars/Fellows/Overseas Trained)?

Q2

Who is responsible for their training and assessment?

Q3

How is this managed?

Q4

Is there any formal documentation (eg clinical privileges, letter of authority) to approve the implantation of permanent pacemakers by unsupervised Trainees?

Q5

How could/should the process be improved?

QUALITY CONTROL SYSTEMS

Q1

What data is collected in relation to insertion of permanent pacemakers and related devices?

Q2

What systems are in place to monitor and report on outcomes and complications following insertion of permanent pacemakers and related devices?

Q3

How is the data reviewed and corrective action taken if required?

Q4

Are complications entered on IIMS?

Q5

How could/should the system be improved?

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