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

## Scientific Report

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

## Scientific Report

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This document is a supplementary 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.

Any enquiries about this publication, or comments, should be directed to:

Alex Warner
Manager, Special Reviews
Clinical Excellence Commission
GPO Box 1614
Sydney NSW 2001
Phone: (02) 9382 7600
Email: alexandra.warner@cec.health.nsw.gov.au

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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 study 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. Complications following implantation of Automatic Implantable Cardioverter Defibrillators (AICD) were not specifically identified and analysed but 41 were included in the file review.

## Methods

*Insertion of pacemakers*

The study is based on pacemakers implanted in 18 hospitals 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 AICD implanted. Consequently, the numbers shown in Table 1 also include a number of AICDs.

Pacemakers were implanted in 12 principal referral hospitals, 4 major metropolitan hospitals, one major non-metropolitan and one ungrouped acute hospital. During this period the smallest centre implanted 20 pacemakers and the largest centre 414 pacemakers. Ten of the hospitals implanted over 100 pacemakers in the reporting period, three hospitals implanted between 50 – 100, and five implanted less than 50 pacemakers.

Usually, the patient came to the implanting hospital the day before or on the morning of the procedure, and was discharged the same day or the following day after evaluation of pacemaker function. The first follow-up was generally scheduled for 3 months.

Pacemaker insertions were performed by qualified cardiologists and cardiothoracic surgeons or advanced trainees of the speciality. The exception was Hospital 18 where pacemakers are inserted by two clinicians 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.

*Data collection*

Identification of hospitals where pacemakers are implanted was obtained from the Health Information Exchange (HIE) using procedure codes from the National Centre for Classification in Health[1] (3). The HIE extract contained data on 2,596 admitted patients who had a pacemaker inserted between 1 November 2005 and 30 November 2006. The extract included the patient's name, date of birth, age, admission date, date of procedure, type and classification of pacemaker, co-morbidities, and gender. Each hospital was given a numeric code to de-identify them for reporting purposes.

[1] Procedure code 38281

**Table 1: Pacemaker implanting hospitals and number of devices implanted [2]**

| Hospital Code | Number implanted |
|---|---|
| 10 | 414 |
| 6 | 319 |
| 3 | 235 |
| 15 | 215 |
| 11 | 208 |
| 16 | 200 |
| 12 | 192 |
| 1 | 153 |
| 17 | 160 |
| 7 | 146 |
| 13 | 86 |
| 2 | 70 |
| 4 | 53 |
| 5 | 45 |
| 14 | 30 |
| 8 | 28 |
| 18 | 22 |
| 9 | 20 |
| **TOTAL** | **2596** |

*The data in this table excludes *non-admitted* patients who had a device implanted.

*Definitions*

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"* (4).

Types of complications were classified according to the definitions used in similar studies (1, 4, and 12):

- Myocardial perforation
- Wound haematoma requiring reoperation
- Infection requiring reoperation
- Dislodgment or dysfunction of the atrial lead or ventricular lead with/without operative adjustment or with/without replacement of the lead because of macroscopic dislodgment, inappropriate pacing threshold or sensing problems[3]
- 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 identified by the HIE extract. 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 files were reviewed for complications that occurred either

[2] Includes single, dual and biventricular pacemakers

[3] Broader definition was chosen in Møller et al's study (1) because it can be difficult to determine the exact reason for lead malfunction and because the important issue for the patient is whether or not a re-operation had to be performed.

during the *index admission* or subsequent *readmission* for the thirteen month study period – no attempt was made to differentiate between early and late complications.

The chief sources of information were from the patient's discharge summary, operating theatre/procedure reports, consent forms, and progress notes. The data collected related to primary implantation and end of life box changes. Records were selected by a stratified random sample with quasi proportional allocation. The pertinent data were entered into an Excel spreadsheet for later analysis. Patients who developed a complication that was detected at the three monthly outpatient follow-up were excluded from the study.

The file reviews were conducted in medical record departments at each implanting hospital. 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 B).

Implanting doctors were identified by their surname and given an alphanumeric code according to their clinical speciality i.e. "S" for cardiothoracic surgeons and "NS" for cardiologists. It was not possible to accurately and reliably differentiate *consultant* implanters from *advanced trainee* implanters as it was often unclear on the operation report who implanted the device.

*Statistical Methods*

Complication rates (the number of individuals with a complication out of the total sampled) were calculated for NSW with incorporation of the sampling scheme and then by hospital using Bayesian shrinkage estimators. The Bayesian shrinkage estimators are used to stabilise the estimates for small samples. Complications are presented both overall and then by type. Logistic regression was used to assess the relationship between important covariates and the complications. Details of the statistical methods can be found in Appendix F.

# Results

*NSW data*

**Table 2: Overall Complication rates for NSW**

| Variable | NSW Percentage (95% CI) | |
|---|---|---|
| All complications | 11.9 (10.6, 13.2) | |
| Complications that required reoperation | 7.3 (6.2, 8.3) | |
| All lead problems (dislodgments and other problems) | 5.7 (4.8, 6.6) | |
| | All Complications | Reoperations |
| **Break down by Complication Type** | | |
| Lead dislodgment not specified | 0.2 (0.2, 0.3) | 0.2 (0.2, 0.3) |
| Atrial lead dislodgment | 2.5 (1.8, 3.1) | 2.4 (1.7, 3.0) |
| Ventricular lead dislodgment | 2.2 (1.7, 2.8) | 2.2 (1.7, 2.8) |
| Other lead problem | 1.0 (0.6, 1.5) | 0.8 (0.4, 1.2) |
| Wound haematoma | 2.6 (1.9, 3.2) | 0.7 (0.3, 1.2) |
| Local infection | 0.6 (0.3, 0.9) | 0.3 (0.2, 0.5) |
| Systemic infection | 0.7 (0.3, 1.0) | 0.5 (0.2, 0.9) |
| Pneumothorax requiring chest drainage | 0.5 (0.2, 0.8) | 0.4 (0.2, 0.6) |
| Haemothorax requiring chest drainage | 0.0 (0.0, 0.1) | 0.0 (0.0, 0.0) |

| | All Complications | Reoperations |
|---|---|---|
| **Break down by Complication Type** | | |
| Myocardial perforation | 0.3 (0.1, 0.6) | 0.3 (0.0, 0.5) |
| Other | 2.7 (2.0, 3.5) | 0.9 (0.4, 1.3) |

Several patients had more than one complication for the one procedure, and for statistical purposes these were counted as one complication. Similar studies (1, 4, and 11) do not report how they dealt with this problem. The overall complication rate for NSW was 11.9%. The data supports a true rate as high as 13.2% and as low as 10.6%. The reoperation rate was 7.3% (95% CI (6.2%, 8.3%)) with the majority of complications, 5.7% (95% CI (4.8%, 6.6%)), relating to lead problems.

There was a crude relationship between insertion of a biventricular pacemaker versus single chamber pacemaker and increased risk of a complication (OR=2.498 p=0.019 95% CI (1.164, 5.360)). No other grouping showed a significantly different complication rate to single chamber pacemakers.

*Data from individual hospitals*

**Table 3: Overall complication rates by hospital**

| Hospital | Total Sampled | Total Complications | Crude Percentages (95% CI) | Shrunken Percentages (95% CI) |
|---|---|---|---|---|
| 1 | 96 | 11 | 11.5 ( 5.9, 19.6) | 11.7 ( 6.9, 16.5) |
| 2 | Not reviewed | | | |
| 3 | 100 | 12 | 12.0 ( 6.4, 20.0) | 12.0 ( 7.2, 16.7) |
| 4 | 41 | 12 | 29.3 (16.1, 45.5) | 17.0 (11.3, 22.6) |
| 5 | 43 | 6 | 14.0 ( 5.3, 27.9) | 12.5 ( 6.9, 18.2) |
| 6 | 180 | 19 | 10.6 ( 6.5, 16.0) | 11.0 ( 7.0, 15.1) |
| 7 | 131 | 19 | 14.5 ( 9.0, 21.7) | 13.4 ( 8.9, 17.8) |
| 8 | 27 | 5 | 18.5 ( 6.3, 38.1) | 13.3 ( 7.3, 19.3) |
| 9 | 20 | 0 | 0.0 ( 0.0, 16.8) | 9.9 ( 3.7, 16.1) |
| 10 | 141 | 22 | 15.6 (10.0, 22.7) | 14.1 ( 9.7, 18.4) |
| 11 | 91 | 10 | 11.0 ( 5.4, 19.3) | 11.5 ( 6.6, 16.4) |
| 12 | 82 | 5 | 6.1 ( 2.0, 13.7) | 9.3 ( 4.3, 14.3) |
| 13 | 54 | 4 | 7.4 ( 2.1, 17.9) | 10.3 ( 4.9, 15.8) |
| 14 | 28 | 1 | 3.6 ( 0.1, 18.4) | 10.1 ( 4.1, 16.1) |
| 15 | 101 | 13 | 12.9 ( 7.0, 21.0) | 12.4 ( 7.6, 17.2) |
| 16 | Not reviewed | | | |
| 17 | 147 | 9 | 6.1 ( 2.8, 11.3) | 8.5 ( 4.2, 12.8) |
| 18 | 22 | 4 | 18.2 ( 5.2, 40.3) | 13.0 ( 6.9, 19.2) |

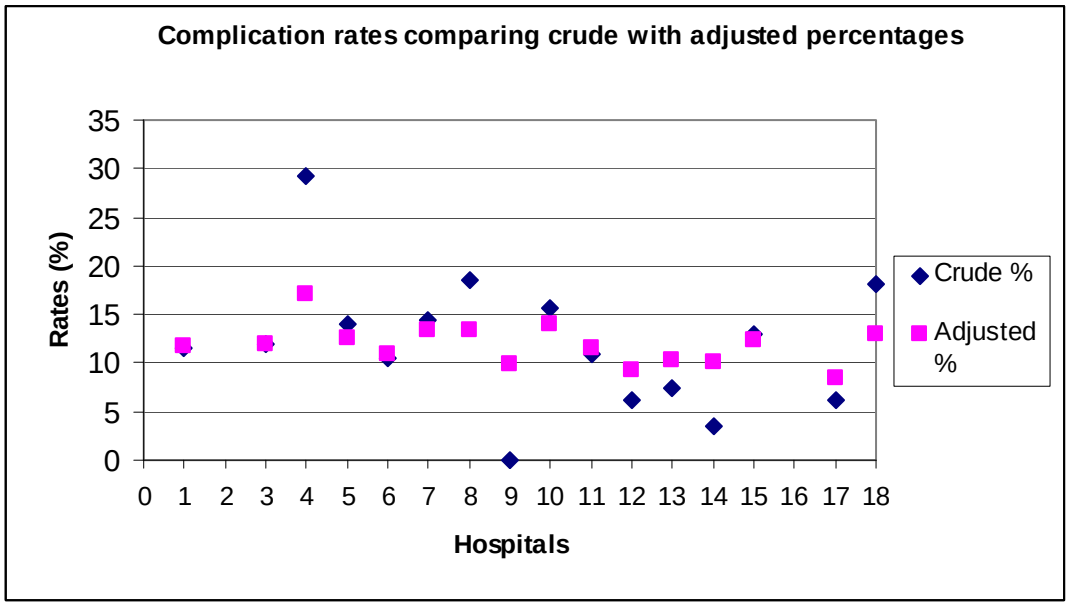
NSW percentage 11.9% with 95% CI (10.6%, 13.2%)

Table 3 shows overall complications by hospital. The crude percentage column gives the complication percentage found in the sample with 95% confidence interval. The “shrunken” percentages show the Bayesian estimates of the true complication rate in each hospital after stabilisation for small samples using the NSW average. Hospital 4 had the highest crude percentage at 29.3%, which reduced to a Bayesian estimate of 17.0% with 95% probability that the true rate lies between 11.3% and 22.6%. There were no complications found in the sample at Hospital 9 giving a crude percentage of 0%. The Bayesian estimate for the hospital is more realistic, 9.9% with 95% probability that the true rates lies between 3.7% and 16.1%.

In terms of the Bayesian estimates Hospital 4 still had the highest rate (17%), the lowest rate was found in Hospital 17 with 8.5%, 95% CI (4.2%, 12.8%).

The table shows that the confidence intervals are large due to the small sample sizes but the Bayesian confidence intervals are smaller because they "borrow" strength from the overall NSW average, the amount of shrinkage to the NSW average is larger the smaller the sample.

**Figure 1: Complication rates comparing crude with adjusted percentages**




The graph in Figure 1 shows the crude complication percentage compared to the adjusted percentage for each hospital. The graph shows how the adjustment stabilises the estimates and smoothes them closer to the NSW average, the smaller hospitals that were further away from the NSW average had the largest adjustment.

**Table 4: Reoperation rates by hospital**

| Hospital | Total Sampled | Total Complications | Crude Percentages (95% CI) | Shrunken Percentages (95% CI) |
|---|---|---|---|---|
| 1 | 96 | 6 | 6.3 (2.3, 13.1) | 6.9 (3.8, 10.1) |
| 2 | Not reviewed | | | |
| 3 | 100 | 7 | 7.0 (2.9, 13.9) | 7.2 (4.1, 10.3) |
| 4 | 41 | 7 | 17.1 (7.2, 32.1) | 9.0 (5.5, 12.6) |
| 5 | 43 | 4 | 9.3 (2.6, 22.1) | 7.7 (4.2, 11.1) |
| 6 | 180 | 10 | 5.6 (2.7, 10.0) | 6.4 (3.7, 9.2) |
| 7 | 131 | 16 | 12.2 (7.2, 19.1) | 9.3 (6.3, 12.3) |
| 8 | 27 | 2 | 7.4 (0.9, 24.3) | 7.3 (3.7, 10.9) |
| 9 | 20 | 0 | 0.0 (0.0, 16.8) | 6.6 (2.9, 10.3) |
| 10 | 141 | 9 | 6.4 (3.0, 11.8) | 6.9 (4.0, 9.8) |
| 11 | 91 | 9 | 9.9 (4.6, 18.0) | 8.1 (5.0, 11.3) |
| 12 | 82 | 5 | 6.1 (2.0, 13.7) | 6.9 (3.7, 10.1) |
| 13 | 54 | 2 | 3.7 (0.5, 12.8) | 6.5 (3.1, 9.9) |
| 14 | 28 | 0 | 0.0 (0.0, 12.3) | 6.3 (2.7, 9.9) |
| 15 | 101 | 11 | 10.9 (5.6, 18.7) | 8.5 (5.4, 11.7) |
| 16 | Not reviewed | | | |
| 17 | 147 | 5 | 3.4 (1.1, 7.8) | 5.6 (2.7, 8.5) |
| 18 | 22 | 2 | 9.1 (1.1, 29.2) | 7.5 (3.8, 11.1) |

NSW average 7.3% with 95% CI (6.2%, 8.3%)

Table 4 shows reoperation rates ranging from 5.6% with 95% CI (2.7%, 8.5%) at Hospital 17 to 9.3% with 95% CI (2.7%, 8.5%) at Hospital 7. Four hospitals (4, 5, 7, 11, 15, and 18) have reoperation rates higher than the NSW average.

**Table 5: Lead dislodgments and lead problems by hospital**

| Hospital | Total Sampled | Total Complications | Crude Percentages (95% CI) | Shrunken Percentages (95% CI) |
|---|---|---|---|---|
| 1 | 96 | 4 | 4.2 (1.1, 10.3) | 5.3 (2.9, 7.7) |
| 2 | Not reviewed | | | |
| 3 | 100 | 4 | 4.0 (1.1, 9.9) | 5.3 (2.9, 7.6) |
| 4 | 41 | 6 | 14.6 (5.6, 29.2) | 6.8 (4.2, 9.4) |
| 5 | 43 | 5 | 11.6 (3.9, 25.1) | 6.5 (3.9, 9.1) |
| 6 | 180 | 9 | 5.0 (2.3, 9.3) | 5.4 (3.2, 7.6) |
| 7 | 131 | 10 | 7.6 (3.7, 13.6) | 6.3 (4.0, 8.6) |
| 8 | 27 | 1 | 3.7 (0.1, 19.0) | 5.5 (2.9, 8.2) |
| 9 | 20 | 0 | 0.0 (0.0, 16.8) | 5.3 (2.6, 8.0) |
| 10 | 141 | 7 | 5.0 (2.0, 10.0) | 5.5 (3.2, 7.7) |
| 11 | 91 | 8 | 8.8 (3.9, 16.6) | 6.4 (4.0, 8.9) |
| 12 | 82 | 4 | 4.9 (1.3, 12.0) | 5.5 (3.1, 8.0) |
| 13 | 54 | 2 | 3.7 (0.5, 12.7) | 5.4 (2.8, 7.9) |
| 14 | 28 | 0 | 0.0 (0.0, 12.3) | 5.2 (2.5, 7.8) |
| 15 | 101 | 9 | 8.9 (4.2, 16.2) | 6.5 (4.2, 8.9) |
| 16 | Not reviewed | | | |
| 17 | 147 | 3 | 2.0 (0.4, 5.8) | 4.4 (2.2, 6.7) |
| 18 | 22 | 2 | 9.1 (1.1, 29.2) | 5.9 (3.3, 8.6) |

NSW average 5.7% with 95% CI (4.8%, 6.6%)

Table 5 shows lead dislodgment and lead problems by Hospital with rates ranging from 4.4% with 95% CI (2.2%, 6.7%) at Hospital 17 to 6.8% with 95% CI (4.2%, 9.4%) at hospital 4. Six hospitals are above the NSW average for lead dislodgment and lead problems – 4, 5, 7, 11, 15, and 18. The amount of Bayesian shrinkage is greater for the lead dislodgments than in the previous analyses due to the decrease in the crude rates compared to all the complications and also a decrease in the amount of between hospital variability.

The analysis found that there was little evidence to suggest that the complication rates are different for surgeons and non-surgeons. With the overall complication rate the crude odds ratio for a complication was 1.006, p=0.974 with 95% CI (0.717, 1.411) for surgeons compared to non-surgeons. This means that ratio of complications to non-complications is only 1.006 times higher in surgeons compared to non-surgeons, a non-significant difference. Similarly for the reoperations the crude odds ratio was 1.179, p=0.442 with 95% CI (0.775, 1.794) for surgeons compared to non-surgeons. An analysis just for lead dislodgments and lead problems had an odds of a complication for a surgeon compared to a non-Surgeon of 1.157, p=0.545 with 95% CI (0.722, 1.856).

Appendix C Table Six shows complication types by hospital. Appendix D Table Seven shows reoperations by type by hospital. Appendix F contains a more detailed description of the statistical methods used in the analysis.

## Discussion

This is the first study in NSW to examine complication rates following pacemaker insertion in multiple centres. The overall complication rate in this study was 11.9%, 95% CI (10.6%, 13.2%), with 7.3%, 95% CI (6.2%, 8.3%), of patients requiring reoperation. In previous studies, Parsonnet et al (4) reported a complication rate of 5.7% during the six weeks after implantation. Ellenbogan et al (9) reported a complication rate of 4.8% at 30 days, 5.5% at 90 days and 7.5% at three years arising after implantation of dual chamber pacemakers. In a study by Harcombe et al (10) the overall complication rate was 3.5%.

Lead problems (dislodgments and other problems) occurred in 5.7%, 95% CI (4.8%, 6.6%), of patients, with reoperation for atrial lead problems in 2.4%, 95% CI (1.7%, 3.0%), of patients and in 2.2%, 95% CI (1.7%, 2.8%), for ventricular lead problems. Møller et al (1) reported a higher than expected atrial lead reoperation rate of 3.2%, and a rate of 2.9% for ventricular lead reoperation. Kiviniemi et al (11) reported early atrial lead dislodgment in 1.1% of patients and ventricular lead dislodgment in 1.4% of patients. In the study by Ellenbogen et al, 1.7% of patients had atrial lead dislodgment and 0.7% had ventricular lead dislodgment in the first 30 days.

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 risk of haematomas is increased by the fact that many elderly patients are on antiplatelet agents or anticoagulant medication. In this study 51.4% of patients with wound haematoma received antiplatelet agents or anticoagulant medication, but there is no evidence that complications are more likely, i.e. of those who did not have a wound haematoma 50.2% were on antiplatelet or anticoagulant medication.

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. This compares with other studies ranging from 0.6% to 1.5% of patients requiring invasive medical intervention.

### Infections

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

- Two patient 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.

There was one pneumothorax following tracheal perforation requiring a chest tube and ICU admission. In the study by Aggarwall et al (15) 0.8% of pneumothoraces required active medical intervention, compared to this study in which 0.4%, 95% CI (0.2%, 0.6%), of patients required active medical intervention. Cooper and Swanton

(16) reported a pneumothorax rate of 0.5% and in the study by Chauhan et al (17) it was 0.6%.

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. In a study by Parsonnet (4) significant difference in complication rates was found between frequent and infrequent cardiologist implanters (1.2% versus 5.4%). Harcombe et al (10) found complications were more common with inexperienced operators (18.9%) than with experienced operators (0.9%). The limitation of this study was collection of data at the doctor level to be able to differentiate between qualified implanters and advanced trainee implanters as information in the medical record was unreliable.

With regard to the problem of how to deal with multiple complications per patient, there may be significant within subject correlation that would need to be taken into account if this were to be analysed. To do this properly requires a multilevel model that would need to be constructed and tested in a program such as WinBugs. If a crude summation were used then we would over estimate the true complication rate. Even if we think about the complications associated with the procedure rather than the person the same issue applies when more than one complication occurs for the one 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 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 (18), the appointment process for Visiting Medical Officers and Staff Specialists (24 and 25).

*Credentialing and defining scope of practice*

Health care facilities are not allowed to appoint specialist medical practitioners without appropriately credentialing and defining 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 (18)
2. Visiting Practitioner Appointment (24)
3. Staff Specialists Appointment (25)

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.

In July 2004, the then Australian Council for Safety and Quality in Health Care - now the Australian Commission on Safety and Quality in Health Care (19) found that the rigour with which processes of credentialing and defining scope of practice had been conducted and documented varied considerably. The effectiveness and adequacy of credentialing processes was identified in the Final Report of the Task Force on Quality in Australian Health Care 1996 as an important area for improvement.
Appointment of Visiting Medical Officers occurs every 3 to 5 years and most Staff Specialists are permanent employees.

## Methods

Semi-structured interviews were held with senior clinicians[4] and managers in each of the relevant Area Health Services. An interview guide in Appendix E 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.

[4] Consultant Cardiologists and Cardiothoracic Surgeons.

## 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 one Area Health Service 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.

*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 clinicians (all cardiologists) had "Insertion of permanent pacemakers" listed as a clinical privilege.

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 to Credentialing (21) 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.

## 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 clinician level, and how these align with existing policies (23, 26 and 27).

There is a close link between credentialing and clinical privileges discussed in Part Two and performance review – one is necessary for the other. The Health Department's policy on delineation of clinical privileges (18) 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" (26) 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" (23). 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.

## Method

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 clinician'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. Several hospitals had pacemaker databases but not all collect data on complications. It is of interest to note that clinicians 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 pretty closely with the data from the file reviews.

The informal systems relied on what one senior clinician 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, clinicians 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 that implant pacemakers.

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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## Review Team

Professor Clifford Hughes (chair)
Clinical Professor
Chief Executive Officer, Clinical Excellence Commission

Associate Professor Lynne Pressley
Consultant Cardiologist, Royal Prince Alfred Hospital

Dr Val Poxon
Project Manager Cancer Registry, Liverpool Hospital

Dr Peter Brady
Consultant Cardiothoracic Surgeon, Royal North Shore Hospital

Dr Bob Giles
Consultant Cardiologist, Eastern Heart Clinic Prince of Wales Hospital
Representative of the Cardiac Society of Australia and New Zealand

Dr Matthew Bayfield
Consultant Cardiothoracic Surgeon, Royal Prince Alfred Hospital
Representative of the Royal Australasian College of Surgeons

## Statistical Analysis

Dr Robin Turner PhD
Biostatistical Officer, Centre for Epidemiology and Research, NSW Health

*Supervisor*
Dr Judy Simpson, PhD, CStat
Associate Professor (Biostatistics)
School of Public Health
The University of Sydney

## Review Team Secretariat

Ms Alex Warner
Manager Special Reviews, CEC

Ms Barbara Herden
Senior Performance Analyst, CEC

## Medical File Review Team

Ms Alex Warner
Ms Bernadette King
Dr Annette Pantle, Director, Clinical Practice Improvement Projects, CEC
Ms Susan Travis, Manager, NSW Birth Defects Register, NSW Health

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## *Appendix A - Abbreviations and Glossary of Terms*

**Abbreviations**

| | |
|---|---|
| AHS | Area Health Service |
| AICD | Automatic Implantable Cardioverter Defibrillator |
| AO | Authorised Officer |
| CEC | Clinical Excellence Commission |
| CI | Confidence Interval |
| HIE | Health Information Exchange |
| 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.

**Health Information Exchange**
The Health Information Exchange is NSW Health's network of corporate data warehouses. Patient data for this review was extracted from the Patient Service Event Data Set *"Admitted Patient Data Collection"*

**Index admission**
The index admission is the episode of hospitalisation under study.

**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.

**Pacemaker functions**
There are two basic functions of the pacemaker: sensing and pacing. Pacemakers today have the capability of monitoring (sensing) the heart's own conduction system and delivering an electrical impulse (pacing) only when the system fails. Thus, with a normal beat the pacemaker is not activated. If, however, the system senses that a normal beat has not occurred, then the pacemaker activates and stimulates the heart to cause a normal contraction.

**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 B – 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 reoperation |
| Y+ | Complication that **did** require reoperation |

**TYPE OF COMPLICATION**

| | |
|---|---|
| NA | Not applicable |
| LD | Lead dislodgment not specified |
| ALD | Atrial lead dislodgment |
| VLD | Ventricular lead dislodgment |
| 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 C – Complication types by hospital*

**Table 6: Complication types by hospital**

| Hospital | Total Sampled | Crude Percentages (95% CI) LD | ALD | VLD | OLP | WH |
|---|---|---|---|---|---|---|
| 1 | 96 | 0.0 (0.0, 3.8) | 2.1 (0.3, 7.3) | 2.1 (0.3, 7.3) | 0.0 (0.0, 3.8) | 1.0 (0.0, 5.7) |
| 3 | 100 | 0.0 (0.0, 3.6) | 1.0 (0.0, 5.4) | 3.0 (0.6, 8.5) | 0.0 (0.0, 3.6) | 2.0 (0.2, 7.0) |
| 4 | 41 | 2.4 (0.1, 12.9) | 4.9 (0.6, 16.5) | 9.8 (2.7, 23.1) | 0.0 (0.0, 8.6) | 4.9 (0.6, 16.5) |
| 5 | 43 | 0.0 (0.0, 8.2) | 7.0 (1.5, 19.1) | 4.7 (0.6, 15.8) | 2.3 (0.1, 12.3) | 2.3 (0.1, 12.3) |
| 6 | 180 | 0.0 (0.0, 2.0) | 1.7 (0.3, 4.8) | 2.8 (0.9, 6.4) | 0.6 (0.0, 3.1) | 2.2 (0.6, 5.6) |
| 7 | 131 | 0.8 (0.0, 4.2) | 4.6 (1.7, 9.7) | 2.3 (0.5, 6.5) | 2.3 (0.5, 6.5) | 2.3 (0.5, 6.5) |
| 8 | 27 | 0.0 (0.0, 12.8) | 3.7 (0.1, 19.0) | 3.7 (0.1, 19.0) | 0.0 (0.0, 12.8) | 11.1 (2.4, 29.2) |
| 9 | 20 | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) |
| 10 | 141 | 0.0 (0.0, 2.6) | 2.8 (0.8, 7.1) | 1.4 (0.2, 5.0) | 0.7 (0.0, 3.9) | 4.3 (1.6, 9.0) |
| 11 | 91 | 0.0 (0.0, 4.0) | 4.4 (1.2, 10.9) | 3.3 (0.7, 9.3) | 1.1 (0.0, 6.0) | 1.1 (0.0, 6.0) |
| 12 | 82 | 0.0 (0.0, 4.4) | 3.7 (0.8, 10.3) | 0.0 (0.0, 4.4) | 1.2 (0.0, 6.6) | 1.2 (0.0, 6.6) |
| 13 | 54 | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 3.7 (0.5, 12.7) | 0.0 (0.0, 6.6) | 1.9 (0.0, 9.9) |
| 14 | 28 | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) |
| 15 | 101 | 0.0 (0.0, 3.6) | 2.0 (0.2, 7.0) | 2.0 (0.2, 7.0) | 5.0 (1.6, 11.2) | 2.0 (0.2, 7.0) |
| 17 | 147 | 1.4 (0.2, 4.8) | 0.0 (0.0, 2.5) | 0.7 (0.0, 3.7) | 0.0 (0.0, 2.5) | 2.7 (0.7, 6.8) |
| 18 | 22 | 4.5 (0.1, 22.8) | 4.5 (0.1, 22.8) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 9.1 (1.1, 29.2) |
| NSW | 1317 | 0.2 (0.2, 0.3) | 2.4 (1.8, 3.1) | 2.1 (1.6, 2.7) | 1.0 (0.6, 1.5) | 2.6 (1.9, 3.2) |

**Table 6 continued**

| Hospital | Total Sampled | Crude Percentages (95% CI) LI | SI | PX | HX | MP | OTH |
|---|---|---|---|---|---|---|---|
| 1 | 96 | 0.0 (0.0, 3.8) | 1.0 (0.0, 5.7) | 0.0 (0.0, 3.8) | 0.0 (0.0, 3.8) | 0.0 (0.0, 3.8) | 5.2 (1.7, 11.7) |
| 3 | 100 | 2.0 (0.2, 7.0) | 0.0 (0.0, 3.6) | 3.0 (0.6, 8.5) | 0.0 (0.0, 3.6) | 1.0 (0.0, 5.4) | 3.0 (0.6, 8.5) |
| 4 | 41 | 0.0 (0.0, 8.6) | 0.0 (0.0, 8.6) | 2.4 (0.1, 12.9) | 0.0 (0.0, 8.6) | 0.0 (0.0, 8.6) | 12.2 (4.1, 26.2) |
| 5 | 43 | 0.0 (0.0, 8.2) | 0.0 (0.0, 8.2) | 2.3 (0.1, 12.3) | 0.0 (0.0, 8.2) | 0.0 (0.0, 8.2) | 2.3 (0.1, 12.3) |
| 6 | 180 | 0.0 (0.0, 2.0) | 0.0 (0.0, 2.0) | 0.0 (0.0, 2.0) | 0.0 (0.0, 2.0) | 1.1 (0.1, 4.0) | 2.2 (0.6, 5.6) |
| 7 | 131 | 3.8 (1.3, 8.7) | 0.0 (0.0, 2.8) | 0.8 (0.0, 4.2) | 0.0 (0.0, 2.8) | 0.0 (0.0, 2.8) | 0.0 (0.0, 2.8) |
| 8 | 27 | 0.0 (0.0, 12.8) | 3.7 (0.1, 19.0) | 0.0 (0.0, 12.8) | 0.0 (0.0, 12.8) | 0.0 (0.0, 12.8) | 0.0 (0.0, 12.8) |
| 9 | 20 | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) |
| 10 | 141 | 0.0 (0.0, 2.6) | 1.4 (0.2, 5.0) | 0.0 (0.0, 2.6) | 0.0 (0.0, 2.6) | 0.0 (0.0, 2.6) | 7.1 (3.5, 12.7) |
| 11 | 91 | 0.0 (0.0, 4.0) | 2.2 (0.3, 7.7) | 0.0 (0.0, 4.0) | 0.0 (0.0, 4.0) | 0.0 (0.0, 4.0) | 0.0 (0.0, 4.0) |
| 12 | 82 | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) |
| 13 | 54 | 1.9 (0.0, 9.9) | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 1.9 (0.0, 9.9) |
| 14 | 28 | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 3.6 (0.1, 18.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) |
| 15 | 101 | 1.0 (0.0, 5.4) | 1.0 (0.0, 5.4) | 0.0 (0.0, 3.6) | 0.0 (0.0, 3.6) | 1.0 (0.0, 5.4) | 1.0 (0.0, 5.4) |
| 17 | 147 | 0.0 (0.0, 2.5) | 0.0 (0.0, 2.5) | 0.7 (0.0, 3.7) | 0.0 (0.0, 2.5) | 0.0 (0.0, 2.5) | 0.7 (0.0, 3.7) |
| 18 | 22 | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) |
| NSW | 1317 | 0.6 (0.3, 0.9) | 0.7 (0.3, 1.0) | 0.5 (0.2, 0.8) | 0.0 (0.0, 0.1) | 0.3 (0.1, 0.6) | 2.7 (2.0, 3.5) |

## *Appendix D – Reoperations by type by hospital*

**Table 7: Reoperations by type by hospital**

| | | Crude Percentages (95% CI) | | | | |
|---|---|---|---|---|---|---|
| Hospital | Total Sampled | LD | ALD | VLD | OLP | WH |
| 1 | 96 | 0.0 (0.0, 3.8) | 2.1 (0.3, 7.3) | 2.1 (0.3, 7.3) | 0.0 (0.0, 3.8) | 0.0 (0.0, 3.8) |
| 3 | 100 | 0.0 (0.0, 3.6) | 0.0 (0.0, 3.6) | 3.0 (0.6, 8.5) | 0.0 (0.0, 3.6) | 0.0 (0.0, 3.6) |
| 4 | 41 | 2.4 (0.1, 12.9) | 4.9 (0.6, 16.5) | 9.8 (2.7, 23.1) | 0.0 (0.0, 8.6) | 0.0 (0.0, 8.6) |
| 5 | 43 | 0.0 (0.0, 8.2) | 7.0 (1.5, 19.1) | 4.7 (0.6, 15.8) | 0.0 (0.0, 8.2) | 2.3 (0.1, 12.3) |
| 6 | 180 | 0.0 (0.0, 2.0) | 1.7 (0.3, 4.8) | 2.8 (0.9, 6.4) | 0.0 (0.0, 2.0) | 0.0 (0.0, 2.0) |
| 7 | 131 | 0.8 (0.0, 4.2) | 4.6 (1.7, 9.7) | 2.3 (0.5, 6.5) | 2.3 (0.5, 6.5) | 0.0 (0.0, 2.8) |
| 8 | 27 | 0.0 (0.0, 12.8) | 3.7 (0.1, 19.0) | 3.7 (0.1, 19.0) | 0.0 (0.0, 12.8) | 0.0 (0.0, 12.8) |
| 9 | 20 | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) |
| 10 | 141 | 0.0 (0.0, 2.6) | 2.8 (0.8, 7.1) | 1.4 (0.2, 5.0) | 0.7 (0.0, 3.9) | 1.4 (0.2, 5.0) |
| 11 | 91 | 0.0 (0.0, 4.0) | 4.4 (1.2, 10.9) | 3.3 (0.7, 9.3) | 0.0 (0.0, 4.0) | 1.1 (0.0, 6.0) |
| 12 | 82 | 0.0 (0.0, 4.4) | 3.7 (0.8, 10.3) | 0.0 (0.0, 4.4) | 1.2 (0.0, 6.6) | 1.2 (0.0, 6.6) |
| 13 | 54 | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 3.7 (0.5, 12.7) | 0.0 (0.0, 6.6) | 1.9 (0.0, 9.9) |
| 14 | 28 | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) |
| 15 | 101 | 0.0 (0.0, 3.6) | 2.0 (0.2, 7.0) | 2.0 (0.2, 7.0) | 5.0 (1.6, 11.2) | 2.0 (0.2, 7.0) |
| 17 | 147 | 1.4 (0.2, 4.8) | 0.0 (0.0, 2.5) | 0.7 (0.0, 3.7) | 0.0 (0.0, 2.5) | 0.0 (0.0, 2.5) |
| 18 | 22 | 4.5 (0.1, 22.8) | 4.5 (0.1, 22.8) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) |
| NSW | 1317 | 0.2 (0.2, 0.3) | 2.4 (1.7, 3.0) | 2.2 (1.7, 2.8) | 0.8 (0.4, 1.2) | 0.7 (0.3, 1.2) |

**Table 7 continued**

| Hospital | Total Sampled | Crude Percentages (95% CI) LI | SI | PX | HX | MP | OTH |
|---|---|---|---|---|---|---|---|
| 1 | 96 | 0.0 (0.0, 3.8) | 1.0 (0.0, 5.7) | 0.0 (0.0, 3.8) | 0.0 (0.0, 3.8) | 0.0 (0.0, 3.8) | 1.0 (0.0, 5.7) |
| 3 | 100 | 1.0 (0.0, 5.4) | 0.0 (0.0, 3.6) | 2.0 (0.2, 7.0) | 0.0 (0.0, 3.6) | 1.0 (0.0, 5.4) | 3.0 (0.6, 8.5) |
| 4 | 41 | 0.0 (0.0, 8.6) | 0.0 (0.0, 8.6) | 2.4 (0.1, 12.9) | 0.0 (0.0, 8.6) | 0.0 (0.0, 8.6) | 4.9 (0.6, 16.5) |
| 5 | 43 | 0.0 (0.0, 8.2) | 0.0 (0.0, 8.2) | 2.3 (0.1, 12.3) | 0.0 (0.0, 8.2) | 0.0 (0.0, 8.2) | 0.0 (0.0, 8.2) |
| 6 | 180 | 0.0 (0.0, 2.0) | 0.0 (0.0, 2.0) | 0.0 (0.0, 2.0) | 0.0 (0.0, 2.0) | 0.6 (0.0, 3.1) | 0.6 (0.0, 3.1) |
| 7 | 131 | 3.8 (1.3, 8.7) | 0.0 (0.0, 2.8) | 0.8 (0.0, 4.2) | 0.0 (0.0, 2.8) | 0.0 (0.0, 2.8) | 0.0 (0.0, 2.8) |
| 8 | 27 | 0.0 (0.0, 12.8) | 3.7 (0.1, 19.0) | 0.0 (0.0, 12.8) | 0.0 (0.0, 12.8) | 0.0 (0.0, 12.8) | 0.0 (0.0, 12.8) |
| 9 | 20 | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) | 0.0 (0.0, 16.8) |
| 10 | 141 | 0.0 (0.0, 2.6) | 0.7 (0.0, 3.9) | 0.0 (0.0, 2.6) | 0.0 (0.0, 2.6) | 0.0 (0.0, 2.6) | 1.4 (0.2, 5.0) |
| 11 | 91 | 0.0 (0.0, 4.0) | 2.2 (0.3, 7.7) | 0.0 (0.0, 4.0) | 0.0 (0.0, 4.0) | 0.0 (0.0, 4.0) | 0.0 (0.0, 4.0) |
| 12 | 82 | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) | 0.0 (0.0, 4.4) |
| 13 | 54 | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) | 0.0 (0.0, 6.6) |
| 14 | 28 | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) | 0.0 (0.0, 12.3) |
| 15 | 101 | 0.0 (0.0, 3.6) | 1.0 (0.0, 5.4) | 0.0 (0.0, 3.6) | 0.0 (0.0, 3.6) | 1.0 (0.0, 5.4) | 0.0 (0.0, 3.6) |
| 17 | 147 | 0.0 (0.0, 2.5) | 0.0 (0.0, 2.5) | 0.7 (0.0, 3.7) | 0.0 (0.0, 2.5) | 0.0 (0.0, 2.5) | 0.7 (0.0, 3.7) |
| 18 | 22 | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) | 0.0 (0.0, 15.4) |
| NSW | 1317 | 0.3 (0.2, 0.5) | 0.5 (0.2, 0.9) | 0.4 (0.2, 0.6) | 0.0 (0.0, 0.0) | 0.3 (0.0, 0.5) | 0.9 (0.4, 1.3) |

## *Appendix E – Interview guide*

CLINICAL EXCELLENCE COMMISSION

PACEMAKER REVIEW INTERVIEW GUIDE

**CONFIDENTIAL**

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**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?

## *Appendix F – data analysis in more detail*

### Data Cleaning

The final data was input into SAS System version 9.1 (5) for data cleaning and analysis. Each variable was summarised and checked for typographical errors and missing values. All missing values were assigned to an "unknown". Typographical errors were either compared back to the original data collection sheets or compared to other variables in the analysis (where possible) to confirm which code was intended.

The information from the HIE extract was then merged to the results file after creating a unique ID for each person based on the MRN, stay number and subject's date of birth. The HIE extract contained information on the type of pacemaker inserted and co morbidities.

### Statistical analysis

The crude complication rate ($p_i$) was calculated as the observed number of complications ($O_i$) out of the total number of reviewed implants ($n_i$) for the $i$th hospital. Exact methods were used to calculate the 95% confidence intervals.

The rate for NSW was calculated using Scheaffer et al's (7) equation:

$$\hat{p} = \frac{1}{N}\sum_{i=1}^{L} N_i \hat{p}_i$$

where $N_i$ is the number available to sample within each strata and N is the total number available to sample. The variance is:

$$\hat{V}(\hat{p}_{st}) = \frac{1}{N^2}\sum_{i=1}^{L} N_i^2 \left(\frac{N_i - n_i}{N_i}\right)\left(\frac{\hat{p}_i \hat{q}_i}{n_i - 1}\right)$$

for a sample of size $n_i$ in the $i$th strata.

The crude expected number of complications ($E_i$) per hospital was calculated using the overall NSW rate multiplied by the number of reviewed implants in each hospital. Bayesian shrinkage was used to stabilise the hospitals with small samples. The Bayesian model was based on a Poisson-gamma distribution. The corrected rate is formulated from a study by Simpson et al (8):

$$rate_{corr} = \frac{\left(O + 1/\upsilon^2\right)}{\left(E + 1/\upsilon^2\right)} \times \frac{E}{n}$$

with standard error

$$SE\left(rate_{corr}\right) = \sqrt{\frac{1}{E + 1/\upsilon^2}} \times \frac{E}{n}$$

where $\upsilon$ is the maximum likelihood estimate of the variance of the random intercepts for the hospital variable. The model was checked with a logistic random effects regression model in WinBugs to confirm the appropriateness of the Poisson-gamma formulas for this data.

Logistic regression models were used to investigate the potential relationship between implanter, type of device and complications. These results are reported in terms of odds ratios that measure the odds of a complication in one covariate level compared to the odds of a complication in the reference level for the covariate.

The majority of the analysis was completed in SAS (5) and the random effects model was calculated in Stata SE 8.2 (9).

**Offices**
Level 3, 65 Martin Place
Sydney NSW 2000
1st Floor
Administration Building
Sydney Hospital
8 Macquarie Street
Sydney NSW 2000

**Correspondence**
GPO Box 1614
Sydney NSW 2000
Tel 61 2 9382 7600
Fax 61 2 9382 7615
www.cec.health.nsw.gov.au