Monitoring Health Care Using National Administrative Data Collections

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Declaration

Except where otherwise acknowledged in the text, this thesis represents my own original work.

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Abstract

With the inevitable adoption of information technology into all areas of human pursuit, the potential benefits for health care should not be overlooked. In Australia, details of most health care encounters are currently recorded for administrative purposes. This results in an impressive electronic data-bank that could provide a national resource for health service evaluation.

Evaluation of health services has become increasingly important to provide indicators of the benefits, risks and cost-effectiveness of treatments. However, if administrative data are to be used for this purpose, several questions must first be addressed: Are the current data collections accessible? What outcome measures can be derived from these data? Can privacy issues be managed? Could the quality of the data be improved? Is the existing infrastructure adequate to supply data for evaluation purposes? Could the existing system provide a basis for the development of an integrated health information system?

The aims of the project were:

- To examine the potential for using administrative data to generate outcome measures and surveillance indicators.
- To investigate the logistics of gaining access to these data for the purpose of research. This to be achieved within the current ethical, political and financial framework.
- To compare the Australian health-service data system with the current international state-of-the-art.
- To develop suggestions for expansion of the present system as part of an integrated health record and information system. This system to manage patient records and provide data for quality management, treatment surveillance and cost-effectiveness evaluation as a routine activity.

The thesis is presented in two parts. In the first part, a historical cohort study is described that involved patients with implantable medical devices. The potential to evaluate outcomes was investigated using all national health-service information currently available in electronic form. Record linkage techniques were used to combine

and augment the existing data collections. Australia's national health databases are to varying degrees, amenable to such linkage and cover doctor visits, pharmaceuticals, hospital admissions and deaths. The study focused on medical devices as an illustrative case but the results are applicable to the routine assessment of all medical and surgical interventions.

For the Australian 'Medical Devices study', the records of 5,316 patients who had medical device implants in 1993-94 were selected from the archives of a major private health insurer. Five groups of medical implants were studied: heart valves, pacemakers, hips, vascular grafts and intra-optic lenses. Outcomes for these patients, including death, re-operation and health service utilisation, were compared and analysed.

A comparison study was performed using data from the Manitoba Health database in Winnipeg, Canada. Manitoba provides a very similar demographic group to that found in Australia and is an example of a prototype integrated-health-information system. One of the principal advantages for research is that *personally identified* data about medical and hospital services are collected for all patients. Selection bias is eliminated because individual consent is not required for this type of research and all selected patients could be included in the study.

The two studies revealed many barriers to the use of administrative data for health outcomes research. Service event data for the Australian cohort could be collected but only after long delays and hospital morbidity data were not available for the entire cohort. In contrast to the situation in Australia, the Manitoba data were both accessible and complete, but were lacking in detail in some areas.

Analysis of the collected data demonstrated that without the addition of clinical data only general indications of trends could be deduced. However, with minimal supplementary clinical data, it was possible to examine differences in performance between brands of medical devices thus indicating one of the uses for this type of data collection.

In the second part of the thesis, conclusions are presented about the potential uses and limitations of the existing system and its use as a basis for the development of a national

Integrated Health Record and Information System (IHRIS). The need for the establishment of a systemic quality management system for health care is discussed.

The study shows that linked administrative data can provide information about health outcomes which is not readily available from other sources. If expanded and integrated, the system that is currently used to collect and manage administrative data, could provide the basis for a national health information system. This system would provide many benefits for health care. Benefits would include the monitoring, surveillance and cost-effectiveness analysis of new and existing treatments involving medical devices, drugs and surgical procedures. An integrated health information system could thus provide for both clinical and administrative needs, while in addition providing data for research.

Unfortunately, in Australia, the use of administrative data for this purpose is not currently feasible. The principal barrier is the existence of a culture within the Australian health care system which is not supportive of research and is deficient in quality and safety measures.

Recent initiatives by both the Commonwealth and state governments have supported the introduction of measures to improve quality and safety in health care. It is argued here that an Integrated Health Record and Information System (IHRIS) would provide an essential component of any such scheme. The results of this study have important policy implications for health care management in both the administrative and clinical domains.

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The desire for safety stands against every great and noble enterprise
Cornelius Tactitus, AD 56-120

Anyone who has never made a mistake has never tried anything new. Albert Einstein.

Preface

This research project was conceived during my time working within the Commonwealth Department of Health in the area of medical device regulation. As medical advisor, I witnessed the limitations of pre-market evaluation of new products, the inadequate system of 'problem' reporting and the challenge of implementing safety alerts and product recalls for faulty devices. When problems with a heart-valve, pacemaker-lead or intra-uterine device were detected, it was often appropriate to advise patients of the need for investigation or removal of the implant. However, since no systematic record is kept about who had what implant, contacting patients and doctors was complicated. It became apparent that a better tracking system existed for motor vehicles than for life-saving medical devices.

An implant tracking system was envisaged; there are several possible approaches available.

- A purpose designed, centralised database maintained by either the public or private sector. Registration may be either obligatory or voluntary. The database may incorporate all devices or be confined to a certain type. (An example is the Norwegian Arthroplasty Register. Outside the medical device area, registries of infectious diseases are widely used.)
- Hospital based registries (ie at place of implantation). This approach has recently become a legislative requirement in the USA for selected implantable devices.
- 'Boutique' registries run by manufacturers. This can occur in an ad-hoc manner where patients return a warranty card as occurs for some cardiac pacemakers.
- The function may be combined with the collection of administrative data. This is the approach adopted for example in Sweden and Norway.

The Medical Devices study, which is the basis of this thesis, examines the last of these options. The original aims of the project were:

- To assess the feasibility and potential health and cost benefits of using routinely collected administrative data to monitor health outcomes of medical device implants.
- To develop a data collection and record linkage model for the routine determination of a range of intervention outcomes.

- To assess the cost benefit of the model.

In Australia, several health administrative data-sets are routinely collected. Almost all doctor visits, hospital admissions and deaths are systematically recorded across the country. The existing infrastructure could provide an appropriate means to collect the additional data needed for a medical implant register. It would probably be the most cost-effective option and would require minimum system changes. Importantly, when clinical detail is added to national administrative data-sets, a powerful resource is created that could be used for health outcomes evaluation. It is this possibility that will be examined in this thesis.

Introduction

To investigate the potential for using administrative data collections for health outcomes analysis I decided to conduct a study that would draw its information from all currently available electronic national data-sets. Health service data are collected by the Commonwealth government in the Medical Benefits, the Pharmaceutical Benefits, the Department of Veterans Affairs, the National Death Index and the National Hospital Morbidity collections. In order to provide the maximum information for analysis, these data sets would require linkage at the patient level. Detailed demographic data is collected by the Australian Bureau of Statistics (ABS). Unfortunately, all personal identifiers have been removed from the ABS collection and as a result these data were not able to be incorporated. To test the usefulness of this linked resource for health outcomes evaluation, it was necessary to select a medical intervention to examine. Implantable medical devices were chosen as a typical, well defined and widely used procedure.

In order to provide a comparison with a state-of-the-art, purpose designed health data system, it was decided to perform a parallel study in Manitoba, Canada. Manitoba Health collects service data specifically for the purpose of health care evaluation, in addition to the needs of administration. These data are available for approved research projects.

During the initial stages of the study, it became apparent that some modifications to the original aims would be required. The changes were necessary because of the limited availability of Australian data and the poor quality of data that was available. Taking this into account, I decided to conduct comparative analyses on three different 'levels' of data quality that were conceivable, if not actually available.

- The currently available Australian data
- The reasonably high quality data collected in Manitoba
- A 'simulated' data-set that might be available from an integrated health information system. This was achieved by using all Australian service data supplemented with detail from a private health insurer.

Because it involved using and evaluating almost all the relevant administration data sets, the implant study provided invaluable insight into the use of nationally collected administrative information. The thesis therefore, has two distinct parts. The first and main part, is concerned with the Medical Devices study. The second part builds from my experience in conducting these studies. It discusses the potential for expansion and integration of the existing administrative data system for the purpose of building an integrated health record and information system (IHRIS) which would be an essential component of a new health care structure based on a quality management philosophy.

In the first part, Chapter 1 describes the history and state-of-the-art of record linkage in Australia and overseas, the need for evaluation and surveillance of new medical interventions and the growing industry of health data collection. Chapter 2 presents an overview of the study methodology while Chapter 3 enlarges on the processes involved in selecting a study cohort. Chapters 4-6 describe the Medical Devices study, its implementation, results and analysis. Chapter 7 describes the Manitoba study and Chapter 8 compares the Manitoba and Australian data collections, pointing out their various advantages and limitations.

Chapter 9, which introduces the second part of the thesis, discusses in more detail the strengths and limitations of the use of administrative data for research and examines the trend towards the introduction of integrated data collections and quality management in health care. The potential for the existing administrative data system to provide a basis for an integrated health information system that caters for systemic quality management is discussed. In Chapter 10, recent initiatives supporting the introduction of a quality and safety system in Australian health care are reviewed. The importance of an IHRIS to support such a system is discussed.

Chapter One

Record linkage and the monitoring of health services

1.1 Introduction

Over the last four decades in the industrialised world, 'health technology' has become an increasingly important component of the health care system, both in its application and in its cost to society. As life expectancy continues to increase there is a greater focus on the influence of health care on quality of life. Great expectations are placed on health care and the evaluation of its effectiveness has become important and complex. In addition, it has become crucial to assess the relative cost-effectiveness of different treatments if we seek to optimise the use of scarce resources. There have also been unprecedented advances in information technology - we now have the ability to record easily and cheaply, information about every health transaction and to access this information instantly no matter where it is stored. If such capabilities were used to their full potential, the evaluation of health interventions would be greatly facilitated. Sadly, this is not the case in any health care system in the world, although much work has been done in both the collection of health data and its analysis. Australia is lagging behind many countries in this endeavour, and some of the reasons for this will be examined here.

This project was conducted to investigate the current status of Australian national health databases and how useful they are for health outcomes evaluation. It assesses the availability of information to researchers, the processes required by current legislation regarding ethics approval and patient consent and the quality and appropriateness of the data available. The project is intended to function at two levels: at the theoretical level, it is intended to investigate the potential of using national administrative data to assess treatment outcomes. This requires discussion of record linkage, data processing, national data collection systems, ethics and privacy issues. At the practical level, the project undertakes two illustrative studies of medical implants in order to examine and compare the various procedures necessary to collect and analyse data from currently compiled Australian and Manitoban data collections. The discussion includes the management of both drugs and medical devices, as many of the problems and their solutions are similar for both groups.

Various record linkage studies have been performed overseas and on an intra-state basis in Australia. This project assesses the potential value of Australia's national health data collections for outcomes analysis, for the first time. Support for this type of research has been provided in the National Health Agreement (Human services and Health 1993) and the National Health Information Development Plan 1995 (AIHW 1995). Literature relating to the relevant disciplines was examined and the current state-of-play is presented.

1.2 Collecting health care data for the evaluation of services

Some might argue that we should collect all health data possible and that having done this, we could produce analyses of all health care interventions. The constraints of reality prevail, however. Time and cost limitations have resulted in the collection of the minimum data sufficient for the task with little foresight about how such data collections could provide other benefits. It is only recently that interest has been shown in evaluating the outcomes of health care in addition to providing health services themselves. As well as this increasing interest in health outcomes and the data needed to support their evaluation, there has been a change in focus towards the rights of the 'consumer'. Concerns about individual privacy have made both providers and consumers cautious about what data are collected, how they are used, and by whom (Sibthorpe, Kliewer et al. 1995). The central issue has been the personal identification of patients' records.

Australia already collects vast amounts of health care data mainly for the purpose of allocating funding to hospitals and paying providers (see Appendix 8B for a description of the contents of the data sets). We need to ask whether better use could be made of these data. If the data are deficient for these purposes, then we must examine whether it would be ethically acceptable and cost effective to improve the quality of these data. Data collected for such administrative purposes are generally lacking in clinical detail, and often are partially or completely de-identified.

The inclusion of personal identifiers in the data has generally been avoided in the belief that privacy may be violated. The privacy concerns unfortunately extend beyond the realm of personal confidentiality into political privacy at the provider, institutional and state levels. Privacy protection is one of the most significant unresolved issues preventing the development of a national integrated health information system in

Australia. The resulting lack of identified data is a major obstacle for research. For this reason identifiers will be discussed at some length. It is also worthwhile to define the additional data items that would be necessary for the purposes of outcomes analysis over those required for administrative purposes, and to outline the system required to collect these.

1.3 Identifiers

A number of personal identifiers are available, including of course personal names. The ideal personal identifier would be unique, computer readable and have some form of internal consistency to allow automatic checking. This type of personal identifier when used in health care has been called a Unique Patient Identifier (UPI).

Personal identifiers can be of various forms and numerous approaches have been trialled over the last few decades. 'Real' personal names are convenient in the sense that everyone has one allocated at birth and is able to produce it on demand. However, real names are not optimal for reliable data linkage as they do not follow a standard format, are not unique and are subject to entry errors. For example names of Asian origin are often written in reverse order; many persons use a second name as their common name and many names are used in abbreviated form.

Derived or "intelligent" numbering systems produce a code that is based on unit details, for example name plus date of birth or country, publisher etc (Green and Bide 1999). This approach has the advantage that codes can be generated at any site without reference to a central allocation point. Examples of this system include the ISBN and ISSN numbers used for books and journals. Alternatively a "blind" number can be used - a specially designed alpha-numeric or numeric code allocated by a central agency using enough digits to cover the entire population with the addition of a 'check digit'. The check digit is produced as a function of the preceding digits (usually the modulus of the sum) and will generate an error if the code is incorrectly entered into a computer. Such a digit is part of the Australian Medicare number. Blind codes are becoming the standard for electronic data exchange and this approach will probably be the most likely contender for a Unique Patient Identifier (UPI). In general there should be no manual entry of identifiers, all codes should be implemented as a bar code (or 'mag strip', as used on the Medicare card) a check digit can then be automatically utilised and entry errors virtually eliminated. Unless physical attributes are used (such as finger-print or

retinal images), human error is still possible; the wrong card can be presented, either deliberately or accidentally.

There have been various attempts overseas to implement unique identifiers. The simplest way to achieve this is to introduce a national patient identifier. Some countries have already done this. It is not as simple and foolproof as it seems. In the pioneering Oxford record-linkage studies of Acheson in the 1960s (Acheson 1967), it was hoped to use the British National Health Service Number. This was found to be impractical - partially because of the inconvenient format of the number itself and the fact that bar coding and scanning were not available at that time.

In the UK, the National Health Service (NHS) number was initiated after national registration in 1939 and was adopted by the NHS in 1948 (Baldwin and Acheson 1987 p44). The primary purpose of the number is the management of NHS patient lists for family doctors. For the purpose of record linkage the number was found to be inadequate, mainly because there was no requirement to use the number, thus it was usually absent from patient records. In addition to this it did not have a standard format; it varied in length from 9-15 digits, contained variable numbers of alpha characters and punctuation and changed over time. It did not have a check digit and since the format varied, entry clerks could not determine whether it was complete.

No national unique patient identifier currently exists in Australia. However, for intra-state health research, patient identifiers are used within each (state) hospital in addition to names. These identifiers do not come close to providing a UPI, but are available within each state for research conducted by the relevant health departments. They are removed before hospital admission data is submitted to the Commonwealth for inclusion in the National Hospital Morbidity Dataset (NHMDS). These state hospital identifiers are thus not available for research using the NHMDS at the national level.

Various moves have been made towards introducing a UPI in Australia over the past year. Strong support is evident from the Health Insurance Commission (HIC) for the use of the Medicare PIN number to be used (Michael Parsons, personal communication, June 1999). This is also the preferred option of the Commonwealth Department of Health (Philip Hagan, personal communication, November 1999). Currently the Australian Capital Territory Department of Health and Community Care is introducing

a Patient Master Index (a type of UPI) to allow accurate identification of clients and the integration of clinical records.

1.4 Record linkage

Record linkage is the process whereby an entry in one list is linked to an entry in another list by using a common piece of information. Most commonly, personal names have been used to achieve this matching process. Because of the non-uniqueness of these 'identifiers' this usually results in confusion between those with identical or similar names. To reduce the number of false matches, personal names are usually combined with other details (such as date of birth) thereby increasing the 'uniqueness' of the identifier. This process is described as 'probabilistic' because a 'guess' must be made each time records are matched – matches are never absolutely certain to be correct. Variations in identifiers are intuitively managed by the average clerk (the only approach possible prior to the availability of affordable computers in the 1960s), but provide a challenge for a computer. Since most data are now stored in electronic form and because data volumes are so large, a computer is generally used. A number of sophisticated record linkage software programs are available. When a unique identifier exists, (usually a specific ID number) the process is greatly simplified and is described as 'deterministic' linkage. In this situation, matches are virtually 100% reliable.

It was as a result of the general non-availability of a reliable identifying number that probabilistic record-linkage was developed. It is a mechanism for dealing with the real-world situation that arises whenever data is entered manually and unique identifiers are not available. Early developments in probabilistic linkage were pioneered by Newcombe who reasoned that if all identifying information was considered, each part could contribute a match probability proportional to its rarity in the dataset. The sum of the various probabilities would indicate the likelihood of a correct match between two different records (Newcombe 1959). Thus such common problems as misspellings, use of middle name as first name, inaccuracies in the recording of birth dates such as reversal of the month and day fields and variations in abbreviations used for addresses could be managed rather than having to simply reject the whole record as a 'non-match'.

1.4.1 The development of record linkage

The classic "Oxford record-linkage study" of the 1960s,(Acheson 1967)has provided a model for a series of studies in many countries. Principal areas of interest have been industrial diseases and drug side effects (Hall, Holm et al. 1990),(Carstensen, Wingren et al. 1990). Record linkage can provide population data with large numbers and minimal selection bias over a significant time period. One of the benefits of routine collection and analysis systems is that new associations can be tested as new hypotheses are developed; data are collected *before* formal research questions have been formulated. Due to the accounting requirements of health care management, large amounts of data are routinely amassed by national and private institutions. In spite of the completeness of the data and the fact that these data are already recorded electronically, these resources are used infrequently for health outcomes research due to lack of system integration, legislative restrictions and privacy concerns.

The early developments in record linkage during the 1960s were all the more impressive considering the minimal computing power that was available at the time. Subsequently there have been developments in both computer hardware and software and also in the technology of data management. Large electronic databases are common in government and industry, standardised data storage formats are available and actual storage space is now cheap. Several commercial software packages are available for probabilistic linkage; one that is used widely by Australian data holders is the Automatch program (Automatch 1998). In one remarkable US study, a demonstration linkage matched 254,000 hospital patients in the Californian mortality file (1.3m records) with the USA social security file (13m records). The linkage produced an 0.1% false positive rate and no false negatives (Newman TB 1997). Such accuracy is usually not achievable and depends entirely on the quality and completeness of the data. As an epidemiological tool, record linkage is a valuable technique for putting together information about the same person that may have been recorded on different occasions, for different purposes in different data collections (Neutel, Johansen et al. 1991).

1.4.2 Record linkage in Canada

Canada's health information system has benefited from the work of Newcombe and others (Newcombe 1988). The Canadian Mortality Database and the National Cancer Incidence Reporting System were established by Statistics Canada in the late 1970s to

provide a centralised follow-up facility under the confidentiality rules of the Federal Statistics Act 1971. Death records are available back to 1950, cancer cases to 1969. What has become a standard record linkage technique is used to match the identities of records to additional databases. The usefulness of this approach has been demonstrated for example by a study supporting the hypothesis that Isoniazid is not carcinogenic. In this study, files of 41,000 persons treated with the tuberculosis drug since 1952 were linked with mortality and cancer databases (Howe, Lindsay et al. 1979).

Record linkage has been used widely for analysis of large electronic data files in the search for causal relationships between exposure and disease. A range of studies have been reported investigating mental disease, cancer and TB (Hobbs, Fairbairn et al. 1976), exposure to carcinogens in Canada (Smith and Newcombe 1980), industrial exposure to such substances as asbestos (Newhouse and Berry 1972), the association between rheumatoid arthritis and lymphoma in Saskatchewan (Tennis 1993) and the consequences of surgery such as vasectomy (Nienhuis, Goldacre et al. 1992). These studies have either demonstrated or refuted a relationship between exposure and disease or alternatively, have flagged areas for further research.

Several Canadian provinces have instituted sophisticated health data systems to enable epidemiological research and to monitor the use of health services. Pioneering examples of the use of record linkage include work done in the province of British Colombia, where record linkage has been used to extend the reaches of the provincial health information system both laterally into other programs and backwards in time to incidents that occurred prior to its inception (Chamberlayne, Green et al. 1998).

The Manitoban health data collections contain accurate and complete information on deaths, hospital admissions, doctor visits and more recently, pharmaceutical use and pathology services. These data are used for analysis of health service allocation and health outcomes by Manitoba Health and the Manitoba Centre for Health Policy and Evaluation (Manitoba Center 1991). The current research use of these data collections is considerable (Roos, Mustard et al. 1993).

The state of Saskatchewan has established an extensive data resource for epidemiological studies. Since 1970, data on hospital admissions (including primary and secondary diagnoses) and all prescriptions has been collected for its one million

inhabitants. This resource has been utilised for a number of projects. For example, the relative risks of hormone use in post-menopausal women was investigated (Risch and Howe 1994). This study examined the use of unopposed estrogens and the oral contraceptive pill over a 21 year exposure period. For this purpose, the provincial cancer registry was linked to the Saskatchewan Health Prescription-Drug-Plan Database and the relative risk for 5 years of unopposed oestrogen use was found to be 1.96. Outcomes from record linkage studies are equally valuable if they refute rather than support a suspected association. Such was the case with a study of the risks of cancer after hip implant which demonstrated no association. This study, by drawing on the Swedish national cancer and death registries was able to examine 58,000 years of patient follow up (Mathiesen, Ahlbom et al. 1995).

The Saskatchewan data has also been used to confirm the results of studies conducted in other populations. A record-linkage study using Medicaid data[1] suggested that beta-blockers may be associated with increased use of antidepressants. This conclusion was controversial, however, it was confirmed by a retrospective cohort study using data from the health database of Saskatchewan (Thiessen and Wallace 1988).

1.4.3 Record linkage in Australia

In Australia, restrictions on the use of record linkage exist at both the state and federal levels. At the national level there are three influential items of legislation. These are the Health Insurance Act 1973, the Privacy Act 1988 and the National Health Amendment Act 1993. The Privacy Act controls any linkage involving Commonwealth databases while the other two affect the Health Insurance Commission databases (the Medical and Pharmaceutical Benefits Schedules - MBS and PBS). The Privacy Act will allow record linkage if informed consent by the study subject is gained (Clause B).

Alternatively the Privacy Commissioner can approve record linkage projects conducted by Commonwealth agencies if satisfied that the public interest 'outweighs to a substantial degree' the public interest in privacy. The NHMRC also has the power to approve guidelines for medical research that, with the approval of the Commissioner, can provide a mechanism to allow Institutional Ethics Committees to approve linkage

1 Medicaid is the US government insurer for low income earners.

with the Commonwealth databases if they too are convinced that the public interest in the research would outweigh the public interest in privacy.

In addition to this, the Health Insurance Act 1973 allows release of specific data from the HIC database with ministerial approval. The National Health Amendment Act required the issue of guidelines for HIC data, these came into effect in 1994. They prohibit the linkage of this data unless there is a serious threat to the health of an individual. Thus for any conceivable epidemiological research project individual patient consent is a requirement for the use of this data resource. This is hardly a situation conducive to the use of record linkage in health outcomes research. Sibthorpe summarises the situation:

> The way forward depends on finding an acceptable balance between individual privacy and public interest.(Sibthorpe, Kliewer et al. 1995)

This approach has long been promoted by the Australian Law Reform commission (1984):

> Privacy interests are not absolute. They must be weighed … against competing public and private interests.

In contrast to these rather restrictive controls, the National Health Information Development Plan (AIHW 1999) states that one of the highest priorities for the development of public health information capacity was to examine the feasibility and usefulness of potential approaches to linking health records. It recommends

> the development of a framework for the systematic collection, aggregation and use of public health information at the national level.(recommendation 3.4.1)

These recommendations continue the consistent calls for the use of linked data for health research (AIHW 1994),(AIHW 1995),(Sibthorpe, Kliewer et al. 1995),(Madden 1996),(NHIMAC 1999). However, actual change has been slow to occur.

Extensive hospital event data has been collected in Australia since 1991 in the National Hospital Morbidity Data Set (NHMDS) for the purpose of maintaining the Australian National Diagnosis Related Groups (AN-DRG) and calculating weightings for Casemix funding (Health and Family Services 1995). These data, which include information on diagnosis and procedures, are however, de-identified; supposedly to *prevent* patient-

level analysis being performed (see 10.6.2). At the time of commencement of the current project, there had been no previous linkage of the NHMDS with other databases. However, there have been several studies which demonstrate the feasibility and legality of record linkage research utilising the Australian MBS database. An early example was a pilot study where a discrete sample of subjects was linked with MBS data (Simons, McCallum et al. 1990). The study selected a cohort from the National Heart Foundation 1989 Risk Factor Survey. The records for these people were linked with records from three different sources; Medicare, the Australian Capital Territory Hospital records and the Cancer Registry.

In 1994, the Commonwealth Department of Health and Human Services, Hospitals and Health Financing Division, conducted a linkage project using hospital morbidity data from three states with data supplied by a number of private health insurers[2] (Commonwealth 1994). In this (draft) report, matching rates with state data were claimed to be over 80% for morbidity data after 1992.

A project is currently near completion within the Commonwealth Department of Health, Portfolio Strategies Division. In this study morbidity data from Western Australia has been linked with MBS and PBS claims data from the Health Insurance Commission (HIC) under special dispensation from the minister. Improved outcomes reported for the five National Health Priority Areas of Cancer, Cardiovascular disease, Diabetes, Mental health, and Injuries were examined as a demonstration of the potential of the system. Extensive problems were encountered in matching records due to the fact that hospital data was only identified with date of birth, gender and Postcode. Further limitations in the analysis resulted from the incompleteness of data (especially for the PBS component where of the total transactions, around 30% were captured and of these, around 20% had invalid identifiers). There were also difficulties in validating the matching process because of the lack of unique identifiers. (Draft report, (Health and Family Services 1999)). The report states that:

> The reports (on the five major health conditions)identify that linked data has the potential to increase efficiency and to improve health outcomes… go on to reiterate that a need exists to establish an adequate information infrastructure to collect, link and report on key national indicators.
>
> In the case of Medicare, the most important priority is to improve the way in which consultations are reported… (the)

2 De-identified patient level ‘accommodation’ and ‘gap’ data

> preferable solution, is to develop a national ambulatory care coding scheme within the frame work of a nationally integrated patient management system.

Record linkage has been little used in this country for medical research, its power to detect rare outcomes and unusual side effects of treatment has been ignored. Various studies overseas have been possible where data collection is more rigorous and personal identification numbers have been accepted with less resistance (Manitoba Center for Health Policy and Evaluation 1991). In spite of legislative restraints, interest in research using record-linkage in Australia has continued. Several studies are underway in Western Australia, focussing on the establishment of registers for maternal and child health (Stanley, Croft et al. 1994), congenital malformations (Bower and Stanley 1983), cerebral palsy (Stanley and Watson 1985) and surgical outcomes (Semmens et al 1998). An initiative of the National Health Information Management Group includes developing priorities for furthering health record linkage in Australia to realise some of the potential for outcomes evaluation of the large reserves of health data that are currently collected (AIHW 1994).

Promising work has recently been conducted at the Australian Institute of Health and Welfare (AIHW) in establishing the National Health Information Knowledgebase (NHIK). This is a meta-database that includes details of all data collections that are available on a

> particular health-related topic or term, and any related official national agreements, definitions, standards and work programs, as well as any linked organisations, institutions, groups, committees or other entities. The Knowledgebase provides direct integrated access to the major elements of health information design in Australia:

- The National Health Information Model
- The National Health Data Dictionary
- The National Health Information Work Program
- The National Health Information Agreement.(AIHW 1997)

The National Health Data Dictionary provides details of health data sets in Australia. These facilities are available on the Internet and can be seen as providing an essential foundation for future integration and use of disparate data sets for evaluation of services and health outcomes research (AIHW 1997).

Western Australia appears to lead the field in utilising electronic health databases for research. Seminal linkage work in the late 1970s established the strength of an association between asbestos exposure and lung disease. In this study personal identifiers from employment records were linked with information from the Pneumoconiosis Board of Western Australia, the cancer registries of five states, discharge records of the public hospitals of Western Australia and the death indexes of three states (Hobbs, Woodward et al. 1980).

The state has an enlightened policy supporting the potential community benefits to be gained from systematic use of electronic health data while attempting to maintain adequate privacy protection of individuals .

> The advantages of population based record linkage include the avoidance of selection bias which can occur in epidemiological case-control and cohort studies, and the avoidance of recall bias, as data are usually collected before the outcome or in ignorance of the outcome. … Other major benefits include large sample sizes, generalizability of results and rapidity of analysis.(Stanley, Croft et al. 1994)

Advantages for researchers in Western Australia include the geographic isolation of their state which minimises population exchange with neighbouring states and the small number of major hospitals, most of which utilise a common patient identifier. Wide ranging research has been conducted utilising state based, linked databases of births, deaths, hospital morbidity and paediatric data including the Birth Defects and Cerebral Palsy registers (Blair and Stanley 1992; Blair and Stanley 1993; Blair and Stanley 1993). The database also provides a sampling frame for analytical studies by WA health epidemiologists and bio-statisticians. Research based on these linked data is used to inform policy development and appropriate preventive health programs.

A recent review by Armstrong and Kricker applauds the work done with the Western Australia Health Services Research Linked database (WAHSRLD) but questions the reasons for the 25 year delay in its establishment (Armstrong and Kricker 1999) (Kelman and Smith 2000). It seems dogged perseverance and adequate funding were the essential ingredients for success. They point to the great but unused potential for linkage with the national Medical and Pharmaceutical Benefits Schedules (MBS and

PBS), and lament the fact that little has been done elsewhere in Australia to realise the potential of linking separate national datasets to produce

> better and more efficient routine measures of the performance of health services.

Holman explains that the rarity of

> large scale systematic application of record linkage for research purposes in the health arena is .. due to significant requirements for long term planning and inter-agency cooperation.(Holman, Rouse et al. 1999)

In New South Wales a number of internal record linkage projects have been performed mainly utilising the hospital Inpatient Statistics Collection (ISC). Several years of linked data are available from the Midwives data collection and the perinatal outcomes files. Specific health issues including injury prevention and poisoning have been examined and some work has recently been conducted examining failure rates following laparoscopic tubal ligation. However, as is common elsewhere, the predominant use of these data has been in analysis of variation in *rates* of surgical procedures and medical diagnoses across different regions. These studies do not generally require identified data and cannot provide comment on the effectiveness of treatments (Close 1992).

In order to determine rates of surgical complications, the Health Services Evaluation and Computing section of the New South Wales Health Department has had to work around the lack of patient identifiers in the ISC by utilising probabilistic record linkage. The matching process relies upon address, date of birth and sex as identifiers and will not capture people who have changed their address. The calculation of re-admission rates, a critical indicator of hospital performance, is also problematic. These are hard to determine without a unique identifier especially if a patient is subsequently admitted to a different hospital.[3]

In Queensland, record linkage has been used to study coronary outcomes (REF). Cancer registry data has been matched with mortality data from the Registrar General. Each week all new deaths were scanned for any that included cancer as a possible cause. Matching was attempted using patient name, sex and *partial* date of birth. This

3 Which will commonly use its own institution based identifier.

process produced only 2% exact matches. The remaining had to be checked manually and 7% were not able to be matched at all. The collection of a complete date of birth has improved the situation. Once again, the desirability of a unique patient identifier is clear.

The small number of linkage projects conducted in Australia for specific research purposes have been summarised by Sibthorpe (Sibthorpe, Kliewer et al. 1995) but as Holman notes, until the development of the WAHSRLD, no comprehensive system of linked health records existed in Australia. Thus for each project, an 'ad hoc' database had to be cobbled together. This is a process that requires considerable investment in planning and a significant administrative burden. He points out the difficulties involved in gaining access to the MBS/PBS data and the resultant rarity of national linkage projects. Indeed the difficulties that he identified were experienced in the Medical Devices study reported in this thesis. For example, it was only possible to access the data after individual patient consent had been gained by contacting patients by mail. This process in itself was only possible because a special arrangement was first made with Medibank Private, who agreed to contact selected members and include a letter from the NCEPH research team.[4]

1.4.4 Record linkage for long-term outcome analysis

In the UK, strong support has long been given to the potential use of record linkage to investigate long term effects of drug therapy (Skegg and Doll 1981),(Skegg 1984),(Venning 1983). Skegg (1984) performed a feasibility study of linking prescription data with morbidity records, demonstrating that adverse events could be detected using this approach. He supports the use of objective rather than subjective data for surveillance. He suggests:

> Apart from revealing the hazards of some drugs a record linkage scheme would provide evidence for the safety of many others. This would be particularly useful when alarms are raised about the safety of a drug. Positive evidence for safety can be provided only by a monitoring method that does not rely on doctors' suspicions but rather involves routine screening of the frequencies of all diseases among people taking each drug.

and concludes:

4 Patient consent is also required for record linkage projects using Medicare data in the USA. However, cohorts may be selected from the database prior to the gaining of consent (Lillard and Farmer 1997).

> Record linkage would be valuable for detecting unsuspected hazards of drugs and for testing hypotheses from other sources. The opportunities for this type of research are greatest in countries with highly organised health services such as the Scandinavian countries and the United Kingdom.

Bergman stresses the importance of post market surveillance using record linkage to provide 'objective histories' for pharmaco-epidemiological cohorts and case control studies (Bergman 1992). While supporting the use of spontaneous adverse drug reaction schemes for the detection of serious events he stresses the limitations of such a system for comparing rates of adverse reactions for similar drugs and the detection of less severe but perhaps more common events. Assembly of cohorts and the performance of case control studies is costly. By comparison, record linkage performs both functions simultaneously, at less cost:

> a computerised record-linkage scheme for drug monitoring can both identify signals of new adverse events and test hypotheses. (p314)

Thacker, writing from an American perspective, believes that

> The major barriers to a successful comprehensive, nationwide, integrated public health surveillance and information system are a lack of appreciation for the value of high-quality provisional surveillance data and a weak societal commitment to public health. (Thacker 1994)

Venning in a study of 18 significant adverse drug reactions since Thalidomide, reports that 8 or 9 of these events would not have been able to have been detected using traditional postmarket surveillance schemes with around 10,000 patients, or voluntary reporting schemes (Venning 1983). He suggests that the most effective approach to earlier discovery is:

> … some form of record linkage, capable of providing at the same time data on incidence of adverse reactions and on prevalence of drug usage in patients with disease suspected of being drug induced.

A pilot study using Australian Pharmaceutical Benefits Schedule (PBS) data linked to prescriptions demonstrated the feasibility of pharmaco-epidemiological research using record linkage in this country, however little appears to have been done since this time (Hurley, McNeil et al. 1992).

Strong support has been provided by the Commonwealth for an integrated health information system in the recent release of the Health on Line report from the

Department of Health and Aged Care (NHIMAC 1999). The report specifically mentions the potential for using clinical and administrative data for assessing performance and outcomes of health care interventions.

> In the health sector... there is a growing demand to systematically assess the quality and outcomes of programs. There is also a greater emphasis on evidence-based health care. These pressures result in significant demands to collect, collate and analyse an ever-increasing volume of health data… Governments and service providers are required… to forecast trends with greater accuracy, determine the cost effectiveness of various treatments and interventions… assess the evidence basis of new and existing interventions, monitor and evaluate quality of care and health outcomes…
>
> In sum, there is a demand from policy makers and program managers (and governments) for better and more information about the effectiveness and efficiency of health program expenditures. (Action Plan p.11)

1.5 The need for evaluation of new health technology

Following rapid advances in all areas of technology during the last few decades, large numbers of novel medical interventions have been introduced. Providers and public alike have been overwhelmed by the promised potential of the technology whose rapid introduction has far outstripped the capacity to evaluate and monitor its consequences. The promised potential of high-technology medicine has a down-side. Recent interest in the evaluation of health outcomes has been stimulated by a series of widely publicised adverse events (see 1.5.6) and a requirement to justify a large financial commitment to medical hardware.

1.5.1 The technology explosion in health care

In the last thirty years innovation in medical therapeutics has increased rapidly (Foote 1987),(Tabbush and Swanson 1996). Vast numbers of new drugs, medical devices, diagnostic technologies and surgical procedures have been introduced. While the rapid progress in the development of information technology has been given wide media coverage, the explosion in the number and complexity of medical devices that has occurred recently is not generally appreciated. It should be kept in mind that X-ray machines, ventilators and plastic syringes were uncommon in hospitals until the late 1950s, prosthetic hips, heart valves and intra optic lenses were first introduced in the 1960s but were not considered to be routine procedures until the 1980s. Long term evaluation of these products although it has always been desirable, has only recently become possible.

Medical device development and manufacture has rapidly become a major industry. A small local medical device industry exists, but the vast majority of medical devices and diagnostic technology are imported from the USA and Europe. In Australia, around 10,000 hip prostheses alone are implanted each year (Deloitte 1995), demand for hips is predicted to increase in European countries by 40% over the next 30 years as a result of demographic change alone. This increase is partially due to changes in age distribution of the population (Birrell, Johnell et al. 1999). When changes due to service availability in Australia are taken into account, demand is expected to double in the next five years (Australian Dr, June 1999). Health care is presently undergoing a period of 'technology driven' expansion.

The annual number of hospital admissions per person has risen by 50-90% in Australia during the last 13 years (Deeble 1999). This change is mainly due to the growth in sophistication and availability of technology. The problems that arise in the management of our increasingly complex health system are new and will require the use of new and more sophisticated approaches to monitor the results and assess the data that is generated.

1.5.2 Current expenditure on medical device implants:

Expenditure on drugs and devices each consumes greater than 10% of the current Australian health budget. In 1995-96 there were around 500,000 Medicare funded operations performed in Australia (HFS 1997). About 22% of operating room procedures involve the implantation of a medical device (Deloitte 1995). Medicare meets the cost of around 50% of procedures, the rest being funded by private insurers and others. Thus there were some 220,000 implants inserted, average cost (prosthesis only) was $2,177 giving an estimate of annual national expenditure on implantable devices of $478m.

1.5.3 Evaluation of new Health Care Technology.

The science of medical device evaluation is in its infancy and only in the recent decades has interest in the rational evaluation of health technology increased. Various units focussing on 'health technology assessment' have been established around the world. Governments have realised the extent of their financial commitment to fund

interventions that have not been evaluated from either a health outcome or cost perspective.

The UK National Health Service manages the Health Technology Assessment program. Their report "When and how to assess fast-changing technologies: a comparative study of medical applications of four generic technologies" (Mowatt 1997) was initiated out of concern for the rapid diffusion of unproven technologies through medical practice. In their recommendations they suggest that new technology assessment should be initiated early and use a variety of complementary assessment approaches. The process should be iterative and tailor-made to suit the particular item. Most importantly, as a general rule, all trials should be randomised from the beginning.

Guidelines for health technology assessment have been developed in Australia by the Australian Health Technology Advisory Committee[5] (AHTAC) (Simes 1992). These (draft) guidelines are based on the UK NHS report of 1992 (Chalmers 1992). The charter of AHTAC includes all interventions aimed at improving health, including medicines, diagnostic equipment, medical devices and professional skills. The focus is on outcomes, ie to assess whether the adopted technologies actually improve the health status or prognosis of the people to whom they are applied. The guidelines emphasise the importance of utilising all available data to assess the effects of health technology. Randomised trials and observational data are the main sources of information and population morbidity and mortality statistics should be included as a mechanism for examining long term trends in population health. The challenge is to ascribe observed changes to particular causes. The committee also notes the poor association that currently exists between evidence-based health technologies and actual clinical practice. Much work needs to be done in changing a culture in which new technologies are adopted with enthusiasm whether or not they have been proven to be effective.

Various centres have been established in other countries to provide evaluation of medical products including devices and drugs; some run by government, others privately. The USA Medical Technology and Practice Patterns Institute (MTPPI) is one of a number of World Health Organisation Collaborating Centres for Health Technology Assessment. The MTPPI notes that health technology assessment activities

5 AHTAC has been dissolved, a more formal process of evaluation is now conducted through the Medical Benefits Advisory Committee process.

were being conducted by 24 countries by 1995, and comments on the fragmented and decentralised nature of health care technology evaluation in the USA (MTPPI 1995). The market for the assessment of new health technology includes insurance companies, hospitals, medical/device manufacturers, consulting firms and health professional societies.

1.5.4 The Current model for the regulatory approval of new treatments.

There is a wide variation in approaches to the evaluation of new medical technology between the industrial nations, ranging from no restrictions to extensive investment in pre-market evaluation by national regulatory authorities. However in spite of the potential rigour of this 'safety net' very little systematic examination occurs of products *after* release onto the market, where arguably most could be learnt.

The Commonwealth Department of Health in Australia incorporates a division that has responsibility for the evaluation and regulation of new medical products including drugs and medical devices; this is the Therapeutic Goods Administration (TGA). Their regulatory model is based on that established by the Food and Drug Administration (FDA) in the USA.[6] The current evaluation process requires an 'application for registration' by the manufacturer (or their agent). The application consists of a detailed account of laboratory and clinical assessments of the product. A professional review of the submitted clinical and scientific data is then conducted in order to assess the safety and efficacy of the product.

This process has its weaknesses. Testing and evaluation of medical devices usually consists of small pre-registration (phase II)[7] clinical trials with little post-market (phase IV) evaluation being conducted. Of necessity, new devices are trialled on small groups of patients in special circumstances cared for by specially trained physicians. Methodological options are more limited than for drug studies; double blind trials of an implantable device are obviously impossible as the inclusion of well patients in an implant study and the use of placebos is usually unethical. Manufacturers are driven by the usual market incentives and long term studies of sufficiently large cohorts of patients are usually not performed. The whole trial may span only a few months, yet

6 The Kefauver-Harris amendments of 1962 added to the Food, Drug and Cosmetic Act (1938) the requirement that drugs be efficacious as well as truthfully labelled and 'safe'
7 Clinical trial phases are outlined in the Glossary

predictions must be made about the long term performance of the new product. In general, problems with new treatments will only become apparent after wide dissemination and extended usage. Despite this, monitoring of the 'post-market' behaviour of treatments is under-funded and sporadic, especially for medical devices. Serious side effects and design limitations may go undetected until large number of patients are affected.

Research, development and marketing in this field is very competitive and new device models are regularly introduced, often with minimal scientific evidence of their additional efficacy. There has been discussion of the similarities between the fashion industry and the orthopaedic implant industry. A British Medical Journal editorial warned in 1993 that: (Bulstrode, Murray et al. 1993)

> This 'fashion trade' in joint replacements is costing the health service many millions of pounds each year and even more important, is causing patients unnecessary pain and distress through early failure of unproved implants.

These comments were prescient. Within a few years, the 3M Capital Hip implant was discovered to have a failure rate at five years of four times the expected rate (Muirhead-Allwood 1998). A Hazard Alert was issued by the Medical Devices Agency requiring up to 5,000 Capital hip patients to be reviewed for replacement (MDA 1998). This event provides an example of the need for systematic surveillance of new prostheses. After release onto the market, new products should be observed critically for an appropriate period in order to detect problems before too many patients are affected. As an example of what can be achieved, Sweden maintains a national register of hip implants which has demonstrated its sensitivity, saving both money and patient suffering. The Swedish register allowed the detection of problems with 'Boneloc' cement after only 15 operations in their country, while in Britain it had already been used in 1,800 patients (Robert, Stevens et al. 1999 p4).

There are many other examples of the over-enthusiastic manner in which new technologies are introduced - the case of refractive surgery for visual acuity problems is representative. Lamellar keratoplasty, hot-needle keratoplasty and hexagonal keratotomy were all widely used before it was found that they caused serious morbidity. These procedures had been propagated among ophthalmologists using the time-honoured system of providing evidence from informal experience, communications in

professional publications and endorsement by prominent surgeons (Waring 1999). In the modern clinical setting, such 'magical' approaches to providing evidence are unacceptable. Waring goes on to stress the importance of also reporting *negative* results from clinical trials. The fact that this in not commonly done is a crucial weakness in the current 'peer-reviewed' journal system.

1.5.5 Monitoring the performance of health technology

In spite of the obvious limitations of projections of device performance from pre-market assessment, further monitoring of these widely used medical products is not done in any systematic manner. Adverse-event reporting schemes exist, but are sporadic and under-funded (see section 1.5.7). As a consequence of this, problems with new treatments are often only detected when they reach the crisis stage and trigger media involvement. Various mechanisms have been proposed to monitor the behaviour of these products in the 'medical market place' using voluntary adverse event reporting schemes, review of the medical literature, product registries, observational studies and systematic analysis of large administrative databases.

Various groups have attempted to determine how to predict which new technologies may be most worthy of evaluation to minimise the risk of both economic and human disasters (Robert, Stevens et al. 1999). It is generally agreed that "it's always too early to (evaluate a new technology), until unfortunately it's suddenly too late" (the Buxton Paradox) and that the very nature of these problems defines their un-predictability. The unavoidable conclusion is that it is necessary to monitor all treatments, or failing this, to be able to monitor any treatment that a comprehensive alerting system reveals to be a potential problem. Various 'early warning systems' of new technologies have been trialled; however, some appear to be based primarily on data supplied by those that are under surveillance. For example the Royal Surgical College of Great Britain proposed the Safety and Efficacy Register of New Interventional Procedures (SERNIP). Indicating the fragmented manner in which new surgical procedures are developed and tested, it was considered important to try to detect what new surgical procedures were actually being used. A register was established to detect and flag new surgical techniques through review of literature, communications and conference reviews. This type of approach appears to be unsuccessful and it is possible that more objective and less biased data could be provided by the actual results of medical practice as portrayed

in clinical databases.

1.5.6 'Post registration' surveillance and patient tracking

There have been several examples of the consequences of catastrophic medical device failures; the Bjork-Shiley heart valve (Ostermeyer, Horstkotte et al. 1987), the Dalcon Shield IUD (Byrne 1992), the silicone breast implant (Brown, Parmentier et al. 1998) and more recently the ACCUFIX Atrial pacemaker lead (Boxall 1999). The failure of these products demonstrated the difficulty of tracking patients who had these devices where no organised registry was kept. In the case of the Bjork-Shiley valve, three years of intensive detective work by the Shiley Research Centre and the ANZ heart Valve Registry located only 85% of these patients. Thirteen Australian patients are known to have died from failure of this product (Callaway 1997).

The Australian experience involving the risk of Creutzfeld Jacob Disease (CJD) after treatments using growth and fertility promoting pituitary extracts in the 1970s and 1980s highlighted many inadequacies in our patient information/medical record system (Lazarus 1985). Great difficulty was experienced in identifying and tracking patients who were thought to be at risk of developing CJD. A similar scenario evolved in the USA with dura mater allograft used for surgical repair of brain injuries and as general surgical 'patches' (Marx and Carlson 1991). Recently there has been further concern about the potential for transmission of this agent via surgical instruments[8] (Holmes, Ironside et al. 1996). The need for accurate documentation and computerised records becomes crucial in retrospectively tracking patients and procedures in such situations.

In general it would appear that the difficulties of monitoring drug and device performance, once registered, has proven to be badly managed and insufficiently funded. Lasagna considers post-registration research to be:

> …the largest methodological challenge facing us.(Lasagna 1987)

8 The causative 'prion' agent survives normal sterilisation procedures and will persist on surgical instruments indefinitely. This may cause infection of any patient subsequently exposed to these instruments. Recently, ten patients were exposed to the risk of CJD in Victoria. Neurosurgical instruments had been re-used after an operation on a patient with dementia. This patient was subsequently found to have CJD.

Similar examples of the problems encountered locating the recipients of particular treatments exist in other areas of therapeutics – it appears that in spite of often good local record keeping in hospitals and clinics, when the need exists to elicit information on a larger scale, it is difficult or impossible to discover what treatments have been performed on which patients. If a group of patients is thought to be at risk of developing a particular disease, it seems desirable in the interests of personal and public health, to be able to define that group. Having defined the group it is important to be able to easily and rapidly contact individuals to inform and perhaps to implement appropriate medical treatment. This would require a unique identifier for each patient with linked electronic access to records and current contact details.

Regardless of the high risk involved with many medical treatments and the scant knowledge of long term effects and despite calls for systematic record keeping for public health use registers have not been made a priority. Follow-up or patient tracking in the event of major side effects is near impossible. This situation exists in spite of the fact that in the accounting domain of the health sector, accurate and complete electronic records are available which catalogue payments for almost all services. These records are managed at state or national level, which at least in principle, should make them readily available for public health use. The difficulties experienced in data collection for this project have revealed that this is not the case. It would seem that the needs of health care have become overshadowed by the contingencies of the financial administration of health care.

1.5.7 Adverse event reporting schemes and product registries

Incident reporting schemes are intended to elicit reports from the field for the attention of the national regulator. These schemes notoriously under-represent the real incidence of adverse events. In the USA it is estimated that less than 1% of medical device incidents are reported to the FDA; Australia has even lower rates (TGA internal report, 1994). In many cases investigation of the problem is managed by the device manufacturer which creates a situation that may not encourage full reporting to national administrations. This presents an ethical dilemma that manufacturers cannot be expected to resolve. Drug incident reporting is better supported but overall rates are still low in most countries (Stricker, Ottervanger et al. 1994). Incident reporting is voluntary and requires an interested party to locate, complete and post the appropriate

form. This process provides a powerful disincentive to comprehensive reporting and suggests that a more streamlined independent system may have benefits.

Adverse events in health care are not uncommon: the quality in Australian Health Care Study (QAHCS) indicated that in 1992, 16.6% of admissions were associated with adverse events and 0.8% led to death and around 51% of adverse events were judged to be potentially preventable (Wilson, Runciman et al. 1995). This study was a medical record audit of 14,210 admissions to 28 hospitals in 2 states, it was not a record linkage study. It clearly revealed the need for ongoing evaluation of health service data to monitor health service performance.

On a national basis the potential exists for the automated examination of centralised health databases for evidence of drug and device problems (Bergman 1992),(Selby 1997). Given the high level of under-reporting by clinicians, it would seem desirable to utilise information that is collected about health services to monitor intervention outcomes in the real world of the medical market place (ie hospitals and surgeries) (Strandberg and Wiholm 1986). This information has the advantage of being both objective and comprehensive in coverage. With the gradual but inevitable introduction of the electronic patient record, it is envisioned that incident reporting could easily be included. This would provide the potential for automatic forwarding of reports to a centralised repository.

As previously mentioned, Norway and Sweden have extensive experience of implantable device registries; the Swedish Hip Registry was established in 1979 and the Norwegian Arthroplasty Register in 1987. Many studies have been based on information contained in these databases and on several occasions, device faults were detected by routine examination of the records (Engesaeter, Furnes et al. 1996).

Strong support for a ‘registry’ based system of outcomes monitoring and analysis has been provided by Baim et al (1994), who suggest that registry data can be used to supplement early single centre reports and focus further randomised studies where appropriate (Baim, Kent et al. 1994). The strength of such a system is based on collection of appropriate data under specified conditions over a significant time period for large numbers of patients. Such a system has been established in the USA by the National Heart, Lung and Blood Institute, in the New Approaches to Coronary

Intervention (NACI) registry. A range of procedure specific information was collected from 36 participating centres covering almost 3,000 patients in the two years from 1990-92. This type of registry allows comparison of outcomes and complications with traditional approaches and provides a trigger for more specific investigations of problem treatments. The registry was pivotal in the early assessment of the new approach of percutaneous transluminal coronary angioplasty (PCTA). Similar registries were established in the 1970s by the National Heart, Lung and Blood Institute to enable the evaluation of new cardiac procedures: the Coronary Artery Surgery Study (CASS) and Balloon Valvuloplasty Registry (BVR). These types of registries are particularly suitable for comparative evaluation of similar procedures but are limited in their ability to provide a control group (Davis 1990).

1.5.8 The use of large databases for 'signal detection' in adverse event detection systems

A system for the automatic 'post-market' monitoring of new treatments would be complementary to the present 'pre-market' evaluation system and would provide an opportunity for the ongoing evaluation of medical products. Alerts generated by such a scheme could be used to trigger further investigation of particular products before the number of patients affected grew to be large.

'Pharmacovigilance' examines the effects of drugs by linking large-scale exposure data to outcomes data. The majority of adverse drug events are currently detected by spontaneous reporting which mainly is useful for detecting the more idiosyncratic and unexpected events (Type B effects) (Meyboom, Egberts et al. 1997). Alternative methods of signal generation (detection of early warning signs) are prescription event monitoring, case-control surveillance and database analysis often utilising record linkage.

Type A effects are relatively frequent and often predictable in that they are consistent with the known actions of the drug and are usually dose related. They are commonly detected in phase III and IV clinical trials backed up with follow up studies and spontaneous reporting.[9] Type C effects are the most difficult to detect; they are unexpected and often the result of multiple causal factors appearing after varying time

9 See Glossary for description of clinical trial phases

periods (tardive effects). For Type B and C effects, both a large sample size and longitudinal data are required with varying requirements for additional clinical data. In this area, the use of large linked databases is particularly appropriate. An example of a type C effect is the possible relationship between oral contraceptives and their long term effects including breast tumours and thrombo-embolic episodes. These data can be used for analysis or to provide a resource for cohort selection.

In the signal detection phase, statistical significance is less important than in analytical epidemiological studies and the focus is more on detection than accuracy, ie sensitivity is more important than specificity. Naturally in this phase, it may be difficult to rule out chance, selection bias or confounders. An example of this approach is found at the pharmacovigilance centre of the FDA where the frequency of reports for a drug is compared for the same drug over time and against comparator drugs. Differences greater than a certain pre-set level automatically raise a warning flag.

In the Netherlands, the Pharmaco Morbidity Record Linkage System (PHARMO RLS) (van der Klauw, Goudsmit et al. 1999) and Scotland (Evans and MacDonald 1999) large national databases are used to study the long term effects and side-effects of drugs. In Canada, an active surveillance system (IMPACT) has been established which allows routine surveillance of post vaccination adverse reactions (Miller, Waight et al. 1998).

In the area of infectious disease control, much has been done to develop effective mechanisms for the detection of outbreaks at the earliest possible stage. The problems in this area are similar to those presented by treatment surveillance schemes for medical devices, drugs and procedures. Farrington presents an algorithm for the detection of outbreaks of infectious disease using data from surveillance systems at the Communicable Disease Surveillance Centre in London (Farrington and Andrews 1996). The system is designed to cope with large amounts of *prospective* data and to manage bias resulting from delays in reporting. The problem of early detection is compared to the ‘quality control’ systems used in industry which use cumulative sum statistics to trigger an alarm when unacceptable levels are reached for predetermined parameters.

Previous work in the area of temporal pattern detection in epidemiology has focussed on retrospective data and has utilised approaches based on indices of clustering (Tango

1984) and test statistics based on the maximum number of cases in disjoint time intervals (Ederer, Myers et al. 1993). A widely used approach using a continuous scan statistic was developed by Naus (Naus 1965).

1.6 Cost-benefit analysis of new interventions

Many writers support the need for cost-benefit and cost-utility analyses of new interventions, particularly medical devices (Chang, Pellisier et al. 1996),(Cohen, Breall et al. 1994). The use of national databases joined by record linkage could provide the large sample size needed to determine accurately the cost and benefits of interventions with rare or delayed outcomes. This is particularly important when determining the differential performance of medical devices where new expensive models displace older technology with little experimental justification (Gillespie, Pekarsky et al. 1995).

Potential savings from the use of such knowledge are impressive in both economic terms and in reduced personal suffering. For example, the Christiansen hip prosthesis cost the Swedish community $27m before its defective design was noted (Ohlin 1990). The poor longevity of the device was eventually observed through an analysis of a national register. Although such poor performance should possibly have been detected earlier, without such a register it may not have been detected at all. Indeed over the border in Norway (whose register was not introduced until 1987), the problem was not detected despite the existence of an incident reporting system which like the Australian system, relied on the individual reporting of problems.

Cowley calls for the establishment of a national outcomes data registry for total hip replacement in Australia, and medium to long term comparative studies of different prostheses (Cowley 1994). Hip prostheses provide perhaps the best example of the need for a system supporting systematic long term ongoing evaluation of medical interventions. In the UK there are an estimated 62 different types of hip prostheses available from 19 different companies. Half of these have been introduced since 1990 and most have not been properly evaluated (Editor, Effective Health Care 1996). Hip prostheses are expected to last from 15 to 20 years; this is longer than the duration of most clinical trials and as a result few longevity trials of these devices have been completed. Most concentrate on short term outcomes such as post-operative infection or loosening. In addition most reported trials lack sound methodology or adequate controls (Faulkner 1998). A large proportion of currently available data on these prostheses is generated by countries (such as Sweden and Norway) that maintain formal

registers of device implants. Accordingly it has been recommended that the UK consider the introduction of an implant register to allow long term evaluation of these products (Fitzpatrick 1998).

1.7 Summary

In the industrialised countries there has been a dramatic increase in the uptake of health technology in recent decades. As treatments and technology have evolved there has been an increase in complexity, scale of costs and the potential for widespread adverse events. The need for a repertoire of approaches to ongoing treatment evaluation has become evident. Clinical trials will always be the gold standard for assessing any medical intervention, especially in the pre-market situation. However, this approach is limited by practical and methodological considerations combined with high costs. An alternative and supplementary approach is possible using the large amounts of post-market data about health care that are collected for administrative purposes. These data, with some limitations, lend themselves to large-scale outcomes analysis and surveillance systems for the detection of adverse events.

Chapter Two

The Medical Devices Study - Methods

2.1 Aims of the project

To reiterate, the aims of the project were:

- To examine the potential for using administrative data to generate outcome measures and surveillance indicators.
- To investigate the logistics of gaining access to these data for the purpose of research. This to be achieved within the current ethical, political and financial framework.
- To compare the Australian health-service data system with the current international state-of-the-art.
- To develop suggestions for expansion of the present system as part of an integrated health record and information system. This system to manage patient records and provide quality management, treatment surveillance and cost-effectiveness evaluation as a routine activity.

A comparison study was performed using the Manitoba Health data collection in Winnipeg. A report of this study is presented in Chapter 6.

2.2 Data compilation and procedures

Although this study did not require the creation of new data, the process of gaining approval, combined with the extraction and compilation of the previously collected data, required careful planning. The analysis was a historical cohort study of health care utilisation by patients who had received selected implantable medical devices in the years 1993 and 1994. To compile health profiles for each patient, linkage with existing national databases was used. For administrative purposes, extensive hospital event data has been collected in Australia since 1985 in the National Hospital Morbidity Data Set (NHMDS). Information about deaths and medical services is collected in the National Death Index, Medicare and PBS databases.

2.2.1 Study Design: A Historical Cohort with Nested Case Controls.

The Australian study cohort was selected from those who had one of the selected implant procedures in the years 1993 or 1994 and who were insured with Medibank Private. This cohort was 'followed' from the beginning of 1993 until the end of 1997. Case-control studies were then performed on subgroups of patients who had particular types and brands of implants. A graphic is included in Appendix 7 showing the various sets and subsets which formed the study cohort.

2.3 Power and Sample size calculations:

Before commencing the study, a feasibility assessment was conducted to estimate the number of patients to be expected in each of the prosthesis groups. This was done using the Operating Room Service Weights Study (Deloitte 1995). This study was performed under the National Casemix Development Program and involved a survey of 49 public and private hospitals across the country. At the time, it provided the best available information on operating room resource usage and costs. (The results of this assessment are presented in Table 3.2)

The numbers in each major group appeared to be sufficient to test the logistics of the process, however some calculations were performed to determine the potential power of the analysis. Detectable odds ratios were calculated for a sample size of 500 for each 'type' group, and 100 for each 'type' subgroup. Table 2-1 presents these odds ratios (OR) for outcomes with background prevalence between 5% and 40%. For example, if the 5-year mortality for three of the brands of hip replacements was 10%, we could detect a significant increase in risk of OR=2.3 for the group of patients who received the fourth type of replacement. Similarly, if the complication rate for subjects receiving one type of IOL was 30% we could detect a comparative increased risk for any of the other IOLs of OR=2.2. The order of magnitude for these odds ratios is about the level where an alarm would be set to investigate a meaningful difference in an on-going monitoring system. In a surveillance system power is very high to detect small fluctuations so a system to avoid false alarms should ideally be set to detect meaningful differences in relevant outcomes, often set at OR=2.0. This project thus was expected to have sufficient power to demonstrate the usefulness and feasibility of such a surveillance system for several of the selected device types.

Table 2-1 Detectable odds ratios according to outcome prevalence

	Prevalence of outcome factor (background)					
	5%	10%	15%	20%	30%	40%
1 brand vs any other brand[1]	3.5	2.7	2.4	2.2	2.2	2.1
1 brand vs all other brands	2.8	2.3	2.0	1.9	1.8	1.8
1 brand vs no device implant[2]	2.7	2.2	2.0	1.9	1.8	1.8

α= 0.05, power=80%
1 Brand of device type, e.g. type of hip prosthesis, assuming 4 major brands identified

2.3.1 Defining the study population - a 'survival cohort'.

No national database of surgical procedures exists in Australia. The selection of a study cohort must therefore be performed at state or hospital level. To extend this to a national level, an unbiased cohort of study subjects was required and this presented a challenge. It was decided that the best chance of selecting a representative cross section of all medical implant patients across the country was to request the assistance of the private health insurance industry. Each insurer is legally required to pay for prostheses according to the "Basic table of benefits for surgically implanted prostheses" (HSH 1995). This requirement results in the maintenance of a comprehensive database of claims which includes records about prostheses at a very detailed level.

Medibank Private agreed to contribute information for this project on condition that members were contacted initially by the company itself and that patients were not contacted directly by the research team until after their consent was gained. Medibank Private maintains an archive of patient claims covering some 12% of all Australian hospital admissions. Records for the last five years are stored in electronic, and thus readily searchable form. The Medibank Private database contains names and updated addresses of all current members. It includes information on all admissions to private hospitals and admissions to public (state) hospitals under private cover.[1]

Implantable devices were chosen as the 'intervention of interest' for several reasons:

- The devices are costly and widely used
- The intended function of the device is clear
- Detailed records were available about brand and model from Medibank Private
- The implantation procedure is relatively standard
- The same models of implants are available nationally and internationally

The five implant types selected for the study were.

- Heart valve prostheses
- Pacemakers
- Hip prostheses
- Vascular grafts
- Intra optic lenses (IOL)

For the purpose of this study, the initial operation for each patient was the pivotal event in the study. The first occurrence of this implant operation during the 1993-94 enrolment period was named the *index* operation for each study subject. Each subject was labelled as belonging to a particular device 'TYPE' group according to the nature of this operation.

2.4 Selection of a potential cohort

All patients were selected from the Medibank Private claims archive who had the chosen implants in the calendar years 1993 and 1994.[2] Thus at the time of operation, the selected group was a survival cohort. This cohort was then observed 'retrospectively' from the date of operation back to January 1993 and 'prospectively' until death or the end of the study period, December 1997. It was an initial requirement of Medibank Private that patients would only be contacted if they were still current members of the fund. If maintained, this restriction would have introduced significant selection bias.

1 All private (and public) admissions also appear in the NHMDS, but in *de-identified* form.
2 The oldest claims archive that was still available in electronic form for searching.

2.4.1 Preparation for initial contact with members (potential subjects)

The selected patient IDs from 1993-94 were compared with the current Medibank Private members register: of the 5,274 selected patients, 3,550 (67%) were still members. The issue of whether non-current patients should be included in the study was discussed. This was eventually resolved by the realisation that exclusion of ex-members would introduce unacceptable bias into the selection process. Death was a major study outcome and it was also a possible cause for discontinuing insurance. For this reason, it was imperative that an attempt be made to contact all members, both previous and current.

In order to compile a mailing list, Medibank Private agreed to supply, in confidence, contact details for all selected members, current and former. A list of names was then prepared including DOB and state of residence. This would be used for the National Death Index linkage. After the linkage was performed, the list provided names, addresses and 'death status' for a mail-out requesting consent to join the study.

2.4.2 National Death Index linkage

Linkage with the NDI was utilised in the project to identify deceased Medibank Private members (and ex-members) and thus allow appropriate letters to be sent to their families requesting their consent to allow their *relative's* electronic records to be used in the study.

2.4.3 Recruiting patients and gaining consent for access to data

It is a legislative requirement that informed consent be secured before the collection of any health data can commence. Access to any identified administrative data was strictly controlled by the Health Insurance Commission, the AIHW and Medibank Private. Gaining individual patient consent was the key to data access and it was thus considered crucial to achieve the highest possible consent rate.

The number of patients eventually recruited into the study cohort was 1,883. This number was a rather disappointingly small percentage (36%) of the 5,275 Medibank Private members initially contacted by mail. Potential study subjects were lost along the way for a number of reasons, however, the most significant loss occurred as a

result of low consent rates. A flow chart showing subject numbers is shown in Figures 3-3 and 3-4.

2.3.4 The database of members:

A small database was created to manage patient details, records of contact, responses and consents. Data was entered using a custom form and member details were imported from a text file supplied by Medibank Private. All mail merges were performed from this dataset. Demographic data supplied by Medibank Private was updated if necessary from information supplied by members on the returned consent form.

Fields were maintained in the database for each letter sent, and for any phone contact. In particular, members who appeared to be offended by the project were flagged for 'no further contact' (61 persons). Some members responded positively and actually volunteered that they were keen to supply further information. These too were flagged as potential recipients for an additional questionnaire if this became necessary (74 persons).

2.5 The national health-service data sets:

Significant collections of administrative health data are gathered by national agencies, the Health Insurance Commission (HIC), the Department of Veterans Affairs, private health insurers and the Australian Institute of Health and Welfare (AIHW). But, access to identified information from these resources is tightly restricted, even for the purposes of public health research. Table 2-2 describes the available datasets and their contents.

Table 2-2 Data available and Custodians

Institution	Database	Contents
The HIC	Medicare database	Doctor visits
	PBS database	Some pharmaceutical prescriptions
	DVA	Most services for veterans
The AIHW:	NHMDS	All hospital admissions, private/public
	NDI	All deaths
Medibank Private†	Claim Archives	All admissions and procedures

† During the early period of the study, Medibank Private was part of the HIC.

Both the National Death Index (NDI) and the National Hospital Morbidity Data Set (NHMDS) are maintained by the AIHW. The NHMDS contains data submitted by the states under the terms of the Health Care Agreements. Access to the NHMDS requires approval from all contributors, ie the various state and territory health departments and the DVA. The NDI also contains data submitted by the states, however, access to this resource requires ethics approval only from the AIHW's ethics committee.

A letter requesting approval for data linkage to the NHMDS was prepared for distribution to all states and territories by the Institute. Prior communication with New South Wales Health had already been established. The potential to decrypt the New South Wales component of the NHMDS to allow a validity check on the linkage process had been discussed with Information Management staff at NSW Health.

Because the average age of the study cohort was around 70 years, many were DVA beneficiaries. The DVA collects extensive data on health services for its clients and uniquely in this country, this data includes pharmaceutical information. As information on drug use is not consistently available from any other source the inclusion of this dataset in the analysis was considered to be desirable. For both these reasons the DVA was approached for permission to access data.[3]

2.6 The Quality of Life questionnaire

All of the 5,274 selected Medibank Private members were mailed a simple QoL questionnaire as part of the initial mail-out. Of the 2,887 who responded, 1,793 completed this questionnaire. The main justification for the questionnaire was to test for bias in the selection of consenting patients. Those contacted were asked to answer the questions; the consenting and non-consenting groups could then be compared. Two questions were taken from the 'SF36' questionnaire (Medical Outcomes Trust 1992), the third was designed to elicit an indication of the level of satisfaction regarding their medical device. (See Section 4.9)

3 An extract of the DVA records is submitted to the AIHW for incorporation into the NHMDS.

2.7 Record linkage with the NHMDS

Extensive discussion was held with the AIHW regarding the feasibility and potential power of the proposed matching with the NHMDS. Outcomes research had not been previously attempted using the NHMDS. However, the Institute decided to perform a pilot study themselves prior to commencing the Medical Devices project. This study, which utilised WA data, provided some indication of the problems and accuracy of the matching process.

Data fields supplied to the Institute were: ID, Surname, Sex, DOB, DOD, Country of Birth, SLA/Postcode (see Appendix 8A). Unfortunately, DOD could not be used to assist with rejecting erroneous matches as the *Automatch* software continued to match those who were known to have died in 1994 with entries for admissions after this date. *Automatch* does not have the capability to perform 'less than' or 'earlier than' comparisons (Automatch 1998). The results of this linkage are discussed in section 4.5.2.

2.8 Data storage and security

Datasets were obtained in electronic form either on disc, by e-mail or on CDROM. All datasets were loaded onto a password-protected PC kept in an office of the NCEPH building. Original discs were kept in a locked filing cabinet, backup copies in a locked cabinet in a separate building. Access to the data was available only to the chief investigator, the research assistant and the IT manager.

2.9 Data collection from the institutions

Before completion of the recruitment process, the three 'institutional' data custodians were contacted regarding procedures for data extraction and formats required for submission of identifiers. Initially all three stipulated that they required the original consent forms. However, a compromise was reached where the AIHW was satisfied with copies of a random sample of consent forms and Medibank Private with the provisions of the mutual contract.[4] The HIC was bound to individually inspect all forms but was able to use photocopies.

4 A contract had been drawn up between the three parties; the ANU, Medibank Private and C Kelman.

The project relied principally on data collected from the national data bases, however some additional information was requested in the initial contact letter. All members were asked to complete the Quality of Life questionnaire, consenting patients were asked to confirm their demographic details and to provide a history of past Post Codes if they had moved within the study period. Death dates were requested from families of the deceased. Questions specific to a particular medical device were not asked prior to consent as this may have been considered to be an invasion of privacy. This highlights the complexity of gathering a cohort of patients without being in a position to know their diagnoses.

2.10 Outcome measures and statistical approach

The historical cohort was examined for utilisation of health resources from one year before until five years after the principal device implantation (the index operation). Various outcome measures were compared between different device type and brand, sex, age-group, state and country.

Comparisons were performed across groups for rates of:

- Death (post-operative and late)
- Episodes of service utilisation (doctor visits, hospital admissions, hospital procedures and pharmaceutical usage (where data available),
- Costs of services
- Complications

It is evident that these outcomes will vary in relevance and indicative potential according to the specific device being examined. For example, mortality is not a particularly sensitive indicator for hip implantation or IOLs and may be confounded by other medical conditions in those receiving heart valve replacements or vascular grafts.

Available outcome measures are also of course limited by the nature of the data available – if more detail was collected in the MBS dataset, or if the ICD9 code had been available for hospital admissions, more sensitive measures could be used. The present study used what were considered to be the best available outcome measures as an indication of the potential of the existing data.

Outcomes for patients were compared for the period before/after the index operation to control for co-morbidity. Survival analysis and logistic regression analysis were performed on the outcome variables available.

2.11 Data 'cleaning' and analysis

Data management and analysis was performed using SPSS 8.0 (SPSS 1999), Microsoft Excel 97, Access 97, Word 97 and the C programming language (Microsoft 1999). Initially, smaller, more manageable working files were distilled from the very large data files (some around 100MB) that were provided by the various institutions. A large amount of additional data were collected to enable later subgroup analysis, however only a small number of fields were required for the initial service-use and survival analysis.

The Medibank Private data required some further preparation to remove duplicate entries and to add missing fees to various hospital services (as explained below). Duplicate entries had in general been 'reversed' by the addition of a further record with a negative cost. This would not have affected the estimation of total costs, but would have resulted in an over-estimate of service utilisation. These entries and any that appeared to be duplicates (as defined by same ID, service date, item number and fee) were removed. Some hospital accommodation costs were not included in the original Medibank Private file due to specific contractual arrangements that existed with certain hospitals. These bed-day costs were added to the file according to estimates from Medibank Private for the average payments made across the range of hospitals they have contracts with. Costs were assigned according to the item number associated with the claim (for example, shared or private ward, ICU or surgical ward). A number of admission item numbers still remained unidentified; an averaged bed-day cost of $319 was assigned to these admissions. This fee was derived as the mean cost for all admissions of one day duration.

Service data was extracted by the HIC for 1,885 patients. Due to corrupted identifiers, 192 of the original 2,077 were not able to be matched with the Medicare registry. A further two patients were removed due to a lack of Medibank Private data, the cohort finally comprising 1,883 persons. The Medicare data also included some duplicate entries that had been cancelled or 'reversed' by adding negative fee entries.

It was not possible to remove all these entries as there were insufficient identifiers to assure accurate matching of the original and the reversed entry. In total however, only 0.2% of entries were reversals and a further 2.5% had no fee attached. It was considered acceptable to ignore these small errors.

For the calculation of rates of service-use and deaths, data were processed to determine times of observation pre and post index operation, either until the end of the observation period, or until time of death. Counts of services used in both these periods were made and rates of utilisation calculated.

It was the intention to measure rates of service use in the 'quiescent' period before and after the index operation. To exclude procedures conducted in relation to the index operation itself, an exclusion period was used. Thus the effect of pre-operative investigations and post-operative follow up on derived measures of service use was minimised. To determine the appropriate length of these periods service utilisation-rate plots were generated (see Fig 5-1), in this way, optimal exclusion periods were derived for each device type. These periods were generally 1–4 months pre-op and around 1-6 months post op. However, for heart valves, a period of 10 months post op was required to exclude all possibly associated follow up. These exclusion periods are shown in Table 5-3 and are marked in on Figure 5-1..

All calculations were performed using subgroups for sex, state, age-group at time of operation and device type. Identical calculations were performed for both the Australian and Manitoban cohorts where the data allowed.

"My mother wanted to donate her body to science and I'm sure she would want her health information used in the study".

"Which device are you interested in, I have six of them – I'm the Bionic Woman!"

The Medical Devices study, cohort member/family member, 1998

Chapter Three

Selection and Recruitment of the Cohort

3.1 Introduction

This chapter discusses the process of enlisting the Australian patient cohort for this study. Major disincentives to the use of linked administrative data for health research in this country are the requirements for ethics committee approval and the gaining of individual patient consent. Most investigators would agree on the importance of these processes for the protection of subjects involved in invasive trials of new interventions. However, for public health based, non-invasive, database studies, the practicalities involved in conformance appear to be overly burdensome to the researcher. An account is provided of the various steps that were followed in this project, criticism is provided of the present system and suggestions are made for changes that would streamline requirements for researchers while not compromising the importance of individual privacy or the protection of study subjects.

3.2 Procedures for obtaining ethics approval and patient consent

One aim of this project was to define the limits to legal access to and use of the national administrative databases. There is perceived to be a high level of public suspicion regarding centralised personal data. This perhaps provides a partial explanation for the highly restrictive legislative controls that surround research use of the administrative data. In addition to access controls, there are stringent requirements for the gaining of 'local' ethics approval – a system which lacks any access to the opportunity for the obvious efficiency gains that would follow from central assessment of national research projects. The current system places the ethical and legal onus on a large number of committees of volunteers in the various institutions who may not be familiar with the particular specialised area which they are asked to assess.

The effect of this distributed system on national research is to introduce extensive delays. In addition, it results in multiple uncoordinated requirements from various separate committees who generally lack any inter-regional communication. Work to improve this situation is under way at

the Australian Health Ethics Committee (AHEC). However it is unlikely that these fundamental issues will be resolved in the near future.[1]

Not unexpectedly, due to the national coverage of the project and the multiple data owners, the process of obtaining consent and approval for this project proved to be a major and lengthy undertaking. To indicate the magnitude of the challenge and as a guide to others who may want to follow this path, the various processes required are documented in this chapter. An indication of the various delays is shown in Table 3-1. A time-line for the entire study is included in Appendix 7

.

3.3 Cohort selection – a contradiction

Because individual patient consent is required before data can be accessed for data linkage, any routine surveillance of treatment outcomes using these data is currently impossible. It is obviously a contradiction to be able to gain consent from relevant patients in advance when performing a surveillance activity. This is a "Catch 22" type situation. To enrol study subjects, information is required about patients' medical history in order to know who to contact, however patient consent is required in order to gain access to such information from the national data repositories. This is currently a major obstacle to research.

To circumvent this complication, an alternative information source was needed. Fortunately Medibank Private agreed to assist with the study considering it to be in the national interest and potentially contributing useful information about outcomes and expenditures for their members. To provide a starting point for enrolling a potential study cohort, they agreed to compile a list of patients who had had the chosen treatments and to write to them asking for their consent to be involved in the project. Thus selection of a cohort from their database was possible because initial contact with these people (customers) was performed by the insurer. Direct contact by a researcher was considered to be unacceptable. After informed consent was received from each person, names and addresses were supplied to the research team. This approach is not suggested

1 (The AHEC is a committee of the National Health and Medical Research Council, it advises the NHMRC on all ethical issues relating to health and advises on the workings of the Institutional Ethics Committees)

as appropriate for future research projects but provided a way around the deadlock that exists at present.

Since the contact information from Medibank Private was only current for those who were still members, it was decided to make an attempt to determine which of these patients were still alive and which had died since their operation - before the subjects were approached. To achieve this, a linkage was performed with the National Death Index (NDI). A report of this process and some measures of the accuracy of the NDI is included in Appendix 1.

3.4 Ethics approvals and contracts

When planning a multi-centre, multi-jurisdiction project it is important to design a methodology that will be acceptable to all parties. Patients were selected from most states of the country,[2] funding was requested from various sources and data was collected from a number of institutions, so multiple contracts and ethics approvals were required. Negotiations with the various centres are described, delays are shown in Table 3-1. A flow chart for the project which places these delays in perspective is in Appendix 7.

Table 3-1 Approval dates and delays incurred by requirements for various approvals.

Centre	**Approval**	**Months**
NCEPH Institutional Ethics Committee (IEC)	Jun-97	1
ANU IEC	Oct-97	5
NHMRC Grant/IEC	Dec-97	8
MP Contract with ANU/CK/MP	Jan-98	11
MP Contract with AIHW	Jan-98	-
AIHW IEC for NDI and NHMDS	Feb-98	4
Manitoba Health Access and Confidentiality	Jun-98	1
Department of Veterans Affairs	Jul-98	2
Health Insurance Commission	Sep-98	18
Consent from each subject	Oct-98	5
NSW Health	Mar-99	18
Other State IECs	Aug-98	1-4

2 Medibank Private was not able to supply data relating to members living in South Australia or the Northern Territory.

3.5 Ethics approval procedures

The process of seeking approval from the 12 ethics committees involved extended into the third year of the project. In general, each IEC was found to have different requirements and unique application forms. Little uniformity was observed and much time was spent on fulfilling the individual needs of the various committees. Many of the comments and suggestions of the committees were valid and appropriate, however, in general it appeared the system of ethics approval was in desperate need of a rational and uniform protocol that could be implemented nationally. The current system provides a definite disincentive to multi-centre or national research projects.

3.5.1 Medibank Private Contract

A contract binding the investigators, Medibank Private and the ANU was developed with assistance from the legal departments of both Medibank Private and the ANU.

3.5.2 New South Wales Health

An application was lodged in October 1997 which passed through several committee meetings. Further information about necessary data fields and justification for the use of the data were repeatedly requested. Complete description of the expected data was difficult as data supplied by each party differ over both time and area. A prospective 'minimum data set' was supplied in July, and further negotiations continued into March 1999 when the project re-appeared before the committee under a new chairperson. The request for justification of each data field was repeated in spite of several explanations of the need to use *all* identifying information available to improve the possibility of acceptable matching. It appeared that there was little understanding amongst the committee members of the scant identifying detail that remains in the NHMDS. It was pointed out that the cohort had already consented to the process and rather than being an invasion of privacy, the information was required to improve the chances that the matching process selected the records of those patients who *had* consented to be part of the study. Permission was eventually granted after 18 months of negotiation.

3.5.3 Other state health departments

Other states were contacted directly by the AIHW, a letter drafted at NCEPH was distributed to the various state Health Ethics committees. Queensland Health stated that they could not supply data without viewing each patient consent form, and would not release identified data under any circumstance. The Department did collect identified data and agreed to link that data for a fee and provide de-identified results. Further negotiation was undertaken by the AIHW. Victoria Health required a copy of the contract between the ANU and Medibank Private to confirm that Medibank Private data would be available. Approval was granted on receipt of this document. Approvals from Northern Territory, Tasmania and the Australian Capital Territory proceeded without further requirements. Approval from Western Australia was granted on 27 August subject to conditions.

3.5.4 Development of the documentation.

The mail-out to potential study subjects included two letters, one from Medibank Private and one from NCEPH. A consent form, a study brochure and questionnaire were developed in consultation with the HIC, Medibank Private and the other stakeholders. The consent form was modelled on one used in an earlier study incorporating HIC data. The process was iterative as each body had different requirements and suggestions about what should be included in the various components of the study package.

Patient letters were worded according to whether the patient was presumed to be alive or dead (from the NDI linkage). The study literature was reviewed by a number of lay people in the appropriate age group. Copies of the letters sent are included in Appendices 3 and 4. The study brochure and consent form are in Appendices 5 and 6.

3.6 Cohort and TYPE group numbers

As mentioned, Medibank Private maintains an archive of patient claims that cover about 12% of all Australian hospital admissions. Prior to commencing the study, an assessment had been made of how many patients would be likely to have had the various implant operations of interest during each year. To provide this estimate, the Operating Room Service Weights Study had been employed, this study provided the most recent available information (Deloitte 1995). Using

the results of this study, it was decided that it would not be worthwhile examining Implantable Defibrillators (AICD) as only around 20 could be expected to be included in the Medibank Private records. The next smallest group, pacemakers, would be likely to include around 694 patients, a large enough group for analysis.

When the cohort was subsequently extracted from the Medibank Private database, predicted numbers of patients were within a factor of two of predictions resulting from the Deloitte study. In general, as might be expected, the procedures that could be considered 'elective' were over-represented within the Medibank Private membership. A comparison of actual to predicted numbers is shown in Table 3-2.

Table 3-2 Annual number of patients with prostheses, predicted and actual (1993 only)

Device type	% patients in Deloitte study	Predicted Number	Actual number (MP 1993)	Ratio Actual/ Predicted
Intra-optic Lens	26.2	4,822	6,227	1.3
Cardiothoracic procs	25.9	2,923	-	-
HIV-related infection	10.8	1,217	-	-
Hip replacement	8.1	1,502	1,502	1.0
Trans-vascular cardiac	7.2	815	-	-
Major limb and joint	5.5	620	-	-
Cardiac pacemaker	3.8	694	346	0.5
Cardiac valve	2.8	516	282	0.5
Spinal procedures	1.9	219	-	-
Implantation AICD	0.2	20	-	-
Cochlear implant	0.1	8	-	-
Totals	-	-	8,357	1.1

Eligible patients were then selected from the 1993 Medibank Private archive. In addition to the above groups, a vascular graft group was selected. This group of potential study members comprised 8,743 persons as shown in Table 3-3..

Table 3-3 1993 Medibank Private archives: numbers in device type groups

Type	N
Heart Valve	282
Pacemaker	346
Hip	1,502
Vascular graft	386
IOL	6,227
Total	8,743

Due to the less than expected overall numbers and the small numbers in some subgroups it was decided to include additional members from the 1994 archives for heart valves, pacemakers, hips and non-acrylic IOLs.[3] Around 500 acrylic IOL patients were then randomly selected from the group of 6,227 which was considered a large enough sample and was of comparable size to the other device 'type' groups. With the non-acrylic IOL patients the IOL group now comprised 949. Final numbers of patients selected from the archives are shown in Table 3-4. It is this group of patients who were asked by mail, to join the study.

Table 3-4 Final numbers for the combined, selected 1993-94 patient groups

Type	N
Heart Valves	495
Pacemakers	685
Hip	2580
Vascular Grafts	565
IOLs	949
Total	5274

A breakdown of the total numbers in each of the device groups of interest is shown in Table 3-5. Some of these main device groups had subgroups with significant numbers of patients. These subgroups would be used to perform inter-group comparisons of different brands of device[4], the results are presented in Chapter 6.

3 Acrylic IOLs are the common and 'standard' lens.
4 Acronyms and brand names are detailed in the Glossary.

Table 3-5 Numbers of patients in each device subgroup

Implant groups	N	% total
Vascular grafts:		
Stent	42	0.8
Synthetic Graft	312	5.9
Bifurcated Graft	192	3.6
Heart valves:		
Tissue HV	103	2.0
Medtronic HV	43	0.8
Carbomedics HV	11	0.2
Starr HV	12	0.2
ST Jude HV	272	5.2
Other HV	54	1.0
Hip prostheses:		
Osteonics Hip	205	3.9
Axis Hip	133	2.5
Zimmer Hip	266	5.0
Austin Moore Hip	198	3.8
Charnley Hip	220	4.2
Exeter Hip	162	3.1
PCA Hip	195	3.7
Precision Hip	136	2.6
SROM Hip	148	2.8
Other Hip	936	17.7
Pacemakers:		
SC VVIC Pacer	170	3.2
SC VVIR Pacer	148	2.8
DC DDDR Pacer	242	4.6
DC DDDC Pacer	125	2.4
Intra optic lenses:		
PMMA IOL	491	9.3
Multi-focal IOL	218	4.1
Foldable IOL	240	4.6
Total	5274	100.0

3.7 Details of the cohort selection process

Selected prosthesis TYPE codes were used to identify members who had had device implants. The Medibank Private claims archive was searched using these codes which identified components of the various prostheses (HSH 1995). Most patients claimed for more than one component for each operation. All patients who had claimed for one or more of these codes were selected, Medibank Private 'book numbers' (their internal version of a Unique Patient Identifier), were used for identification. A graphic showing the process is in Appendix 7.

3.7.1 Stage 1

Some processing was necessary to determine which claims best represented the operations of interest. The aim was to select a claim that referred to the *major* procedure during the 1993-94 period. In the Medibank Private claims database, there were of course many different prosthesis claims for each patient. It was the intention to compile a list of patients each classified according to their *most significant* implant operation. Once this had been determined, this operation became for the purpose of this study, the *index* operation and the patient was defined according to the type of implant; heart valve, pacemaker etc.

To determine which procedure to use as the index operation, some manipulation of the data was necessary. The technical details are described here briefly. The claims records for the 5,274 patients of interest were first grouped for each patient and then sorted by Book/DOB/benefit (ascending). The last item (most costly) was flagged and selected as the 'index' record for each patient. The intention was to collect unique patient IDs associated with the item that was the most significant expenditure. This approach was used to indicate the "genuine" implant cases. All flagged records were then linked to the departmental benefits schedule(HSH 1995) to determine what the claim actually referred to by attaching a text description. All entries were examined individually and unidentified codes were sent to Medibank Private to be decoded. There were some erroneous codes for various items these entries were not included.[5] Records were then sorted by TYPE and description to gather patients into the five prosthesis groups.

3.7.2 Stage 2

Codes were submitted to Medibank Private for comparison with the current members register. Of the selected patients 67% were found to still be current members. The issue of whether non-current patients should be included in the study was again discussed and Medibank Private agreed to supply contact details for all current members and the last known address for former members. A list of names was then prepared including DOB, country of birth and contact details.

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5 For example code H742, - cement restrictor, screws, used alone in procedures unrelated to this study, by various surgeons.

The list was submitted to the AIHW for comparison with the NDI. The matching was performed against the two halves of the NDI, one containing full DOB the other calculated year of birth (both contain around 1,000,000 records, current to late 1997). The matching process suggested that 849 patients had died. This represents 16% of the device cohort and infers that only 17% of the total group had ceased membership with Medibank Private in the four years since 1993 (ie, 16% had died, 17% had discontinued insurance). The two sets of matched patients were amalgamated and sorted by Medibank Private book number, this showed that 20 patients were matched to both halves of the NDI, the stronger match was thus selected (in all cases this was the match with the fuller part of the set). NDI Matches were made for 90 patients who appeared to be still paying insurance premiums. Many of these members were thought to have paid their fees ahead, some up to one year in advance.

3.7.3 Stage 3

After patient consent had been finalised, the Medibank Private archive was searched for the period from 1993 – 1997 inclusive for all claims relating to the consented patient book numbers. Records of all procedures were extracted. Records were collated under book numbers, with additional identifying information being added from the returned consent forms (Medicare number, date of death etc). IDs for each patient were then extracted for matching with the NHMDS and Medicare archives. (See Table 4-5 and Appendix 8A for details of data fields utilised).

3.8 Accuracy of the NDI matches:

As all consenting patients (or families of patients) had supplied full personal details including, where relevant, date of death, it was possible to make a comparison between actual and possible death dates as predicted by the matching process with the National Death Index. As mentioned previously, this process was completed prior to the initial mail-out in an attempt to ensure that appropriate letters were sent to the families of members who had died since their operation in 1993-94. It was considered important to, in particular, avoid the situation where a bereaved family was sent a letter requesting the cooperation of their dead relative. Overall the NDI was

found to have a sensitivity of 91%,[6] specificity of 98%. Further discussion of the accuracy of the NDI is included in Appendix 1

Although the emphasis had been placed on avoiding sending letters to those that had died, it was actually the opposite scenario that produced the most negative feedback.
A significant number of calls were received from disgruntled members and families who considered it insulting to be labelled dead when they were in fact alive – one family member construing it to be an extreme example of 'ageism' for the researchers to have written to the family instead of directly to her elderly father!

3.9 Logistics:

In addition to providing the required data free of charge, Medibank Private agreed to partially fund the mail-out stage of the project. This stage was complicated by the fact that Medibank Private became a separate entity to the Health Insurance Commission in April 1998. Further negotiations were required as the HIC mail room, which formerly managed mailings for Medibank Private, was no longer under any obligation to do additional tasks. The mail room however, agreed to perform the mail-out for a nominal fee in addition to their normal responsibilities. The Medibank Private relocation was a cause of considerable delay in initiating the mail-out.

Medibank Private had agreed to allow mail contact with both current members and ex-members, though of course addresses for ex-members would not necessarily be up to date. It was agreed that contact must originate from Medibank Private, as NCEPH had no right to such personal information until consent was obtained from those willing to participate in the study. Contact numbers for both Medibank Private and NCEPH were included in the letters, although no free-call number was provided on the first contact letter

3.9.1 The mail-out

A pilot mail-out was conducted to test the package and assess response rates and times. 50 members were selected at random from the database, the entire package including letters from Medibank Private and NCEPH, the study brochure, the consent form and a reply paid envelope

6 An error in this article has been corrected here.

were sent on April 27 1998. 14 members responded within three weeks; after which a reminder letter was sent. This second letter included a "1800" (free-call) number; 6 members phoned with queries. By six weeks after the original letter 30 responses had been received: 15 consents, 10 refusals and 5 'return to sender' (RTS). It appeared that an initial letter followed by one reminder would constitute a reasonable attempt to enrol patients taking into account cost and time constraints.

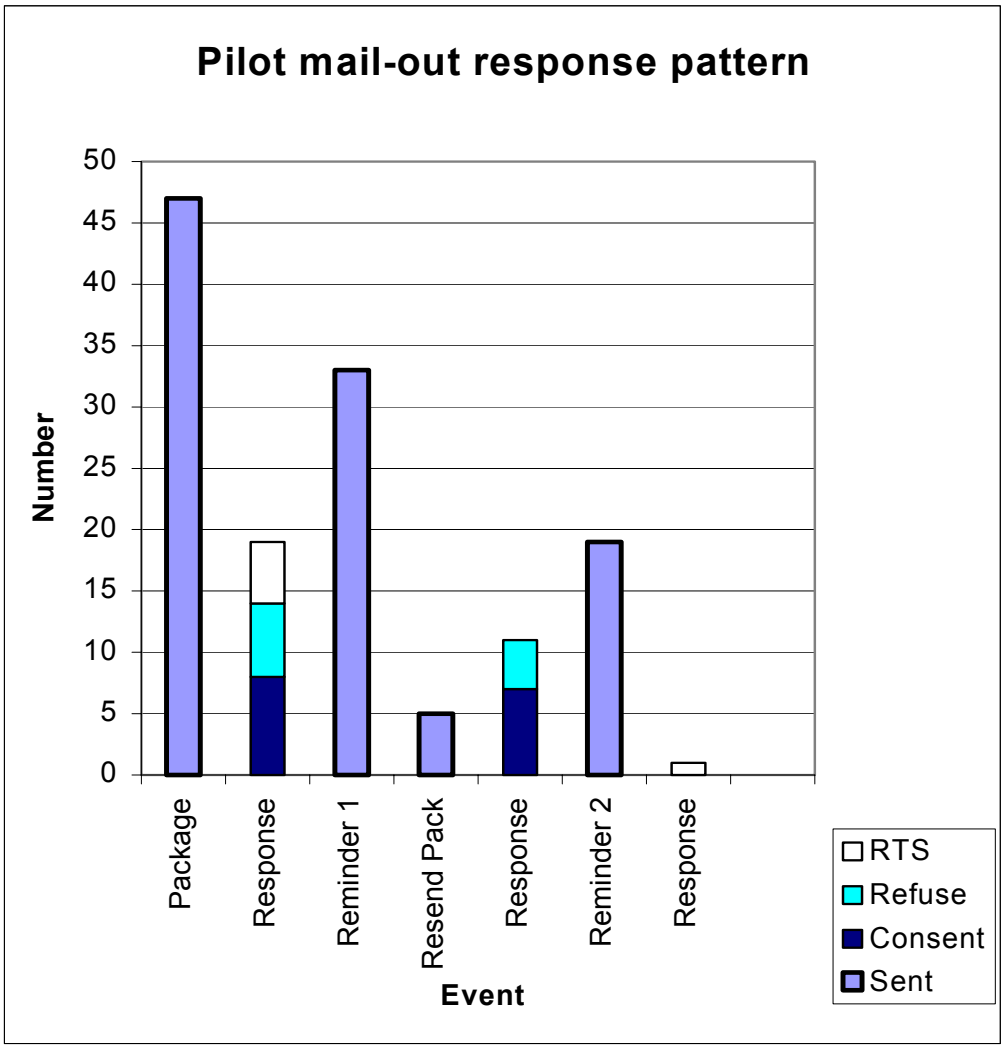
Responses indicated that several changes should be made to the various letters:

Prostheses names should be listed rather than just referred to in general. Some patients thought that their implant was not one of interest to the study as it had not been specifically mentioned.

Emphasis was needed to be given to return both the questionnaire and the consent form.

Repatriation Benefits (RPBS) number to be included in the data requested. (This to allow matching with the Department of Veterans Affairs pharmaceutical database.)

Figure 3-1 Pilot mail-out response pattern



On June 16, the main mail-out was conducted. All letters were individually addressed by performing a mail-merge with the database of names and addresses supplied by Medibank Private. The packages (Appendices 3,4,5 and 6) were then delivered to the HIC mail-room for collating, enveloping and mailing. Medibank Private envelopes were used as contact with members should be perceived to have originated from the insurer until such time as consent for direct contact with the research team was gained.

3.9.3 The responses:

Within the first week Medibank Private had received around 80 complaint calls, NCEPH around 30. Many living persons found a letter to their relatives on their behalf, assuming their death, to be offensive and contacted one of the agencies by phone or mail. All of these occasions were of course the result of mis-matches with the NDI and this explanation plus the occasional apology letter was sufficient to calm the waters. Medibank Private was somewhat distressed initially that so many members had been 'offended' however in the circumstances it was agreed that the best result possible was achieved.

Many members provided unsolicited support for the project, a few comments are quoted here:

"Why hasn't this been done before?"

"Desperately needed research".

"Very worth while",

"Am willing to supply any further information".

"My mother wanted to donate her body to science and I'm sure she would want her health information used in the study".

"Which device are you interested in, I have six of them – I'm the Bionic Woman!"

One minor problem that did delay the response somewhat was the fact that the wrong 'reply paid envelope' was included in the initial mail out. This was the result of poor communication between NCEPH, Medibank Private and the HIC mail-room. The standard Medibank Private envelope was included instead of a specially printed envelope addressed to NCEPH. This meant that all responses were forwarded through the various state offices. This detour introduced extra delays into the process.

3.9.4 Follow up

The mail-out of a second reminder letter was postponed because the initial response was very extended and did not start to taper off until around seven weeks after the mailing date. A meeting was held with Medibank Private staff on June 30 and the content of the proposed reminder letter was discussed. Due to the negative feedback generated by the first letter, Medibank Private initially resisted the idea of allowing a reminder to be sent. Again it was stressed that considerable bias could be introduced if the reminder letter was not sent. It was eventually agreed that this letter would be from the ANU and that Medibank Private's involvement would be down-played. This does constitute a complete reversal of their initial policy, however, management was keen to avoid any possibility of further adverse publicity. Letters were composed for the four groups: current and non-current members, living and presumed-dead. An ANU free-phone number was included and no contact details or phone number were supplied that could link the letter to Medibank Private. Samples of these letters were supplied to Medibank Private for review.

In addition, to minimise any further possible offence, a list of "non-responders, assumed dead" was provided to Medibank Private for a thorough search of those who may still be alive and on their records. All those who were still paid-up current members were addressed as if they were alive, even though some had been matched as dead by the NDI.

Medibank Private Staff changes during this period contributed to further delays. As a consequence of this, Medibank Private fearing further negative response, decided on August 12 that it was not prepared to allow the previously approved reminder letters to be sent, (unfortunately these letters had already been printed). Further negotiations were undertaken, the reminder letter was again emphasised as an essential part of the project. It was noted that a different group of potential subjects respond to a second letter and that to use only the initial responders would bias the sample. Of course, additional subject numbers were also desired. Agreement was reached with staff on August 25 and a new letter was developed on Medibank Private letterhead, certain conditions regarding classification of members were agreed upon as discussed below. Apart from the legally required company registration number (ARN) no contact details for Medibank were provided on their letterhead.

The reminder letter was mailed on August 27, around ten weeks after the initial letter, 2,996 letters were sent, 488 of these to families of those presumed to be deceased. Further to those already mentioned, various other groups of members were excluded at the express request of Medibank Private. Most importantly, those who had been recorded in the member database as responding negatively to the first mail-out. Sixty individually tailored letters were sent to people that had responded incompletely or had specific queries. The queries mainly related to uncertainty about eligibility due to their having ceased to be members of Medibank Private, or being unsure whether they actually had an implantable device. Over 100 Patients were contacted by phone to answer questions about the purpose of the study or to clarify their eligibility.

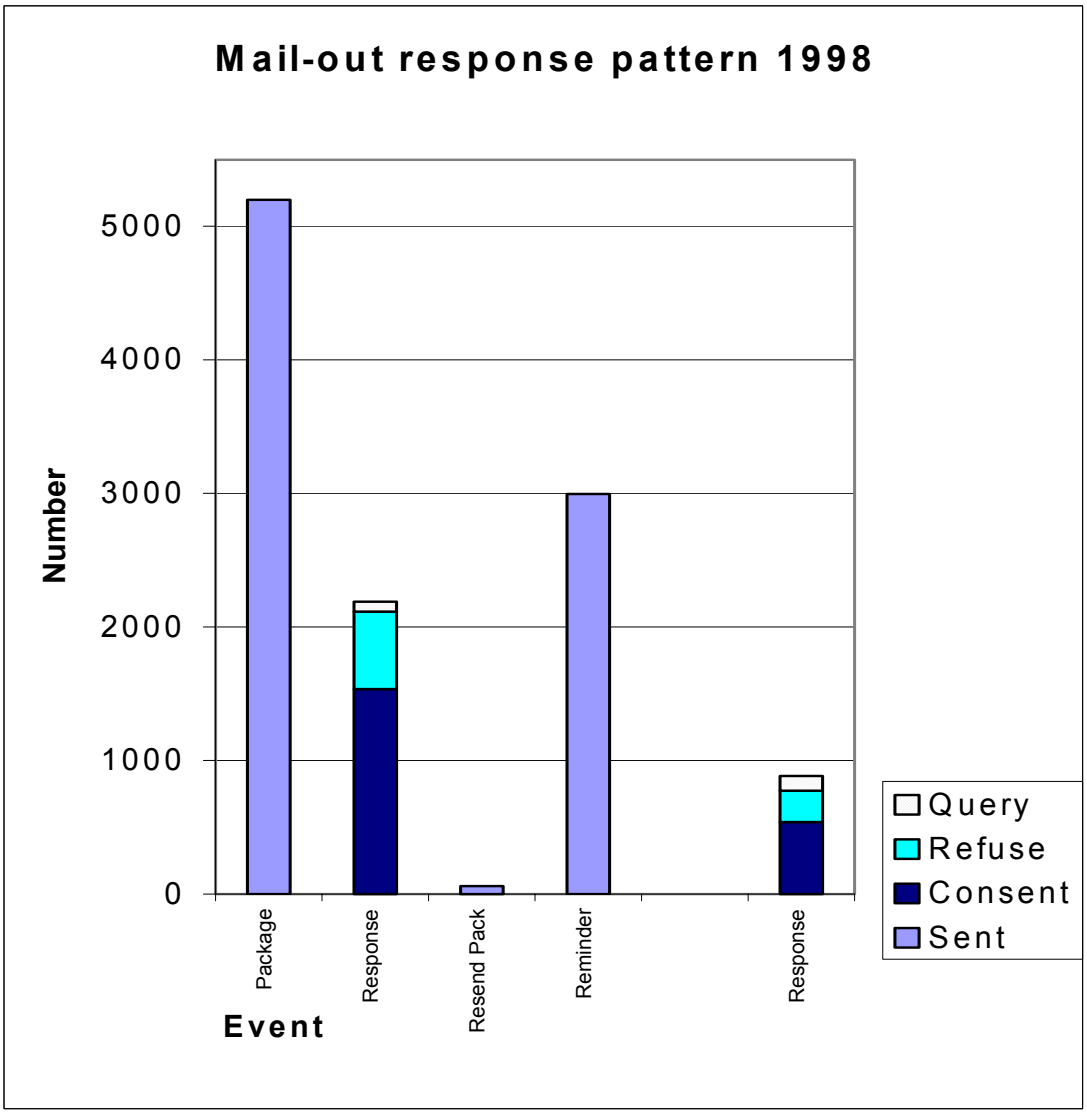
The letters were mailed on August 27 in Medibank Private envelopes including another copy of the study brochure and consent form. An ANU free-phone number was quoted, however members were requested to respond directly by mail as all required material had again been supplied.

Response rates are shown below in Table 3-6 and Figure 3-2. The number of letters 'returned to sender' was not able to be assessed due to the fact that in the second mail-out, letters were returned via the Medibank Private state offices and these "RTS" letters were discarded.

Table 3-6 Mail-out sequence and details of responses

Event	Package	Response	Resend Package	Reminder For all non-responders	Response	Total response rate %	Total numbers
Date	16-Jun	27-Aug	06-Aug	27-Aug	19-Oct		
Sent	5,274		60	2,996		100.00	5,274
Consent		1,530			540	39.9	2,079
Refuse		579			234	15.6	813
Query		72			110	3.5	182
No reply		3,021			2,002		
Response Totals		2,253			994	59.1	

Figure 3-2 Mail-out response pattern



3.10 Response rates

Response rates varied according to the sex, age and type of operation and whether persons were still insured. For those deceased, response rates depended on the availability of family member or other authorised person to provide consent. A detailed description of the consenting cohort is provided in section 4.3.

3.10.1 Response rate dependant on current membership.

Of the 5,189 patients selected from the 1993-93 archives, not all were still current MP members when they received a letter asking them to participate in the study in 1998. As could be

expected, some had changed address and thus were not contactable, others considered a letter from Medibank Private to be irrelevant and thus did not respond. Overall 2,883 of the initial group responded by mail to the request, while others telephoned either NCEPH or Medibank Private. An additional 50 patients responded after the closing date and were thus not able to be included. Thus around 60% responded in some way, which was considered to be a good rate.

Actual consent rates were somewhat better from those who were current MP members at the time of the mail-out as shown in Table 3-7. Thirty four percent of ex-members refused to join the study compared to 26% of current members. (Membership status was missing for 9 persons).

Table 3-7 Consent rates considered by membership status

Consent:	Total	Ex-member	Current	% Ex-member	%Current
No	813	257	556	31.6	68.4
Yes	2070	495	1575	23.9	76.1
Total	2883	752	2131	-	-
%No	28.2	34.2	26.1	-	-
%Yes	71.8	65.8	73.9	-	-

3.10.2 Sex ratios of total group and those who responded

Among consenting patients the sexes were evenly balanced. However more females than males took the trouble to respond even though they were less likely to agree to be part of the study. Concluding from a number of conversations with cohort members, this possibly reveals a higher level of competency in dealing with mail combined with a greater level of caution about the privacy of their medical data.

A response rate of 56% and a consent rate of 41% was considered to be around what could be expected considering that since the time of operation when all contact addresses were current, 33% no longer had insurance with Medibank Private and of these, 42% had died. Figures 3-3 and 3-4 below account for patient numbers:

Figure 3-3 The consent process and numbers consented

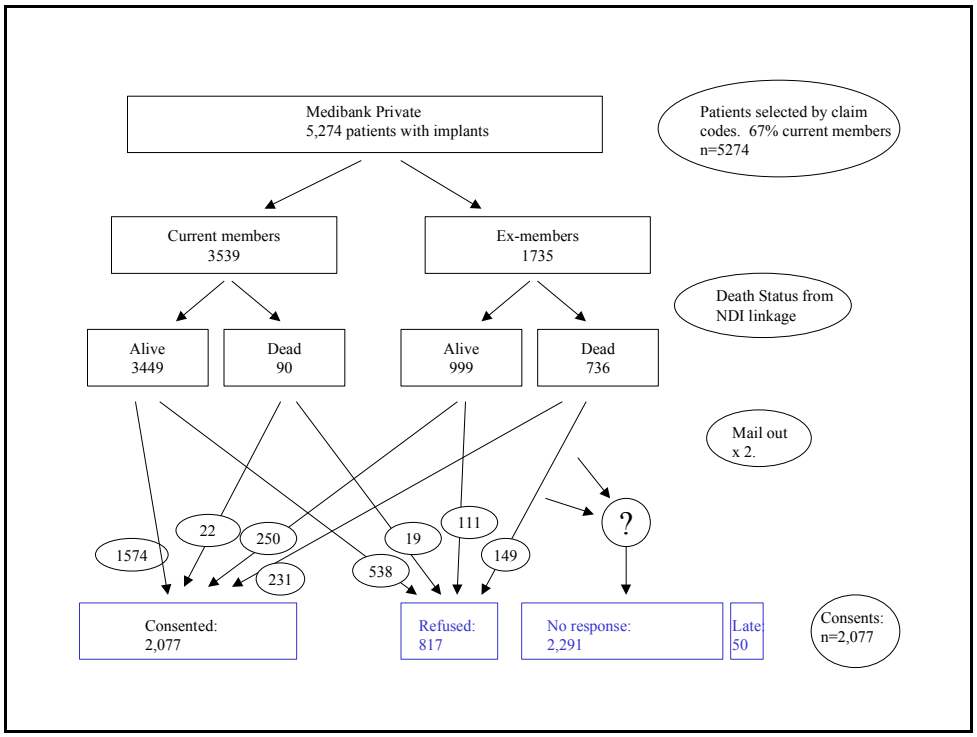
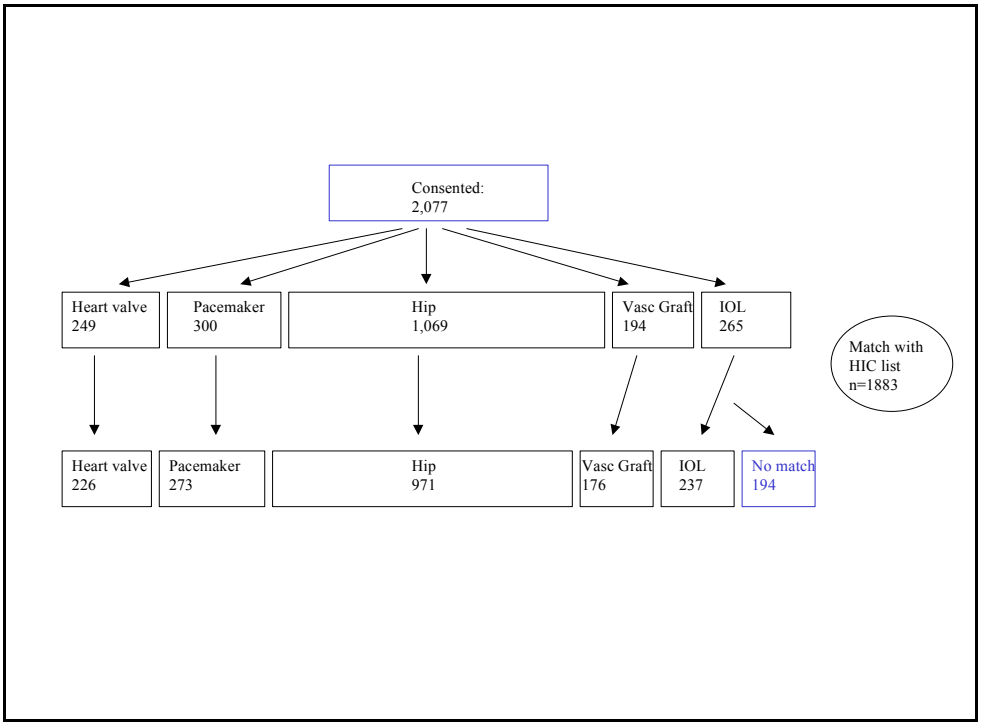


Figure 3-4 Consented patients in each device type group showing final numbers after the HIC matching process



The final consented, matched and enrolled cohort numbers are shown in Table 3-8.

Table 3-8 Final cohort numbers for each type of device

Type	Frequency	Percent of final cohort
Heart Valve	226	12.0
Pacemaker	273	14.5
Hip	971	51.6
Vascular Graft	176	9.3
IOL	237	12.6
Total	1,883	100.0

3.11 Available data

The observation period extended from January 1 1993 until December 31 1997. Each selected patient had an implant operation in 1993 or 1994 allowing three to five years potential follow up. On analysis of the MP claims file it was noted that many patients had no claims prior to their 'index' operation. Thus from the MP records it was not possible to make comparisons of service use rates pre and post op – this comparison required the addition of data from other sources, ie the MBS and NHMDS files. As the NHMDS was not available for this study, comparison using admissions data was not possible for this group of patients.

3.12 Decoding the data:

Data were coded for services, providers and hospitals. The text 'translation' for these codes was obtained only with some difficulty which suggests that this type of research is not commonly conducted. For example, all services were coded according to the Commonwealth Medical Benefits Schedule. This is a large set of codes describing service events that is revised and published every few months, until recently, only on paper. Electronic versions of these tables were available on the Internet for the months September 1998 until January 1999. However due to the fact that the information was stored in a proprietary format (in addition, the most useful edition contained significant formatting errors), a 'C' program was written to re-format the data

to enable it to be used. Descriptions of services were then edited to produce a 'condensed description' of each service for use in this study.[7]

To utilise this data a table was produced that could be combined with the table of prosthesis codes (available electronically) and accessed via a "lookup" function. In this way comprehensible individual case histories for all patients were produced that could be examined for clinical consistency and would be appropriate for distribution to patients if validation was deemed to be required. Analysis of these data is included in chapter 6.

3.13 Discussion

Many barriers exist for those who wish to conduct this type of national research. The principal delays experienced in this project were related to the gaining of funding, ethical approval, patient consent, institutional contracts and the coordination of data collection. A significant disincentive also exists as a result of the high data collection charges imposed by some of the institutions, in particular the HIC. These charges are required to cover the extensive staff time requirements of verifying individual patient consent. More efficient mechanisms for this process could be devised, thus saving time and money and perhaps encouraging the appropriate utilisation of these resources by health researchers. A large amount of time was consumed in this project preparing and tailoring applications to the requirements of the multiple independent Institutional Ethics Committees (IECs) across the country. Suggestions for improving this situation, both for the overworked (usually voluntary) members of the IECs and for researchers are made in Chapter 10.

7 Codes that were discontinued before September 1998 were not available electronically and had to be copied from paper versions of the tables.

> Administrative data are readily available are inexpensive to acquire, are computer readable and typically encompass large populations. They have identified startling practice variations across small geographic areas and supported research about outcomes of care.
> Iezzoni, 1997

Chapter Four

The Australian Study - Part A

4.1 Introduction

In the next three chapters, results for the Australian study are presented and analysed. In the discussion, the potential for an approach using administrative data supplemented with increasing levels of clinical detail will be explored. The potential for this approach will be examined by using service event data and focussing on the comparative performance of implantable devices and in Chapter 6, by including associated adverse events.

4.2 Potential biases

The use of information that has been collected for purposes other than research has the risk of introducing bias in several ways. The various possibilities are examined.

4.3.1 Sample selection bias:

It is likely that selecting privately insured patients could produce a biased sample. Members of Medibank Private may not be typical of the general population. They are most likely to be from the higher SES[1] groups and are possibly more informed about the availability of health care services. It is known that they are more likely to be admitted to hospital (Deeble 1999), however, no significant bias was found for private health insurance status in the pilot record linkage study by McCallum (McCallum, Lonergan et al. 1993, p24). For the purpose of this study, where brands of implants are to be compared with each other, the fact that all patients were privately insured is not considered to be a problem. This bias may be of some importance when the Australian cohort is compared with the Manitoban cohort and will be discussed further in Chapter 8.

1 Socio-economic status.

4.2.2 Survivor cohort bias:

In an attempt to assess the extent of any selection bias in choosing only those patients who have had good results and are still alive, all patients who had the selected implants were contacted and families were encouraged to consent on behalf of dead relatives. Eleven percent of the cohort is comprised of patients who were entered into the study posthumously by their families. This strategy was fairly successful considering around 15% of the total contacted were in fact dead. About 56% of persons who were contacted responded in writing; of the 'live' group, 74% consented to join the study, while of those who were deceased, 61% were 'consented' by their families.

4.2.3 Response bias:

It was a concern that bias may have been introduced by the selection process wherein patients would be more likely to consent if they felt positive about the results of their surgery. This was examined in part, by comparing the general health of those who consented to be included in the study against those who, while answering the questionnaire, declined to join the study. In the case of those who were consented posthumously by their families, the estimate was impossible as the questionnaire was only valid if completed by the patient themselves. To estimate the extent of this influence, all respondents were encouraged to complete a quality of life questionnaire included in the mail-out package, whether or not they agreed to be part of the study (See 4.9).

4.2.4 Differential recall bias

Differential recall bias is not a problem with a study of this kind where the data are collected from electronic records. Because patients are not required to recall their past medical histories this approach has the advantage of objectivity, but may suffer from other causes of inaccuracy where coding is involved.

4.2.5 Bias from Membership exclusion period

To provide a comparison period, patients' records were collected for around twelve months prior to their operation and for up to five years after. In estimating rates of service utilisation, it could be suggested that a bias exists because patients might join a private insurance scheme shortly before they expect to require surgery. This appears to

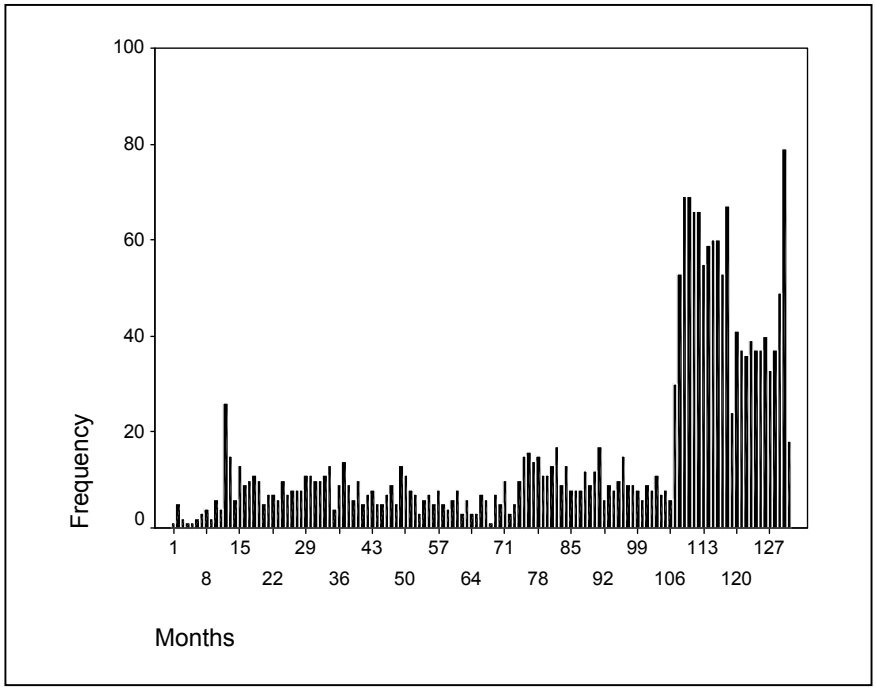
not be the case; average time of membership prior to the index operation was 93 months. Although Medibank Private imposes an exclusion period of 12 months for hospital treatments requiring implants, only 1.3% of the cohort (28 patients) were possibly influenced by this. Figure 4-1 shows membership times pre-operation, with this small rise in membership at around twelve months prior to the operation. The large rise around 105 – 135 months pre-op is due to Medibank Private having commenced trading in 1976 but 're-dating' all early memberships to Feb 1984.

4.2.6 Lack of information about public hospital admissions

The majority of admissions for the cohort of privately insured patients would have been covered by Medibank Private, and thus were included in the analysis. Privately insured patients are occasionally admitted to public hospitals as public patients either in emergency situations or to avoid 'gap' payments. As a result of the non-availability of the NHMDS data, (discussed in 4.5.2) a small number of these *public* hospital admissions were most likely not included in the analysis. A visual check was made against the small amount of matched data supplied from the NHMDS and it appeared that the number of public admissions for the cohort patients was small. This deficiency is unfortunate, but should have little effect on the comparisons drawn between the Australian device type groups, as all patients were similarly affected. This problem will require further examination when the Australian patients are compared to the Canadian cohort in chapter 8.

At present in Australia, no other source of 'intervention-specific' patients is readily available to researchers; identified data on individual procedures is not collected by the HIC or the AIHW. A possible but limited alternative would have been to approach a large public hospital or to enlist the help of a state health department. However, the primary purpose of this study was to demonstrate feasibility of a *national* evaluation system with sufficient sensitivity to detect major outcome differences. For these reasons, this less than ideal situation was accepted as being unavoidable.

Figure 4-1 Months of MP membership at time of index operation



4.3 Description of the cohort

All 5,274 selected Medibank Private members and ex-members were contacted by mail, using the address of their last contact with the insurer. Of these nearly 3,000 responded either by mail or phone, and 2,077 consented (the cohort). Rates of consent were strongly influenced by the actual device type implanted. After IOLs,[2] the hip implant was the most common device while heart valve patients were the most likely to consent to the study. Numbers of patients and consent rates are presented in Tables 4-1 – 4-4 by device type, age-group, sex and state of residence. Some consenting patients were not able to be included as their records were not identifiable at the HIC. Final numbers for the 'matched' HIC cohort were N=1883.

2 Numbers for acrylic IOLs having been restricted to 500.

Table 4-1. Frequency and consent rate by device type

Type	Frequency N	% of N	% Consent rate
Heart valve	226	12	52
Pacemaker	273	14	45
Hip	971	52	43
Vascular graft	176	9	36
IOL	237	13	28
Total	1883	100	

Table 4-2 Frequency and consent rate by sex

Sex	Frequency N	% of N	% Consent rate
Female	925	49	37
Male	958	51	45
Total	1883	100	

Table 4-3 Frequency and consent rate by age-group

Age group	Frequency N	% of N	% Consent rate
0-9	2	0.1	8
10-19	4	0.2	26
20-29	11	0.6	37
30-39	31	1.6	33
40-49	106	5.6	45
50-59	299	15.9	53
60-69	622	33.0	48
70-79	595	31.6	39
80-89	203	10.8	28
90+	10	0.5	19
Total	1883	100.0	41

Table 4-4 Frequency and consent rate by state of residence

State	Frequency N	% of N	% Consent rate
NSW (+ ACT)	530	28	40
QLD	289	15	41
TAS	75	4	45
VIC	875	46	41
WA	114	6	42
NT[1]	-	-	-
SA[1]	-	-	-
Total	1883	100	-

1. NT and SA data were not available from Medibank Private

Consent rates varied with type of device and membership currency, but little with state of residence. Only 28% consented who had IOLs, while of those contacted who had heart valves, 52% consented. This would be expected given the high level of patient commitment required by the comparative complexity and invasiveness of the procedure. Patients in the age-group 50-59 had the highest consent rate, those aged under 10 the lowest. The effect of membership currency was discussed in section 4.2.5.

4.4 The data – sources and types collected

Six national health-databases were used in this study, the various managing institutions and contents are shown in Table 4-5. Fields used for linkage between the datasets are shown in the right-most column and are labelled to show their commonality. Most of these links are 'probabilistic'. Only the Medicare number (H) and the Medibank Private 'book number' (B) are unique identifiers that can reliably be used for deterministic linkage. The DVA number, although unique is not 'universal' to this cohort as not all are covered under this scheme. The contents of the various national datasets are presented in Appendix 8B.

Table 4-5 The data sets: fields and available linkage variables

Database	Fields Used	Links
Demographic data (Medibank Private Members details)	Name (full)	**A**
	Book Number (ID)	**B**
	Address (last notified)	**C**
	DOB	**D**
	Sex	**E**
	State	**F**
	Membership currency	
Demographic data (Additional data elicited by mail, with request for consent)	Name (full)	**A**
	Address (current)	
	Previous postcodes	**G**
	Medicare/DVA number	**H**
	DOD (where relevant)	
	COB	**I**
Medibank Private Claims archive	Book Number (ID)	**B**
	Date of service/admission	**J**
	Date of discharge	**K**
	Service code	
	Provider code	
	Hospital code	
	Bed-days	
	Cost	
Medicare and DVA	Name (full)	**A**
	Medicare/DVA number	**H**
	Address (last notified)	
	Date of service	
	MBS service code	
	Provider code	
	Referring provider code	
NHMDS	Admission date	**J**
	Separation date	**K**
	Sex	**E**
	DOB	**D**
	COB	**I**
	State	**F**
NDI	Name, first and second	**A**
	DOB	**D**
	Sex	**E**
	State	**F**
PBS	Medicare/DVA number	**H**
	Supply date	
	Drug code (PBS)	
	Pharmacy code	

4.5 The data

All available service event data for the consenting cohort of patients were requested from the institutions. Medicare numbers had been provided by all consenting patients.

With the exception of the NDI and the NHMDS, all service records were accurately identified with either the Medicare number or a Medibank Private ID number. Thus *deterministic* matching was used to link the MBS, DVA and PBS datasets, providing virtually 100% reliability. *Probabilistic* matching was required to associate members with their records within the NDI and NHMDS datasets, with varying degrees of accuracy. [3]

4.5.1 Data variables used

Each data custodian required justification to be provided to support the request for specific data variables, thus the minimum number of variables was requested. The variables were chosen for two reasons. All identifying variables were requested to allow the best possible identification of the patient for the NDI and NHMDS matching process. Other variables were requested for their potential usefulness in providing detail about the actual service provided. For example, an indication of the magnitude of the service (eg cost, time in hospital) or 'outcome' (eg death, rate of service use, re-operation). Variables were also collected about the *nature* of services that could later be used to distinguish services related to co-morbid conditions from services related to the implanted device. This process examined in Chapter 6.

4.5.2 Obtaining service data from the institutions

Details of the consenting cohort included all identifying information about each person, dates of death for those who had died and quality of life surveys for most. A list of 2,077 names and identifiers was submitted to the HIC, Medibank Private and the AIHW for data extraction. All records relating to each subject within the years 1993 – 1997 inclusive were requested. Considerable delays were experienced due to staff shortages and the fact that the work was not considered to be 'core business'. Details of fields supplied to and requested from these agencies are outlined in Appendix 8A.

3 Personal name is not a unique or reliable identifier.

It was eventually accepted that the AIHW would not be able to supply hospital admissions data for this study. They had experienced difficulties conducting the probabilistic matching of patient identifiers to the de-identified NHMDS records. Apart from a recent internal study using patients in Western Australia, no previous attempt has been made to match the NHMDS data at the patient level. Some progress was made, but due to limitations of time and resources, they were unable to extract data for all subjects and had to limit the process to New South Wales residents only. Consequently, the Medibank Private data was the only source of information about hospital admissions that had sufficient coverage to be useful for the study.

The availability of information from the NHMDS for research use was therefore not demonstrated. Verification of the limited results that were achieved will require use of the specialised data matching software 'Automatch' (not available to this researcher) and will be addressed in a later AIHW project (Automatch 1998).

4.6 **Mortality**

Mortality is used here as a crude indicator of outcomes. It does have the advantage of being an accurate and widely collected statistic but it should be remembered that in comparing different medical devices, mortality may not be a particularly representative or relevant indicator of treatment outcome. For example, mortality rates would not be expected to be useful in making comparisons between different hip implant or IOL brands.

Dates of death were supplied by relatives at the time of consent. In most cases these corresponded well with dates derived from the NDI (for those matches which were correct). Crude death rates over the observation period are compared in Table 4-6 for device type. Age specific death rates are presented in Table 4-7.

Table 4-6 Australian cohort - Crude death rates by Type of device

Type	Total	Av Op age	No. died	Mean survival (months, for those who died)	Crude Death rate (per 100 person years observed)
Heart Valve	249	65	32	25	2.5
Pacemaker	300	71	66	25	4.4
Hip	1069	67	83	25	1.5
Vasc Graft	194	68	47	23	4.7
IOL	265	72	29	31	2.1
Total	2077		257	21.5	(mean) 2.4

Table 4.6a Pre and post-operative observation times

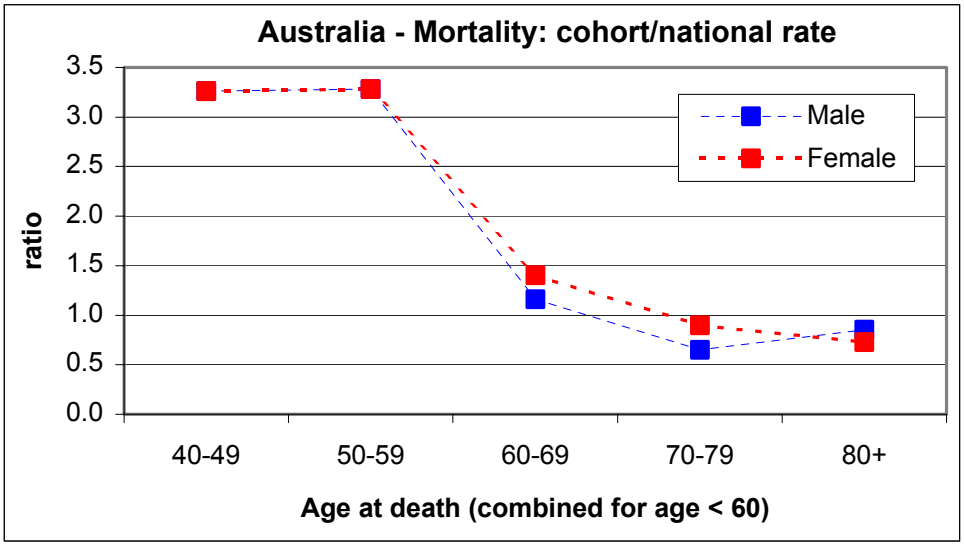
	Months pre-op	Months post-op
Mean	12.2	60.7
Median	10.7	62.1
Std. Deviation	7.8	7.2
Minimum	0.1	48.0
Maximum	26.0	71.9

Table 4.7 Age-specific death rates per annum

Age	Deaths	Total n	Rate/1000 per annum
0-9	0	2	0.0
10-19	0	5	0.0
20-29	0	11	0.0
30-39	0	33	0.0
40-49	3	118	5.1
50-59	12	334	7.1
60-69	54	688	15.4
70-79	73	650	22.3
80-89	69	226	60.6
90+	6	10	119.7

Indirect standardisation was used to produce standardised mortality ratios (SMRs) for age-group and sex. The SMR represents the risk of death for the cohort subgroups compared to their peers4. Figure 4-2 presents these results graphically, Table 4-8 numerically.

Figure 4-2 SMRs by age group and sex



4 Actual death rates were standardised using national rates derived from the Australian Bureau of Statistics, Death rates for Australia 1994.

In Figure 4-2, all points above the line showing 1.0 represent groups with above expected mortality compared to national rates for that age-group. Varying selection effects can be seen. Patients who have one of the implant procedures when they are relatively young, are in fact generally sicker than the average population. They are more likely to die during the follow-up period than their age cohort. In contrast, those that have one of these procedures in their latter years are generally more healthy than their age cohort, possibly as they are well enough to undergo surgery, they are survivors and their death rate is somewhat less than the national average. Results for males and females were combined for ages less than 60 years due to the small sample size in these groups.

Table 4.8 Observed and Expected numbers of deaths, by sex and age-group

Age group	observed		expected		SMR[1]	
	M	F	M	F	M	F
40-49	1	2	0.7	0.4	1.4	5.1
50-59	12	5	5.8	1.1	2.1	4.5
60-69	41	20	35.4	14.2	1.2	1.4
70-79	45	40	69.0	44.5	0.7	0.9
80-89	40	45	46.8	61.8	0.9	0.7
90+	0	6	0.0	0.0	-	-

1 Adjusted using Australian ASDR

Table 4-9 compares SMR for device type, age group and sex. The selection effects are clearly demonstrated as occurring in the groups that have had the more invasive procedures. Young patients who require major interventions such as heart valve replacements and pacemakers are generally unwell and at high risk, whereas older patients who receive these devices have been selected for their 'hardiness'.

Table 4.9 SMR by type, age-group and sex

Age group	H Valve		Pacer		Hip		V Graft		IOL	
	M	F	M	F	M	F	M	F	M	F
40-49	-	52.0	23.5	-	-	-	-	-	-	-
50-59	3.5	-	5.0	-	-	6.2	5.9	-	3.6	-
60-69	1.3	2.2	1.9	1.9	0.5	1.0	2.6	5.7	1.5	1.1
70-79	1.0	0.8	0.8	1.4	0.4	0.6	1.1	2.6	0.2	0.7
80+	1.1	-	1.0	0.8	0.6	0.7	3.0	1.2	0.2	0.6

4.6.1 *Survival function*

During the study period 257 cohort patients died from all causes. For a simplistic overview, crude survival functions for the various type groups are plotted below in Figure 4-3. Figure 4-4 shows crude survival function by state of residence. A more detailed Cox regression analysis follows. Without the benefits of age adjustment, the hip implant group appears to be the most likely to survive the observation period, closely followed by the IOL group. As could be expected the pacemaker and vascular graft groups are the most at risk.

Figure 4-3 Crude Survival function by device type

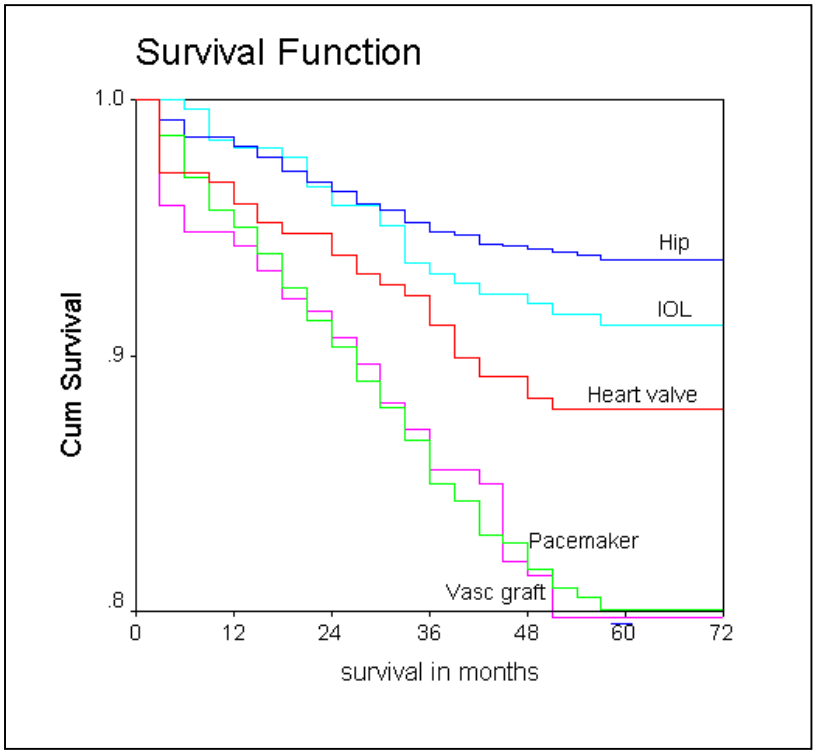
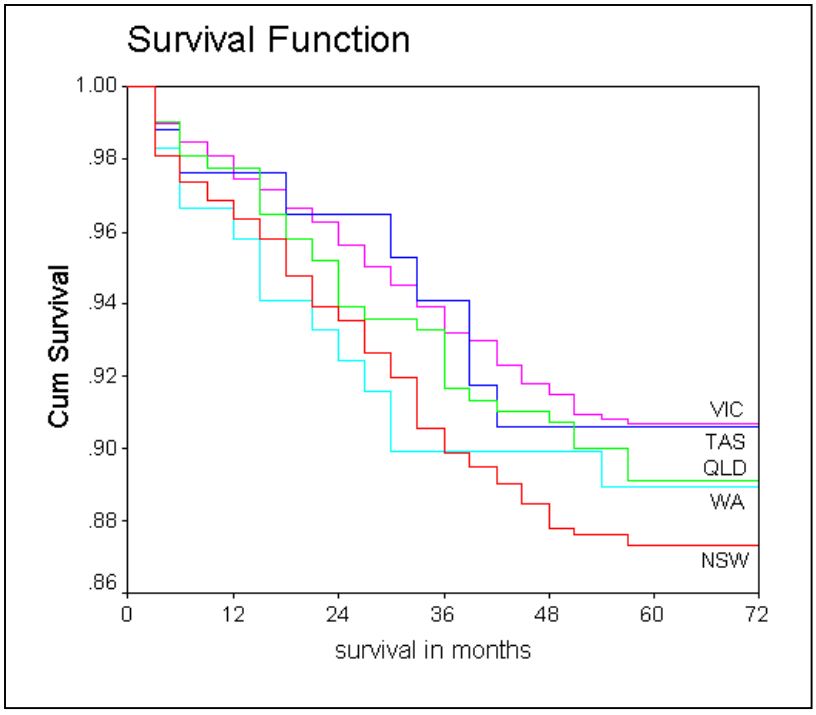


Figure 4-4 Crude Survival function by state of residence



4.6.2 Cox Survival analysis

A survival analysis was performed using Cox regression, the proportional hazards assumption held approximately for these data. Some groups were however too small to support the reliable estimation of confidence intervals. The Cox model allows for the adjustment of Hazard Ratios by selected variables, thus allowing the true effect of the variables of interest to be revealed. For example, where we are interested in comparing the relative efficacy of individual brands of prostheses we would like to remove the confounding effects of age.

Table 4.10 Survival analysis using Cox regression: (n = 2077)

			Crude			Adjusted	
Variable	**n/N**	**HR[5]**	**Lower**	**Upper**	**HR**	**Lower**	**Upper**
Brand‡[1]							
IOL (index)	29/265	1.00	-	-	1.00	-	-
Heart valve	32/249	1.42	0.83	2.45	**2.18**	**1.25**	**3.80**
Pacemaker	66/300	**2.41**	**1.49**	**3.90**	**2.37**	**1.46**	**3.86**
Hip	83/1069	0.71	0.44	1.14	1.01	0.63	1.63
Vasc graft	44/194	**2.47**	**1.48**	**4.14**	3.30	1.94	5.60
Agegroup‡[2]							
80+ (index)	104/280	1.00	-	-	1.00	-	-
0 - 49	2/156	**0.04**	**0.01**	**0.15**	**0.03**	**0.01**	**0.14**
50 - 59	16/304	**0.13**	**0.07**	**0.23**	**0.12**	**0.06**	**0.21**
60 - 69	49/675	**0.21**	**0.15**	**0.31**	**0.19**	**0.13**	**0.28**
70 - 79	83/662	**0.34**	**0.25**	**0.47**	**0.32**	**0.23**	**0.44**
p for trend		<0.0001			<0.0001		
Sex‡[3]							
Male (index)	137/1064	1.00	-	-	1.00	-	-
Female	117/1013	0.81	0.62	1.06	0.70	0.53	0.92
State‡[4]							
NSW (index)	75/573	1.00	-	-	1.00	-	-
QLD	34/312	0.83	0.55	1.25	0.80	0.53	1.22
TAS	11/85	0.72	0.35	1.50	0.86	0.41	1.78
VIC	120/988	**0.72**	**0.53**	**0.98**	**0.73**	**0.53**	**0.99**
WA	14/119	0.87	0.48	1.57	0.84	0.47	1.52

‡ Adjusted for 1=age/sex/state 2=type/sex/state 3=type/state/age 4=type/sex/age. 5 HR = Hazard Ratio.
Bold indicates significance at p=0.05 or higher

4.7 Discussion

A significance level of 0.05 was chosen for the purpose of demonstration. In reality, if a surveillance system were to be established, a first-pass screening level of 0.05 might be used but in order to reduce the number of 'false alarms', a level of 0.01 may be more appropriate.

At the 0.05 level, several results were significant. Age at time of operation was the most significant variable. Patients who had heart valves or pacemakers were at least twice as likely to die during the observation period as those who had IOLs or hip prostheses. Vascular grafts appeared to engender the greatest risk but the results did not reach significance. Patients in Victoria appear to fare significantly better than those in New South Wales. The result for groups with small n should be interpreted with caution.

The good result for Victoria is interesting and deserves further investigation. It could however be merely an artefact resulting from multiple testing. Where 20 tests are performed at p=0.05, one would be *expected* to erroneously appear significant.

4.8 Post-operative deaths

Deaths which occurred within the 30 day period after the index operation were classified as 'post-operative deaths'. The risk of post-operative death appears consistent with the expected severity of illness associated with each condition requiring an implant. For example the high rate for vascular graft patients reflects the fact that these patients are often suffering from acute surgical emergencies such as a ruptured abdominal aortic aneurysm. Due to the small numbers of deaths these data were not analysed further.

Table 4.11 Deaths within 30 days post-operation

Type	Deaths	Total n	%
Heart Valve	4	226	1.77
Pacemaker	1	271	0.37
Hip	3	969	0.31
Vascular Graft	7	174	4.02
IOL	0	233	0.00
Total	15	1873	0.80

4.9 The Quality of Life Questionnaire

To estimate the extent of response bias and to assess differences in health status between the various device groups, a questionnaire was designed to survey the self-assessed-health of all respondents. This questionnaire was distributed with the initial contact letter. The questions asked were:

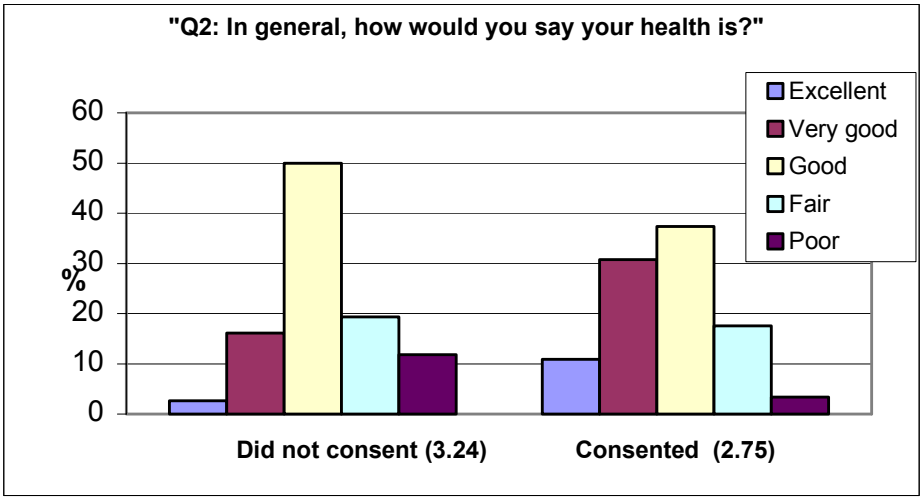
Q1: How has your medical device affected your health?
Q2*: In general, how would you say your health is?
Q3*: Compared to one year ago, how would you rate your health in general now?
*From the Rand Corporation SF36 questionnaire (Medical Outcomes Trust 1992)

Of the 5,316 patients asked, 1,793 completed the questionnaire; of these 186 were non-consenters. A 'morbidity index' was created for each of these questions, (scoring: much improved = 1, improved = 2, unchanged =3, worse = 4 and much worse = 5), these categorical results were factored, summed and averaged to provide the index. Greater values of the index reflect poor quality of life.

4.9.1 Assessment of consenting v non-consenting patients.

It was expected that patients who were generally well would be more likely to consent to a study of this type. This expectation was borne out by the response to the questionnaire. In Figure 4-5, it can be seen that a bias exists; average response using the 'morbidity index' was 3.22 for 'non-consenters' compared to 2.72 for those who did consent: patients who feel worse about their health appear to be less likely to consent. The two groups were significantly different using a χ^2 analysis ($p < 0.01$)

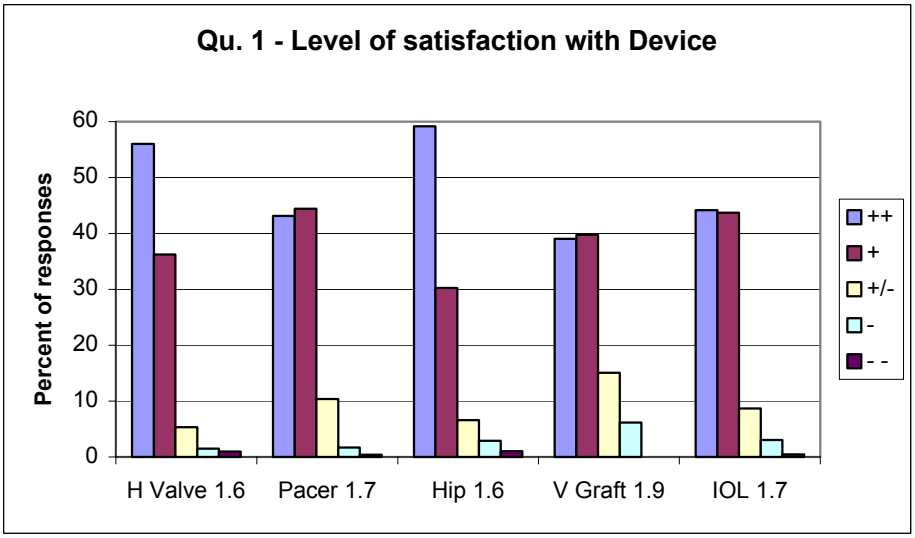
Figure 4-5 Self assessed health status, Consenting v non-consenting patients



4.9.2 Satisfaction with the implanted device

In Figure 4-6, the device groups are compared according to how the patients perceived their device had affected their health. It can be seen that patients who responded to this questionnaire were generally satisfied with their medical device.

Figure 4-6 Q1: How has your medical device affected your health?

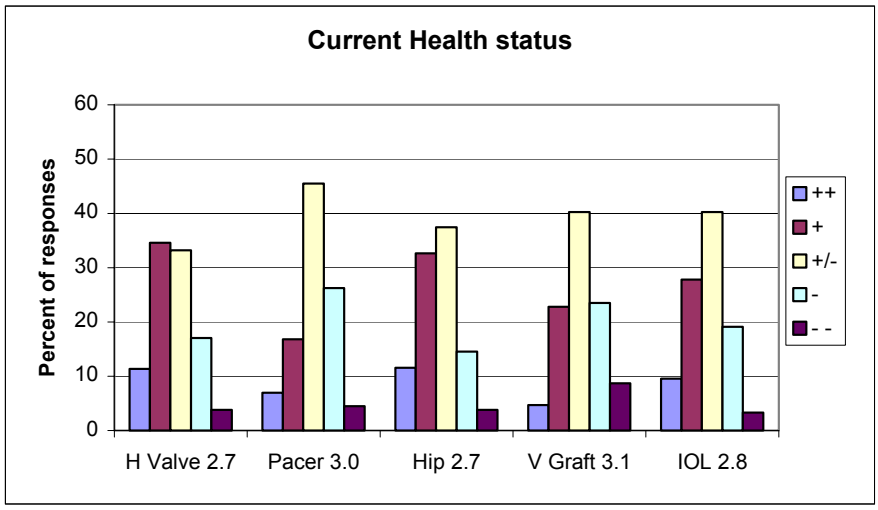


(Much Improved(++) Improved(+) Unchanged(+-) Worse(-) Much Worse(--).)

4.9.3 Investigation of the relationship between current health and device type

The results of Question 2 are compared for device type in Figure 4-7. This shows that in general, patients with pacemakers or vascular grafts considered themselves to be less well than those with the other implants. Differences according to this measure are however, small.

Figure 4-7 Q2: In general how would you say your health is?



4.10 Summary

This study provided an opportunity to compare various methods of appraising health status and ways of representing trends in status over time. It should be stressed that this data set is limited in size and may not have sufficient numbers in each group to detect clinically meaningful differences in treatment outcomes (if they exist). Medibank Private covers around one million Australians, the 'potential cohort' is around 5% of the population and after excluding those who did not consent for the research, the remaining cohort probably represents between 2% and 4% of the total number of patients who received the selected implants for the chosen years across the country. This low rate of coverage demonstrates the limitations on research imposed by the current access controls for health data. The need for streamlined access to information about larger cohorts is evident.

It should also be noted that response bias is a strong confounder in this study. Medibank Private members have been shown to be more likely to consent to the study if they considered that the results of their implant procedure were favourable (Figure 4-5). This provides a strong argument for surveillance systems to be exempt from the need for individual patient consent.

It would be of some interest to examine the outcomes produced by individual surgeons and hospitals if larger numbers of patients were available. Such information is highly sensitive politically and further examination was not conducted in this study.

In the next two chapters, various methods of detecting changes in health status are explored. Information is examined both without and with clinical detail to compare the potential of the current system with what would be possible with an integrated health information system where detailed service data would be augmented with clinical information recorded at the time of service provision. Such a system has recently been proposed by the NCEPH health informatics group (Mount, Kelman et al. 2000).

Chapter Five

The Australian Study - Part B

5.1 Analysis of basic health-service data

In this chapter, various approaches to the analysis of basic health administration data are explored. Data used is restricted to numbers and costs of services alone. This represents an approximation of what is available to the researcher using data that is collected purely for the purposes of financial management. This level of detail is currently available from the HIC database for doctor services and (potentially) from the NHMDS for hospital admissions. As mentioned, the NHMDS data was not available for this study. To compensate for this, additional data about hospital admissions was supplied by Medibank Private.

5.2 Indicators of morbidity

Without individual clinical information about patients, it is difficult to assess levels of general health. The challenge of using generic health service information to deduce measures of patient well-being is to make the best use of each fragment of information to develop useful and indicative parameters. The most commonly used and available indicator, mortality, is a useful but 'crude' indicator of the absence of health - other parameters were sought that would provide a more detailed insight into morbidity and quality of life. Using the assumption that people only see doctors or have operations when they are unwell, rates of service usage could arguably provide a proxy for morbidity, and changes in rates, an indication of changes in general health. An approach using this assumption is developed. There are of course many reasons why people use health services, however in this country where health care is at least in theory, freely available to all, the use of numbers of services used could provide a simple and useful measure of well being. The rationale behind this approach is discussed in more detail in section 9.6.

The various parameters and indicators of morbidity discussed are:

Measures:
Monthly ***rates*** of:

- Service use both pre and post-operation.
- Costs of services provided pre and post-operation
- Numbers of days in hospital pre and post-operation

Outcome indicators:

Changes in rates of service use pre-operation compared to post-operation for*:*

- Numbers of services
- Costs of services provided
- Numbers of days in hospital

Analysis:

These ***changes in service use*** were then analysed by examining:

- Differences in pre- to post-operative rates
- Ratios of pre- to post-operative rates (logarithmic)
- Logistic regression of differences in pre- to post-operative rates.

5.2.1 Monthly rates of service use.

As a simple indicator to portray the overall changes in health status experienced by the various groups of patients, plots of *service use rates* were prepared.[1]

Significant periods of observation were available for most patients both pre- and post-operatively. A description of these periods is shown below in Table 5-1; on average around 11 months pre-op and 40 months post-op were available for analysis.

Table 5-1 Statistics for pre- and post-op observation times

	pre-op	post-op
N	1,882	1,882
Mean[1]	11.2	40.2
Median	9.9	44.7
Std. Deviation	7.2	17.6
Minimum	0.1	0.0
Maximum	24.0	59.9

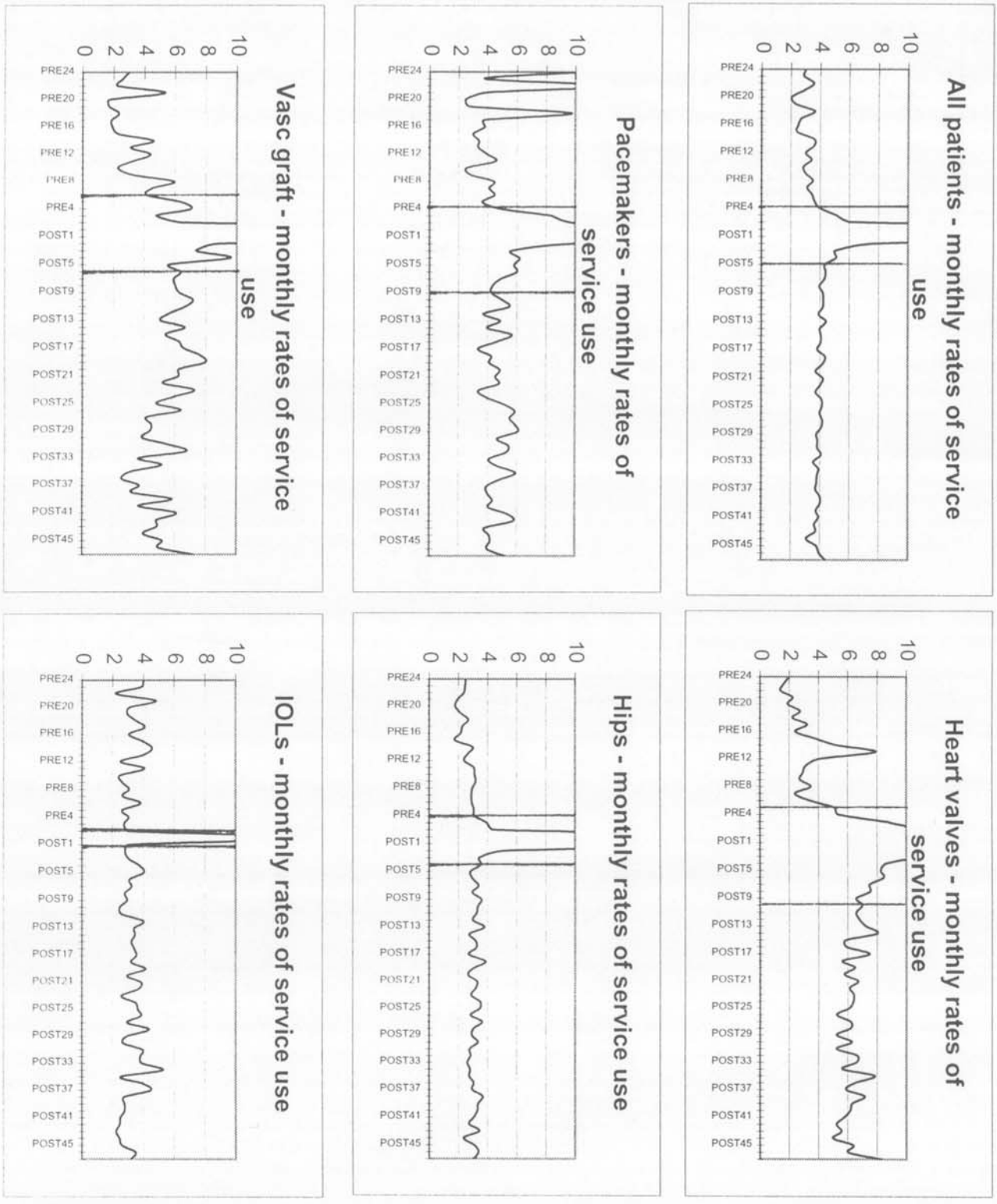
1. time in months

Rates of usage per month were then calculated for each patient for each month in a 'moving-window' period that was determined individually for each patient for the period surrounding the 'index' operation, up to 24 months pre-operatively and 60 months post-operatively. This is a process of synchronisation whereby all patient histories are aligned according to the date of their index operation. See Appendix 10 for an example of the SPSS code used to achieve this.

1 Services in this context include all doctor visits and any itemised hospital services including pathology, but not including pharmaceuticals due to the incomplete data available from the PBS database.

In the next three Figures, these simple measures of general health are portrayed graphically. In the first plot of Figure 5-1, all patients from the five device types are combined and the average rates of service utilisation for each month shown. Monthly service rates of around 3.5 services per month pre-op rise to around 4 per month for the four years post-operatively. In the remaining five plots contained in Figure 5-1, usage rates for each device type are shown individually. Calculation of service rates involved selectively excluding all service events that were derived from HIC data, for patients who had died or left Medibank Private during the synchronised 60 month post-op period. Patient-months that fell outside the Jan 93 – Dec 97 observation period were also excluded. In this way, it was guaranteed that measurement of service usage was only made during the time that each patient was a member of Medibank Private and thus that all records relating to both doctor services and hospital admissions were available.

Figure 5-1 Average rates of monthly service use



In Figure 5-1, a significant surge in usage can be observed around the time of the 'index' operation for all devices. Service usage rates do not in general appear to return to pre operative rates after the implant operation. This may indicate a deterioration in health of merely the result of further ageing of an aged population.

The following plots are the results of using the same approach examining the *costs* of services provided (Figure 5-2) and the number of *days in hospital* per month (Figure 5-3). Average costs of services could be expected to impart more information than is conveyed by mere numbers of services as some indication of severity (or complexity) of the service is contained in the fee charged. This assumption is limited by the fact that the Medicare 'schedule of fees' does not bear a simple relationship to clinical severity, particularly in the area of minor surgical procedures. However, as a general approximation, where information on co-morbidity is not available, additional information is certainly provided over simply using the *number* of services. Similarly, days in hospital per month could be expected to indicate the degree or severity of illness.

In Figure 5-2, in parallel with number of services used, costs per month appear to increase slightly from pre-operative levels.

In Figure 5-3, days in hospital per month appear to remain the same after the index operation as before.

Figure 5-2 Average monthly fees for services

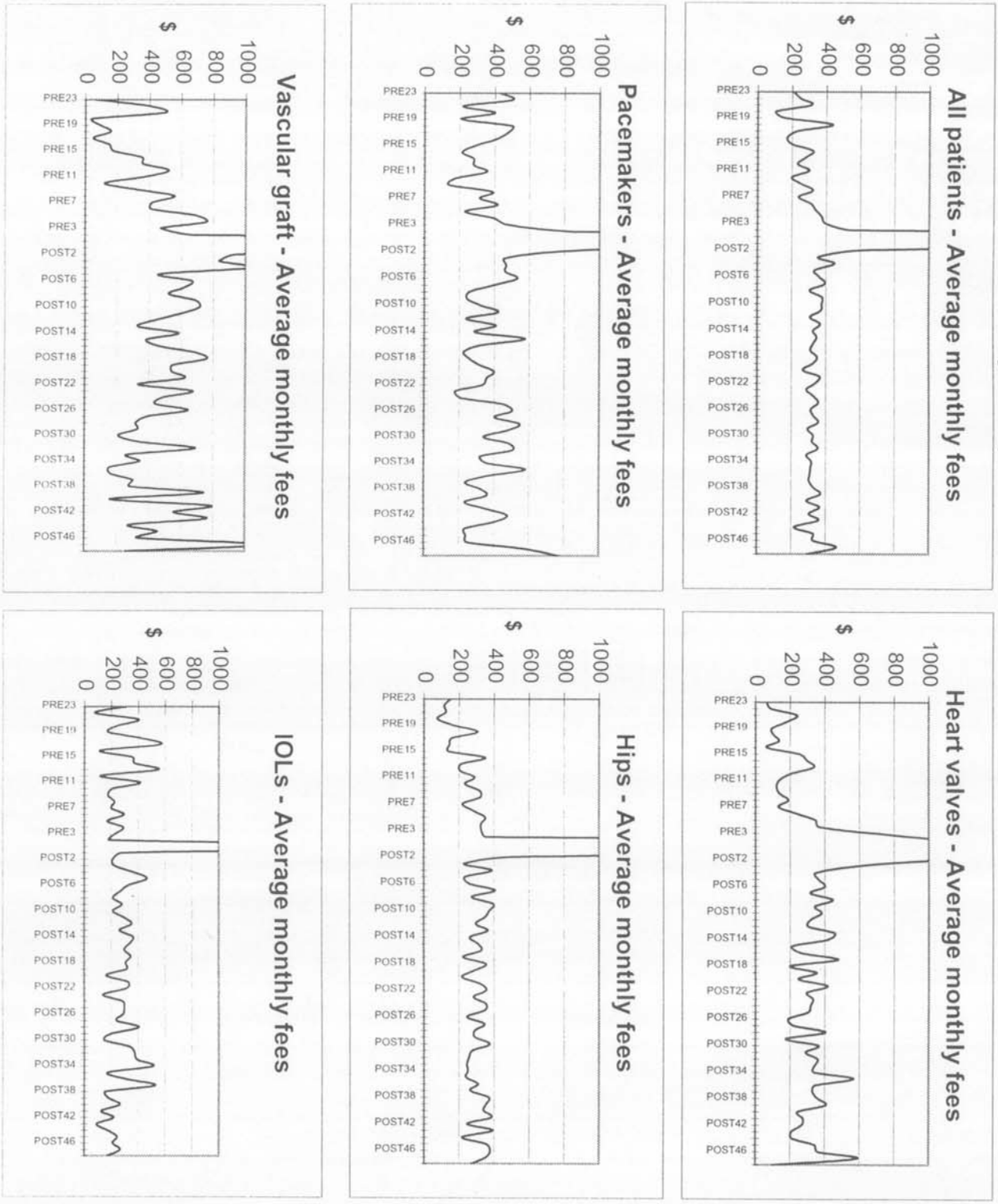


Figure 5-2 Australia: Average monthly fees for services.

Figure 5-3 Average monthly rates of days in hospital

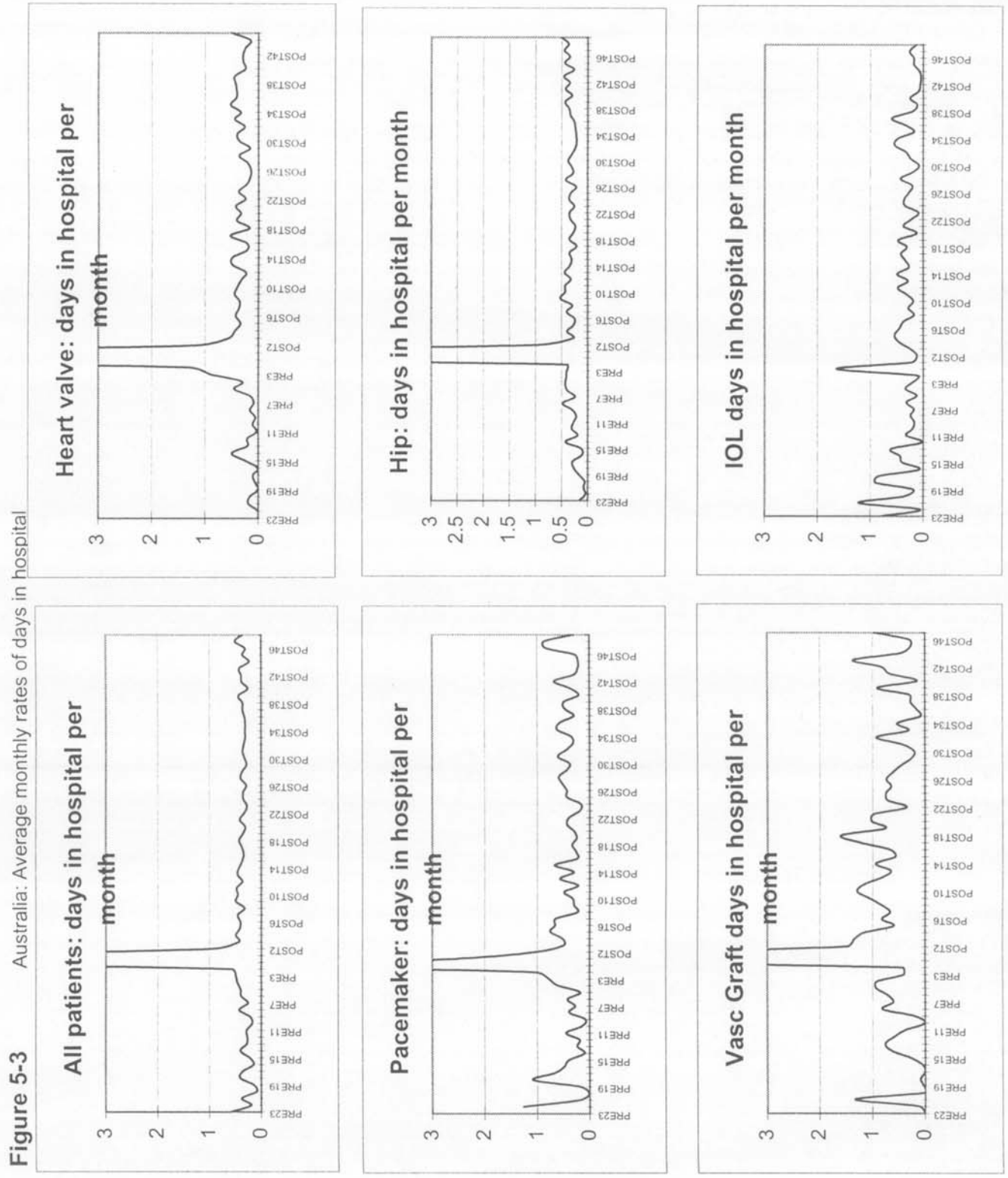


Figure 5-3 Australia: Average monthly rates of days in hospital

5.2.2 Limitations in the presentation of monthly changes.

A major shortcoming of this method of presentation is that all patients are grouped and the potential to utilise an individual's pre-operative rate of service use as a control for their post-operative rate is not exploited. This opportunity is incorporated in the next stage of the analysis where 'ratio' and 'difference' measures are introduced to compare each patient's pre-operative rate of usage with their own post-operative rate. These indicators are then averaged across the group.

5.3 Patient based service-rate ratios

Several approaches to the analysis of changes in service use rates are examined. The basis of all these measures is to compare monthly rates of service use in the pre-operative period with monthly rates in the post-operative period and thus to indicate any changes in health status. These approaches, which in effect use each patient as their own control, reduce the confounding effect of co-morbidity.

All service events were collated to produce a virtual "case history" for each patient, ie all events and services including deaths, hospital admissions, in-hospital services and doctor visits were combined from the Medibank Private, Medicare, NDI and DVA files for each patient. In an attempt to produce a meaningful picture of actual changes in health status, service use parameters were calculated in several different ways. For all measures, total numbers of services used by each patient in the pre and post-op periods were summed and divided by the individual's total number of months of observation for the pre-op and post-op periods. These pre- and post-operative rates were then compared in three ways.

5.3.1 'Ratio' indicators

Appealing in its simplicity, an 'arithmetic ratio' was calculated by dividing the pre-operative rate by the post-operative rate for each patient and then averaging the resultant ratio across all patients in the group. However, this approach could not be used as the distribution of the rates bore little resemblance to a normal distribution and produced inconsistent results. In an attempt to transform the data into a normal distribution, (natural) logs were taken of the pre/post service ratios of all patients and these were then averaged – change in health status being indicated by a divergence from zero. This approach was used to generate the 'log ratio' indicator.

5.3.2 'Sign test' and 'Difference' indicator

A second approach used was to subtract the average post-operative rate from the pre-operative rate for each patient and then to compare the number that had 'improved' with the number that had 'worsened' (ie used more services per month on average after the operation than before). This is a simple 'sign test' that can be used to indicate the overall effect of the procedure. This approach is immune to the effect of differing variances.

Alternatively the proportion of patients that had a change in usage can be used as a quantified indicator of change. The results of this approach are used for a logistic regression analysis and are presented later in Table 5-6. For the 'difference indicator', the *magnitude* of the average difference in rates pre- to post-operation was used; the extent of the difference could be argued to have some significance in indicating the magnitude of change in health status.

5.3.3 Limitations

Both the 'ratio' approaches were somewhat restricted by the fact that between 10% and 20% of patients (depending on the length of the exclusion period) had made no claims during the follow up period and these cases were thus unable to be included in the calculations.[2] The ratio measures also suffer from the weakness that varying observation times are used for each patient both pre- and post-operation. Estimates of pre and post-operative rates will differ in their precision due to these varying time periods resulting in different variances. Caution should be exercised in using the t test in this situation. An adjustment could possibly be made by using weighted least squares. A discussion of the problems encountered in using this type of skewed data is included in Appendix 2.

2 The process would produce a 'division by zero' error during computation. The difference methods were not affected by this problem.

5.3.4 An example to demonstrate the various indicators

To demonstrate the different measures and to test their possible usefulness, the results for a small sample group of three patients is examined. Assume three patients who had pacemaker implants. Patient A had 3 services in the month pre-operation and 1 in the month post-operation, an apparent improvement. Patients B and C doubled their use of services from 1 to 2 per month. If this was representative of a large group it would appear that two out of three patients were being disadvantaged by the procedure, however, this state of affairs is not consistently represented by the four indicators (the averages of the indicators for each patient). The Arithmetic Ratio indicates that this procedure has benefits, the Sign test shows a deterioration, the Difference indicator suggests no effect. The Log ratio suggests that the procedure has a small detrimental effect on rates of service use (-0.10).

Table 5-2 Comparison of measures of morbidity

	Services per month		Indicators			
	Pre-op	Post-operative	Arith. ratio	Sign test	Difference	Log ratio
Patient A	3	1	3.00	+	2	1.10
Patient B	1	2	0.50	-	-1	-0.69
Patient C	1	2	0.50	-	-1	-0.69
	Average of measures		1.33	-	0	-0.10

The results of the various analyses are presented below with these limitations in mind.

5.4 Pre- and post-operative exclusion periods

An exclusion period was used to minimise the influence of peri-operative treatment and pre-operative investigations on morbidity indicators based on measures of service use. An arbitrary 30 days post-operative period is often used, because for many procedures the patient will be out of hospital and will be utilising principally ambulatory services. However for this study, we are interested in excluding *all* services used in relation to the procedure whether provided as an in-patient or out-patient. Longer exclusion periods were found to be necessary. Similarly, for a cost benefit analysis, in estimating the total procedure cost it would be necessary to include all costs associated with the procedure, (both pre- and post-operation). To achieve this, extended *inclusion* periods were required.

Various periods were trialled to determine their effect on results. A sensitivity analysis was performed using periods of 90, 30, 14, 7 and 1 day pre and post-operatively. The results were as would be expected, with a falling off of service use after 14 – 30 days post-operatively. An alternative and more appropriate method for determining exclusion periods relevant to each of the different types of procedures is to derive the periods from the plots of average service use rates (as were shown in Figure 5-1). For example it can be seen in Figure 5-4 that for a hip replacement, a pre-operative exclusion period of around 4 months is required to exclude pre-operative investigations and thus determine a representative 'pre-operative service utilisation rate'. Similarly, a period of around 4 months post-operation is needed. These periods contrast with those required for IOL procedures of around 1 month both pre- and post-operation. The 'customised' exclusion periods used are shown in Table 5-3.

Figure 5-4 Deriving the exclusion periods pre- and post-operation

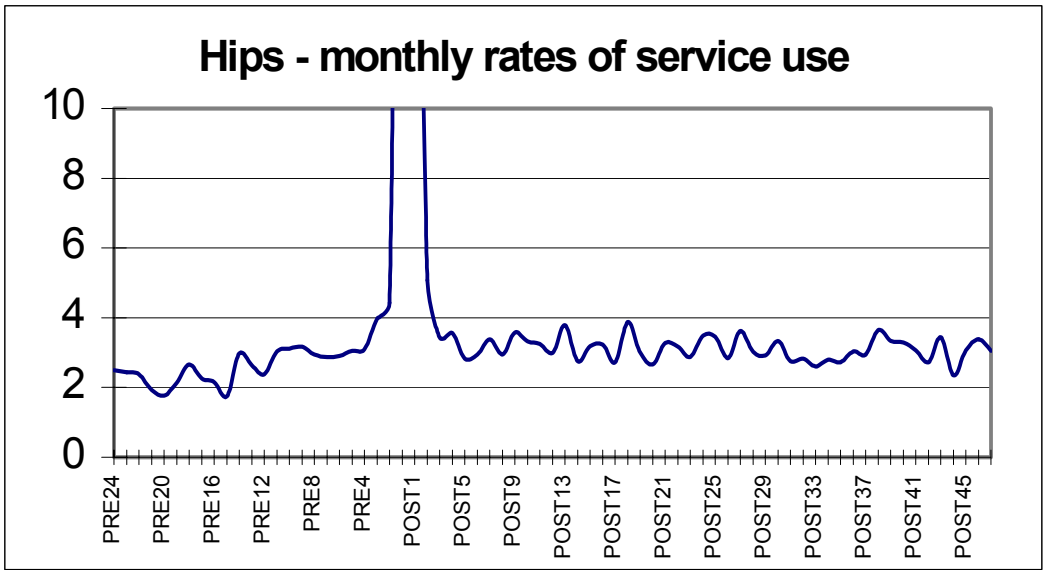


Table 5-3 Customised exclusion periods used, in months

Device	Pre-op period	Post-op period
All combined	4	5
Heart valve	5	10
Pacemaker	4	9
Hip	4	4
Vascular graft	6	6
IOL	1	1

5.5 Comparisons of pre to post-operative rates of service use

In the following tables (See Figure 5-5 for service use indicators by device type) monthly rates of service use, fees and days in hospital for the pre-operative period are compared with monthly rates for the first year *after* the procedure (services include doctor visits and in-hospital procedures including pathology). Using the two measures, results *greater than zero* suggest an improvement in post-operative health status. In the plot, means and 95% confidence intervals are shown, albeit with the limitations expressed above.

Table 5-4 Changes in service use using *Difference measures

Type	Services	Fees	Bed-d
Heart Valve	-3.43	-220.10	-0
Pacemaker	-1.50	-130.12	-0
Hip	-0.26	-65.01	-0
Vasc Graft	**0.08**	**14.00**	-0
IOL	-0.47	-65.01	-0

* Positive results (in bold) suggest improvement

Table 5-5 Changes in rates of service use using *Log ratio measures

Type	Services	Fees	Bed-days
Heart Valve	-0.78	-0.57	**0.47**
Pacemaker	-0.28	-0.36	-0.39
Hip	-0.08	-0.21	-0.33
Vasc Graft	-0.15	-0.25	**0.09**
IOL	-0.11	-0.17	**0.07**

* Positive results (in bold) suggest improvement

These results do not appear to support the contention that prostheses reduce the number of health care services or reduce costs. In Figure 5-5, it appears that generally, the number and cost of services per month increase after these operations (ie means below the x axis), however, the vascular graft procedure seems to produce some improvement in both frequency and cost of services in the difference measures but shows a different pattern using the ratio measure. It can be seen from the plots that one of the problems

here is lack of precision resulting from small sample size and overlapping confidence intervals.[3]

3 The confidence intervals are however, valid due to the fact that the central limit theorem applies to means even when variances of individual observations differ (Weiss and Hassett 1988 p287).

Figure 5-5 Service use indicators for the five types of device

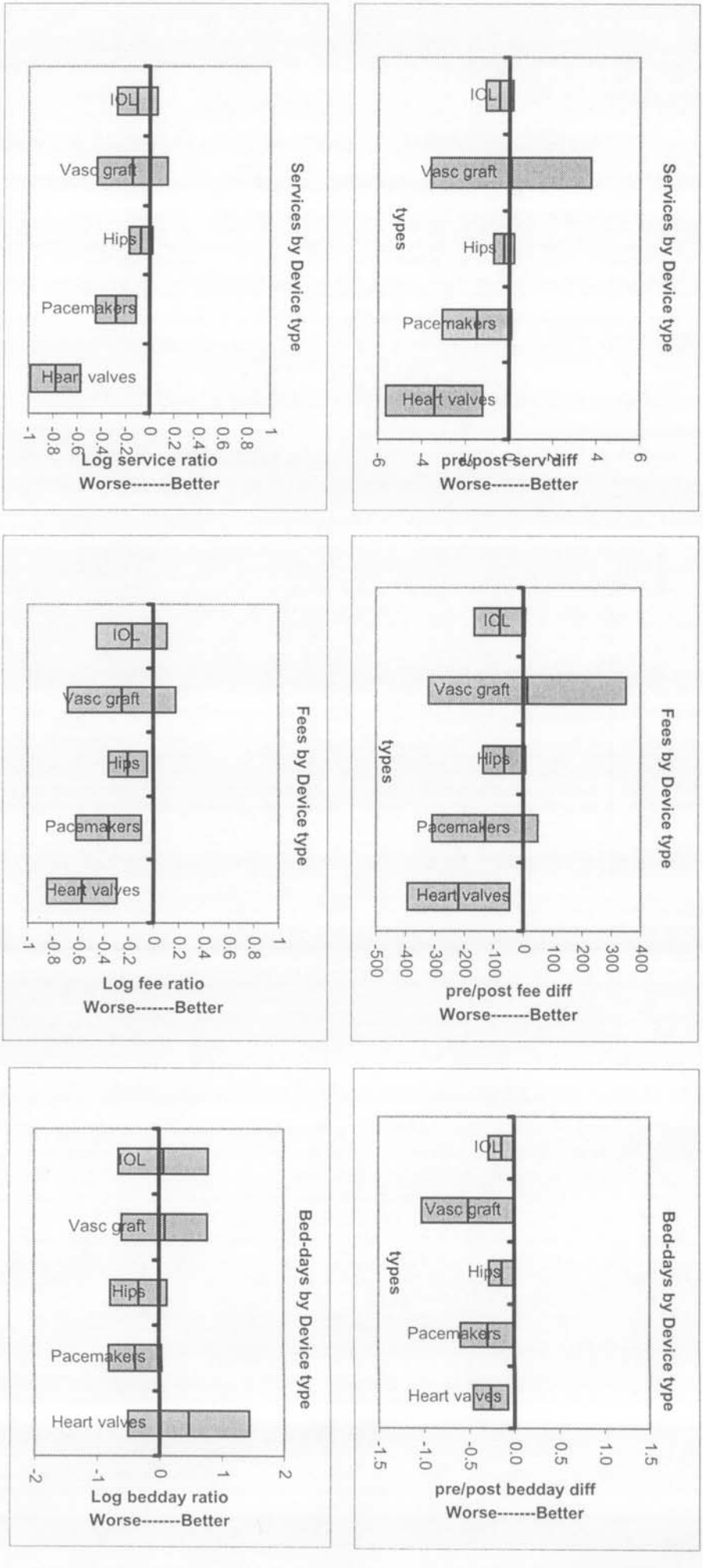


Figure 5-5 Australia Service use indicators for the five types of device (customised exclusion periods, follow up for 1 year)

5.6 The effect of ageing and follow up period on service utilisation.

For an initial assessment of the data, only the first year of post-operative data was compared with the pre-operative observation period. This minimises the effect of ageing on the cohort. To include longer post-operative follow up periods, age adjustment of rates of service use would have to be performed against a reference population.

5.7 Device brand differences – subgroup analysis for hips

One of the potential uses of linked service data is to assess performance of particular brands of devices or drugs, techniques of surgery or even surgeons. Monitoring of individual practitioners will not be attempted in this study as ethics approval was not extended to include this.

To investigate any possible performance differences in the current dataset, the hip implant group was chosen for examination, because this was the group with the greatest number of patients and a reasonable number of differentiated subgroups.

Hip brands were compared with each other using the various service use indicators. One brand (Osteonics) appeared to outperform the others. (See Figure 5-6, hip type comparisons). This brand was then compared with all the other hip brands combined. (See Figure 5-7, Osteonic hips v rest). Differences are evident but not significant at the 0.05 level.[4] As has previously been mentioned, the analysis is experimental and the results are presented as a demonstration of a mechanism that could be used to detect 'signals' of outcome differences if large sample sizes were available. Further work is required to develop the uses of these indicators.

4 Sample sizes were 68 Osteonics and 786 'all other hips', these numbers being less than the total in each group as some patients had insufficient observation periods to be included.

Figure 5-6

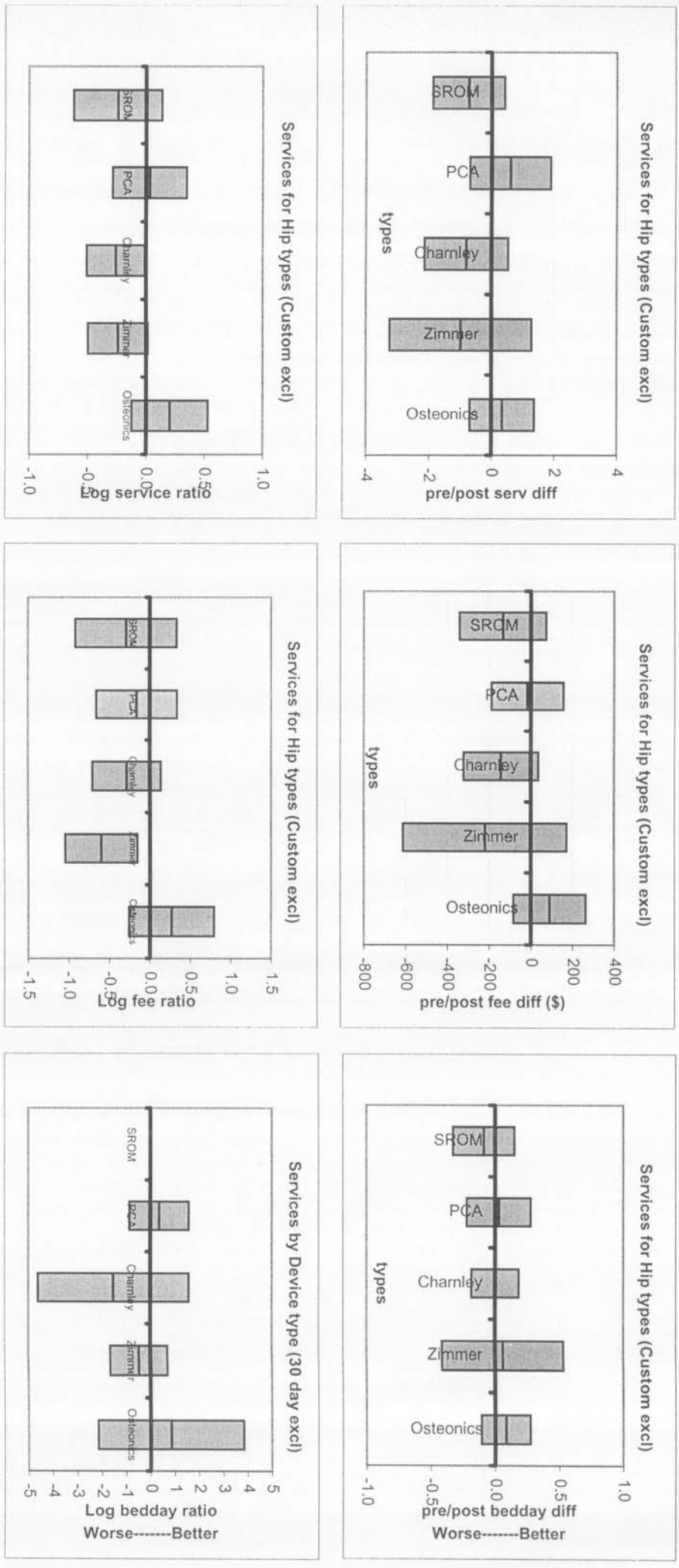
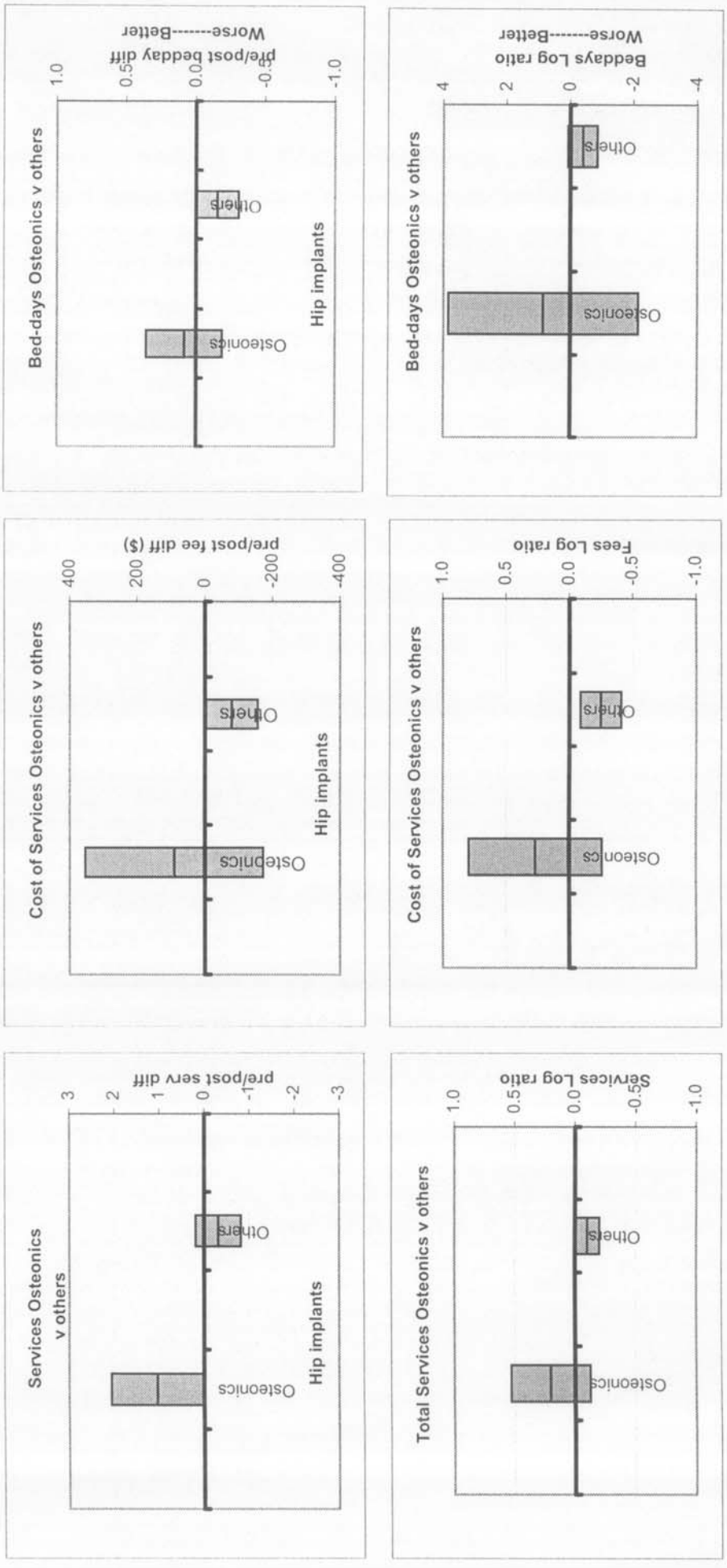


Figure 5-6 Australia Five brands of hip prostheses compared: Service differences and log ratios

Figure 5-7 Osteonics compared with other hip prostheses



5.7.1 Logistic regression

For an alternative approach that avoids the problems of non-normal distribution, a logistic regression was used. In a similar way to the 'difference measure', this approach does sacrifice available information. It takes account only the *direction* of change in service usage rather than incorporating its magnitude.

A regression was performed using the pre to post-operative difference in each of the variables service use, cost and bed-days as the dependent variables. Dichotomous outcomes were produced by assigning 1 to the situation where *more* services per month were used post-operation compared to pre-operation, 0 to the reverse. Patients were included in the analysis only if sufficient observation time was available (arbitrarily set at six months) – this meant that to allow for a pre- and post-operative exclusion period of four months, a total of at least ten months observation period was required. In the hip group, 356 patients fulfilled these requirements. Implant types were compared (Table 5-6) and hip prostheses were examined alone, individual hip brands being compared with each other (Table 5-7).

Table 5-6 All types: Fee-outcomes†, crude and adjusted rates

Variable	n/N[5]	Crude RR	Crude OR§	95% CI Lower	95% CI Upper	Adjusted‡ OR	95% CI Lower	95% CI Upper
Type‡[1]								
IOL (index)	39/64	1.00	1.00	-	-	1.00	-	-
Heart Valve	58/80	1.19	1.69	0.84	3.41	**2.11**	**1.02**	**4.38**
Pacer	64/105	1.00	1.00	0.53	1.89	1.06	0.55	2.03
Hip	234/356	1.08	1.23	0.71	2.13	1.44	0.82	2.53
Vasc Graft	30/43	1.14	1.48	0.65	3.37	1.90	0.81	4.44
Agegroup‡[2]								
80+ (index)	63/89	1.00	1.00	-	-	1.00	-	-
0 - 49	32/56	0.81	0.55	0.27	1.11	**0.46**	**0.22**	**0.95**
50 - 59	58/93	0.88	0.68	0.37	1.27	0.57	0.30	1.11
60 - 69	123/187	0.93	0.79	0.46	1.37	0.71	0.40	1.26
70 - 79	149/223	0.94	0.83	0.49	1.42	0.79	0.46	1.38
P for trend			0.07			0.06		
Sex‡[3]								
Male (index)	211/327	1.00	1.00	-	-	1.00	-	-
Female	214/321	1.03	1.10	0.79	1.52	1.07	0.76	1.51
State‡[4]								
NSW (index)	126/200	1.00	1.00	-	-	1.00	-	-
QLD	72/110	1.04	1.11	0.68	1.81	1.13	0.69	1.87
VIC	212/313	1.08	1.23	0.85	1.79	1.32	0.91	1.94
WA	15/25	0.95	0.88	0.38	2.06	0.90	0.38	2.12

† Post operative compared with pre-operative service use
§ Logistic regression
‡Adjusted for: 1=age/sex/state 2=brand/sex/state 3=brand/state/age 4=brand/sex/age (No patients eligible from Tasmania). 5, n/N =number with outcome/number of cases.
(**Bold** indicates significance at p=0.05 or higher)

In Table 5-6 the various implant types were compared with the IOL group. As could be expected, all types experienced less favourable outcomes compared with this group which could be considered to be a 'placebo' control group for these patients. Twice as many heart valve recipients consumed more services after their implant operation than did IOL patients, this difference is significant at the 0.05 level. Age was a borderline significant factor, although only at the p=0.06 level when tested for trend.

In Table 5-7, individual hip brands were compared with the combined 'other' group and also with a group comprised of Zimmer and Austin Moore prostheses. These brands were chosen because they are both well established and widely used.[5] Differences which appeared significant in the crude analysis disappeared when adjusted for age, sex

5 Once again the effects of multiple testing should be considered here.

and state. This result is explained by the fact that these brands are often used in elderly and more debilitated patients. It should be noted that the 'fee outcome' is dependent on patient age, with younger patients showing a greater improvement after their procedure. The 'p for trend' for age is 0.01 for adjusted rates.

Table 5-7 Hip prostheses only: Fee outcome† for brands, with adjustment

		Crude		95% CI		Adjusted	95% CI	
Variable	**n/N[5]**	**RR**	**OR§**	**Lower**	**Upper**	**OR**	**Lower**	**Upper**
Brand‡[1]								
Zimmer (index)	33/43	1.00	1.00	-	-	1.00	-	-
Osteonics	24/39	0.80	0.48	0.19	1.26	0.60	0.22	1.60
Axis	8/13	0.80	0.48	0.13	1.82	0.80	0.20	3.20
Austin Moore	9/11	1.07	1.36	0.25	7.37	1.23	0.22	6.81
Charnley	35/54	0.84	0.56	0.23	1.37	0.51	0.20	1.28
Exeter	17/25	0.89	0.64	0.21	1.93	0.67	0.22	2.05
PCA	27/43	0.82	0.51	0.20	1.31	0.61	0.23	1.61
Precision	11/19	0.75	0.42	0.13	1.32	0.43	0.13	1.42
SROM	19/29	0.85	0.58	0.20	1.63	0.89	0.30	2.65
Other	51/80	0.83	0.53	0.23	1.24	0.61	0.25	1.44
All v (Zim+A/M)	192/302	0.83	**0.50**	**0.25**	**0.99**	0.58	0.29	1.17
Agegroup‡[2]								
80+ (index)	31/40	1.00	1.00	-	-	1.00	-	-
0 - 49	20/35	0.74	0.39	0.14	1.05	**0.35**	**0.13**	**0.98**
50 - 59	35/58	0.78	0.44	0.18	1.10	0.40	0.16	1.04
60 - 69	65/107	0.78	0.45	0.19	1.04	**0.41**	**0.17**	**0.97**
70 - 79	83/116	0.92	0.73	0.31	1.70	0.75	0.32	1.77
p for trend			0.02			0.01		
Sex‡[3]								
Male (index)	104/156	1.00	1.00	-	-	1.00	-	-
Female	130/200	0.98	0.93	0.60	1.44	0.84	0.53	1.33
State‡[4]								
NSW (index)	67/113	1.00	1.00	-	-	1.00	-	-
QLD	36/51	1.19	1.65	0.81	3.35	1.88	0.91	3.90
VIC	120/175	1.16	1.50	0.92	2.45	1.58	0.96	2.61
WA	11/17	1.09	1.26	0.43	3.64	1.30	0.43	3.89

† Post operative compared with pre-operative service use
§ Logistic regression
‡ Adjusted for: 1=age/sex/state 2=brand/sex/state 3=brand/state/age 4=brand/sex/age (No patients eligible from Tasmania). 5, n/N =number with outcome/number of cases
(**Bold** indicates significance at p=0.05 or higher)

Caution should be used in making comparisons between brands to choose 'better' or 'worse' performers. Any further judgment of performance differentials, must be conducted with reference to the relevant probability distributions of Order Statistics.[6]

5.7.2 Analysis using Mantel-Haenszel statistics

Cochran's and Mantel-Haenszel statistics are used to test for independence between a dichotomous factor variable and a dichotomous response variable. The Mantel-Haenszel common Odds Ratio is computed and this ratio adjusted for other independent variables which do not need to be dichotomous. This approach was applied to compare dichotomous groups created by combining various subgroups, hence patients aged less than 50 years were compared against all others, patients who had vascular grafts were compared with all other types. Alternatively, patients with a particular type of implant can be compared with one other type group. Many comparisons were tested, none reaching significance. A sample of these results is presented in Table 28.

Table 5-8 Fee outcome†: Mantel-Haenszel analysis

	Crude				Adjusted				
	p[1]	OR	Lower	Upper	p[1]	OR	Lower	Upper	adj for
NSW v others	0.355	0.85	0.60	1.20	0.306	0.83	0.59	1.18	type
NSW v VIC	0.271	0.81	0.56	1.18	0.209	0.79	0.54	1.14	type
VIC v others	0.267	1.20	0.87	1.66	0.167	1.25	0.90	1.73	type
Agegroup 5 v rest	0.266	1.32	0.81	2.15	0.304	1.30	0.79	2.12	sex
Agegroup 1 v rest	0.166	0.68	0.39	1.18	0.162	0.67	0.39	1.17	sex
Vasc Graft v rest	0.55	1.23	0.63	2.40	0.465	1.29	0.66	2.52	age
Heart valve v rest	0.166	1.44	0.86	2.43	0.119	1.52	0.90	2.56	age
Female v Male	0.566	0.91	0.66	1.26	0.703	0.94	0.68	1.30	age

† Post operative compared with pre-operative service use
1. None are significant at 0.05

This approach provides a mechanism of comparing risks but is not limited to situations where the incidence is rare (cf Odds Ratios). It also allows for adjustment which is not possible with standard Relative Risk ratios. However, only one factor can be input at a time. Although none of the above results are significant, they are presented to demonstrate the method which could be useful if larger patient numbers were available.

6 This approach is beyond the scope of the present study but is discussed by Casella. (Casella and Berger 1990 sec 5.5).

5.8 Summary

The approach detailed in this section uses various methods to examine rates of service use as a proxy for changes in levels of morbidity, and thus by inference, for general health status. The approach has limitations but may be appropriate when only limited data is available as is the case when using administrative databases that were not designed for clinical or health outcomes research. Results that appear as aberrations from the norm should be regarded as 'signals' for further investigation. In this way such an approach may provide a simple and low cost surveillance system.

Chapter Six

The Australian Study – Part C

6.1 Analysis using service codes to identify intervention outcomes

In this chapter, the skeletal data analysed in part B are supplemented with more detailed clinical information available from the Medibank Private archive. The level of detail contained in this resulting combined data set would be easily achievable with an integrated health record information system (IHRIS) (Mount, Kelman et al. 2000), as discussed in Chapter 10..

The majority of reported studies using administrative datasets have attempted to exploit the potential of service codes as proxies for clinical information. In Australia, detailed service codes are not included in any of the national databases except for the NHMDS, which is de-identified and has thus not previously been used for this purpose. As mentioned, the NHMDS was not able to be used in this study. This was unfortunate as ICD9 codes from the NHMDS would have allowed a more detailed analysis of outcomes to have been performed. As a partial substitute for this, the Medibank Private claims archive was used. It provided information about all private hospital admissions for the study cohort, it did not include diagnostic codes but allowed reasonably accurate inferences to be made about procedures and treatments received.

Thus an analysis was conducted using claim codes from Medibank Private hospital admission data in order to compare the results achieved using this approach with that used in the previous chapter (which used service event and cost data alone). Again, the hip implant group was selected as it comprised a reasonable number of patients and had several sizeable subgroups. Sample analyses are presented to demonstrate an approach that could be used routinely to detect relative differences in performance between brands. Service codes were available from Medibank Private for all events and these codes were used to identify whether a particular service was possibly related to the primary 'index' condition.

6.1.1 Selecting service codes to detect events related to the implant procedure

Medical Benefits Schedule (MBS) and prosthesis codes were selected that indicated a possible event related to the hip implant operation. The selection of these codes is of course crucial and merits the attention of an expert committee. A basic (and

incomplete) set has been selected for the purpose of this demonstration. These 'related' events were classified into four types, the procedure codes selected to identify these events are detailed in Appendix 11.

- Post-operative complications occurring within thirty days after the index operation, for example, deep venous thrombosis, dislocation, fracture of femur or acetabulum and events suggestive of infection. ("Related" code 1, in appendix 11)
- Other hip implant related complications occurring any time after thirty days post-operatively, principally dislocation or fracture of the hip. (Code 2)
- Revision procedures, ie where the hip implant was replaced. Specific procedure codes are available to identify this situation. (Code 3)
- Any subsequent 'days in hospital' were considered to be possibly related and were assessed as a separate indicator.

Many patients returned to hospital during the follow-up period for contra-lateral hip prostheses. Some of these claims were evidently revisions,[1] for example, one patient had two additional prostheses, neither was tagged as a revision. Unfortunately since 'side' of operation is not included in the data, the extent of this miscoding is impossible to determine.

The service database was searched for these 'related' codes and patient groups were compared. There were 851 hip implant patients who appeared to have related services in the post-operative period. The total number of hip implant patients was 971, so the majority were considered to have had some kind of implant-related event in the follow up period (Table 6-1). Several cases were examined to validate this process and ensure that relevant events were detected. A sample case history in included in Appendix 9 for one patient who, according to this process, appeared to have had a poor outcome after her initial hip implant in 1993.

1 Revision means that the operation is a 'repair or replace' procedure of an earlier prosthesis.

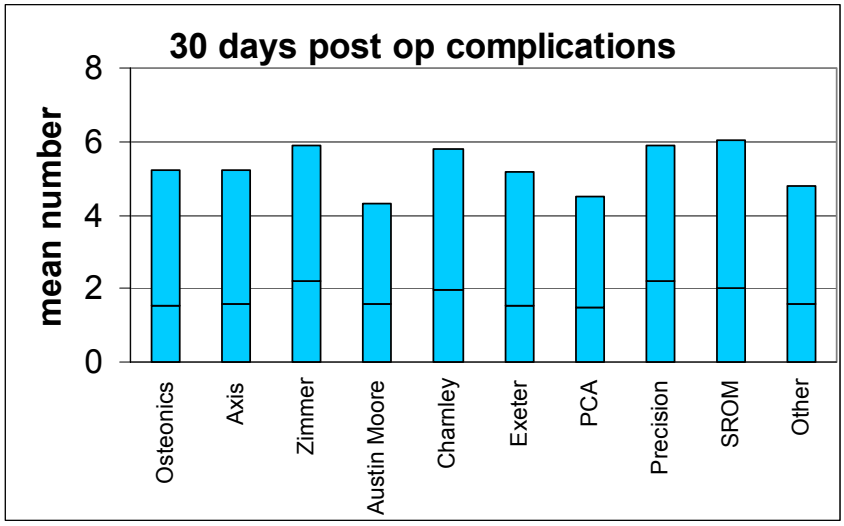
Table 6-1 Numbers of hip patients with post-operative† complications

Brand	All patients	Revision	Rev'n %	Early comp	E comp %	Late comp	L comp %
Osteonics	76	6	7.9	44	57.9	2	2.6
Axis	44	1	2.3	27	61.4	4	9.1
Zimmer	97	5	5.2	67	69.1	8	8.2
Austin Moore	27	2	7.4	19	70.4	1	3.7
Charnley	84	6	7.1	57	67.9	3	3.6
Exeter	63	3	4.8	39	61.9	2	3.2
PCA	114	6	5.3	70	61.4	4	3.5
Precision	46	-	-	37	80.4	-	-
SROM	69	5	7.2	45	65.2	2	2.9
Other	351	24	6.8	223	63.5	15	4.3
Totals	971	58	6.0	628	64.7	41	4.2

† Complications occuring within 30 days post index operation.

One of the most convincing parameters of hip implant performance is the rate of Revisions. However, in this series the numbers are too small for significant comparisons to be made.[2] Early post-operative complications (occurring within 30 days) were more common and a plot comparing mean number of services per patient is shown below in Figure 6-2 (with CI at the 95% level). Slight differences are evident between brands, however none are significant at this level.

Figure 6-1 Mean number of early post-operative complications per patient by brand



2 It should be noted again that *side* of operation is not recorded and thus some revisions could be to replace earlier implants of unknown-type .

6.2 Logistic regression to assess the effect of brand on outcomes

Logistic regressions were performed on dichotomous indicators derived from a count of 'related' incidents.[3] Regression results are shown for the three indicators: revision procedure (Table 6-2), early complications (Table 6-3) and late post-operative complications (Table 6-5).

It should again be noted that small sample size and various biases could have large effects on results. Tables are presented for regression analyses of each of the three outcome measures, adjusted for age, sex, state of residence and brand type. As would be expected, age was the most significant risk factor for post-operative complications. Relative Risk (RR) is also shown as many of the outcome measures were common. The Odds Ratio, which is applicable to 'rare' outcomes, while maintaining its level of statistical probability, could be somewhat inaccurate when outcomes are more common than say 1 in 100.

3 If one or more related incidents were suspected the indicator was set to one, else zero.

Table 6-2 Hip revisions†, crude and adjusted by age, brand, state and sex

		Crude		95% CI		Adjusted‡	95% CI	
Variable	**n/N[5]**	**RR**	**OR§**	**Lower**	**Upper**	**OR**	**Lower**	**Upper**
Brand‡[1]								
Zimmer (index)	5/97	1.00	1.00	-	-	1.00	-	-
Osteonics	6/76	1.53	1.69	0.49	5.79	1.76	0.50	6.20
Axis	1/44	0.44	0.46	0.05	4.09	0.43	0.05	3.92
Austin Moore	2/27	1.44	1.51	0.27	8.31	1.31	0.23	7.53
Charnley	6/84	1.39	1.44	0.42	4.93	1.43	0.41	4.96
Exeter	3/63	0.92	0.92	0.21	4.02	0.98	0.22	4.33
PCA	6/114	1.02	1.07	0.32	3.64	1.26	0.36	4.38
Precision	0/46	-	-	-	-	-	-	-
SROM	5/69	1.41	1.57	0.43	5.67	1.57	0.42	5.93
Other	24/351	1.33	1.39	0.51	3.75	1.38	0.50	3.80
Agegroup‡[2]								
80+ (index)	9/101	1.00	1.00	-	-	1.00	-	-
0-49	5/67	0.84	0.82	0.26	2.58	0.63	0.19	2.08
50-59	7/141	0.56	0.53	0.19	1.49	0.46	0.16	1.35
60-69	18/295	0.68	0.66	0.29	1.53	0.59	0.24	1.44
70-79	19/252	0.85	0.83	0.36	1.91	0.75	0.31	1.79
Sex‡[3]								
Male (index)	25/372	1.00	1.00	-	-	1.00	-	-
Female	33/463	1.06	1.06	0.62	1.81	0.98	0.57	1.69
State‡[4]								
NSW (index)	19/224	1.00	1.00	-	-	1.00	-	-
QLD	10/122	0.97	0.96	0.43	2.14	0.97	0.43	2.17
TAS	3/25	1.41	1.47	0.40	5.37	1.52	0.41	5.55
VIC	26/401	0.76	0.75	0.40	1.38	0.77	0.41	1.43
WA	0/63	-	-	-	-	-	-	-

† As specified in the Medibank Private claims archive
§ Logistic regression
‡ Adjusted for: 1=age/sex/state 2=brand/sex/state 3=brand/state/age 4=brand/sex/age.
5, n/N =number with outcome/number of cases (**Bold** indicates significance at p=0.05 or higher)

In Table 6-2, small sample sizes have contributed to wide confidence intervals. Nevertheless, the size of some of the relative risks (such as the difference between Osteonics and Axis brands in the subsequent hip revisions) are clinically significant and warrant further investigation using larger numbers of patients and longer observation periods.

In addition, potentially serious biases are not adequately controlled for in these analyses. Again using the Osteonics compared to Axis brand, (Table 6-2), the result may be due to the fact that we are unsure whether the revision is for the known

prosthesis or the contra-lateral hip. It is possible that the Axis hip has become more fashionable among younger surgeons who are not revising as many hips. Revisions are most commonly performed by the surgeon who performed the original operation. If the 'original' operation was on the contra-lateral hip and the surgeon used an Osteonics prostheses, it would appear in the records as a revision but it would not be apparent whether it was a revision for the known Osteonics prosthesis or for another. It is clear that only limited causal association can be deduced from these data without well designed follow-up studies. However, this approach demonstrates the potential usefulness of these types of analyses. If a statistically significant association is noted for a clinically significant difference in outcome, the alarm is raised. It will then be possible to focus additional research efforts to confirm (or deny) the possible association.

In Table 6-3, significant differences can be seen for all ages less than 70 years, and a highly significant trend for age exists. Females appeared to have a greater risk of early complications than males. The importance of adjusting for covariates can also be observed in the results for 'all types compared with Zimmer, Precision and Austin Moore brands'. From examination of the crude OR column, it can be seen that these three brands have worse outcomes (higher ORs) than the others. However after adjustment this difference is greatly reduced although the results did not reach significance. As previously mentioned, Zimmer and Austin Moore are two of the original and trusted brands that are frequently used in higher risk, elderly patients. This situation highlights the dangers of superficial analyses, where a more effective procedure may be condemned for the very reason that it has been chosen for use in a high-risk patient group.

Table 6-3 Hip, early post operative complications†

Variable	n/N[5]	Crude RR	OR§	95% CI Lower	95% CI Upper	Adjusted‡ OR	95% CI Lower	95% CI Upper
Brand‡[1]								
Zimmer (index)	70/97		1.00	-	-	1.00	-	-
Osteonics	45/76	0.82	0.56	0.30	1.06	0.81	0.41	1.60
Axis	27/44	0.85	0.61	0.29	1.30	0.88	0.39	1.97
Austin Moore	19/27	0.98	0.92	0.36	2.34	0.61	0.22	1.66
Charnley	57/84	0.94	0.81	0.43	1.54	0.69	0.35	1.35
Exeter	40/63	0.88	0.67	0.34	1.32	0.59	0.29	1.21
PCA	73/114	0.89	0.69	0.38	1.23	0.81	0.43	1.52
Precision	37/46	1.11	1.59	0.68	3.72	1.61	0.65	4.00
SROM	45/69	0.90	0.72	0.37	1.41	1.24	0.61	2.53
Other	225/351	0.89	0.69	0.42	1.13	0.84	0.50	1.42
All v (Z+P+AM)	126/170	1.03	**1.62**	**1.11**	**2.35**	1.28	0.86	1.90
Agegroup‡[2]								
80+ (index)	85/101	1.00	1.00	-	-	1.00	-	-
0-49	46/67	0.82	**0.41**	**0.20**	**0.87**	**0.35**	**0.15**	**0.80**
50-59	97/141	0.82	**0.42**	**0.22**	**0.79**	**0.35**	**0.17**	**0.74**
60-69	205/295	0.83	**0.43**	**0.24**	**0.77**	**0.39**	**0.20**	**0.77**
70-79	195/252	0.92	0.64	0.35	1.19	0.66	0.33	1.31
p for trend			0.001			0.002		
Sex[3]								
Male (index)	266/434	1.00	1.00	-	-	1.00	-	-
Female	372/537	1.13	**1.42**	**1.09**	**1.86**	**1.50**	**1.13**	**1.99**
State‡[4]								
NSW (index)	133/224	1.00	1.00	-	-	1.00	-	-
QLD	88/122	1.21	**1.77**	**1.10**	**2.85**	**1.89**	**1.16**	**3.10**
TAS	10/25	0.67	0.46	0.20	1.06	0.48	0.20	1.14
VIC	319/401	1.34	**2.66**	**1.86**	**3.82**	**2.97**	**2.04**	**4.31**
WA	61/63	1.63	**20.62**	**4.96**	**85.79**	**23.95**	**5.71**	**100.37**

† Complications occurring within 30 days post-op, cut-off set at one or more events
§ Logistic regression
‡ Adjusted for: 1=age/sex/state 2=brand/sex/state 3=brand/state/age 4=brand/sex/age.
5, n/N =number with outcome/number of cases (**Bold** indicates significance at p=0.05 or better)

For the purpose of comparison, this analysis was also performed using the Mantel-Haenszel Common Odds Ratio estimate. Results are shown in Table 6-4. Adjustment for one variable at a time only is possible, and only results that reached significance are presented. Levels of significance are generally higher because this approach compares one subgroup with *all other* patients, thus greater power is available. Comparison between the two approaches indicates good agreement, both methods producing the same result for the group "Zimmer + Precision + Austin Moore" v rest (un-adjusted). Similarly, for Female v Male the OR of 1.43 agrees well with the previous logistic OR of 1.42.

Table 6-4 Hip, early post operative complications: Mantel-Haenszel analysis

	Crude		95% CI		Adjusted		95% CI		
	p	**OR**	**Lower**	**Upper**	**p**	**OR**	**Lower**	**Upper**	**adj for**
NSW v rest	<0.0001	**0.43**	**0.32**	**0.58**	<0.0001	**0.43**	**0.32**	**0.57**	sex
					<0.0001	**0.41**	**0.30**	**0.55**	age
					<0.0001	**0.41**	**0.30**	**0.56**	brand
WA v rest	<0.0001	**17.81**	**4.33**	**73.30**	<0.0001	**18.41**	**4.49**	**75.47**	sex
					<0.0001	**17.18**	**4.20**	**70.27**	age
VIC v rest	<0.0001	**1.63**	**1.25**	**2.14**	<0.0001	**1.68**	**1.28**	**2.21**	age
NSW v VIC	<0.0001	**0.42**	**0.31**	**0.58**	<0.0001	**0.40**	**0.29**	**0.55**	age
Age >80 v rest	0.005	**1.98**	**1.23**	**3.18**	0.01	**1.87**	**1.16**	**3.01**	sex
					0.007	**1.95**	**1.20**	**3.17**	state
Age <50 v rest	0.05	**1.64**	**0.41**	**1.00**	0.07	1.65	0.40	1.05	state
Zimmer, Prec + Aus Moore v rest	0.011	**1.62**	**1.11**	**2.35**	0.082	1.40	0.96	2.05	age
Female v Male	0.009	1.43	1.09	1.85	0.009	1.43	1.09	1.85	type
					0.032	1.33	1.02	1.75	age
					0.002	1.56	1.18	2.08	state

(**Bold** indicates significance at p=0.05 or greater)

6.2.1 Variation between States

In Table 6-3 most states appeared to have higher rates than New South Wales, particularly Western Australia with an adjusted OR of 24. Consent bias is an unlikely explanation for this (see Fig 4-4 for consent rate by state), however, it is possible that some of the Western Australia early complications have been accounted for as 'late complications', as shown in Table 6-5. This explanation is not however supported by Table 6-7 which shows a regression analysis for *all* complications across states. Western Australia still appears to have a highly significant increased Odds Ratio for post- operative complications, however RR is still fairly low at 1.18. The indicator for detection of an early post-op complication had been (arbitrarily) set at a cut-off level of one, ie any patients that experienced one or more of the selected events were classified as having had a post-operative complication. To investigate this situation further, a sensitivity analysis was performed by setting the cut off level

at three, any patients that experienced three or more events were flagged. The results of this comparison are shown for state only in Table 6-8.

Trends evident with the lower cut-off level are still evident with a cut-off set at three or more, however the magnitude is reduced. It appears that with the exception of TAS, all states report a higher OR for post-operative complications than New South Wales, WA having the largest ratio. These ORs are actually increased when age, sex and brand are adjusted for.

Table 6-6 Late complications†

Variable	n/N[5]	RR	Crude OR§	95% CI Lower	95% CI Upper	Adjusted OR	95% CI Lower	95% CI Upper
Brand‡[1]								
Zimmer (index)	8/88	1.00	1.00	-	-	1.00	-	-
Osteonics	2/65	0.34	0.32	0.07	1.55	0.37	0.07	1.89
Axis	4/37	1.19	1.21	0.34	4.30	1.23	0.33	4.60
Austin Moore	1/24	0.46	0.43	0.05	3.66	0.31	0.04	2.73
Charnley	3/74	0.45	0.42	0.11	1.63	0.36	0.09	1.43
Exeter	2/57	0.39	0.36	0.07	1.78	0.37	0.07	1.84
PCA	4/97	0.45	0.42	0.12	1.45	0.56	0.16	1.98
Precision	0/42	-	-	-	-	-	-	-
SROM	2/58	0.38	0.36	0.07	1.75	0.43	0.08	2.18
Other	15/309	0.53	0.51	0.21	1.24	0.52	0.21	1.29
Agegroup‡[2]								
80+ (index)	11/100	1.00	1.00	-	-	1.00	-	-
0-49	4/67	0.54	0.52	0.16	1.71	0.47	0.14	1.66
50-59	5/140	0.32	**0.30**	**0.10**	**0.89**	**0.30**	**0.10**	**0.94**
60-69	9/293	0.28	**0.26**	**0.10**	**0.64**	**0.26**	**0.10**	**0.68**
70-79	12/250	0.44	**0.41**	**0.17**	**0.96**	**0.39**	**0.16**	**0.95**
Sex‡[3]								
Male (index)	13/372	1.00	1.00	-	-	1.00	-	-
Female	28/463	1.73	1.76	0.90	3.46	1.60	0.81	3.17
State‡[4]								
NSW (index)	10/221	1.00	1.00	-	-	1.00	-	-
QLD	9/122	1.63	1.70	0.67	4.32	1.82	0.71	4.64
TAS	2/23	1.92	1.86	0.38	9.02	2.01	0.41	9.82
VIC	19/400	1.05	1.06	0.49	2.33	1.10	0.50	2.42
WA	1/63	0.35	0.35	0.04	2.75	0.37	0.05	2.93

† Later than 30 days post-operatively
§ Logistic regression
‡Adjusted for: 1=age/sex/state 2=brand/sex/state 3=brand/state/age 4=brand/sex/age.
5, n/N =number with outcome/number of cases (**Bold** indicates significance at p=0.05 or greater)

Table 6-7 All complications

Variable[1]	n/N[2]	RR	Crude OR§	95% CI Lower	95% CI Upper	Adjusted OR	95% CI Lower	95% CI Upper
State								
NSW (index)	221/264	1.00	1.00	-	-	1.00	-	-
QLD	122/137	1.06	1.58	0.84	2.97	**1.84**	**1.19**	**2.85**
TAS	23/34	0.81	**0.41**	**0.18**	**0.90**	**0.53**	**0.25**	**1.14**
VIC	400/450	1.06	**1.56**	**1.00**	**2.42**	**2.54**	**1.83**	**3.51**
WA	63/64	1.18	**12.21**	**1.65**	**90.05**	**30.98**	**7.45**	**128.79**

§ Logistic regression
1, Adjusted for: brand/sex/age.
2, n/N =number with outcome/number of cases (**Bold** indicates significance at p=0.05 or greater)

Table 6-8 Sensitivity analysis for early post-operative complication†

Variable[1]	n/N[2]	RR	Crude OR§	95% CI Lower	95% CI Upper	Adjusted OR	95% CI Lower	95% CI Upper
NSW (index)	31/222	1.00	1.00	-	-	1.00	-	-
QLD	31/122	1.82	**2.10**	**1.20**	**3.66**	**2.36**	**1.33**	**4.19**
TAS	2/24	0.60	0.56	0.13	2.50	0.61	0.13	2.75
VIC	115/401	2.05	**2.48**	**1.60**	**3.83**	**2.69**	**1.72**	**4.20**
WA	32/63	3.64	**6.36**	**3.41**	**11.86**	**7.10**	**3.75**	**13.46**

† (cut-off set at 3+ events)
§ Logistic regression
1 Adjusted for: 1=brand/sex/age.
2, n/N =number with outcome/number of cases (**Bold** indicates significance at p=0.05 or greater)

6.3.1 Results for WA and TAS

The reason for the disparity in odds ratios for WA and TAS post-operative complications is not readily apparent. The result is significant and cannot be explained by the variables available. It is probably an artefact resulting from variations in the method of classifying claims in the two states and may be a consequence of various incentives for 'enthusiastic billing'. However, it could also be the result of variations in quality of health care or co-morbidity in the population. It is interesting to note that a similar trend was evident in the analysis of survival rates in Table 4-10. The fact that a difference is detected is an example of the type of surveillance application appropriate for this analytic approach. Follow up investigation would need to be conducted to examine in more detail the various factors contributing to this result.

6.3.2 Variation between hospitals

Variation was found between hospitals at the p=0.03 level. A regression was performed categorising individual hospitals, (there were 225 hospitals) six hospitals were found to have a significantly reduced post-operative complication rate.

6.3.3 Variation between providers

Data of this type can provide an indication of variability between different practitioners. This is a contentious issue however, and although this type of comparison may seem useful for practice audit and even, as recently suggested in the USA, to provide informed choice for the consumer (Schneider and Epstein 1998), it is essential to adjust for all variables. For example, USA surgeons have been compared by using mortality rates; many prominent surgeons were found to score badly using this approach, the true explanation being that these were the providers who in fact were referred the most difficult cases with the highest risks (Localio, Hamory et al. 1997).

6.4 Discussion

Computerised service data of this nature invites automated analysis for the detection of possible adverse events. This type of data would support an ongoing quality control system of the kind used in industry. Various approaches are possible as discussed in 1.5.8 however, all depend on the setting of carefully chosen 'alarm thresholds'. For example, if variation in the rate of post-operative complications between two brands of hip exceed, say 30%, it would be appropriate for the system to flag this as an 'exception' for further examination. The complete automation of such a system is challenging due to the many confounders that exist. For example as previously discussed, some well known hip prostheses may appear to have poor outcomes merely because they are the brands used for problem cases. For these situations, it is essential to canvas expert opinion. Nevertheless, these situations are still worthy of examination and will provide opportunities for further refinement of the detection algorithm as specialist knowledge is incorporated into the model. In general, a surveillance algorithm will compare observed results to expected results on an ongoing basis, the setting of the alarm levels will determine the proportion of false positive to false negative exceptions that are flagged. This setting must however, be

determined by trial and error. The consequence of making 'multiple comparisons' will also produce erroneous results and this must be factored into the interpretation of exceptions raised.

The inclusion of basic 'clinical' data in administrative databases can vastly improve the power of these resources. While basic surveillance activities and some preliminary analysis can be performed using only basic records of attendances and costs, detail regarding the *nature* of the service is indispensable for health outcomes analysis.

Further work is required to choose the most appropriate indicator codes for 'related' incidents if this approach is to be used. The selection of these indicators is a crucial task and will require the attention of specialist groups consisting of clinicians, health researchers and coding experts.

In the next chapter, the Manitoba study is presented; in the chapter following, the results are compared with those achieved in Australia. A review of the strengths and limitations of the Australian national health datasets is presented in section 10.7. Suggestions are made at that point for possible improvements in the existing system.

Chapter Seven

The Manitoba Study.

7.1 Rationale for the Canadian arm of the study

Recognising the limitations in our country, the Australian component of this study was performed to establish the potential for and limitations of using administrative data for this 'unplanned' purpose. In Australia, problems were encountered with all stages of the data collection; identifying the cohort, establishing ethics approval, gaining patient consent and actual data gathering and matching.

The Canadian dataset had several advantages; it included patient identifiers, it was comprehensive and was available without the requirement of individual patient consent. Fortuitously, data were available for a similar cohort of patients over a similar time period, thus it was possible to perform a direct comparison of the two cohorts. The processes involved in performing the two studies highlight the research potential for an integrated health record and information system (IHRIS) and the many barriers and shortcomings of the present system in Australia.

It should be pointed out that Manitoba is a Province of Canada and thus the implementation of their health information system is analogous to an Australian "state" health system. Nevertheless, the system that has been established would be easily extended to incorporate other provinces and thus provides a model for an Australian national system.

7.1.1 Research use of administrative data as a valid pursuit.

As discussed, health service data are collected in Australia specifically for the purpose of paying service providers and assessing overall expenditure. The fact that the datasets collected comprise a unique resource for the investigation of health outcomes and the monitoring of health interventions, has been little exploited. Further, the use of this national data has been specifically restricted due to possible privacy concerns of individuals and 'self-protective' behaviour by the States. Like the USA, Australia is restricted in its use of national health data because this data is managed by multiple data holders. Linkage of one dataset to another is invariably impeded by legislative, political and administrative constraints.

This situation does not exist in Manitoba. The Canadian government created a central statistical agency, Statistics Canada, in the 1970s (Statistics Act. 1970-71-72). At this time public concern was high regarding the importance of health hazard detection and quantitative estimation of risks, especially in the work environment and in association with long term exposure (Whittle, Steinberg et al. 1993). A system which allowed the use of statistical data for such purposes was established and this approach has encouraged the provinces to take a similar initiative in the way that provincial health data is managed (Beebe 1980).

7.1.2 History and politics

Manitoba is located in the central region of Canada, with a population of approximately 1.1 million. Statistics Canada, a national agency, has implemented an approach which supports the use of collected data for public benefit. Based on this philosophy, Manitoba Health collects an extensive range of health service data. Since 1984, this has been collected electronically. All entries in the current database are stored under a unique patient identifier, the Personal Health Identification Number (PHIN). Earlier data collection, though extensive, did not use a unique identifier.

Although Canadian legislators recognised the need to protect individual privacy, it was realised early on in the development of the Manitoba health system that such data should properly be utilised for both health service administration and health service evaluation. Thus, health data in Manitoba collected by Manitoba Health (provincial government) are analysed by Manitoba Health and contribute to the Manitoba research registry. This resource was specifically developed to facilitate longitudinal studies, working within strict confidentiality controls. Identified records for each individual known to Manitoba Health since 1970 can be retrieved. Information is supplied to the Manitoba Centre for Health Policy and Evaluation (MCHPE) at the University of Manitoba to form the 'Data Repository'. All records in the Repository have been processed by Manitoba Health to remove names and addresses while preserving the capacity to link records together to form individual histories for health care use. This Repository, is central to the versatility and efficiency of research conducted by MCHPE. The University assumes the responsibility of securing these records of health care use. Confidentiality is maintained in the Repository through a number of

procedures and security measures. Names and addresses of patients or physicians are not included in the data base. Privacy and misuse of the information is assured by periodic security audits and is controlled by restricting access to personnel who have signed a confidentiality agreement and restricting use to approved projects which are reviewed according to the different arrangements controlling the two centres. Projects are reviewed by the Access and Confidentiality Committee and when appropriate, by the Health Ethics Committee.

Recent ambitious changes to the health information system including an electronic network to connect providers and hospitals was contracted to 'Smart Health' P/L. These changes have been supported by legislation describing the requirements and obligations for use of personal health information. Severe penalties exist for violations (Manitoba. 1997). This legislation is currently undergoing staged introduction to be completed by December 2000. However, there have been some delays in the introduction of the 'Smart Health' project due to cost overruns and changes in government.

7.2 Gaining project approval and patient consent

Approval for the Medical Devices project was sought from the Access and Confidentiality Committee. The approval was granted promptly without modification to the study protocol. Resources were made available for this project on site at the Manitoba Health office in Winnipeg during October 1998. There was no requirement for the gaining of individual patient consent, however, a confidentiality agreement was signed prior to release of the data.

7.3 Potential biases

The Manitoba Health dataset is population based and is not a sample. As a consequence of the 'research-friendly' environment, and in contrast to the situation in Australia, selection, response and survivor cohort biases were not present.

All patients selected were insured under the Manitoba Health Insurance Scheme – a public scheme that provides health cover to all. In spite of this, a known bias exists towards the supply of high-tech medical care to the more wealthy members of society

(Roos and Sooden 1998, p9). For the purpose of this research it was considered that this bias would be unimportant as the patient cohort was selected with the requirement that a major procedure had already been completed, a similar argument was used for the Australian cohort. However, when comparisons in outcomes were made between the two cohorts, the Australian privately insured group and the Manitoban population group, these difference in socio-economic status (SES) did become influential.

7.4 The PHIN: A Unique Patient Identifier

In 1984, Manitoba introduced a "Unique Patient Identifier" the Personal Health Identification Number (PHIN). This ID allows reliable and simple (deterministic) linkage of the various health databases. Reliability of the PHIN is considered to be good but somewhat less than 100%. Confusion can occur between people with similar names as the actual PHIN number is not always used to identify a patient on admission Rather the 'simpler' entry of their name is used and thus the wrong electronic file can be called up. To ensure privacy, an encrypted PHIN (the PID) is produced for the purposes of research studies.

7.5 Selection of the patients and the prostheses:

Wherever possible, identical procedures were used in Manitoba as those that had been developed for the Australian study. A similar approach was therefore used to identify patients in Manitoba and to extract data. A comparable level of detail about operations was available in the hospital admissions database as is contained in the Medibank Private archive. However, specific codes for individual prostheses types and components are not recorded. Payment for these items is from the provincial health budget and is not itemised.[1] The set of tariff codes relating to the five groups of prostheses was determined for hips, heart-valves, pacemakers, IOLs and vascular grafts.

The Manitoba health service data have been collected and stored in a manner that facilitates electronic access and analysis. All records are coded with the PHIN.
In order to select the cohort, the hospital admissions database was searched for codes relating to the five implant operations during the two year period from April 1993 –

1 A similar situation exists in Australia for Medicare (public hospital) patients, no detailed record is kept of individual prosthesis brands or components.

March 1995. All patients who were Manitoba residents and who had received one or more of these prostheses were selected. Patients who had entries for more than one procedure were followed in the study according to the less common procedure; thus patients who had both a cardiac valve replacement and an IOL insertion during the selection period were enrolled as cardiac patients. Due to there being no requirement for individual patient consent, all patients were able to be included in the study.

7.6 The patient cohort.

All patients who during the two year selection period, had a service claim submitted on their behalf for one of the five procedures were selected. This group initially included 10,985 patients, with each implant group represented as shown in the table above. Of these, 8,834 were IOL (cataract) patients and of these, 2,500 were randomly selected. This provided a sufficiently large sample group for this type of procedure while supplying a 2:1 ratio control group for the largest other single device group (hip implants with 1,127 patients). Thus the final cohort comprised 4,578 patients.[2]

Previously published totals for this period of 9,000 cataract operations and 1,100 hip replacements compared favourably with the study numbers as it seems likely that most procedures were correctly identified (Brownell and Roos 1996 P19). Details of the cohort are presented Tables 7-1, 7-2 and 7-3.

Table 7-1 Patient numbers by device type

Type	Total N	Cohort N	Percent of total cohort	Mean age at operation
Heart Valve	270	270	5.9	64.3
Pacemaker	294	293	6.4	68.8
Hip	1127	1115	24.4	69.1
Vasc Graft	460	457	10.0	71.9
IOL	8834	2443	53.4	74.1
Total	10985	4578	100.0	71.8

2 A small number of patients were excluded as their records appeared to be incomplete or in error

Table 7-2 Sex and mean age at operation

Sex	Frequency	Percent	Mean age at operation
Female	2559	55.9	73.0
Male	2019	44.1	68.8
Total	4578	100.0	-

Table 7-3 Age at time of operation by decade

Age group	Frequency	Percent
0-9	4	0.1
10-19	12	0.3
20-29	26	0.6
30-39	61	1.3
40-49	127	2.8
50-59	365	8.0
60-69	1016	22.2
70-79	1872	40.9
80-89	1012	22.1
90+	83	1.8
Total	4578	100.0

7.7 The data sets

Four data sets were used in this study and as all the data sets were identified with the PHIN, probabilistic linkage was not required.

- The Physician Claims File (doctor visits)
- Hospital claims Abstract File (admissions)
- Drug Program Information Network (DPIN, most prescriptions)
- The Population Registry File (PRF, Deaths)

These files are described below, in the format that existed in 1998 and was used for this study.

7.7.1 The Physician Claims File

This file records most clinician encounters, it has 53 fields with 150 characters per record. Various encounters are not captured in this file, including individual services provided by salaried physicians and nurses. These 'invisible' services include medical services such as immunisation.

7.7.2 The Hospital Claims Abstract File

This file records all hospital admissions and outpatients procedures, it has 298 fields and 1,150 characters per record. Procedures conducted in private clinics are not included, however a claim for these procedures will usually appear in the medical claims file (Roos, Walld et al. 1996). Detail included in this file is more extensive than the Australian NHMDS with up to 16 diagnosis, 12 anaesthetic, 12 procedure and 12 service code fields.

7.7.3 DPIN – Drug Program Information Network

Pharmacies have supplied computerised information on medications prescribed since April 1994. Due to a 'safety net' arrangement similar to the Australian PBS scheme, benefits are provided at two levels. Thus the benefit assigned to each prescription varies according to whether the drug was dispensed before or after the personal threshold was reached in any given year.

7.7.4 The population Registry file (PRF).

This file records deaths and departures from Manitoba. Treatment information is available about patients who left the province for a period of up to three months, after this time responsibility is transferred to the receiving province and an entry made in the PRF recording the date of transfer. Deaths occurring in Manitoba are recorded with date and place of death. Due to earlier system problems, cause of death was not available at this time.

7.8 Mortality

During the observation period, 781 cohort members died from all causes. Details of deaths were obtained from the PRF. The number of patients who died with death rates for each device category are shown in Table 7-4 and by age group in Table 7-5. Mortality rates for the cohort were then compared to the Provincial rate for each age group. These results are presented in Table 7-6 and Figure 7-1.

Table 7-4 Canadian cohort – Death rates and survival times by type of device

Type	Total N	Av Op Age	No. Died	Mean Survival Time (months)	Crude Death rate (per 100 person years observed
Heart Valve	270	66.5	46	14.8	4.3
Pacemaker	293	73.5	68	16.5	5.7
Hip	1115	74.8	134	18.1	3.0
Vasc Graft	457	75.8	125	13.7	6.6
IOL	2443	77.4	408	20.5	4.1
Total	4578		781	16.7	(mean) 4.2

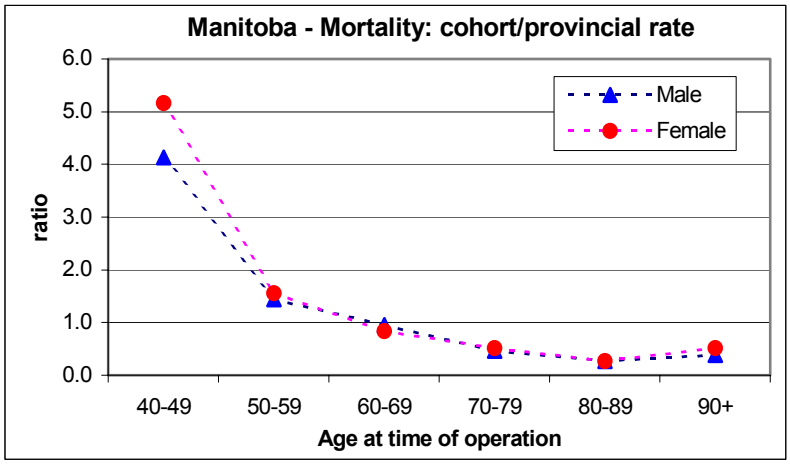
Table 7-5 Age-specific death rates per annum

Age	Deaths	Total	Rate/1000 per annum
0-9	0	4	0.0
10-19	0	12	0.0
20-29	2	26	20.4
30-39	5	61	20.4
40-49	14	127	27.5
50-59	30	365	20.3
60-69	121	1016	29.2
70-79	331	1872	43.3
80-89	243	1012	59.1
90+	35	83	104.5

Table 7-6 Expected deaths v observed, by sex (Using Manitoba ASDR)

Age	Observed		Expected		SMR	
	M	F	M	F	M	F
40-49	8	5	1	1	6.7	8.8
50-59	21	10	9	4	2.3	2.6
60-69	74	41	48	31	1.5	1.3
70-79	168	151	224	183	0.7	0.8
80-89	113	143	247	318	0.5	0.4
90+	13	29	20	34	0.7	0.9

Figure 7-1 Manitoba cohort, mortality rates by age and sex



In Table 7-6, the indirect standardisation method was used to produce an SMR.[3] Ratios were calculated for each age group and sex. It can be seen that in this study, younger patients of both sexes were more likely to die than older patients.

Table 7-7 shows a further breakdown of the cohort. Mortality rates are compared with Provincial rates by age-group and sex for the five device types. Insertion of a vascular graft can be seen to be one of the higher risk operations.[4]

Table 7-7 Ratio of Cohort rate/Provincial rate by type, age-group and sex.

Age	**H Valve**		**Pacer**		Hip		V Graft		IOL	
	M	F	M	F	M	F	M	F	M	F
40-49	12.1	23.8	-	-	5.8	7.9	-	75.4	7.8	-
50-59	2.2	-	5.6	6	1.3	2	4.8	-	1.9	3.6
60-69	2.2	3.3	2.6	2.4	1.3	1	1.8	1.8	1.3	1.2
70-79	0.6	1.2	1.2	1.2	0.4	0.5	0.9	1.8	0.8	0.8
80-89	0.5	0.5	0.5	0.3	0.4	0.5	0.7	2.2	0.4	0.4

From these tables, it can be seen that those patients having a procedure that does not have major systemic involvement (IOL and Hip replacement) demonstrate a strong selection effect. Hip and IOL patients fare better than others who have had operations for conditions with greater systemic involvement. The 'selection effect' for age can also be observed. For example, persons in their 40's who required a heart valve or pacemaker would generally have consequent morbidity from thrombo-embolic episodes, infarction or from the unwanted effects of anticoagulant therapy. However, in the older age groups, a protective effect is seen. The selection process works in reverse; patients who have reached a greater age and are still fit enough to endure a major operation are selected. Patients (in both Manitoba and Australia) who have IOLs in their 70s and 80s have half the annual death rate of others in their age group.

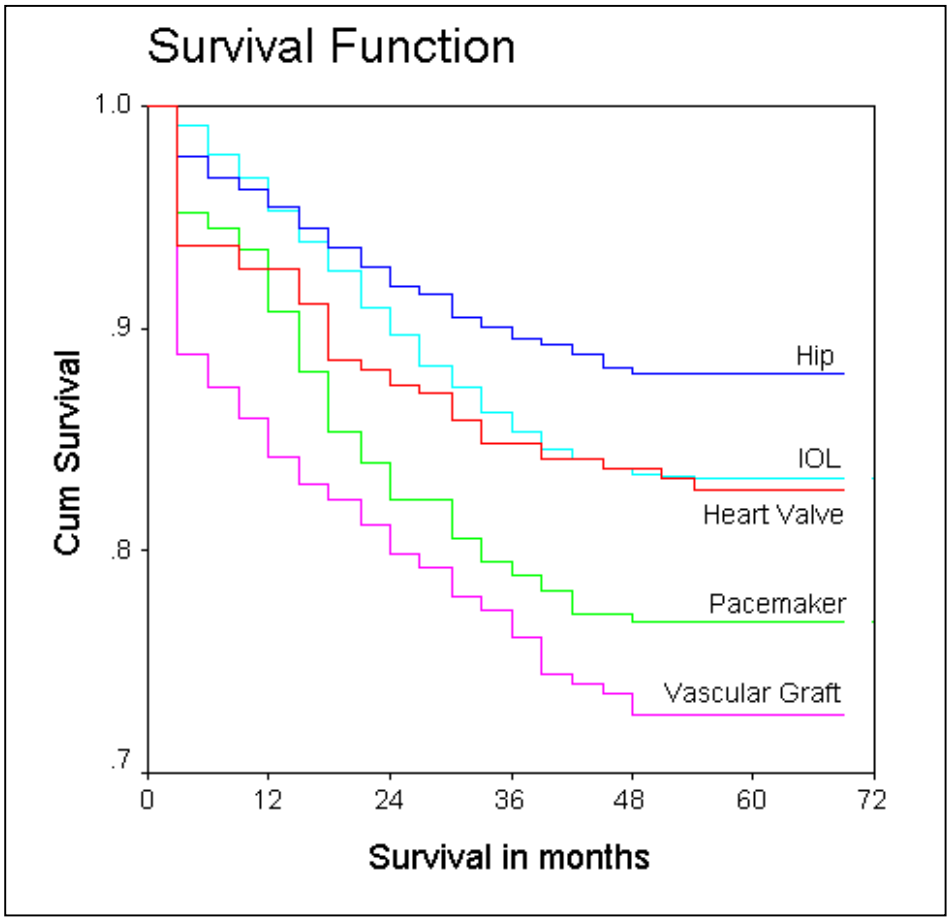
7.8.1 Survival function

Survival functions for the various type groups are plotted below in Figure 7-2. Similar to the Australian situation, the hip and IOL groups present a different profile to the

3 Numbers of actual deaths are compared with numbers that were expected calculated by using the age-sex specific death rates for the total Manitoban population from Statistics Canada. 1992.
4 The apparent high risk for young females is unreliable due to small sample size.

other four groups, having low post-operative death rates and better long term survival. The pacemaker and vascular graft groups have the highest mortality.

Figure 7-2 Survival function by device type



A survival analysis was performed on the entire dataset using Cox regression; the proportional hazards assumption holds approximately for these data.

Table 7-8 Survival analysis

		Crude	95% CI		Adjusted	95% CI	
Variable	**'n/N4[4]**	**HR[5]**	**Lower**	**Upper**	**HR**	**Lower**	**Upper**
Type[1]							
IOL (index)	408/2443	1.00	-	-	1.00	-	-
Heart Valves	41/270	1.05	0.78	1.43	1.35	0.99	1.84
Pacemaker	68/293	**1.47**	**1.14**	**1.90**	**1.57**	**1.21**	**2.03**
Hip	132/1115	**0.71**	**0.58**	**0.86**	0.83	0.68	1.02
Vasc graft	115/457	**1.82**	**1.49**	**2.23**	**1.82**	**1.48**	**2.24**
Agegroup[2]							
80+ (index)	273/1088	1.00	-	-	1.00	-	-
0 - 49	20/230	**0.33**	**0.21**	**0.51**	**0.27**	**0.17**	**0.42**
50 - 59	31/367	**0.30**	**0.21**	**0.43**	**0.26**	**0.18**	**0.37**
60 - 69	116/1024	**0.42**	**0.34**	**0.53**	**0.37**	**0.30**	**0.47**
70 - 79	324/1869	**0.66**	**0.56**	**0.77**	**0.62**	**0.53**	**0.73**
p for trend		**<0.001**			**<0.001**		
Sex[3]							
Male (index)	394/2019	1.00	-	-	1.00	-	-
Female	370/2559	**0.72**	**0.63**	**0.83**	**0.63**	**0.55**	**0.73**

Adjusted for: 1=age/sex 2=type/sex 3=type/age. 4 n/N =number with outcome/number of cases.
5 HR=Hazard Ratio. **Bold** indicates significance at p=0.05 or higher

7.8.3 Discussion of survival analysis

The Manitoba cohort was over twice as large as the Australian cohort and there were proportionally more deaths; 781 patients compared to 257 in Australia. As a result of the larger numbers, greater statistical power was available with consequently smaller confidence intervals.

In Table 7-8, the Hazard Ratio for vascular graft and pacemaker patients is high when compared with the IOL group (as was shown graphically in Figure 7-2). These differences remain even after adjustment for age and sex. As would be expected a strong protective effect was associated with age, although patients less than age 50 at time of operation appeared to fare worse than those aged 50-59.[5] Female sex also provides a strong protective effect. Adjusted trend for age was significant at higher than the 0.001 level.

5 It should be noted that these results are not standardised against the population as was done to produce the SMRs shown in Table 7-6.

7.9 Post-operative deaths

Deaths which occurred within the 30 day period after the index operation were classified as 'post operative deaths'; 82 patients died within this period. The risk of post-operative death appears consistent with the expected severity of illness associated with each condition requiring an implant. It is interesting to note that the overall death rate for pacemaker patients was high in this study, however the post operative rate was unremarkable compared with that for heart valves and vascular grafts. Numbers of post-operative deaths in each group are shown in Table 7-9.

Table 7-9 Deaths within 30 days after the index operation

Type	Deaths	Total N	%
Heart Valves	17	270	6.30
Pacemaker	6	293	2.05
Hip	17	1115	1.52
Vasc graft	39	457	8.53
IOL	3	2443	0.12
Total	82	4578	1.79

Table 7-10 shows a Cox regression is used to compare the hazard ratios of subgroups of those patents who died in the post-operative period.

Table 7-10 Cox regression of post operative deaths

		Crude			Adjusted	
Variable	**'n/N[4]**	**HR[5]**	**Lower**	**Upper**	**HR**	**Lower**	**Upper**
Type‡ [1]							
Hip (index)	17/1115	1.00	-	-	1.00	-	-
Heart Valves	17/270	**4.28**	**2.18**	**8.38**	**5.12**	**2.59**	**10.11**
Pacemaker	6/293	1.35	0.53	3.41	1.27	0.50	3.23
Vasc graft	39/457	**5.81**	**3.29**	**10.28**	**5.15**	**2.86**	**9.27**
IOL	3/2443	**0.08**	**0.02**	**0.27**	**0.06**	**0.02**	**0.22**
Agegroup‡ [2]							
80+ (index)	31/1088	1.00	-	-	1.00	-	-
0 - 49	3/230	0.46	0.14	1.49	**0.17**	**0.05**	**0.57**
50 - 59	2/367	**0.19**	**0.05**	**0.79**	**0.10**	**0.02**	**0.42**
60 - 69	19/1024	0.65	0.37	1.15	**0.39**	**0.21**	**0.70**
70 - 79	27/1869	**0.51**	**0.30**	**0.85**	**0.34**	**0.20**	**0.58**
p for trend		**0.02**			**0.0001**		
Sex‡ [3]							
Male (index)	48/2019	1.00	-	-	1.00	-	-
Female	34/2559	**0.56**	**0.36**	**0.86**	**0.58**	**0.37**	**0.91**

‡ Adjusted for: 1=age/sex 2=type/sex 3=type/age. 4 n/N =number with outcome/number of cases.
5 HR=Hazard Ratio. **Bold** indicates significance at p=0.05 or higher

The analysis presented in Table 7-10 reveals that the risk of death within the 30 day post operative period is highly dependent on device type, age and sex. Types were compared with hip implants. Heart valve and vascular graft procedures were about five times more likely to lead to death in this period than hips. IOL procedures were around twenty times less likely. These results were expected considering the nature of the condition being treated and the invasiveness of the surgical procedure. Death rates for males were found to be almost twice as high as for females in the post-operative period.

7.10 Comparisons of service use for device types

A similar analysis to that already reported for the Australian data was performed on the Manitoba data. Larger numbers of patients in some device groups allowed greater levels of confidence, however due to the lack of information available regarding device sub-groups (brands) comparisons at that level were not possible.

Significant periods of observation time were available for the cohort patients (Table 7-11). Around twice as many months were available for the pre-operative period as for the Australian cohort.[6]

6 . This is due to the short period of time that records are kept in accessible form by Medibank Private.

Table 7-11 Statistics for Manitoba pre and post-operative observation times

	Months pre-op	Months post-op
Mean	13.6	48.8
Median	13.9	48.5
Std. Deviation	7.0	7.0
Minimum	0.0	37.4
Maximum	26.0	61.3

7.11 Overview of service use rates.

Monthly rates of pre-operative and post-operative service use were calculated for the five device types. Customised exclusion periods were derived from plots of service use against time for each device type. In general 3 month exclusion periods were found to eliminate the majority of pre-operative investigations and post-operative treatments. However, heart valves required a 4 month pre-operative period and a 6 month post-operative exclusion period. The measures utilised for the Australian data were used here, pre/post differences and geometric ratios of service use, fees for services and days in hospital.

Service use ratios as shown in Figure 7-3 give slightly clearer trends than in the Australian data. In general, as would be expected, patients continue to increase their service use as they age. However, there are some encouraging indications that hip implants and IOL procedures may actually lead to a reduction in rates of service use and the costs of those services. It also appears that having a hip prosthesis may reduce the average number of days spent in hospital.

As for the Australian study, results produced by this approach provide a starting point for further investigation. The analysis provides an overview of treatment outcomes, however, more detailed study is necessary to determine the causes of such results. In the next section a logistic regression is conducted on measures produced by using the pre- to post-operative differences in service use costs as the dependent variable.

Figure 7-3 Service use ratios for the five device types

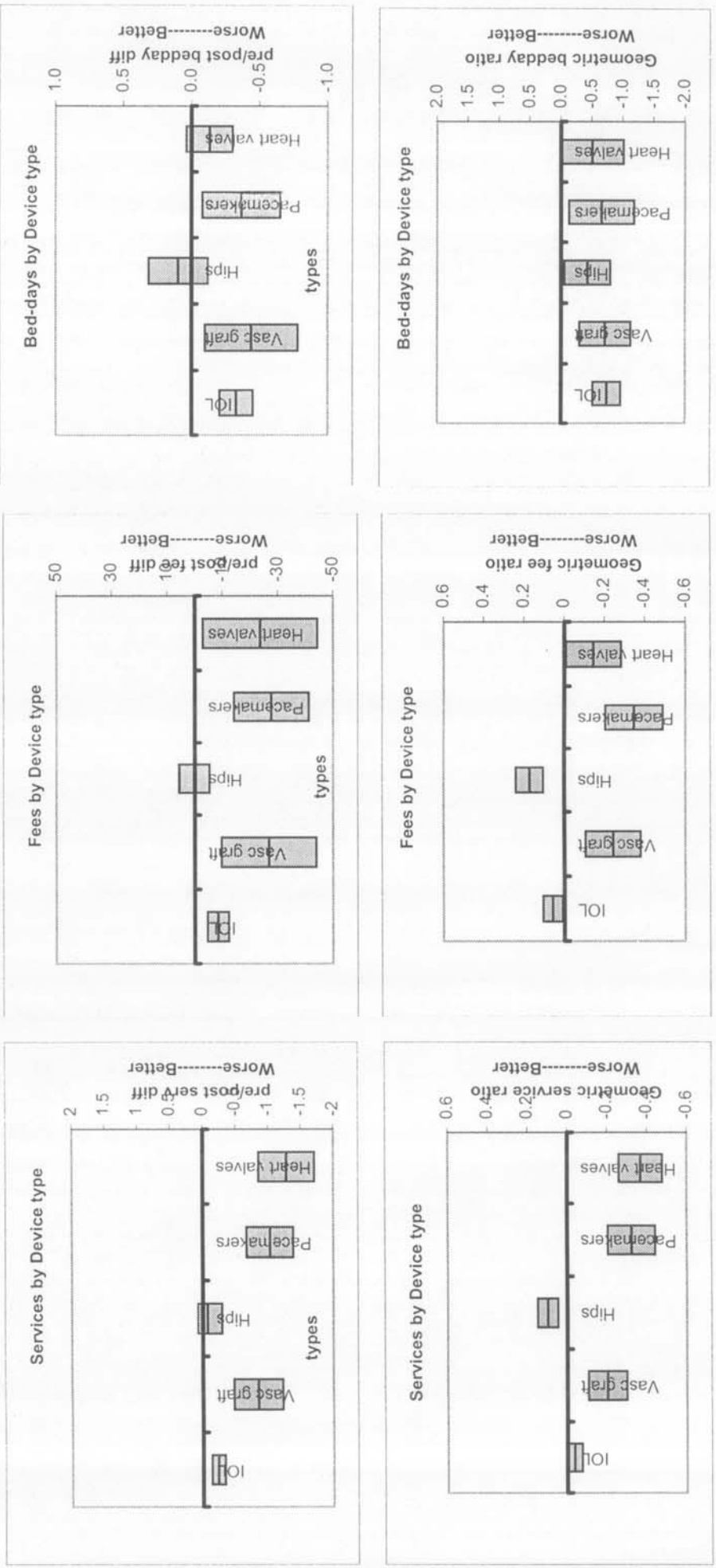


Figure 7-3 Manitoba, Service use ratios for the five types of device (customised exclusion periods, follow up for 1 year)

7.12 Analysis using Logistic Regression

In the same manner as was done with the Australian data, a regression was performed using pre to post-operative data. A dichotomous 'fee-outcome' indicator[7] was created from the pre-post difference measure. Implant types, age-groups and sex were compared and the results adjusted for all other variables, Table 7-12.

Table 7-12 Fee-outcomes†, crude and adjusted rates

			Crude	95% CI		Adjusted	95% CI	
Variable	**n/N[4]**	**RR[5]**	**OR**	**Lower**	**Upper**	**OR**	**Lower**	**Upper**
Type‡[1]								
IOL (index)	896/1432	1.00	1.00	-	-	1.00	-	-
Heart Valve	104/159	1.05	1.13	0.80	1.60	1.11	0.78	1.58
Pacer	102/161	1.01	1.03	0.74	1.45	1.05	0.74	1.47
Hip	467/674	1.11	**1.35**	**1.11**	**1.64**	**1.33**	**1.09**	**1.62**
Vasc Graft	105/208	0.81	0.61	0.46	0.82	**0.64**	**0.48**	**0.87**
Agegroup‡[2]								
80+ (index)	381/600	1.00	1.00	-	-	1.00	-	-
0 - 49	110/151	1.15	**1.54**	**1.04**	**2.29**	**1.56**	**1.04**	**2.34**
50 - 59	150/223	1.06	1.18	0.85	1.64	1.19	0.85	1.65
60 - 69	353/583	0.95	0.88	0.70	1.12	0.90	0.71	1.14
70 - 79	680/1077	0.99	0.98	0.80	1.21	0.98	0.79	1.21
P for trend			0.07			0.06		
Sex‡[3]								
Male (index)	675/1118	1.00	1.00	-	-	1.00	-	-
Female	999/1516	1.09	**1.27**	**1.08**	**1.49**	**1.32**	**1.12**	**1.55**

† 'Fee outcome' is an indication of reducing expenditure post-op.
‡ Adjusted for: 1=age/sex 2=type/sex 3=type/age. 4 n/N =number with outcome/number of cases. (**Bold** indicates significance at p=0.05 or higher)
5 Relative Risk ratios are included as incidence of the outcome is common.

7.13Discussion of service use rates

In Table 7-12, the various implant types are compared with the IOL group. As could be expected, most types appeared to have less favourable outcomes compared to this group which could be considered as a 'placebo' control group for these patients. Significantly more hip prosthesis recipients consumed more services after their implant operation

7 An indicator was assigned the value 1 if an average monthly service fees *decreased* after the operation, 0 if they increased).

than did IOL patients. This difference was significant at the 0.05 level, RR was 1.33 when adjusted for age and sex.[8]

It is interesting to note that adjusted ORs indicate that vascular graft patients tend to use less services after their procedure. This result is opposite to the trend noted in the Australian data and is probably the result of variation in classification of the procedure between the two countries. Significantly increased risks are observed for females which actually increase after adjustment. This result was further investigated; it was found that a large number of patients (585) with poor 'fee-outcomes' were in the category Female plus IOL implant. The IOL group comprised 53% of the total cohort, and of this group, 63% were female. This would be expected to produce some bias of the grouped 'fee-outcome' rates.

Individual hip brands could not be compared using the Manitoba data as prosthesis codes are not collected at this level of detail. Consequently, an analysis of adverse events resulting from the procedure could not be performed. Although the Manitoba data is reliable, complete and available, and far superior in quality to its counterpart in Australia, it is seriously lacking in detail if performance of specific types of prostheses is to be examined. The Manitoba dataset does contain highly detailed information about each service including diagnosis, type of provider and outcomes for hospital admissions and an ICD code for medical services. Pharmaceuticals are fully defined down to brand type. However, this detail is not extended to medical devices, which due to their persistence in the body, perhaps merit even more diligent documentation than do drugs. This is surprising for an otherwise advanced health information system. The logistics of collecting such data may be complex due to the way that prostheses are funded. The situation is similar to that found in Australian public (state) hospitals where prostheses are paid for out of a general budget and records kept in the supply inventory are not linked to individual patient records.

7.14 Discussion

The Manitoba health information system provides a model for Australia, however, it also demonstrates limitations that we would be wise to avoid. The lack of prosthesis

8 Australian hip patients also did not fare well according to this measure, however the result was not considered significant.

details in the database not only prevents the surveillance of these products but foils any attempt to generate a device 'register' that could be used to track faulty products. Although it would be simple to determine which patients have received for example a prosthetic heart valve, it would not be possible to identify the group of all patients who have received a particular brand or model of valve. It is this type of information that is essential for the purposes of product evaluation and in the event of adverse events, for product recalls.[9]

It should be remembered that this level of detail is not generally available in Australia and the detailed analysis presented for this country was only possible as a result of privileged data being made available by Medibank Private. Such detail is not collected by Australian state hospitals as payment for individual prostheses is included as part of the DRG descriptor. Medibank Private, being a private insurer, of necessity, records details of each treatment component for claims purposes.

This study underlines the importance of the collection of specific details about treatment components (especially medical devices). In addition, it is necessary to record the *reason* for treatment to allow meaningful outcomes analysis, surveillance and product recall to be performed.

9 Such an event occurred in Australia and the USA with the Bjork Shiley heart valve as discussed in chapter 1.

Chapter Eight

Australia-Manitoba comparison

8.1 Introduction

The two studies previously described involve collection of similar information about comnparable population groups over the same time frame. This chapter presents a comparison of results between the two counties.

The selected cohorts come from countries with similar demographics, economies, occupation and life styles. The distribution of age, sex and type of operation are comparable in both cohorts. The two cohorts are described and compared, and differences of note are discussed. Crude death rates are shown and rates for both cohorts are standardised against the Australian ASDR and compared. Finally a Cox proportional hazards analysis is used to provide adjustment for age, sex and device type.

A general description of total numbers and numbers of deaths in both cohorts is presented in Table 8-1. To allow the comparison of death rates, a subgroup of patients was selected and 'observed' for the same time period in both countries. This involved selected patients only if a period of 28 months post-operative follow up was available.[1]

Table 8-1 Description of the '28 month' subset of the Australian and Manitoban cohorts

	Total N		Av. Op age years		No. died		Mean survival months	
Cohort	AUS	MB	AUS	MB	AUS	MB	AUS	MB
Heart Valve	236	261	65	67	17	37	10.3	9.0
Pacemaker	276	280	71	74	35	55	13.9	12.0
Hip	1046	1079	67	75	43	98	12.6	11.4
Vasc Graft	176	429	68	76	21	97	10.7	7.1
IOL	253	2326	72	78	11	291	14.7	14.4
Total/Mean	1987	4375	67.4	71.6	127	578	12.5	12.1

1 Those who died during this period were included, those who died at a time *greater* then 28 months were excluded. The period of 28 months was the optimal period that full service details were available for patients in both cohorts.

Some differences between the two cohorts are noted. In general, Manitoban patients are two to eight years older before reaching the operating table and have higher mortality rates after the operation. Reasons for differences in age at operation are most likely related to the differing structure and availability of health services in the two countries. In particular, it is known that a major incentive for belonging to a private health fund in Australia is the promised reduction in waiting times for elective surgery. In Manitoba, all patients are essentially public patients and during the period of the study waiting times for surgery are known to have been of concern. This is further discussed in section 8.3.

When comparing the mean post-operative survival periods it should be kept in mind that this represents a conditional distribution of mean survival time. It demonstrates the mean survival time for the first 28 months of the post-operative period. These results suggest that the Australian patients in general survived for approximately 10% longer than their Manitoban cousins. This difference can partially be explained to be a result of the slightly greater age at time of operation, it will be further examined in section 8.2 where rates are standardised for age. It should also be noted that a major confounder in this comparison is that the Australian cohort is more likely to be selected from the highest SES group, while in Manitoba the cohort includes a cross section of the entire population. A report by Mustard et al suggests that Manitoban death rates may be between 40-60% higher in the lower SES groups compared with the highest group. (Mustard, Derksen et al. 1999). Similar trends have been noted in Australia (Turrell, Oldenburg et al. 1999 p33). Crude death rates for both countries are presented in Table 8-2.

Table 8-2 Comparison of cumulative mortality rates Australia and Manitoba for the 28 month post-operative period

	AUS	95% CI		MB	95% CI	
	% rate	low	high		low	high
Heart Valve	7.2	3.8	10.6	14.2	9.9	18.5
Pacemaker	12.7	8.7	16.7	19.6	14.9	24.4
Hip	**4.1**	**2.9**	**5.3**	**9.1**	**7.3**	**10.8**
Vasc Graft	**11.9**	**7.0**	**16.8**	**22.6**	**18.6**	**26.6**
IOL	**4.3**	**1.8**	**6.9**	**12.5**	**11.1**	**13.9**
All	**6.4**	**5.3**	**7.5**	**13.2**	**12.2**	**14.2**

Differences significant at greater than 0.05 in **bold**

8.2 Comparison of Standardised Mortality Ratios

To allow an age-standardised comparison between the two different populations, death rates for both (complete) cohorts were adjusted using the *Australian* standardised death rates. A comparison of age specific death rates for the two regions is presented in Table 8.3. Results for Manitoba are shown in Table 8-4.[2]

2 The results for Manitoba presented here differ from those shown in the previous chapter which were standardised against *Manitoba Provincial* death rates.

Table 8.2a Comparison of Age specific death rates 1994*

	Male		Female	
Age group	AUS	MB	AUS	MB
40-49	2.4	2.8	1.4	1.9
50-59	6.1	7.4	3.6	3.9
60-69	18.8	19.8	9.9	10.9
70-79	48.2	49.7	27.1	26.8
80-89	132.6	125.4	102.7	76.7
90+	-	231.8	-	198

* Australian Bureau of Statistics and Statistics Canada 1994.

Table 8.3 Manitoba cohort: SMR by sex and age-group†

Age group	Observed		Expected		SMR	
	M	F	M	F	M	F
40-49	8	5	1	0	9.5	-
50-59	21	10	6	3	3.5	3.1
60-69	74	41	49	22	1.5	1.7
70-79	168	151	176	150	1.0	1.0
80+	113	143	219	349	0.5	0.5

† Standardised using **Australian ASDR**

Standardised Mortality Ratios are compared for age-group, sex and device type in Table 8-5. All device types are combined in the two right hand columns. Some subgroups are small, several having no deaths (for these groups, no result is presented). Ratios for small groups should be interpreted with caution. Bold type is used to indicate the situation where both cohorts provide subgroups greater than 30 patients.

Table 8.4 Ratio of SMRs, Australia / Manitoba by age-group, device type and sex

Age group	H Valve		Pacemaker		Hip		V Graft		IOL		All types	
	M	F	M	F	M	F	M	F	M	F	M	F
40-49	-	1.7	-	-	-	-	-	-	-	-	-	-
50-59	1.0	-	0.7	-	**0.0**	**1.2**	**0.9**	-	1.4	-	**0.7**	-
60-69	**0.7**	0.6	**0.9**	0.6	**0.4**	**0.7**	**1.4**	2.4	**1.3**	**0.8**	**0.8**	**0.9**
70-79	**1.3**	**0.5**	**0.6**	**1.0**	**0.9**	**1.1**	**0.9**	1.1	**0.2**	**0.8**	**0.7**	**0.9**
80+	1.4	-	**1.3**	2.4	1.0	**1.6**	1.6	0.4	0.5	**1.7**	**1.3**	**1.6**

Subgroups with more than 30 members (in both countries) are in bold

On examination of Table 8-5, younger patients appear to fare better in Australia, older patients in Manitoba. It is likely that differences in the younger age groups are mainly

accounted for by differences in SES between the two countries. That is, patients in Australia are likely to be from a higher SES than their cousins in Manitoba. The explanation for the relatively poor survival of older patients in Australia is not clear, but could be related to possible incentives for treatment that may exist when private insurance is available. This explanation is however, contentious.

It can be seen that in general, the poorer prognosis for Manitoba that is evident in the analysis of crude death rates (Table 7-4) appears to have been reduced by standardising for age. However, Manitoban patients still generally fare somewhat worse unless they are over the age of 80.

An alternative approach to the comparison of the two countries will be presented in the Cox survival analysis of Table 8-5, where Hazard Ratios for the various groups are calculated. In addition, the two cohorts are combined and comparisons made across device type, age-group and sex.

			Crude			Adjusted	
Variable	**n/N[5]**	**HR[6]**	**Lower**	**Upper**	**HR**	**Lower**	**Upper**
Brand†[1]							
IOL (index	426/2680	1.00	-	-	1.00	-	-
Heart valve	69/496	0.94	0.74	1.21	**1.51**	**1.17**	**1.96**
Pacemaker	118/566	**1.36**	**1.11**	**1.66**	**1.74**	**1.40**	**2.16**
Hip	185/2086	**0.55**	**0.46**	**0.65**	**0.82**	**0.68**	**0.98**
Vasc graft	145/633	**1.69**	**1.41**	**2.03**	**1.97**	**1.63**	**2.38**
Agegroup†[2]							
80+ (index)	341/1342	1.00	-	-	1.00	-	-
0 - 49	21/373	**0.20**	**0.13**	**0.31**	**0.18**	**0.12**	**0.28**
50 - 59	42/639	**0.23**	**0.17**	**0.32**	**0.22**	**0.16**	**0.30**
60 - 69	156/1632	**0.35**	**0.29**	**0.42**	**0.33**	**0.27**	**0.40**
70 - 79	383/2475	**0.57**	**0.49**	**0.66**	**0.55**	**0.47**	**0.63**
p for trend		<0.0001			<0.0001		
Sex†[3]							
Male (index)	449/2977	1.00	-	-	1.00	-	-
Female	494/3484	**0.76**	**0.67**	**0.87**	**0.65**	**0.57**	**0.73**
Country†[4]							
Manitoba (index)	764/4578	1.00	-	-	1.00	-	-
Australia	179/1883	**0.53**	**0.45**	**0.63**	**0.57**	**0.48**	**0.68**
Aust (IOLs only)	18/237	**0.43**	**0.27**	**0.68**	**0.46**	**0.28**	**0.73**
Aust (not IOLs)	181/1646	**0.53**	**0.44**	**0.64**	**0.59**	**0.49**	**0.71**

† Adjusted for 1=age/sex/countrye 2=tyep/sex/country 3=type/country/age 4=type/sex/age. 5 number dead/number in group. 6 HR = Hazard Ratio. **Bold** indicates significance at better than 0.05

The analysis in Table 8-5 also suggests that Manitoban patients are at greater risk of death than Australian patients when adjusted for age, device type and sex. The comparison was made with and without the IOL group, as this group varied in size between the two countries and may comprise a different cross section of patients. Any differences between the device groups nevertheless, proved to have minor effects on the overall result. This analysis compares the cohorts directly unlike the previous approach shown in Table 8-4, where standardised results are compared. The overall trends are however, similar. The survival functions are presented graphically below in Figure 8-1 and a comparison of survival for device types for the combined cohorts of both countries is shown in Figure 8-2. This figure shows again the excellent prognosis that is achieved with hip prostheses.

Figure 8-1 Survival function comparing the two cohorts

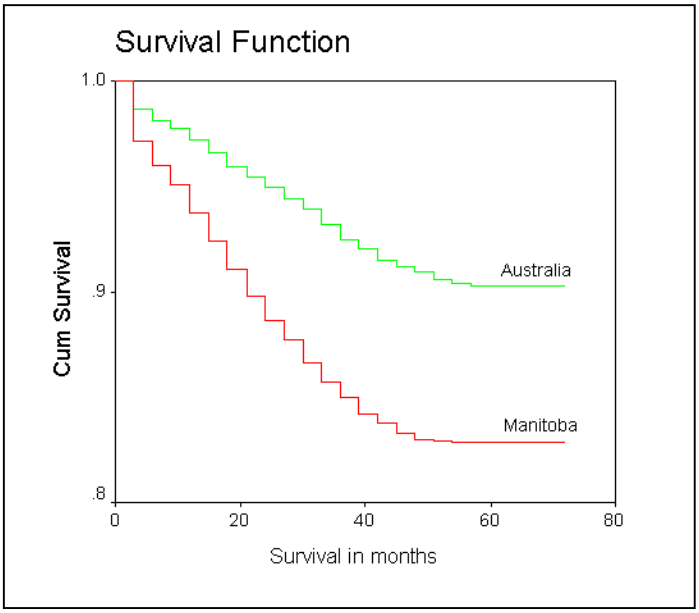
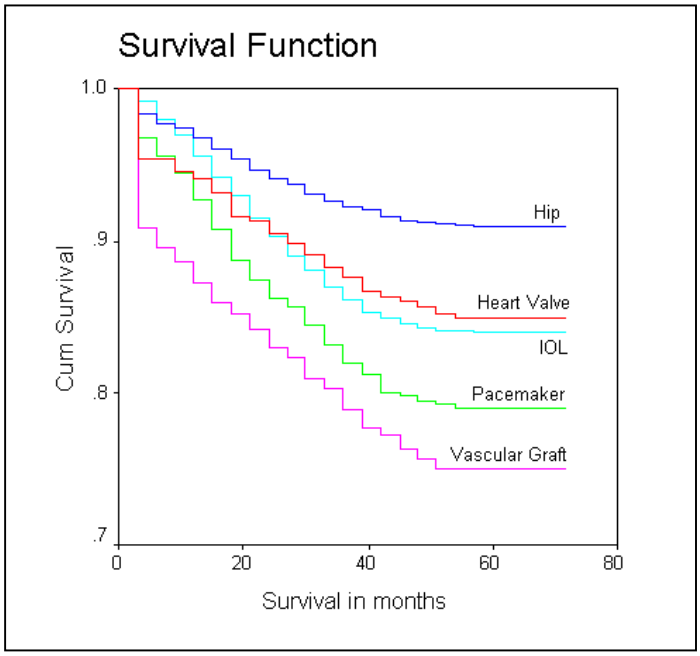


Figure 8-2 Survival function for both cohorts combined, by type of implant



8.3 Early post operative deaths compared

Deaths that occurred during the 'standard' 30 day post-operative period were compared between the two countries. A Cox regression was performed and is presented in Table 8-6.

Table 8.6 Cox regression of post-operative deaths for the two cohorts

Variable	'n/N[2]	Crude HR	Crude Lower	Crude Upper	Adjusted HR	Adjusted Lower	Adjusted Upper
Cohort‡							
Manitoba (index)	82/4578	1.00	-	-	1.00	-	-
Australia	15/1883	**0.44**	**0.26**	**0.77**	**0.31**	**0.17**	**0.54**

‡ Adjusted for 1=type/sex/age.
2 number dead/number in group. **Bold** indicates significance at 0.05 or greater.

Although numbers of deaths are small for the Australian cohort, the results suggest that Manitoba patients are at a significantly increased risk of death in the post-operative period. When adjusted for age, sex and device type the risk is three times as high for these groups of patients. This surprising result is supported by the results of a study performed by Roos et al where Manitoba hospital mortality data for the period 1979 – 1992 was compared with similar data from New England. The study reported

a significantly increased risk of post-operative death for Manitoba patients after hip fracture repair. This study utilised administrative data and suggests that long waiting-times for patients in Manitoba hospitals during the early 1990s may have contributed to these poor outcomes (Roos, Walld et al. 1996).

8.4 Discussion

In general, it appears that the chance of dying after one of these procedures is significantly greater in Manitoba. This could be the result of selection bias in the recruitment of subjects in Australia, these patients were shown in section 4.9.1 to be more likely to consent to join the study if they felt that they had achieved a favourable outcome from their procedure. In addition, privately insured patients would be expected to be from the higher SES groups and thus may have lower expected death rates than their counterparts in Manitoba. Selection bias due to 'purpose-specific' private insurance status was shown to be an unlikely influence in Figure 4-1. Members were unlikely to have had their major operation until several years after joining Medibank Private, so membership is generally not arranged with a particular operation in mind.

Another explanation for the poorer outcomes apparent in Manitoba should be considered. Not only are waiting times usually shorter for insured patients (ie the Australian cohort), but due to the extended waiting times mentioned above for this era in Manitoba, these patients may be generally more unwell by the time they reach the operating theatre for their medical device.

Possibly these results truly indicate that better health care is being provided in Australia (for insured patients), however, a wider spectrum of indicators should be examined before such a conclusion is drawn. It should also be noted that the TYPE groups will not correspond directly across the two countries. For the group having IOL operations, the procedure is fairly uniform, however the 'vascular grafts' group may include a different set of devices and a different set of procedures. The larger numbers in the Manitoban vascular graft group compared with that in Australia tend to support this (see Table 8-1). There is no internationally agreed coding system for

medical interventions. As a consequence, comparisons between countries present a challenge.

8.5 The research environment: A comparison between the Australian and Manitoban System

An entirely different culture exists around the use of health data for research in Canada, and contrasts strongly with the current situation in Australia. The two most important factors that facilitate the conduct of projects within the research-friendly environment of Manitoba are the use of a unique personal identifier and the existence of a system that manages approval for research projects in a rational centralised manner. However, it was not possible to make a full comparison between the health information systems of the two countries as national health databases were examined in Australia and these were compared with provincial (equivalent to state) datasets in Manitoba.

8.5.1 A Unique Patient Identifier UPI

The Manitoba Identifier (PHIN), allows accurate and simple (deterministic) linkage of the various health databases (within the limits of entry errors as discussed). Such an identifier is lacking in Australia, even within states. The Australian Capital Territory, New South Wales and Western Australia are however introducing their own patient identification systems at present. It would seem preferable to introduce a national identifier that would allow nationwide linkage of data. As previously mentioned, work is currently underway in the Commonwealth Department of Health and Aged Care to implement such a scheme.

8.6 Conclusion

The opportunity to compare the health data systems of the two countries has provided an interesting exposé of the strengths and weaknesses of the two systems. There is much to be learnt by Australian health policy developers from the Manitoba system. The opportunity exists to avoid various shortcomings that have become evident in their system when used for the purpose of outcome evaluation.

The existence of a streamlined process for the ethics approval of health research projects and the use of a UPI contributed greatly to the ease and accuracy of the Manitoba project. The fact that a comprehensive service data collection is maintained for the dual purposes of administration and health research has enabled a large number of research initiatives to be performed that would not be possible in Australia.

To allow the most productive use of health data in Australia, significant system changes will be necessary. In the next chapter, some of the necessary changes will be discussed.

Tracking clinical performance will require not just clinical data stored in information systems, but an integrated health information framework… Health plans should anticipate the use of computerized patient records and prepare their data management for an information framework… (The National Committee for Quality Assurance. Washington, 1999)

In the health sector... there is a growing demand to systematically assess the quality and outcomes of programs. There is also a greater emphasis on evidence-based health care. These pressures result in significant demands to collect, collate and analyse an ever-increasing volume of health data… Governments and service providers are required… to forecast trends with greater accuracy, determine the cost effectiveness of various treatments and interventions… assess the evidence basis of new and existing interventions, monitor and evaluate quality of care and health outcomes… (NHIMAC, Canberra 1999)

The major barriers to a successful comprehensive, nationwide, integrated public health surveillance and information system are a lack of appreciation for the value of high-quality provisional surveillance data and a weak societal commitment to public health.(Thacker 1994)

Chapter Nine

Information for Quality in Health Care

9.1 Introduction

The project described in the preceding chapters provided a practical demonstration of what could be achieved using national administrative databases to assess health outcomes for implantable medical devices. For this purpose, the current administrative data system has many serious shortcomings. Not only is the information lacking in detail, but access to the resource is tightly restricted.

With the growing complexity of health interventions and continual increase in costs, the need for a systemic quality management system in health care has become a priority. Pressure to implement a scheme which guarantees quality health care within a climate of 'continual improvement' has come from both consumers and providers (Wellington 1999). For any 'quality system', reliable and timely information is required about output. An integrated health data system is needed. In this chapter, the contribution that can be made to this by expanding the current administrative data system is examined. A major contribution to systematic data collection will be provided by the Electronic Patient Record (EPR).

9.2 Quality management in health care

The concept of 'quality management' initiated by W. E. Deming in the 1940s has had widespread impact on many areas of industry. Quality management includes quality control, quality improvement and quality assurance. A number of international standards have been developed to support the discipline which has several components.

- management systems (ISO 9000, ISO 14000)
- philosophies - total quality management (TQM. ISO 8402)
- methodologies - business process management, continual improvement
- tools and techniques - process charts, failure mode and effects analysis, statistical process control, quality function deployment

Eight 'principles' of quality management are described in ISO 9000. Three of these are directly applicable to the requirements of health care:

- customer-focused organisation
- process approach - continual improvement is a permanent objective of an organisation
- factual approach to decision making - effective decisions are based on the logical analysis of data

Of particular interest for providers of health services is the requirement that quality be measured from the *customer's* (patient's) point of view. There has been much discussion in the USA, the Netherlands and Germany about adapting quality management to the needs of the health care industry. Schneider, a member of the National Committee for Quality Management (NCQA) based in Washington DC, recently discusses the collection and use of health care data and suggests that effective performance measurement requires timely access to detailed and accurate data (Schneider, Riehl et al. 1999). He examines the recent NCQA report which provides a 'road map' for a health information framework:

> Tracking clinical performance will require not just clinical data stored in information systems, but an integrated health information framework. Seven features are essential to this framework:
>
> - it specifies data elements;
> - it establishes linkage capability among data elements and records;
> - it standardizes the element definitions;
> - it is automated to the greatest possible extent;
> - it specifies procedures for continually assessing data quality;
> - it maintains strict controls for protecting security and confidentiality of the data; and
> - it specifies protocols for sharing data across institutions under appropriate and well-defined circumstances.
> - The framework is not a "data warehouse". Data are not collected in a single storage area. Rather the framework creates the capacity to query existing databases used for administration and routine clinical care and merges these data for measurement.

The data is stored in a 'distributed data warehouse' which allows multiple data managers and requires agreed standards for data structure and communication formats. The report also mentions the need for computerisation of health records:

- Health plans should anticipate the use of computerized patient records and prepare their data management for an information framework by
- expanding and improving the capture and use of currently available data;
- creating an environment that rewards the automation of data;
- improving the quality of currently automated data;
- implementing national standards;
- improving clinical data management practices;
- establishing a clear commitment to protecting the confidentiality of enrollee information; and
- careful capital planning.

The report goes on to suggest that providers will most likely need some incentive to submit such information:

> Health care purchasers can provide the impetus for implementing the information framework if they demand detailed, accurate data on the quality of care.

There has been extensive debate about the need for evaluation of health and welfare services in Australia since the release of the 1979 Senate Standing Committee report on Social Welfare (Commonwealth government 1979). The report discusses the importance of defining program objectives, the need to incorporate client opinions into evaluation and the quality and availability of data. The report emphasises that evaluation should be an integral component of all agency operations and should be planned from the beginning of any new initiative. The conclusions presented in this report are still valid and important. However, with advances in information technology, we are now in a position to vastly increase the scope of evaluation and audit systems.

In 1991, the Australian commonwealth government implemented the "Review of Compensation and Professional Indemnity in Health Care" (Tito 1995). This initiative was stimulated by concerns about:

- Poor compensation arrangements for those who suffer medical mishaps and the cost and delays incurred in these settlements
- The current 'fault based' compensation scheme sometimes is in conflict with public health policies
- The current indemnity, legal and compensation arrangements are ineffective in the prevention of adverse patient outcomes.

This review resulted in the development of Quality Assurance legislation that promoted the wider use of quality assurance measures by providing for the confidentiality of information collected for the purpose of QA activities (Commonwealth Government 1994). This legislation has made feasible a number of important studies and has set the scene for a change in culture that is supportive of a quality management approach in Australian health care. The first of these studies, the Quality in Australian Health Care Study of 1993 (Wilson, Runciman et al. 1995) examined

- Underlying causes of adverse patient outcomes and factors contributing to them
- Strategies to reduce the incidence and severity of adverse patient outcomes
- Mechanisms for routinely collecting data to monitor the incidence and severity of adverse patient outcomes

In 1994, the Task Force on Quality in Australian Health Care was established. This group submitted its report to the Australian Ministers for Health in 1996, with a vision for Health Care Safety and Quality Principles. In 1999, the National Expert Advisory Group on Safety and Quality in Australian Health Care (NEAG) proposed the formation of an Australian Council for Safety and Quality in Health Care. The Council was established in February 2000. Its purpose is to coordinate the various quality improvement activities taking place around Australia and to support the transfer of results across health services, States and Territories for the benefit of others (Wooldridge 1999).

The actions highlighted in the report cover matters such as:

- improving information flow
- strengthening consumer involvement in health care
- learning from incidents and adverse events

- improving legislative arrangements to allow for thorough investigation of incidents and near misses
- improvements to formal quality improvement and accreditation mechanisms
- increasing the focus of quality and safety in education and training.

Quality management in Australian health care has now started to receive the recognition that it deserves. The introduction of a systemic quality management initiative would be well served by the development of a national integrated health information system. Some of the issues involved in the collection of data and methods of analysis are discussed below.

9.3 Health care evaluation

It is not a simple exercise to decide which parameters to examine in evaluating health services. Important work was done by Donabedian who, in the 1960s, developed a conceptual framework for quality assurance (Donabedian 1966). He classifies health service variables into three categories; structure, process and outcomes. The term 'structure' is used to refer to the institutional components of health services including size and complexity of hospitals and facilities. 'Process' is concerned with the functioning of the hospital and the implementation of treatments. It is focussed on what happens to the patient while under medical care. Measurements of process assume a correlation with patient outcomes that may be unclear. 'Outcomes' measurement involves the use of end results of medical care as a measure of its effectiveness, patient satisfaction of various proxies such as infection rates, extent of return to normal function, complication rates and mortality are commonly used. (These are the 'five Ds': Death, Disease, Disability, Discomfort and Dissatisfaction.) There are of course many confounders and ultimately it is difficult to attribute 'good health' to a specific cause.

Donabedian discusses the desirability of examining outcomes as a measure of the quality or success of health care. Correct choice of *which* outcome is crucial and some outcomes are easier to measure than others (death being the easiest and least disputable). Measures of patient satisfaction and physical or social disability appear to be more relevant to the individual but are less tangible. Fortunately, some advances have been made since the time of his writing with the development of quality-of-life instruments. He suggests also

that it is valid to examine the *process* of care itself; if one assumes the value of treatments provided, then examination of the process of provision of such services will give an indication of the adequacy of care provided. A much simpler approach is to measure 'structure'; to examine the settings and instrumentalities of health care provision, the adequacy of facilities and equipment, ie the 'plant' required. This approach is of course based on the assumption that good facilities will lead to good care. Despite its obvious limitations, this is a frequently chosen method of assessing and comparing health services between different areas and countries.

Over the last fifteen years there has been a high level of enthusiasm in the USA and other countries for the examination of health care outcomes in the quest to improve the quality of care. One of the reasons for this enthusiasm is the concern that for the majority of health services, the association between desired outcomes and process or structure of care is unproven (Hammermeister, Shroyer et al. 1995). Hammermeister argues that for optimal and efficient assessment and improvement of quality of care, the use of all three elements of Donabedian's triad of quality will be required. Currently, the principal 'outcomes' measures used have been mortality and morbidity; functional and general health status, which relate more closely to the patient's day to day experience, are of course more difficult to assess and interpret.

Process based measures of health care are those that are based on observing the activities conducted in the hospital to draw conclusions about outcomes.

> Quality measures can be based on either achieving health care outcomes or completing processes that experts agree have been shown by scientific evidence to improve outcomes. Process based measures are especially suitable when the user needs to know how to improve quality… When measures are needed to evaluate health care that is intended to improve long-term outcomes. (Palmer 1997)

The examination of service record data to evaluate health outcomes that has been presented here in the Medical Devices study, fits best into the 'process' and 'outcome' categories. The analysis assumes that services are only used if there is a need for them (ie perceived ill health). Such use examines the 'process' of health care at the patient level. 'Outcomes' too are contained in this data in the sense that treatments (process) may cause changes in service use patterns and thus infer an outcome. The use of

mortality and patient satisfaction assessments also falls under the 'outcomes' classification.

9.3.1 Randomised controlled trials v service data analysis

It is generally agreed that the randomised controlled trial (RCT) is the gold standard for evaluation of interventions. There are however, several reasons why it is often not practical to utilise this approach. The principal reasons include the high cost of implementing RCTs; ethical constraints which prohibit randomisation of treatments; and the fact that a formal RCT often does not reflect real life clinical practice and is thus only useful in the early stages of the evaluation of a new treatment. A clinical trial may only examine a specific subgroup of patients (sometimes for example, only males) these patients are then treated in optimal circumstances by trained, motivated practitioners. In this artificial setting it could be expected that the 'Hawthorne effect' would account for a significant part of the so-called placebo effect – ie because subjects perceive themselves to be of special interest to the researchers, outcomes are improved. The requirement for informed consent ensures that subjects know that they are being studied and thus it is not possible to avoid this effect.

Flood (Flood 1990), considers that

> …large data bases, despite their many known faults, are an important and currently under-tapped resource for assessing quality of care.

She mentions Brook's important distinction between efficacy and effectiveness in the applicability of large databases to the evaluation of technology (Brook and Lohr 1985). *Efficacy* in medical care refers to the capability of medical technology to improve the outcomes of patients, while *effectiveness* of medical care refers to the capability of the provider to realise the outcomes expected from a technology. With the former, the technology is under investigation, with the latter, the skill of the operator. In studies of efficacy, it has been generally agreed that RCTs are the preferred approach. Flood argues that for the assessment of effectiveness, the RCT is inferior to the use of database analysis for several reasons. The reasons include the ethical problem of random assignment of patients to suspected inferior treatments and the 'hothouse' nature of most formal clinical trials. Large databases reflect real world clinical situations far more accurately than rigid clinical trials and with the addition of clinical data made possible by

linkage with other databases, can provide a cost-effective, large scale resource of accurate and complete data.

However, subtle selection bias problems do exist for administrative databases. These problems can be exacerbated in those lacking clinical detail. Record linkage studies reported by Roos (Roos, Wennberg et al. 1989) and also Hargreave (Hargreave, Heynes et al. 1996) suggested that transurethral prostatectomy (TURP) had a higher long term mortality than the seemingly more invasive procedure of open prostatectomy. These conclusions were rigorously evaluated by Fisher et al (Fisher, Malenka et al. 1990) who performed detailed chart reviews for all open prostatectomy cases and a sample of TURP cases using case data from a teaching hospital in Manitoba which supported the conclusions. Because this finding was counter-intuitive, randomised trials were called for – it was assumed that comorbidities not included in the datasets (or case notes) were pivotal in the choice made by surgeons about which procedure to adopt. It was thought that sicker patients had been offered the less invasive treatment, thus leading to an unmeasurable selection bias. It appears that this was in fact the case. Reports by Concato (Concato, Horwitz et al. 1992) and also Crowley (Crowley, Horowitz et al. 1995), with additional information on comorbidity and degree of illness, found no significant difference. This result provides both a warning for those interpreting the results of large database analysis and a stimulus to health care managers to choose carefully the clinical data that must be added to health databases if they are to be used for outcomes evaluation.

Hannan et al performed a study comparing the usefulness of administrative versus clinical data for predicting in-hospital mortality. They used administrative information from the Health Care Financing Administration (HCFA) and data from the cardiac surgery reporting system (CSRS) of New York state (Hannan, Racz et al. 1997). Two suggestions are made to deal with the problems associated with using only administrative data for outcomes analysis;

> Efforts to distinguish complications of care from comorbidities should be undertaken.
>
> Much more accurate assessment may be obtained by appending a limited number of clinical data elements to administrative data before assessing outcomes.

They conclude that, although administrative data have been widely used to screen for quality of care problems, they are not well suited for use in assessing quality of care without the addition of clinical detail. The addition of just three clinical data elements to the administrative data eliminated much of the difference in effectiveness of the two datasets. They recommend that to support the use of administrative data for outcomes assessment, a) limited clinical data and, b) information indicating whether a comorbidity exists at the time of admission should be included. The latter has already been implemented in California state and in the New York system (SPARCS).

It is generally agreed that very few medical interventions and policies have been adequately evaluated; Hornberger estimates that only 20% of clinical policies are based on randomised studies. He supports the cautious use of observational data to support policy development (Hornberger and Wrone 1997).

> Advances in information systems permit the collection of observational clinical and administrative data. The relative ease and low cost with which such data can be analysed offers an attractive alternative to randomised trials at a time when pressures are mounting to quickly identify clinical policies that promise to maintain or improve health outcomes while containing the growth of health expenditures. However, medical history has repeatedly shown the risks of relying too heavily on only the analyses of observational data. (p 702)

He cautions that mechanisms must be developed to assess the validity of conclusions drawn from analyses of large databases.

Temple of the FDA expresses concern about another problem common to studies utilising health databases (Temple 1990). He mentions the problem of 'multiple comparisons', (otherwise known as 'data-dredging' or 'data-mining'), where repeated analyses are performed until one is found to be significant. This is a controversial approach; while it is discouraged in research institutions, it is commonly practiced in industry and has obvious benefits. The pursuit is particularly tempting for researchers with large amounts of raw electronic data at their disposal and can only be 'justified' academically by the routine prior identification of primary end-points in the study protocol.

Iezzoni, more enthusiastically, suggests that administrative data are probably most useful as a screening tool to highlight areas for further in-depth investigation

> Although the clinical content of administrative data includes only the demographic characteristics and diagnoses of patients and codes for procedures, these data are often used to evaluate the quality of health care, Administrative data are readily available are inexpensive to acquire, are computer readable and typically encompass large populations. They have identified startling practice variations across small geographic areas and supported research about outcomes of care. (Iezzoni 1997 p666)

The potential to utilise very large numbers of patients with the associated statistical power is appealing to researchers, especially for the detection of rare outcomes. There has been a high level of interest amongst researchers and government funding agencies over the last decade as large health care databases have become more commonplace. The data are particularly appealing because of their coverage of large numbers of patients, unbiased representation of ordinary medical practice, availability and (potentially at least), low cost. The wide use of administrative data in the 1970s and early 1980s to describe variations in practice patterns across different jurisdictions had provided evidence of the potential power of this tool. Similarly changes in the type of treatments used were monitored, for example the rapid increase in the use of the prosthetic hip (Roos and Lyttle 1985). Operation rates were tracked between 1973 and 1978, mortality rates and 'days in hospital' were both found to reduce as a result of the new treatment.

9.4 Limitations and strengths of administrative databases for health outcomes evaluation

Ray summarises the limitations of administrative databases for outcomes evaluation. Although they have been used for this purpose, they are not designed for such use and as a result have deficiencies which reduce their applicability. Foremost amongst the problems are poor data quality, lack of concurrent controls and the effects of comorbidity. Service use may be used as a marker for outcomes, however, the less serious or asymptomatic events will not be detected.

> Outcomes may represent changes in health status or utilization of medical care.
>
> hospitalisation, nursing home residence and use of medications in the past year are important predictive factors for various diseases. (Ray 1997)

Administrative databases have been used for analysis of the effects of policy change, for example the effects of changes in the US Medicaid programs to restrict drug

reimbursement (Soumerai, Ross-Degnan et al. 1993). The Medicaid database has also been useful in showing that the history of medical care encounters provides a surrogate for case-mix.

Roos et al note the advantages of using administrative data for health research, which includes: (Roos, Roos et al. 1989) (my comments in italics)

- Population based
- If linked, can provide data for 'effectiveness studies'
- Large n, over considerable time spans
- Immune to patient recall bias
- No consent bias *(this is not so in Australia!)*
- Multiple hypothesis testing *(caution should be exercised here)*
- Flexibility possible in design during the study
- Data sets can be used for multiple studies
- Possible to evaluate 'risks' of therapies, old and new.
- Modelling of probabilities is possible following an index event.

Selby mentions the opportunities available to researchers with increasing coverage of electronic health databases managed by the various US Health Management Organisations (HMO) (Selby 1997). There were 12 members of the "HMO Research Network" at the time of writing . The capture of the 'complete health care experience' of large representative populations is an impressive resource. However, there is a lack of data about comorbidity and the relative severity of disease. He points out that with large numbers of service events, the relevance of rates of events and service utilisation to public health increases. These data collections include costs and descriptions of service and are accurate enough to support cost effectiveness analyses (Simon, VonKorff et al. 1996). Costs can also be used to provide a mechanism to compare total utilisation rates between groups of patients. Simon cites two examples typical of HMO research; one on the effect of a co-payment at Outpatient Department attendance on patients' health; the other on variation in the rate of use of angiography and re-vascularisation.

9.4.1 Validity of administrative data for research purposes

The bulk of health service research is currently conducted using massed de-identified data; such broad service delivery parameters as numbers of operations per month, waiting times, and Diagnosis Related Groups (DRG) estimations can be deduced from this type of information. However, to determine treatment outcomes and individual patterns of service use and to link data from more than one source requires a unique personal identifier. The potential use of such data for outcomes research cannot be realised using de-identified data. This fact provides one of the most compelling justifications for the inclusion and maintenance of identifiers when collecting health service data.

Information included in administrative data sets such as time in hospital and mortality is usually both available and reliable, however, details such as procedure codes, diagnoses and other treatments (including pharmaceuticals and nursing services) are usually not. The reliability of procedure codes can be undermined by various influences including 'code creep' - where a financial incentive exists for the hospital to upgrade the coded severity of a clinical incident. The reliability of diagnostic coding is also suspect. The process of coding for a principal and other significant diagnoses from a lengthy medical record by the junior registrar or medical records clerk cannot be expected to be definitive. An additional problem with using administrative data is the possible difference between the population represented in the data set and the population of interest. This introduces a bias that is usually not able to be quantified. Associations derived from analysis of these data remain only suggestive. The analysis is purely a descriptive one. The value of this approach should not be discounted but it should be realised that follow up investigations of a controlled nature will usually be necessary to confirm suggested associations.

A significant USA initiative was funded in 1992 to investigate (inter alia), the potential of using claims data. The project was managed by the Agency for Health Care Policy and Research (AHCPR) and the Office of Technology Assessment (OTA). The purpose was to conduct research to identify effective medical care and the relative cost-effectiveness of different approaches to the provision of care. An attempt was also made to assess whether particular medical interventions can actually improve people's health. The project stressed the potential for the use of claims data in 'determining the outcomes, effectiveness and appropriateness' of different therapies. A series of studies was

established by the Patient Outcomes Research Teams (PORT). A number of these interdisciplinary teams were funded to study specific medical conditions and the effectiveness of medical practice to diagnose, treat and manage these conditions (OTA 1994).

The most demonstrably successful of these PORT studies was one designed to investigate the outcomes of cataract surgery. The cohort included almost 338,000 patients, half the number of patients who received this procedure in the year of study across the USA. This study detected an increased risk of retinal detachment after the use of laser capsulotomy, a finding that would have been unlikely to have been achievable using any other approach (Javitt, Vitale et al. 1991). Nevertheless, these contentious results were disputed in the profession. The criticism was that the data were critically limited in that the researchers could not be certain whether the adverse event occurred in the operated eye or its companion. Such limitations are typical of the type of inadequacies found in administrative data sets. A further study was funded to investigate this question, a nested case control study was conducted with the addition of clinical data (Tielsch, Legro et al. 1996). The results confirmed the original conclusions and the entire process provided a useful demonstration of both the power of database research and its weaknesses.

The overall conclusions of the OTA review were mixed: it was suggested that administrative databases as they currently exist, do not contain sufficient complete clinical detail to reliably support outcomes analysis. This conclusion would of course be expected as these databases are invariably designed for accounting purposes. Without the ability to link the data electronically to detailed patient histories, it would be surprising if administrative data alone would be sufficient to provide a substitute for actual clinical trial data.

> Administrative databases have not proved useful in answering questions about the comparative effectiveness of alternative medical treatments…
>
> Administrative databases are very useful for descriptive purposes, (eg exploring variations in treatment patterns) but the practical and theoretical limitations of this research technique usually prevent it from being able to provide credible answers regarding which technologies, amongst alternatives, work best.

The collection of credible data

> demands a trade-off, - the credibility of clinical data versus the expense and feasibility of data collection. (OTA 1994)

It was suggested that it was possible to distil three dimensions of quality from administrative data: access, limited 'outcomes' (eg death) and limited 'process'. Usefulness naturally increased if diagnostic data were included in the database. Administrative data provide a useful screening tool that highlights areas in which quality should be investigated in greater depth by using detailed clinical information. The report concluded that research using administrative data can provide the 'signal' for further investigation. Such results from the screening phase, should not be published as gospel until this detailed investigation has been completed. However, in certain situations, where serious adverse effects are detected early by a screening process, it would seem unethical to withhold such information.

The use of current administrative data was also supported for identifying potential participants for prospective studies (cases and controls), identifying rare adverse events, estimating costs and measuring selected outcomes. In spite of the rather restrained support from this major 1994 review, with the inevitable (but so far slow) introduction of electronic clinical records, the potential for research use of linked administrative data appears to be most promising. There will of course be issues concerning privacy protection to be resolved, but even with current technology, these are surmountable. Initial work in this area is occurring within the HMO system in the USA. It includes the integration of disparate clinical records from separate organisations that are merged in cooperation with an academic institution (Kahn 1997).

9.5 Privacy protection and the collection of health data

Health care records are considered to be one of the most intimate and sensitive forms of personal information. The need for health care information and the need for personal privacy will to some extent, always be in conflict. Since the failed introduction of the Australia Card Bill in 1985, public opinion has been said to be strongly opposed to the introduction of any means by which government could monitor activities of an individual (Sibthorpe, Kliewer et al. 1995).

The Australia Card program was the result of a perceived need for taxation reform. It was proposed that a unique identifier for each Australian would lead to reduction of tax evasion and incorrect payments of health and welfare benefits and would assist government agencies to more effectively carry out their functions (HIC 1986). The proposal was rejected by the 'Joint Select Committee on an Australia Card' because the committee was not convinced that the Card would achieve these objectives and was concerned that its introduction would threaten the privacy of individuals. Instead, a number of alternative taxation reforms were proposed.

Some earlier debate had been conducted regarding the potential to use demographic data collected for the Australia Card as a resource for epidemiological and statistical purposes. However, the concept was rejected as being too sensitive to include in the initial proposal. It was recommended that these further issues should be referred to the Australian Law Reform Commission for report and be subjected to community debate before the development of legislation (Parliament 1986). Such public debate and the development of appropriate legislation has again become topical in 2000 and resolution of these issues will be essential before further advances in the collection and use of health care data are possible.

Subsequent to the defeat of the Australia Card proposal, the Privacy Bill of 1986 made a general exception from Information Privacy Principle II for medical research. This was however, removed from the Privacy Act as a result of public criticism. The Privacy Commissioner noted that:

> While not doubting the critical role of good medical research for the Australian community, to have left medical research as a general exception to IPPs would have been widely condemned. (O'Connor 1989)

It is intriguing to compare recent debate about the privacy implications of record linkage and electronic medical information in Australia with the debate that occurred in Canada and the USA in the 1970s. At that time there was a move to press industry and government to take responsibility for collecting information that would facilitate the epidemiological follow up for the detection and measurement of delayed risks. A resolution of the 1975 Canadian Policy Conference of the United Steel workers of America called upon federal and provincial governments to:

> Enact legislation providing for… a complete work history of every industrial worker which, coupled with a complete medical profile, will enable us to quickly identify and eliminate potentially hazardous working conditions. (Valentine 1978)

Partially in response to these public sentiments, the USA had decided to create their National Death Index, but they were also responding to the fact that,

> Pressure was growing in Congress to remove some of the obstacles that the Privacy Act of 1974 has placed in the way of the solution of environmental health problems by epidemiological means. (Editorial 1979)

Unfortunately for the cause of health care evaluation both in the USA and Australia, influential voices in health care politics and the privacy lobby would have it believed that popular opinion has swung away from this perspective. Perhaps even that individual privacy is valued above personal or community health. There has been some recent moderation of this extreme position; a report from the Consumers Health Forum supports the concept of 'parallel objectives' of personal privacy and community benefit, and that cooperation between consumers and organisations wanting to use peoples' personal health information would be productive (CHF 1998).

9.6 The relationship between illness and service use

Why do people become patients and seek out health care services? Health care is not a 'good' in the traditional economic sense and its consumption cannot be described by simple supply and demand market psychology.

Social and behavioural factors associated with health service use have been examined in studies performed in Sweden and the USA and more recently in Australia (McCallum, Lonergan et al. 1993). The original 'behavioural model' developed in the 1970s by Andersen has been expanded by Coulton and Frost (Coulton and Frost 1982) and is widely used. It proposes that levels of health care use can be explained by three general categories of variables:

Predisposing age, sex, ethnicity, living arrangements, marital status.

Enabling private health insurance, employment status, education, income, family support, social isolation (these

> factors indicate an ability to use health care services if the need arises)
>
> **Needs** depression, physical function, social function, role impact of physical health, presence of a health condition.

McCallum (McCallum, Simons et al. 1996) discusses the relationship between White's 'disturbance in sense of wellbeing' of the patient and their use of health services. It is argued that given predisposing and enabling factors, people use health services when they need them because of symptoms of ill health (McCallum, Simons et al. 1996). Thus since around 80% of the variance for health service use (in Northern USA and in an Australian study) is accounted for by the 'need' variables, it could be suggested that the number or amount of service use by patients should be closely correlated with the degree of their 'need' and thus their degree of 'sickness'.

A small amount of work has been done to provide further evidence for this contention; an association was found by Wolinsky between high hospitalisation rates and poor perceived health plus prior hospitalisation (Wolinsky, Stump et al. 1995). Stump writes of an association between functional status and clinician utilisation;

> Declines in each of the functional status measures are significantly associated with increases in physician utilization.. (Stump, Johnson et al. 1995)

Mor mentions a link between baseline functioning and hospital use:

> Both baseline functioning and functional change were related to hospitalization. … it documents the link between functional decline and increased hospital use. (Mor, Wilcox et al. 1994)

White suggests that information about mortality and morbidity is of limited value in describing actions taken by individual physicians and patients about disease and ill-health. He suggests that:

> …in the context of medical care, the patient may be a more relevant primary unit of observation than the disease, visit or admission. … Little is known about the process by which persons perceiving some disturbance in their sense of well-being or health decide to seek help. (White, Williams et al. 1961)

However it is known that few will seek out health care if they do not perceive 'some disturbance'.

Due to the nature of the data contained in datasets whose collection is motivated by the needs of managers and accountants, it is risky to infer clinical cause and effect relationships. Certain patterns of service usage are of course highly suggestive of associations between interventions and their results. For example if a large number of patients treated with a new drug were observed to subsequently require hospital admission for a certain investigation, it would be reasonable to closely examine the reasons for this. However most 'associations' are not clear-cut and the confounding effects of co-morbidity are hard to control for.

Because most Australian national datasets are lacking in patient identifiers as well as clinical data, their usefulness for health outcomes research is further limited. The Medicare database is almost totally lacking in clinical or diagnostic detail, while the Hospital Morbidity dataset, although containing information on diagnoses, procedures and providers, is de-identified. Thus outcomes research based on these data cannot at present rely on the approach generally used whereby inferences are made about cause and effect of treatments by analysing clinical (ICD-9) codes.

In an attempt to deal with these data limitations, rates and costs of service use were examined in the Medical Devices study, and only general comments made about the relationship between interventions and the ensuing health status of patients. Where large numbers of patient records are available, changes in rate and type of service use appear to be useful indicators of the effects of specific interventions, both beneficial and adverse.

9.7 Measures and metrics of health status

Administrative databases are used increasingly to study, monitor and improve health resource allocation. As has been described, they are also occasionally used to assess health outcomes. Suggestions were made that problems associated with using administrative data for the purpose of researching health outcomes can be off-set by the inclusion of clinical data. Determining which clinical parameters to include is of fundamental importance.

Clancy et al describe the need to measure health outcomes and the problems of defining what is to be measured (Clancy and Eisenberg 1998). The challenge has stimulated

researchers to expand the methods and metrics used to evaluate the effects of health services. Traditional assessment of mortality, and various surrogate measures of 'health' such as blood pressure and laboratory parameters are not closely related to outcomes or patients' subjective health status. Measuring definable clinical events may be useful for health care planners but has little relevance to the individual. Subjective measures of health status should be regarded with respect; it has been shown in many studies over many populations that an individual's rating of their overall health is a powerful predictor of mortality and that this far surpasses the usefulness of other more 'objective' measures (Kaplan and Camacho 1983),(Yu, Kean et al. 1998),(Moum 1992).

Clancy goes on to summarise the various parameters used to define the dimensions of health status including functional measures, preference based measures and patient satisfaction. Since measures of patient satisfaction and clinical severity are rarely available within the databases, process measures such as the number and cost of services must be used as a proxy for morbidity. This approach may provide a mechanism for generating an objective measure of the utility of treatments and thus allow assessment and surveillance of medical interventions from limited administrative data alone.

Palmer is optimistic about the future for the use of process data that has been augmented with additional clinical data as a result of the increasing use of data capture for electronic records (Palmer 1997). Iezzoni suggests that with the introduction of integrated electronic patient records, the development and use of standardised coding systems and data transmission formats (eg Health Level 7) (Murray, Anderson et al. 1995),(HL7-WG 1987-99), vast amounts of accurate clinical information will be generated as a by-product. Systems for the standardised coding of diseases (ICD9 CM and ICD 10 CM), medical terms (SNOMED) and others are being incorporated into the Unified Medical Language System (UMLS) by the National Library of Medicine (Cimino 1996),(Payne and Martin 1993). With the rapid advances in networking technology and its implementation, access to data and linkage of this data can be made readily available to researchers and practitioners.

9.8 Discussion

The recent recommendation for the establishment of an Australian Council for Safety and Quality in Health Care provides evidence of the mounting interest in a national coordinated approach to quality management in Australian health care. Data collection will be improved and the sharing of information increased.

Opinions vary about the value of administrative data for examining the outcomes of health care. However, there is general agreement that administrative data combined with basic clinical detail can provide a unique resource for health care evaluation. The collection of computerised clinical data will continue to grow rapidly with the inevitable introduction of electronic patient records. The impetus for of a combined administrative and clinical database is already becoming evident. The two components are most efficiently combined to form an Integrated Health Record and Information System (IHRIS) and if properly managed, could provide a cost-effective information resource for a systemic quality management system.

To allow implementation of this system, structural changes will be required within the current administrative organisation. Re-assessment of the parallel interests of public health and individual privacy will have to be achieved. Communication infrastructure will be necessary to connect doctors, hospitals and administrators. Existing barriers between state and Commonwealth funders will have to be resolved. To achieve this cultural change will be challenging, but with the political and economic imperative of maximising cost-effectiveness, combined with an increasing public concern for quality assurance in health care, it cannot be ignored.

In the final chapter, the findings of the project are summarised, recent Australian developments in quality and safety management are discussed, and a vision for an IHRIS is presented.

Chapter Ten

A National Health Information System

10.1 Introduction

Despite the sophistication of modern health care, remarkably little is known about the effectiveness of medical treatments or the rates of adverse events resulting from them. This is surprising in a society where quality management has become one of the cornerstones of contemporary industrial practice. The situation exists despite the fact that vast amounts of service event data are routinely collected for administrative purposes. With minor modifications, this data collection could provide an economical resource for the analysis of outcomes, surveillance and product registries. For a variety of reasons, this potential has not yet been realised.

The research described in this thesis was conducted to investigate the potential for health outcomes evaluation and surveillance in Australia using administrative data and to examine the ethical, methodological, political and practical issues involved in its use. The study assessed the current availability of health service data to researchers and the quality and usefulness of those data. The results provide support for an expansion of the current data management system as part of a more comprehensive Integrated Health Record and Information System (IHRIS) (Mount, Kelman et al. 2000). In addition to managing patient records for clinical care, an IHRIS would facilitate the collection of administrative data and would generate a resource for the monitoring of all treatments, including drugs, medical devices and medical and surgical procedures. An IHRIS should itself be introduced as a component of, and a contributor to, a systemic quality management system for health care on a nation-wide basis.

Recent developments in Information Technology provide the foundation for these initiatives. The progressive introduction of the Electronic Patient Record (EPR) and the widespread availability of the Internet could provide the electronic platform for an IHRIS.

There are many barriers to be overcome before such a scheme could be implemented. I believe that all of these barriers are surmountable. However, to create a fully

integrated health care system, changes will be necessary at all levels of the health care industry. In this chapter, results of the Medical Devices study are summarised. Recent support for the introduction of quality management into health care is discussed and various suggestions for enabling the development of an IHRIS are presented.

10.2 Quality management in health care: Recent initiatives

In July 1998 the Australian Health Ministers asked The National Expert Group on Safety and Quality in Health Care to identify national goals for safety and quality in health care. The final report "Implementing Safety and Quality Enhancement in Health Care" was released in July 1999 (DHAC 1999). This report is highly supportive of the introduction of a quality management culture, and suggests the need for the integrated management of health care data both at the patient and systemic level. It strongly supports the systematic collection of adverse event data and emphasises the need for legislative provision to be made to ensure the protection of those engaged in the investigation of incidents. The following extracts indicate the support for establishing a quality management culture.

Recommendation 2 indicates the basic philosophy:

- That Health Ministers support the need for national actions for safety and quality enhancement in the following areas:
- Strengthening the consumer voice
- Fostering best clinical practice
- Learning from incidents, adverse events and complaints
- Developing frameworks for quality improvement and management
- Developing information systems to support quality
- Education and training for safety and quality improvement (p 18)

A number of 'national actions' are presented in the report. Some of these will provide a catalyst for the transition to a quality management culture, others are supportive of the introduction of an IHRIS:

- Support methods to enable increased consumer participation in health care.
- Facilitate implementation of evidence-based practice
- Develop strategies and partnerships to improve information flows between all parties about areas for quality improvement…
- Develop legislative changes that will allow the detailed, thorough investigation of adverse events…
- Facilitate agreement on common systems for the collection and analysis of incidents, adverse events and complaints
- Develop a national framework for health service performance measurement and reporting
- Facilitate improvements in the quality of current accreditation mechanisms that address the safety and quality of the systems in operation.
- Facilitate improvements to the design and management of the health system that promote smoother transitions for consumers across health service boundaries.
- Research and develop clinical and administrative information systems that have a system-wide focus and application.
- Agree on national requirements for education and training for all health care providers to support their involvement in quality management and collaborative approaches to health care delivery. (p v)

Strong support is given to the development of information systems that support quality management. The agenda is:

- To promote a nationally uniform approach to more effective information management within the health sector
- To promote the efficient and effective use of information technology in health.
- To develop a partnership with the private health and information technology sectors.
- To encourage the development of a market for Australian health information technology and services.
- To protect the public interest, particularly in relation to privacy. (p 16)

National Action number 9 is to:

> Research and develop clinical and administrative information systems that have a system-wide focus and application. (p 16)

In response to this report, the "Australian Council for Safety and Quality in Health Care" was established in February 2000 by the federal Minister for Health. Its role is to lead national efforts to promote systemic improvements in the safety and quality of health care in Australia with a particular focus on minimising the likelihood of error (ACSQHC 2000). The council identified a number of priority areas in which it will focus its efforts, they include:

- Develop and implement a national strategy which ensures that Australia has in place the required national reporting systems and datasets to inform change in priority areas for safety improvement.
- Promote quality and compatibility of national datasets
- Ensure that practicing clinicians, health administrators, consumers and other key stakeholders have meaningful and accurate access to feedback from national datasets.
- Promoting effective approaches to clinical governance and accountability which address the competence of(both)organisations and individuals
- Redesigning systems and creating a culture of safety within health care organisations. (pp 3,4)

10.3 The vision: An Integrated Health Record and Information System (IHRIS)

The 'National Expert Advisory Group' and the 'Council' recommendations for the development of clinical and administrative information systems are consistent with the conclusions of this thesis. No detail is given about the design of the health information system that is suggested in the report. The system will, nevertheless, be required to manage population data for adverse event detection and performance measurement as well as clinical records for individual patients. In addition to this it will need to fulfil the functions of the existing health administration system. Although it would be possible to achieve some of the stated goals with separate information systems designed for specific purposes, an integrated information system would appear to be more efficient. There are many different possible architectures for such a system. Before discussing the limitations of the current information systems, a brief description of a possible IHRIS implementation is presented.

10.3.1 Development of an IHRIS

The development of an IHRIS will be an 'organic' process. Designers will need to be sensitive to the needs of all stakeholders. The architecture of the system will be

dependent on the technology available at the time. This area is evolving rapidly and a new system should include the flexibility to incorporate appropriate advances in technology as they become available.

Introduction of an integrated system will involve changes at all levels in health care. Essential components for the establishment of an integrated system will include national legislation to provide consistent powers across the country, the establishment of unifying guidelines to ensure uniform data formats, standards and communication protocols and nationally accepted security mechanisms. The success of such a system will rely heavily upon a sense of community ownership and to achieve this, consumer and provider involvement will be essential from the beginning.

10.3.2 The IHRIS system architecture

The IHRIS will be based on a networked system in order to provide national coverage and ready access for patients to their records. It would not be possible to implement a successful system based on patient-held records. Whether the new system is based on a centralised or a distributed database is a matter that will require debate. Taking into account the many stakeholders and their multiple motivations and interests, it would seem likely that a distributed data system would be chosen.

There are a number of choices for connecting the various providers and the distributed data centres. It will be necessary to connect all medical practices, hospitals, laboratories, pharmacies and administrative centres via a network of hubs located around the country. With the increasing speed and availability of the Internet, it would appear that this existing infrastructure would be worthy of investigation. Other possibilities include the purchase of bandwidth on commercial networks. This is the approach currently used by the HIC and various telecommunication providers.

10.3.3 Communications standards

Agreed standards will be required for the exchange of health care data by electronic means. Many of these standards are already in existence. It would be important for government to manage the introduction of a consistent national approach to ensure that all health information and communications systems are compatible. A repeat of the state ‘rail gauge’ problem must be avoided.

10.3.4 *Standard datasets*

Standardised minimum datasets will need to be defined. These will include the basic, essential detail generated from each health care encounter. All services including hospital care, community care, primary care, pathology, radiology, nursing, out-patient care and pharmacies will need to be included.

This 'minimum data' could be collected by the various providers as a function of a computerised practice-management program. A range of these programs is already becoming available from a number of commercial software developers. The early development of agreed formats for health care data and communications will encourage these initiatives.

10.3.5 Patient records and ownership

Patient records will most appropriately be controlled and owned by the patients themselves. Access to stored personal data will be controlled by some form of personal code possibly stored on a 'smart card'. An extract of their health care record may also be stored on this card. However their primary record will be stored in a secure and purpose designed database managed at the local level for a number of practices. The management of these local data repositories will require careful planning and could develop into a significant new industry. It is possible, in the case of general practice for example, that regional groups (or Divisions) will take on this responsibility. Management at the individual practitioner level is not practical because of the requirement that information must be available on-line at all times. Management of data security and the provision of adequate backup facilities calls for specialised expertise to assist providers to achieve the required standards.

10.3.6 Intellectual property of providers

One of the issues that has generated debate is the ownership of the 'intellectual property' contained in medical records. While significant further discussion will be needed to resolve this issue, it is evident that there are basically two components to a medical record – The first or 'institutional' component includes objective and derived information about the patient including demographic details, medical history, diagnoses, investigations and treatments ordered. The content will be at or greater

than the level described by the minimum dataset. The second component constitutes a 'personal note pad' for comments relevant to the case – an 'aide memoire' for the doctor or nurse. In order to preserve completeness and accuracy it will be necessary to define an approach that will encourage both doctor and patient to continue to contribute to this combined document that constitutes a patient's medical history. A system that does not provide for a clinician to make informal notes and comments would constitute an impediment to good clinical practice.

This dilemma could easily be handled by practice-management software. The personal note section will require a high level of protection, however the institutional component should be accessible by the patient and other selected clinical staff as appropriate.

10.3.7 Security

Standards will need to be developed for minimum levels of required security. With current information technology, security is achievable at 'military' standards. The challenge will be to establish management structures within institutions that ensure access to personal information is restricted to relevant persons. This challenge is currently being confronted in several countries including the UK and some provinces of Canada.

10.3.8 Access to data for the monitoring of health care

The large amount of accurate and current health care data that would be collected by an integrated system would allow for detailed analysis of health outcomes, interventions and surveillance for adverse events. Much of this could be achieved with automated systems that would produce results without requiring investigator involvement, thereby ensuring personal privacy.

In clinical care, personal health data would only be available to health care staff with the consent of the patient.[1] For the purpose of research, several options would need to be considered. Patients could be allowed to 'opt-out' of the research side of the system. This may be the most appropriate manner to establish public confidence in the system, although it would potentially introduce bias into research data. Public education could be conducted to emphasise the benefits of allowing one's information to be used for research purposes, such as the opportunity for early advice regarding possible adverse events associated with drugs or devices. Some persons would be happy to contribute to a system which they considered of community benefit.

1 The system must include the facility to allow emergency access to a patient record in certain clinical situations.

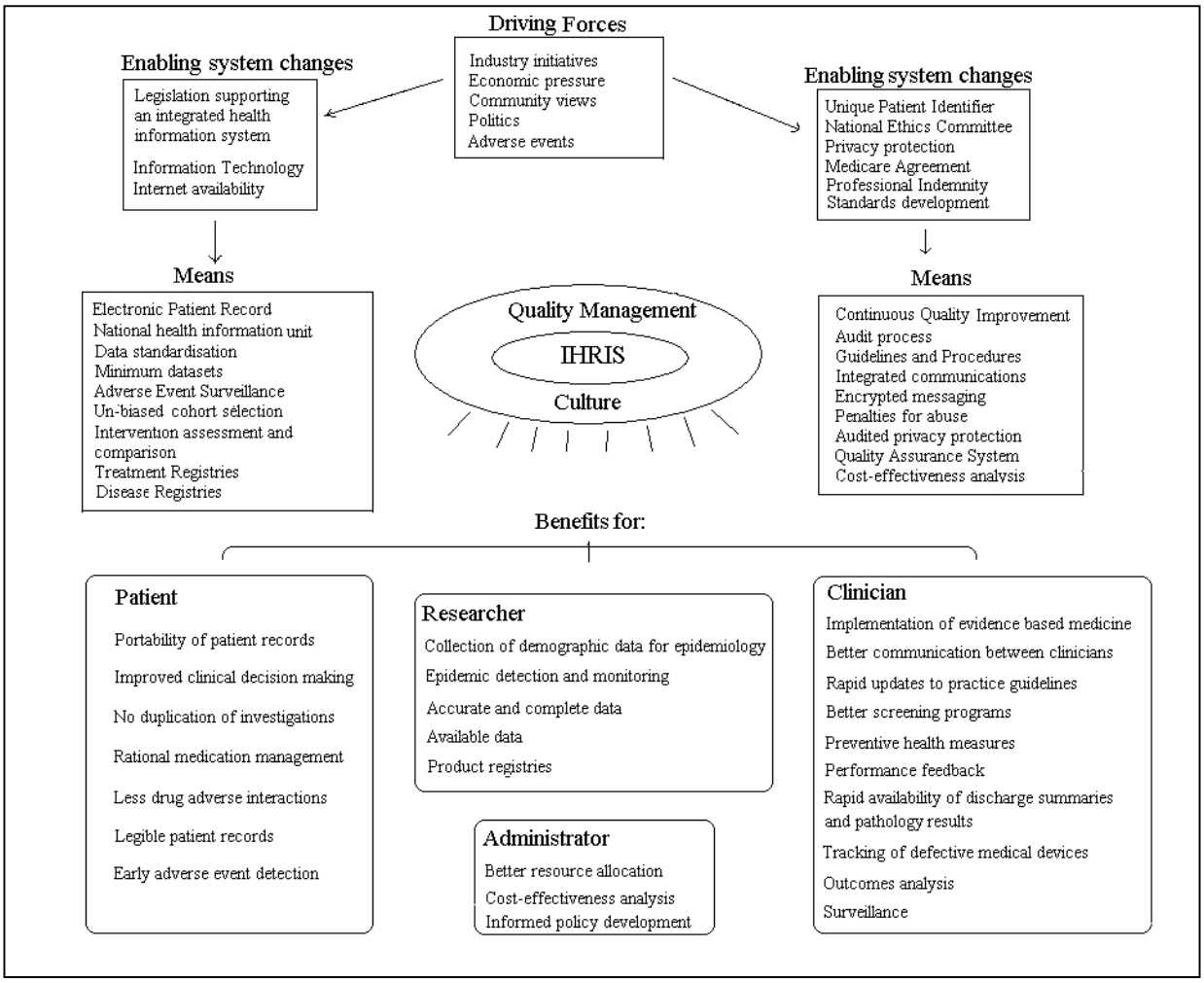
.

It would also be possible to establish a process where data collected from the various distributed databases would be automatically linked with the individual's UPI and then de-identified for analysis. As is done in Manitoba, researchers could in addition be required to sign a confidentiality agreement and observe protocols for the protection of identified data. A moral and legal obligation could be reinforced by appropriate penalties. It would be important to develop a popularly accepted mechanism to allow research use of these data. The research benefits to be gained from an integrated national dataset are extensive.

It is important to realise that effective and efficient management of these large data sets will not be instantly achieved as soon as the data is available Time will be required to gain experience with each data collection and any proposed system must allow for training of staff and the development and testing of algorithms for analysis. Specific approaches will be necessary for the examination of different interventions (a new drug will require a different approach to that required for a new hip prosthesis for example). At the present time, insufficient expertise would be unlikely to be readily available. The implications for increases in funding for training in research methods, epidemiology, biostatistics and data management are great.

There are many societal factors driving these changes and integration and alignment of the various forces will be required if an optimal system is to be developed. Figure 10-1 shows some of the relevant factors involved in this evolution and some of the possible benefits to be derived.

Figure 10-1 The IHRIS within a Quality Management culture



10.4 Some possible benefits of an IHRIS

Many conceivable benefits would be available from an IHRIS. The most important at the individual and community level are as noted by Mount, Kelman et al (2000):

Individual level benefits:

- improved clinical decision making
- reduced duplication of diagnostic testing, imaging and history taking,
- better medication management
- increased adoption of screening programs and preventive health measures

Community level benefits:

- better informed policy development,
- improved resource allocation and management,

- outcomes, and cost-benefit analysis of interventions,
- identification of causes and risk factors of disease,
- more efficient collection of demographic data for management and epidemiological purposes,
- monitoring of disease outbreaks and adverse reactions,
- establishment of registers for diseases, devices and treatments, and
- post-marketing surveillance of drugs, devices and procedures.

For an example of the scale of potential benefits to be gained from an integrated information system focused on quality and safety, the direct cost to the country of unsafe medical care is estimated to be over $1b per year (APSF 1996). Inappropriate prescribing, an area that would be transformed by the use of computerisation, has been estimated to result in at least 80,000 hospital admissions in Australia each year at a cost of around $350m (Roughead 1999). Around half of these admissions are considered to be preventable.

10.5 A change of culture required

In order to encourage a coordinated change in focus, leadership and direction must be provided at the national level. The Review of Professional Indemnity in Health Care (1991) was an important start to the process and the recent establishment of the Australian Council for Safety and Quality in Health Care certainly suggests that a change in philosophy is occurring.

A fundamental change in the culture of health care management will be required to allow the creation of an IHRIS. As suggested by the National Expert Group, the adoption of a 'quality management mentality' will be necessary. The present culture is strongly dominated by administrative and accounting requirements and does not cater for the needs of evidence-based health care and public health. Considerable resources are directed towards the collection of health service data to allow for the payment and allocation of services. The possibility of using this information to see whether these services are effective, to keep track of who has had specific treatments and whether adverse events have occurred, is almost totally ignored. The crucial quality-assurance feedback loop that should exist between output and input has not

been established. In sections 10.6 and 10.7, the limitations of the existing system are reviewed.

10.6 Barriers to the introduction of a national integrated system

As a result of the current 'accounting based' culture, various barriers exist to the establishment of an integrated health record and information system. These problems will only be overcome within an environment supportive of quality management.

X.1.1.1 The factionalism of health funders in Australia

To ensure consistent collection of and reliable access to health service data it would be desirable to review the current arrangements where health care is funded by multiple programs administered by all levels of government. This system is administratively complex and encourages the totally non-productive process of 'cost-shifting' between different levels of government. The present funding structure also encourages a culture of 'possessiveness' whereby data are jealously protected by 'owners'. This is most likely a result of the need for the states to compete for Commonwealth funding and the associated temptation to conceal their activities. From the public health perspective, these institutions are more properly 'custodians' of a national resource that should be made available for appropriate use both to monitor and improve health care.

10.6.2 Legislation and ethics committee control of research

The Australian health system is a unique and complex product of many legal, constitutional, professional and political influences. The use of national health service data is restricted under a number of Commonwealth[2] and state[3] constitutional powers. Many of these controls relate to a Constitution that was developed at a time before a national health system was envisaged, and the most recent amendments[4] certainly predate the advent of information technology. Various legislation has been introduced since this time including at the national level, the Health Insurance Act 1973, the Privacy Act 1988 and the National Health Amendment Act 1993. This legislative environment present a number of barriers for health care research. As in

2 Commonwealth Health Insurance Act 1973. Disclosure of Medicare data to external bodies is prohibited. Certain exceptions apply as were used for the Medical Devices study.
3 For example in NSW, Section 141 of the Health Services Act 1988, prevents Commonwealth access to state hospital records. The legislation emphasises the need for protection of patient privacy.
4 Constitution, s 51 (xxiiiA), 1946

other areas of technological growth, legislation sadly lags behind science and in this case, results in a system that is not able to be readily used for public health purposes.

Research involving human subjects is controlled by a system of decentralised Institutional Ethics Committees (IECs). The committees are based in health care institutions (hospitals) and also in state health departments. They are overseen by the Australian Health Ethics Committee (AHEC) which is a principal committee of the NHMRC. The system of IECs is intended to provide relevant local assessment of research projects according to the 'Statement on Human Experimentation and Supplementary Notes' (NHMRC 1992)[5]. For research projects spanning more than one region, separate applications are required. Coordination between committees is rare, although there would be obvious advantages in terms of efficiency. The requirement for approval from multiple ethics committees is a major disincentive to national research projects. It results in complex administrative obligations and extensive delays. It may also threaten the consistency of a national research project by requiring different study protocols in different jurisdictions.

A report from the 'Committee for the Review of the Role and Functioning of IECs' to the Minister for Health and Family Services (HFS 1996), made a number of recommendations including:

> AHEC should be provided with proper resources to cover the development and publication costs of a Manual of Procedures for IECs (Recommendation 11, section 5.4)
>
> AHEC should develop a statement of core competencies for IEC members to assist in the development of courses for their in-service training. (Recommendation 15, chapter 7)

The establishment of regional ethics committees was not recommended, however:

> IECs should continue to develop mechanisms for improving the efficient consideration of multi-centre research protocols; through increased communication between IECs, by accepting a singe technical assessment of research and through greater administrative consistency. (Recommendation 3, section 4.7)

For the purposes of routine surveillance activities and national research projects using data generated by an IHRIS, it would be desirable to place the responsibility for ethics approval under a *national* ethics committee.

5 This document inter alia, describes the composition, functions and roles of the IECs.

10.7 Review of the Australian national health datasets

As a consequence of performing the Medical Devices study, the various national datasets were able to be assessed for their usefulness for health outcomes analysis. It should be noted that these data collections, except for the National Death Index, were not originally designed with epidemiological purposes in mind.

10.7.1 Use of the National Death Index (NDI)

Use of the NDI requires ethics committee approval and the payment of a fee. The Index was found to be reasonably accessible for this research project and relatively up to date though it did have certain limitations. The principal problem was the lack of a unique identifier for individuals. This is not an inherent property of the NDI, but is the consequence of a systemic inadequacy. As a result of this, matching against NDI data had to be performed using probabilistic record linkage. Matching depended to a large extent on using date of birth. Unfortunately, due to historical reasons, only about half of the entries in the dataset had a full date of birth. This greatly reduced accuracy of the matching process.

If information regarding middle name, country of birth, marital status and current address had been available for the cohort, a small improvement in match rate could have been expected. However, to achieve any significant improvement in matching accuracy, a unique patient identifier (UPI) is needed.

Overall the NDI was found to have sensitivity of 89% and specificity of 98% (see Appendix 1). By comparison, the USA National Death Index is reported to have sensitivity of 97% and specificity of 99% when utilising the national Social Security Number for matching. In the USA this personal identifier is used for many purposes including health care. USA accuracy rates were also assessed using *only* names and dates of birth for matching, as was the case here. This approach was found to produce similar accuracy indices to those found for the Australian NDI. For use in outcomes analysis and surveillance, the low sensitivity of the Australian NDI is a significant limitation. This finding provides further support for the introduction of an Australian UPI, which would provide an efficient and inexpensive solution to this problem.

10.7.2 Use of the National Hospital Morbidity Dataset

This data collection was initially considered to have great potential for use in the Medical Devices study. It is the only national health dataset that contains details of diagnoses and surgical procedures. It is comprehensive and covers virtually all private and public hospital admissions. Data submission has been complete and comprehensive for all States since 1992-1993. Potentially, it provides the most significant resource for research in health care that is currently collected.

Unfortunately, its utility for outcomes research has been almost totally undermined by two fundamental characteristics of the data collection – de-identification and non-availability. Significantly, personal identifiers have been removed from all records. This process is performed by the states before submission of their records to the AIHW. When using these data for outcomes research, there is no way to determine whether two admission entries refer to the same person. Thus it is not possible to reliably perform any kind of longitudinal studies using this dataset at the national level.

It should be reiterated that although the AIHW manages the NHMDS, it does not have jurisdiction over the contents of the database. Approval from each state contributor is required for research access to the data.[6] The result is that multiple approvals are required with individual assessment by each of the state Departmental IECs. This is in addition to the ethics approval granted by the Institute. It is an extraordinary and inconsistent situation that hospital admission information collected by the states and supplied to the Commonwealth under the Health Care Agreements does not become the property of the Commonwealth. It imposes unrealistic restrictions on those who may attempt to use this data resource for epidemiological research. For this study, negotiations lasting up to eighteen months were required with individual states; a significant disincentive for any researcher. These arrangements appear to contribute little to the protection of personal privacy.

Acknowledging these limitations, considerable effort was expended in attempting to include hospital admission data from the NHMDS in the Medical Devices Study. However, as was discussed in 4.5.2, this was finally not possible. Despite gaining

6 Interestingly, NDI mortality information is also submitted by the states, however, management is delegated to the AIHW and access to the NDI is controlled entirely by the AIHW ethics committee.

consent from all patients, the AIHW and all states and territories, the data were not forthcoming. AIHW staff explained that the record linkage process required to extract the relevant data involved considerable staff time and computing resources and that it would not be possible to complete the linkage other than for those patients who lived in NSW. This was a rather disappointing outcome especially considering an arrangement for cost recovery was in place.

Thus the NHMDS, while having great potential for health research is, in its current form, neither suitable nor available for research. This is a major deficiency and merits urgent review.

10.7.3 The Health Insurance Commission databases

The MBS data collection was used to identify all doctor visits that were claimed under Medicare for the entire cohort including those covered under the Repatriation Benefits Scheme. Access to this database required proof of individual patient consent and the payment of a substantial fee. The service provided was reasonably streamlined but there were significant delays. Matching was reliable as each study subject had been asked to supply their Medicare number. Although this number is not a unique personal identifier, it does reliably identify families. The MBS database is potentially useful for research. It is the only national record of services provided by doctors. Unfortunately, the power of MBS data is severely limited as it includes virtually no clinical information.

The PBS data was extracted at the same time as the MBS data. This dataset does include a drug identification code and if linked to the NDI and hospital admissions data, it could provide a powerful resource for drug surveillance and adverse event detection. In this study, these data were not used because of the limited coverage currently available. Many commonly prescribed drugs are not recorded in the dataset as they fall below the PBS threshold price; only around 30% of total transactions are actually recorded with an identifier (HFS 1999). Drugs dispensed for those who have a Health Care card are included. However, as the cohort included in this study were all privately insured, they generally did not hold this concession.

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10.7.4 The Medibank Private claims archive

Every private health insurance fund must by law pay benefits for all medical devices included in a Commonwealth table of benefits. A comprehensive record of all implant procedures and relevant devices is therefore maintained. The records specify individual prostheses down to the level of brand and model. This level of detail is crucial if comparative analyses of device performance are to be performed. Such analysis was not possible during the study which examined data from Manitoba, despite Manitoba's reputation for maintaining a state-of-the-art health data collection. The Manitoba collection, while having many advantages, is seriously deficient in detail regarding medical devices.

It would have been possible to have approached all the private health insurance funds. However, Medibank Private is the only fund which operates in all states and one from which a balanced national sample could be obtained. This data collection is not generally available for research use but has some important features that are not included in any of the national data collections

10.8 Comments on using the existing administrative datasets for research

Several more general problems were encountered when attempting to utilise the national data collections for research use. These problems highlight the scope of changes that would be necessary to modify the present system and to provide an environment more supportive of research and health outcomes assessment.

10.8.1 Delays, availability and costs

The principal delays were the result of the requirements for ethics approval, patient consent, institutional contracts and the coordination of multiple data custodians. As mentioned, approval from 12 separate ethics committees was required. Approval from one of these committees involved a delay of 18 months, despite the fact that the patients themselves had already given their consent to be included in the study. Reasons for the various delays were numerous; overworked committees, infrequent meetings, changes in chairmanship and so on. Research projects appear to be very low on the priority list for most data holders. The result is that delays are so extensive as to seriously discourage all but the most determined of researchers. If public health research is to be encouraged and supported these administrative barriers will need to be removed.

As mentioned, strict legislative controls have been imposed on the national health care datasets making access to these data a costly and time consuming process. In addition to these legislative controls, data-holders were generally found to be resistant to allowing their data to be used, even after ethics approval and the required individual patient consent had been gained from those to whom the data referred. The state authorities in particular were observed to be somewhat protective of 'their' data. Even after approval was granted, not all data became available as was the case for the NHMDS.

A significant disincentive also exists as a result of the high charges imposed by some of the institutions, in particular the HIC. These charges are levied to cover the extensive staff time required to perform verification of individual patient consent. More efficient and less costly mechanisms for this process could be devised.

10.8.2 Cohort selection for population based research

Without resorting to special dispensation from the Privacy Commissioner or the Minister for Health,[7] the only mechanism available to the researcher for gaining access to the national data collections is to elicit individual patient consent from potential subjects. Thus it is not possible to use these data collections in advance to establish a group of persons with a specific medical condition who could then be invited by mail to join a study. In any case, clinical content is so limited that in their current form, selection from the whole population would not be possible.

In the Medical Devices study, information from a private health insurer was used to select a group of potential study subjects. However, cohort selection could be a potential use of the national data collections if a small amount of clinical detail were included. The addition of an ICD-9 or ambulatory care code would be sufficient[8]. The opportunity to select an un-biased group is crucial for the process of cohort selection and is not achievable in any other manner. A national IHRIS containing even basic clinical detail could provide this facility.

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7 This was the method used for the record linkage study conducted by Portfolio Strategies Division (HFS 1999)

8 Experimental ambulatory care codes have been developed but are not yet in general use

It will be important to manage access to such data collections carefully. It might be possible to grant exemptions from the requirement for patient consent for approved research projects and routine surveillance activities conducted by approved organisations. However, both types of exemption would need to be publicly disclosed.

10.8.3 Assessment of Provider performance

Ethics approval was not requested for examination of the relative performance of providers in the Medical Devices Study. Performance measures for individual practitioners are nevertheless crucial and if used appropriately, could lead to improvements in consistency and quality of practice. It is important to encourage the continued supply of accurate and complete data by practitioners and for this reason alone, such 'audit' information must be handled with absolute confidentiality. In addition, certain measures will require sophisticated interpretation and adjustment for variations in case-mix. To achieve optimal commitment from providers, it may be most appropriate for this type of information to be managed by the professional organisations and colleges. The most appropriate use of these measures would probably be for the internal audit of members allowing a confidential report to be provided to each practitioner. His/her performance may be compared with the group mean. This approach has been used to provide feedback to anaesthetists and to monitor anaesthetic incident rates in the very successful Anaesthetic Incident Monitoring Scheme (Beckmann, Baldwin et al. 1996).

10.8.4 Assessment of variation in performance between hospitals

Minor variations in outcomes were found between the hospitals examined in the Medical Devices study. This approach could be used to detect both under- and over-performers for the purpose of practice audit or for further investigation of variations in management and process.

While public hospitals continue to be under the control of the States, hospital data will tend to be guarded within the state organisations. Various alternative funding arrangements have recently been suggested that may provide a partial solution to this problem including 'Regional Health Authorities' that are provided with funds to manage all aspects of health care in their area. Unfortunately it is likely that these

regions will be too small to encourage integrated data collection without legislative obligation.

10.9 'Enabling' an integrated health information system

Several important challenges must be addressed to enable the establishment of an integrated system. Most of these questions must be resolved at the national level to ensure consistency between jurisdictions and to prevent the development of new barriers to the exchange of information.

10.9.1 Legislation

The establishment of an integrated national system for the management of health records and information is problematic due to the nature of the legislative environment on which our health system is built. While it is envisaged that the Commonwealth would lead and manage a national system, it does not have the constitutional powers[9] to support policy dominance in the health area.

> The limited nature of the Commonwealth's direct legislative power over health, combined with the Commonwealth's reliance on a mixture of legislative and financial powers to implement major programs like Medicare, have contributed substantially to the lack of integration in the health system…(Wheelwright 1995)

The success of an integrated system will depend on appropriate supportive legislation. Issues regarding motivation for data collection, ownership and management of data and privacy protection will need to be resolved. It will be necessary to encourage state and institutional data holders to provide information to a national body for public health benefit. The census and statistics power in s 51(xi) of the constitution may be sufficient to enable compulsory collection of health statistics for research and planning purposes (Wheelwright 1995). However the Commonwealth has so far explored relatively few of its legislative powers or tested their support for more comprehensive regulation of the health area (McMillan 1992). Using the Commonwealth's 'grants power' (s 96) through the Health Care Agreements, Commonwealth funding for state hospitals is tied to various requirements including quality control and patient rights. The extent of these conditions is not limited and

9 The available constitutional powers are limited to the 'health and welfare power' in s 51(xxiiiA), the 'appropriations power' in s 81 and the 'grants power' in s 96.

provides an opportunity for the Commonwealth to ensure that public hospital service delivery conforms with Commonwealth policy.

In order to encourage a 'no blame' culture for the collection of information about adverse events other significant legislative changes will be required. The Health Insurance (Quality Assurance Confidentiality) Amendment Act 21 December 1992 was an important start along this path. Recent work in privacy legislation[10] has encouraged debate on the issue of privacy protection but will most likely require further development for the specific management of health information.

10.9.2 A Unique Patient Identifier (UPI)

The bulk of health service research is currently conducted using massed de-identified data. Such parameters as numbers of operations per month, waiting times, and DRG estimations can be deduced from this type of information. However, a unique personal identifier is essential to assess treatment outcomes and to link data reliably from more than one source. Without a UPI it is not even possible to identify re-admissions in a different facility in the same state. At the clinical level, such an identifier is crucial to both appropriate patient management and also privacy protection. In Australia, no such identifier is presently available. A personal number does however, exist within the Health Insurance Commission (the PIN) although it is not available to researchers or health professionals. It is important that any UPI is allocated and managed nationally, rather than each state producing its own. The PIN appears to be the most logical choice for a national identifier.

In general, patient records are currently managed in a highly un-coordinated manner. Records for the same person will exist at many sites, each with a different ID code. Personal names are not unique and do not provide reliable identification. To enable use of some of these data for health research, probabilistic record-linkage has been developed. This technique is complex and time consuming and can never attain 100% accuracy. The current requirement for individual patient consent for the use of administrative data results in considerable consent bias and thus is problematic for research. With modern information technology, it is no longer necessary to de-identify records to protect personal privacy. Encryption and access control protocols can provide far better protection.

10 Privacy (Private Sector) Bill 1999. (Attorney General 1999)

Although it has proved useful for combining existing 'legacy'[11] system records, probabilistic record-linkage is not a desirable technology for the purpose of health research and surveillance. A future integrated health system should neither use nor require this approach. All linkage should be 'deterministic' (ie a one-to-one match) using the UPI in an appropriately 'protected' environment where access to private information is controlled and audited.

10.9.3 Privacy protection

Privacy issues have unfortunately been used by various interest groups to discourage the uptake of many of the components of an integrated health information system. There are of course valid concerns. Electronic databases have an inherent potential for misuse that cannot be matched by their paper equivalents. In order to provide a health system that has the support of the community, considerable input from consumer groups, industry and providers will be required. The "Australia Card" scenario provides a recent warning of the need for sensitive management of the introduction of a UPI. However, a patient identifier is one of the most important first steps towards an integrated health record.

In principle, all persons who access the health care system are benefiting from the experiences of those who lived before them. There would be no modern medicine without this historical resource of 'medical experimentation'. The science of health care is a community resource elicited from community experience. It could thus be argued that individuals have a moral obligation to allow their medical records to be used for the benefit of others. This is in addition to the fact that individuals may benefit personally from contributing to surveillance systems and product registries. Such 'community' use of personal information must be appropriately respected and controlled, but is an essential component of the evolving discipline of medicine.

It is concluded here that the present disjointed system is urgently in need of major review because of the lost potential to provide efficient and evidence-based health care. The existing system does not demonstrate current best practice and does not perform any of its functions in an optimal manner. Privacy protection is just one of

the areas that is very poorly managed. Advancements in information technology could be used to improve this situation.

10.9.4 The potential contribution of Information Technology to Privacy Protection

Information technology has the power to create a threat to personal privacy and also to provide a solution. The existing technology of public key cryptography[12] already provides secure communications in various industrial settings including banking and the military and is currently making a rapid entry into e-commerce. It could readily be adapted to the needs of health care.

Several components are required for a reliable and confidential electronic communication system for health care transmissions. The three main requirements for secure communication are authentication, confidentiality and integrity. In other words, it must be possible to verify the identities of both the sender and recipient and also encrypt the message in such a way that only the recipient can read it and that the transmission can be verified to have not been modified by a third party.

Any health care communication system must be reliable and secure. It must be capable of generating alerts when breaches of protocol occur and include an auditing capability to provide an electronic 'trail' to allow for message tracing. Once established, such a system could provide far superior privacy protection than is available with the disjointed combination of paper, fax and verbal communication that currently exists.

10.9.5 Electronic health records provide data capture

Over the next decade information technology will become an integral part of health care in both the ambulatory and hospital settings. The progressive introduction of electronic patient records is considered to be inevitable.

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11 Meaning that if these data was collected now, they would be collected along with some form of identifier that was useable for analysis.

12 Public key cryptography is the most common technique used in the public domain. It requires both a public key (a code which can be openly distributed) and a private key (which is kept secret) to encrypt messages.

At both the clinical and administrative levels, the management and practice of medicine requires the collection, storage and processing of vast amounts of complex data. It involves the constant updating of data and the management of diverse interactions and relationships between data elements. In the clinical setting, these requirements are combined with a need to prioritise according to the constraints of cost and availability of services. Such a challenge is best met with computer assistance, and a new industry to cater for these needs is growing rapidly. Previous efforts to evaluate health care have principally focussed on structure and process; the collection of electronic health data provides an opportunity to look at outcomes. These data will comprise a previously unavailable resource and will contribute an essential component for a quality management system.

10.9.6 Standards for data collection

As was shown in the study and discussed in Chapter 9, identified administrative data have the potential to be useful for simple analyses of health service utilisation and general surveillance. Without additional clinical detail it is difficult to determine treatment outcomes or compare interventions. With the addition of clinical data, much more detailed analysis became possible in the Medical Devices study. For example, differences in outcome between brands of hip implant were able to be examined. The introduction of electronic patient records provides the possibility of automating the collection of these additional data.

The quality and scope of clinical data collected will require the development of 'minimum data sets' and appropriate standards. For example, 'ambulatory care codes' will be required for outpatient services. These codes, linked to records of treatments and investigations, would provide sufficient depth to allow for the detection of adverse events and outcomes analysis. Significant investment and debate will be required to develop these minimum datasets. It will also be important to determine the extent of information needed for quality management and surveillance compared to and distinguished from, the needs of an individual's personal health management.

10.10 The Manitoba experience

The opportunity to compare the health data systems provided insights into the strengths and weaknesses of the two systems. There is much to be learnt by

Australian health policy developers from the Manitoba system and the opportunity exists to avoid various shortcomings that have become evident in the system when used for the purpose of health outcomes evaluation. Australia is now in a position to be able to develop a 'state-of-the-art' health data system.

10.11 Desirable system changes to support a national IHRIS

As a result of this research, a number of system changes have been identified which would be consistent with an approach based on quality management and would constitute a basis for the development of a national IHRIS. This system would be used to manage clinical data at all levels and in addition, provide a resource for quality management, the monitoring of treatments, adverse event surveillance and product registers. It would also provide for administrative needs.

Motivation for data collection

- *To ensure 'best practice' and to facilitate the implementation of 'evidence-based medicine', the focus of administrative data collection should be encouraged to evolve from one of mere accounting to include epidemiology and quality management.*

Enabling legislation

- *Legislation at both the Commonwealth and state level would be needed to support an IHRIS. Significant issues include data ownership, data management and privacy protection.*
- *The IHRIS would require initiation and direction at the Commonwealth level. Management of the system may be most appropriately delegated to a federal body.*

Identification of patients

- *A national Unique Personal Identifier is required for the management of health data. This identifier should be restricted to use in health care. Contact details for each person should be regularly updated.*

National Health Ethics Committee

- *A Commonwealth funded National Health Ethics Committee is desirable to oversee quality management activities using data generated by an IHRIS or derived from administrative data collections. These activities*

would include routine surveillance, treatment monitoring and cost-effectiveness studies.

- *Exemption from the need for individual patient consent would be desirable for these quality management activities. Such exemptions will make it feasible to use the IHRIS for cohort selection thus avoiding the selection bias inherent in the current process. A national IHRIS could include an 'opt-out' clause or, alternatively, exemptions for the need for patient consent could be managed by the National Health Ethics Committee.*

Surveillance and product registers

- *Drawing on information contained in the IHRIS, a routine system for the surveillance of new and existing products and interventions could be established. This system should provide:*
  - *a) Early indications of adverse events with new interventions.*
  - *b) Cost-benefit comparisons for competing interventions*
  - *c) Potential to detect delayed and rare complications of treatments*

- *Details of medical devices implanted could be recorded at the time of operation in the various state admission datasets. Details recorded should include the side of operation, brand and serial number to allow comparative evaluation and product recall when required.*

Data management

- *A 'minimum data set' will need to be developed. This standard will define the requirements for data collection at the point of service.*

- *Service data collected should include a field detailing the condition requiring consultation. An ambulatory coding system for out-patients will need to be developed for this purpose.*

- *The introduction of appropriate security measures will be essential to protect personal health data and to promote public confidence in the system.*

The National Hospital Morbidity Dataset

- *Management of and access to the National Hospital Morbidity Dataset could be greatly improved. It is highly desirable that this national resource be upgraded to provide appropriate information for health outcomes assessment and product registers.*

- *State hospital admission data should be made available to the NHMDS in identified form. This requirement would properly be included in the 'Health Care Agreements'.*

- *Full control of the NHMDS should be delegated to the AIHW. Access to this resource for research use should be controlled by the AIHW ethics committee or the 'National Health Ethics Committee'.*

10.12 Conclusion

The present national health administration system collects data about health care services for the purpose of health care administration and the payment of providers. Comprehensive data are collected about doctor and hospital services, and deaths. Incomplete data are collected about dispensed pharmaceuticals for patients on various benefit schemes. The clinical component of these collections is small. In this thesis, the potential to use this data resource for health outcomes assessment was examined.

After confronting exceptional difficulties in gaining ethics approval and data access, these data resources were found to be available to varying degrees and when linked, to provide a primitive data resource that could be used for limited health outcomes research and treatment surveillance. However, when simple clinical information was added, the power and potential of the resource was greatly improved.

The current system provides a starting point for the development of an Integrated Health Record and Information System (IHRIS). The capability of information technology in both the management and analysis of health data holds great potential for the provision of more efficient and evidence-based health care. Many of the technical problems facing the introduction of an IHRIS are soluble with existing technology. However, the most important barriers are political and cultural.

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Glossary and Acronyms

ABS	Australian Bureau of Statistics
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers Advisory Council
AHTAC	Australian Health Technology Advisory Committee
AICD	Automatic Implantable Cardiac Defibrillator
AIHW	Australian Institute of Health and Welfare
ANU	Australian National University
ASDR	Australian Standardised Death Ratios
Bjork-Shiley	Widely used brand of prosthetic heart valve, infamous for various models that failed catastrophically
COB	Country of Birth
Commonwealth Department of Health	A generic name for the evolving federal department
CJD	Creutzfeld-Jacob Disease – a prion mediated disease transferred by biological implants and surgical implements
Dalcon	A brand of Intra-uterine device, infamous for its failure
DOB	Date of Birth
DOD	Date of Death
DRG	Diagnosis Related Groups
DVA	Department of Veterans Affairs (Commonwealth)
EPR	Electronic Patient Record
FDA	USA Food and Drug Administration
HIC	Health Insurance Commission
HMO	Health Maintenance Organisation
HR	Hazard Ratio
ICD-9	International Classification of Diseases, ver 9
IEC	Institutional Ethics Committee
IHRIS	Integrated Health Record and Information System
Index operation	The operation of interest in the Medical Devices study
IOL	Intra-optic lens (prosthetic lens for cataract patients)
MB	Manitoba province
MBS	Medical Benefits Schedule

MP	Medibank Private, a health insurance agency
NCEPH	National Centre for Epidemiology and Population Health at the ANU
NDI	National Death Index
NEAG	National Expert Advisory Group on safety and quality in Australian health care
NHMDS	National Hospital Morbidity Data Set (maintained by the AIHW)
NHMRC	National Health and Medical Research Council
NHS	UK National Health Service
OR	Odds Ratio
OTA	The USA Office of Technology Assessment
PBS	Pharmaceutical Benefits Schedule
PHIN	The Manitoba Personal Health Identification Number
PIN	Personal Identification Number
PMMA	Poly-Methyl-Methacrylate (acrylic) the most widely used IOL material
PRF	The Manitoba Population Registry File
QAHCS	Quality in Australian Health Care Study
Prion	The transmissible agent thought to be responsible for CJD
RCT	Randomised Controlled Trial
RR	Relative Risk
SES	Socio-Economic Status
SHCEC	The NSW Statewide Health Confidentiality and Ethics Committee
SMR	Standardised Mortality Ratio
SNOMED	Systematised Nomenclature of Medicine
TGA	Australian Therapeutic Goods Administration
TURP	Trans-Urethral Prostatectomy
UMLS	Unified Medical Language System
UPI	Universal Patient Identifier

Clinical Trial Phases:

Phase I: First studies in humans (healthy volunteers or patients, depending on nature of drug/device).

Phase II: Exploratory studies in people with the condition being treated. Usually examine: dose response, dose selection; short- to medium-term efficacy and safety.

Phase III: Confirmatory studies in people with the condition being treated. Usually examine: confirmation of selected dose, medium- to long-term efficacy and safety, comparative efficacy and safety against registered drugs, efficacy and safety in patient subgroups,

Phase IV: Post-marketing studies. Usually examine: long-term efficacy and safety, comparative efficacy and safety against registered drugs,
Cost-benefit analysis.

Brands of heart valve prostheses:
Carbomedics
Medtronic
Starr
ST Jude

Brands of Hip prostheses:
Capital 3M
Austin Moore
Axis
Charnley
Christiansen
Exeter
Osteonics
PCA
Precision
SROM
Zimmer

Descriptions of Pacemakers:

SC	Single Chamber (atrial lead only)
DC	Dual Chamber (atrial + ventricular leads)
VVIC/VVIR	
DDDC/DDDR	Describes the mode of pacing; where sensing and pacing occurs, and whether it is rate-adaptive

Appendix 1: The NDI

The Australian National Death Index; an assessment of accuracy.[1]

Abstract

Objective
The Australian National Death Index (NDI) provides a comprehensive and accessible source of mortality information for epidemiological research. Use of the index requires a probabilistic matching process that inevitably results in some inaccuracy. In this paper, accuracy is assessed.
Methods
Results of a matching process against the NDI performed by the Australian Institute of Health and Welfare in Canberra were compared with information provided by the "Medical Device Outcomes" study cohort and their families (n=2990). Indices of accuracy for the NDI were calculated.
Results
For this particular study, the NDI has sensitivity 89% and specificity 98%
Conclusions and implications
The relatively low sensitivity is of some concern to those using the NDI for health outcomes research. The importance of such a national database is evident; however, to improve accuracy the introduction of a national unique patient identifier is necessary.

Introduction

Health outcomes researchers face many challenges; not the least of which is to determine which outcome measures reflect changes in health status that are meaningful and useful to the individual. There is no dispute about the fundamental measure of death. A register of births and deaths is a vital resource for the development of a public health program in any community. In the early days of Australian colonisation registers of births, marriages and deaths were established by the church, the maintenance of these registers was later taken over by the states with the first civil register being introduced in Tasmania in 1839.[1]

A National Death Index was proposed in 1979 by the National Health and Medical Research Council. A cooperative agreement was forged between the Australian Institute of Health, the state and Territory Registrars, and the Australian Bureau of Statistics. The NDI was endorsed by the Australian Health Ministers' Conference (AHMC) in 1984. The NDI became fully operational in 1994 and contains records of all deaths occurring in Australia since 1980. The information is available for health research only and is designed to facilitate the conduct of epidemiological studies. Prior approval from the Institute's ethics committee is required and a fee is charged for the service.[2]

This paper is an account of the results of using the NDI during a research project investigating health outcomes of patients with medical implants. The project involved selecting a cohort of patients from the archives of a private health insurer (Medibank Private). The implant operations were performed in 1993-94, four or five years prior to the commencement of the study. As most patients were elderly it was assumed that a percentage would have died during this period. In order

1 This article was published in the April 2000 edition of the Australian and New Zealand Journal of Public Health. (Kelman 2000)

to proceed with the project it was first necessary to gain consent from all participants. To minimise possible distress to families it was decided to determine whether to write to the patients themselves or if they had died, to their families. The NDI was utilised to distinguish these two groups.

Methods

The Medical Device Outcomes study

The cohort selection process involved examination of the claim archives of the insurer. All patients who had a record indicating that they had received one of the five specified types of medical implant during the years 1993-94 were selected. These 5,316 patients were then sent a package containing information about the study and a consent form. Around 30% of these persons were no longer members of Medibank Private - it was not known how many of these had died and how many had simply discontinued private insurance.

The NDI matching process

Details contained in the NDI include names, date of birth, race, state (or territory) of death, cause of death, maiden name and marital status. For historical reasons, the dataset comprises two complementary sets of records, one with complete date of birth, and the other, of similar size contains only an estimated year of birth. Records are updated by the states every one to three months. Available information from the insurer about each study subject included first name and family name, sex, date of birth and state of residence (at the time of last contact with the insurer).

To search the NDI 'probabilistic matching' is used; this is a computerised process involving a kind of 'fuzzy logic'. The process is similar to that performed by a clerk required to match up two lists of names where various spellings for the same person may exist. Hence the software program will assign a probability that patient "Jonathon William Brown" is the same person as "John W Brown" in the NDI. The program produces a list of possible matches that are then reviewed manually by the researcher.[3] Ultimately a list of names is produced – in this case, 849 cohort members presumed deceased.

Data sources

After the matching process, letters were sent to all 5,316 persons requesting consent for the study. A customised letter was sent to the families of those who were considered to be deceased on evidence provided by the NDI.

Results

A total of 2,990 persons responded to the letter (2,077 persons consented to join the study however others provided information without consenting) of these, 442 persons were reported by their families to have died and a date of death was supplied. Thus from a total of 5,316, information was available for a sample of 2,990. The mortality status for these persons is presented in Table A1-1. As some families may have returned the 'refusal to consent' form while not reporting the death of their relative, results are also shown for the group that *did* consent to the study (n = 2,077) whose mortality status was known to be reliable.
As a further complication, some deaths occurred after the last updates of the various state registers were submitted to the AIHW (December 1997) but before patients actually received the study letter

(June 1998). Results are shown for both the group whose deaths could *theoretically* have been matched with the NDI and the actual group who received letters based on slightly out of date information.

Table A1-Error! No text of specified style in document.**-1** Mortality status from the NDI: 'Theoretical' and 'actual' for the 'all responses' and 'consented' group.

	'All responses' n=2990		'Consented' n=2077	
	Actual Dead	Actual Alive	Actual Dead	Actual Alive
NDI dead*	370 (371)	38	215 (216)	36
NDI alive	45 (71)	2492	27 (42)	1804
Totals	415 (442)	2530	242 (258)	1840

* Included in brackets are the 'actual' numbers of patients contacted, ie including patients that died **after** the last NDI update and thus could not have been detected by the NDI match.

Measures of NDI Accuracy

The principal reason to use the NDI in this study was to minimise the number of letters that were inappropriately sent to patients who had died or conversely, to families of patients that were still alive. The measures that best indicate these scenarios are the false positive and false negative rates. The false positive rate is calculated by dividing the number of those wrongly thought to have died by the total number of patients actually alive. The false negative rate is the number of patients wrongly thought to be alive divided by the number actually dead.

Alternatively, Sensitivity is the percentage of records of persons who were found to be dead (as reported by their families) that were matched with a NDI record (ie correctly identified as dead). Specificity is the percentage of persons known to be alive that were not matched with a NDI record, (ie correctly identified as alive) Indices are shown in Table A1-2

Table A1-Error! No text of specified style in document.**-2**NDI Performance Indices: 'Theoretical' and 'actual' for the 'all responses' and 'consented' group.

	%, 'All responses', n=2990	%, 'Consented', n=2077
NDI false positive*	1.5 (1.5)	2.0 (2.0)
NDI false negative	11.0 (16.1)	11.2 (16.3)
Sensitivity	89.1 (83.9)	88.8 (83.7)
Specificity	98.5 (98.5)	98.0 (98.0)

Results in brackets indicate the 'actual' rates for this study - including those that died after the last update of the NDI.

Potential biases

The primary intention of using the NDI match was to avoid offending families of deceased patients (false negatives), however in practice it was the false positives that produced the most feedback from patients. People were disturbed to be contacted via their families under the assumption that they were deceased. It is possible that these people were more likely to respond to the investigators to correct this error, independently of whether they wished to consent to the study. Some bias could be expected to result from this ie. letters addressed to the families of those correctly identified as dead may have been less likely to elicit a response than letters mistakenly written to families of those who were in fact still alive. However, as shown in Table 2 it appears that the

opposite occurred and that those whose mortality status was correctly identified were more likely to take the time to return the 'refusal to consent' form. These differences are in any case fairly small.

Discussion

For the purposes of the medical devices study, the NDI provided a useful resource which in most cases allowed appropriate letters to be sent to the families of deceased members. This project is not necessarily typical of the use that is made of the NDI; because individuals were to be contacted directly, the lowest number of false negatives was sought. It is customary for the researcher to be involved in the clerical review of possible matches and accuracy indices will vary slightly according to the emphasis of the project.

Results are shown for the 'theoretical' and 'actual' accuracy of the NDI. Due to the fact that time was required to extract data from the NDI, to prepare mailing lists and for other inevitable delays, mortality information was no longer current by the time the letters were received by patients. For studies of this type the importance of minimising delays between NDI matching and the use of the information should be stressed, especially when dealing with elderly patients.

Several other contributory causes of inaccuracy were evident. In this study cohort, many patients had similar Anglo-Saxon names and thus the matching process was likely to produce some false positives. Due to this similarity of names, date of birth became a crucial matching variable, however, as mentioned, around half of the records in the NDI contained only an estimated year of birth. For future studies this situation will improve as registrars now routinely collect full date of birth, but for this study additional false negatives would have been expected.

Personal data held by Medibank Private was generally found to be accurate, however, there were a small number of errors in recorded birth date. More importantly, if middle name, race and marital status had been available for the cohort a small improvement in match rate could have been expected. A large improvement in matching reliability could be achieved if a unique patient identifier (UPI) was available - a number that is assigned to each individual for the purposes of accurate management of their health care data. Such a number presently exists and is used within the Health Insurance Commission, but is not available to researchers or health professionals. The introduction of a UPI is currently on the national agenda as a fundamental component of the proposed Integrated Health Records and Information System.[4,5]
By comparison, in the USA a personal identifier is used for many purposes including health care. The USA National Death Index is reported to have a sensitivity of 97% and specificity of 99% when utilising the national Social Security Number for matching. Rates utilising only names and dates of birth for matching have similar but slightly lower accuracy indices than found here for the Australian NDI.[6]

Conclusion

The Australian NDI is an up-to-date and accessible resource for health researchers. It is limited in accuracy due to the absence of an available UPI. The lack of such an identifier is a major impediment to health outcomes research in Australia and its proposed introduction is awaited.

Amongst other benefits, the sensitivity of the NDI could then be expected to improve to a level comparable with that of the USA NDI.

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Appendix 2: Non-normal distributions

Statistical methods for the analysis of cost/utilisation data that is non-normally distributed

Cost and utilisation data is usually non-normally distributed, thus invalid results are produced if the standard parametric procedures are followed for analysis, however, this approach has frequently been used. Zhou reports on this problem noting that for two-sample comparisons, three methods were commonly used, each being flawed. The Students t test applied to untransformed costs ignores the skewness in the cost data, the Wilcoxon test on untransformed costs ignores unequal variances, and the Student t-test on log-transformed costs tests the wrong null hypothesis (Zhou, Melfi et al. 1997).
The distribution of service utilisation and cost data is often highly skewed due to the fact that a small proportion of patients use a large proportion of services. However this distribution is usually log-normal and taking logs can ameliorate this problem.

Zhou proposes the use of the Z-score method; assuming the mean costs of the two groups are M_1 and M_2 the null hypothesis, H_0 is

$$M_1 - M_2 = 0$$

Assuming that log transformed costs in the two groups are normally distributed with means μ_1 and μ_2 and variances σ_1 and σ_2 and because

$$\text{Log } M_1 = (\mu_1 + \sigma_1^2) \text{ and } \text{Log } M_2 = (\mu_2 + \sigma_2^2)$$

H_0 now becomes

$$(\mu_2 + \sigma_2^2/2) - (\mu_1 + \sigma_1^2/2) = 0$$

The test is a Z-score based on an estimate of $(\mu_2 + \sigma_2^2/2) - (\mu_1 + \sigma_1^2/2)$ divided by its SE. The P value of the test is obtained from the standard normal distribution table for the Z statistic. (Zhou, Gao et al. 1997)

Rubin discusses the use of 'propensity scores' to estimate causal effects from large data sets (Rubin 1997).

> Such (administrative) data are relatively inexpensive to obtain, however, and often do represent the spectrum of medical practice better than the settings of randomised experiments. Consequently, it is sensible to try to estimate the effects of treatments from such large data sets, even if only to help design a new randomised experiment or shed light on the generalizability of results from existing randomised experiments. However standardised methods of analysis… can be deceptive for these objectives because they provide no warnings about their propriety.

This approach reduces background characteristics to a single composite measure that appropriately summarises the collection, thus controlling for naturally occurring systematic differences between the treatment and control groups. An assessment is then possible as to whether the treatment and control groups overlap enough with respect to background characteristics to allow a reasonable estimation of treatment versus control effects from the dataset. The function of these confounding covariates

forms the propensity score – the propensity to receive treatment 1 rather than treatment 2. The score is found by using a logistic regression or discriminant analysis on the confounding covariates and allows sub-classification into a small number of groups, no matter how many initial covariates existed. This method has been used in the comparison of randomised trial to compare varying mastectomy procedures (Office 1994) and medical versus surgical approaches to the treatment of triple vessel cardiac disease (Myers, Gersh et al. 1987)

Appendix 3: Sample letter

(Sent to Medibank Private members – living)

«Title» «Fname» «Sname»
«Street»
«Suburb» «Town» «Pcode»

Member No. «Book»

Dear «Title» «Sname».

I am writing to you regarding your possible assistance in a research project that is being conducted by the National Centre for Epidemiology and Population Health (NCEPH).

The NCEPH, which is located within the Australian National University in Canberra, is an internationally respected public health research centre. The Centre is conducting a 'Devices and Health' research project to examine the health issues involved in a range of implantable medical devices including pacemakers and defibrillators, heart valves, vascular grafts, intra-optic lenses and hip replacements. This project will compare the effectiveness of the various medical devices currently available and predict the effectiveness of future devices. I have enclosed an information package prepared by the principal researcher for the project, Dr Christopher Kelman, which describes the study in more detail.

The NCEPH has requested information about Medibank Private members whose treatment has involved the use of an implantable medical device. However, while Medibank Private considers that the objectives of the study are very worthwhile, we will only provide information about your health care to the NCEPH with your consent.

If you wish Medibank Private to release information about your medical treatment to the NCEPH, we ask that you answer the three questions at paragraph (**A**) overleaf, complete the green consent form, and **return this page and the green one** to Medibank Private in the reply-paid envelope at your earliest convenience. You will not be asked to have any further medical tests or investigations. However, if your treatment has been particularly complicated, Dr Kelman may write to you at a later date and ask you to complete a short questionnaire about your experiences.

If you do not want information on your medical treatment to be made available to the NCEPH, you should indicate this at paragraph (**D**) overleaf. However, Dr Kelman has requested that you answer the three questions at paragraph (**A**). This will enable the NCEPH to confirm that those persons who are included in the NCEPH's study provide a representative sample of all patients who have been treated with implantable medical devices. We ask that you return this page at your earliest convenience in the reply-paid envelope, and you will not be contacted further about the project.

Finally, I wish to emphasise that Medibank Private has established a legally binding arrangement which requires the NCEPH to strictly safeguard the confidentiality of all information provided to it, to ensure that no patient names will be included in any published research results, and to ensure that information provided to the NCEPH is only used for the purposes of the study.
Once again, I greatly appreciate your assistance in this matter and, should you require any further information, please contact Mr Alan Skeates on (02) 6208 9558.

Yours sincerely

Michael Whelan
General Manager, Finance and National Operations
Medibank Private June 2, 1998

A Three quick questions:

General Questions on quality of life.

Please circle the word which best describes how you feel:

How has your medical device affected your health?

Much improved Improved Unchanged Worse Much worse

In general, how would you say your health is?

Excellent Very Good Good Fair Poor

Compared to one year ago, how would you rate your health in general now?

B Now please complete the green consent form and

C Return this page and the consent form to us.

OR **D** Complete the refusal section below and return this page to us.

Refusal to participate in the study:

Please only fill in this form if you are **not willing** to participate in the study.

I ……
(name of member)
do not give permission for records relating to myself to be used in the study.

Signed …….

Date:……..

Appendix 4: Sample letter

(Sent to family Medibank Private members – presumed dead)

Family of «Title» «Fname» «Sname»
«Street»
«Suburb»
«Town»«Pcode»

Member No. «Book»

Dear relative or friend

I am writing to you regarding your possible assistance in a research project that is being conducted by the National Centre for Epidemiology and Population Health (NCEPH). I greatly appreciate your consideration of this matter.

The NCEPH, which is located within the Australian National University in Canberra, is an internationally respected public health research centre. The Centre is conducting a 'Devices and Health' project to examine the health issues involved in a range of implantable medical devices including pacemakers and defibrillators, heart valves, vascular grafts, intra-optic lenses and hip replacements. This project will compare the effectiveness of the various medical devices currently available and predict the effectiveness of future devices. I have enclosed an information package prepared by the principal researcher for the project, Dr Chris Kelman which describes the study in more detail.

The NCEPH has requested information about former Medibank Private members whose treatment involved the use of an implantable medical device. However, while Medibank Private considers that the objectives of the study are very worthwhile, we will only provide information about «Title» «Sname»'s health care to the NCEPH with your consent, should you be in a legal position to give this consent. (You may, for instance, not be in a legal position to give consent where the estate has not yet been settled or you are not the executor of the estate).

If you do not wish to consent to the release of data, or are not in a position to do so, I would appreciate it if you would indicate this on the form overleaf and return it to Medibank Private in the reply-paid envelope.

If you wish Medibank Private to release data relating to «Title» «Sname» to the NCEPH and if you are in a position to give consent, I would appreciate it if you could complete the green consent form and return it to Medibank Private in the enclosed reply-paid envelope as soon as is convenient to you. Your consent will enable the NCEPH to link the data held by Medibank Private relating to «Title» «Sname» with any information held by the other organisations listed on the consent form. However, whether or not you choose to consent to the release of data, no further information will be sought from you.

Finally, I wish to emphasise that Medibank Private has a legally binding arrangement which requires the NCEPH to strictly safeguard the confidentiality of any information relating to former Medibank Private members about whom any information is provided, to ensure that no patient names will be included in any published research results, and to ensure that any information provided to the NCEPH is only used for the objectives of the project.

Once again, I greatly appreciate your assistance in this matter and, should you require any further information on these issues, please contact Mr Alan Skeates on (02) 6208 9558

Yours sincerely

Michael Whelan
General Manager
Finance and National Operations
Medibank Private June 2, 1998

Refusal to participate in the study:
Please only fill in this form if you are **not willing, or not in a position** to give permission for us to include your relative in the study.

I ……
(name of next of kin or next-friend)
do not give permission for records relating to my next of kin/friend to be used in the study.

Signed …….

Relationship to member:……

Date:……..

Appendix 5: The Study Brochure

Your privacy rights
Under Australian law, governments must make sure that you have all the information you need to make an informed decision about participating in a research study. Also under the law you have the right to have information about you and your care kept private. We will comply fully with these requirements.

If you agree to participate:
you can be assured that the study will collect, store and use information about you in a way that respects your privacy and ensures confidentiality.
you will have access to someone to talk to if you have a question or concern during the Study. The name and contact details of that person are included below.
you have the right to lodge a formal complaint with the Health Complaints Commissioner in your State/Territory
you can be assured that the information about you will be collected in a fair, lawful and non-intrusive way and also that the purpose for which information is collected will be explained to you.
you can access information about you which is kept by the Australian National University, and you have the right to amend this information where it is incorrect.
you can be assured that all information will be used only for the purposes of the study as described.

For more information, please contact the chief researcher:

Dr Christopher Kelman
The National Centre for Epidemiology and Population Health

Australian National University
Canberra ACT 0200

Telephone 02-62495602
Fax 02-62490740

The Medical Devices and Health Study

INFORMATION FOR STUDY PARTICIPANTS

The National Centre for Epidemiology and Population Health

The Australian National University

What is the aim of the study?
The research will investigate the effectiveness of treatments involving medical devices. Although new devices are tested before approval is given for their use, limited information is available on their effectiveness in the longer term. Devices that will be examined in this study include pacemakers and defibrillators, heart valves, vascular grafts, intra-optic lenses and hip replacements.
To assess the effectiveness of these devices, we will collect information about individual use of health-care services (ie. visits to doctors and hospitals). Using this information, we will be able to construct patient histories and thus determine how each person has fared after their operation. Some of this information is already stored in various health data collections compiled by Medibank Private, the Health Insurance Commission and the Australian Institute of Health and Welfare.

What are we asking you to do?
Read the enclosed information, answer the questions on the back of the Medibank letter (section A) then complete and sign the consent form (section B, the green page). Return these to Medibank Private in the envelope enclosed.
At a later stage, some will be asked to fill out a mailed questionnaire. This questionnaire will ask for more detail about your health over the past five years.

Please note that you will *not* be asked to have any medical tests or examinations as part of this study.

Who is responsible for the study?
A team of researchers at the National Centre for Epidemiology and Population Health (NCEPH) will conduct the study.

What information about you will be collected from the databases?
The information about you that will be collected is:
Identifying information: age, sex, addresses, date of birth, country of birth and Medicare card number.
Information about your use of medical services from Medibank Private, the Health Insurance Commission, the Australian Institute of Health and Welfare, the Department of Veterans Affairs and state Health Departments.

This information is about your:
Visits to hospital; dates, treatments and diagnosis
Visits to your doctor; dates and specialty.

What period will the study cover?
The study will include information about health services that you received between 1992 and 1997 inclusive.

Why do we need your Medicare number?
The Health Insurance Commission will use your Medicare Number to collect information on all your medical services. These details were used by the Health Insurance Commission to pay your doctor and pharmacist for the services provided.

How will the information be used in the study?
The information will be used to develop a profile of your health care service use and later to assess the effectiveness of your treatment. Profiles of all participants will then be pooled for statistical analysis and you will not be identifiable in any of the results or reports arising from the study.

What if you later want to withdraw from the Study?
You have the right to withdraw your consent at any time. If you withdraw, your name will be removed from the file and no additional information will be requested. However any information already collected that has been de-identified will not be able to be tracked and will therefor remain as part of the study. (A withdrawal form will be supplied on request).

Who can consent for, or on behalf of, a member?
A guardian, next of kin or legally appointed 'next-friend' can consent on behalf of a member.

In the case of deceased persons who were members of Medibank Private, every effort has been made to contact their next of kin who is most likely to be in a legal position to consent to the release of information on the deceased person to the NCEPH. Documentary evidence of the next of kin's relationship to the deceased person is not required to be sighted by Medibank Private.

Devices and Health Study.

Appendix 6: The Consent Form

Section B: page 1

This form should be completed by the member themselves or by the member's guardian or next of kin (or legally appointed 'next-friend').

I ……..

authorise all of the following agencies to release information:
Medibank Private
Health Insurance Commission (Medicare and Pharmaceutical Benefits Scheme)
Department of Veterans Affairs (if applicable)
Australian Institute of Health and Welfare
State Health Departments

about …… **(myself, or name of member. If member is not completing this consent form, include the relationship to the member.)**
regarding my medical treatments to the National Centre for Epidemiology and Population Health, Australian National University (ANU), for their use during the Devices and Health Study.

I have read the study information (yellow brochure) which explains the request for access to **my/the member's** records. I consent to the release of information to the ANU by the listed agencies about medical and pharmaceutical services. The study will use information about services used between the beginning of 1992 and the end of 1997**.**

2. I understand that the ANU will have access to information about individual service use that identifies the member. This will include information about medical, pharmaceutical, hospital, outpatients and private health care services.

3. I understand that I can withdraw my consent for further participation in the Study at any time. Should I wish to do this, I will inform the research team at the Australian National University in writing. No further information will then be requested for the purposes of the study. Information that has been collected will be erased if it has not already been de-identified.

5. Before signing this document, I have been given the opportunity to ask any questions about the Study.

I understand that the information may be collected, stored, and analysed only for the purposes of the Study. The results of the Study may be published provided that no participant's name is released and that the participant's identity cannot be determined in any way from the materials published.

Continued over…

CONSENT FORM page 2

Please complete this form in BLOCK LETTERS.

Member's Family Name ……..

Given Name/s …… Sex __

Address ……..…….. Postcode __ __ __ __

Date of Birth (day/month/year) __ __ /__ __ /__ __ __ __

Country of birth……

(Date of death (day/month/year) __ __ /__ __ /__ __ __ __
if you are completing this form for a member who is deceased)

If you have changed address in the last six years, it would assist us if you could supply

postcodes for each period: 1992 __ __ __ __ 1993 __ __ __ __ 1994 __ __ __ __

1995 __ __ __ __ 1996 __ __ __ __ 1997 __ __ __ __

Medicare Card Number: __ __ __ __ - __ __ __ __ __ - __

Subnumerate: __
(the number to the left of member's name on the card)

Health Care Card Number. ……..
(if applicable)

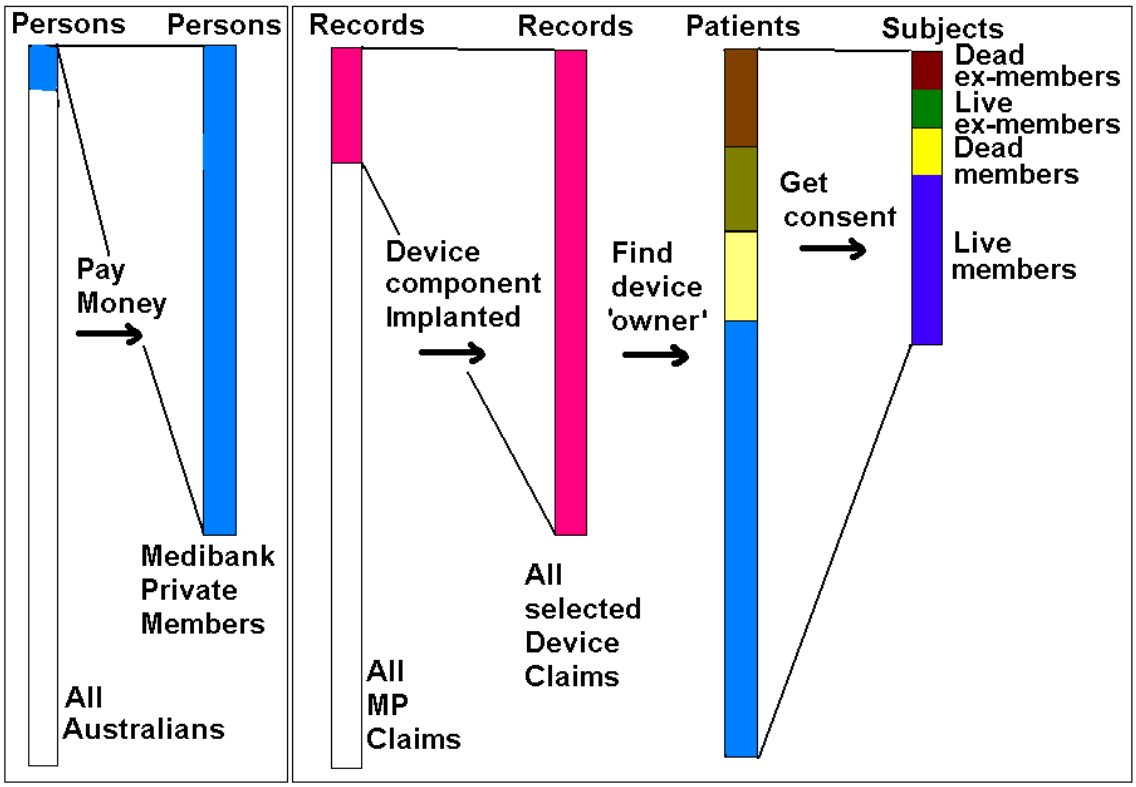
Pension/Veterans File Number. __ __ __ __ __ __ __ __ __ __
(if applicable)

Member/Guardian Signature: …….. **Date:** __ __ /__ __ /__ __ __ __

Relationship if you are signing for the member: ……..

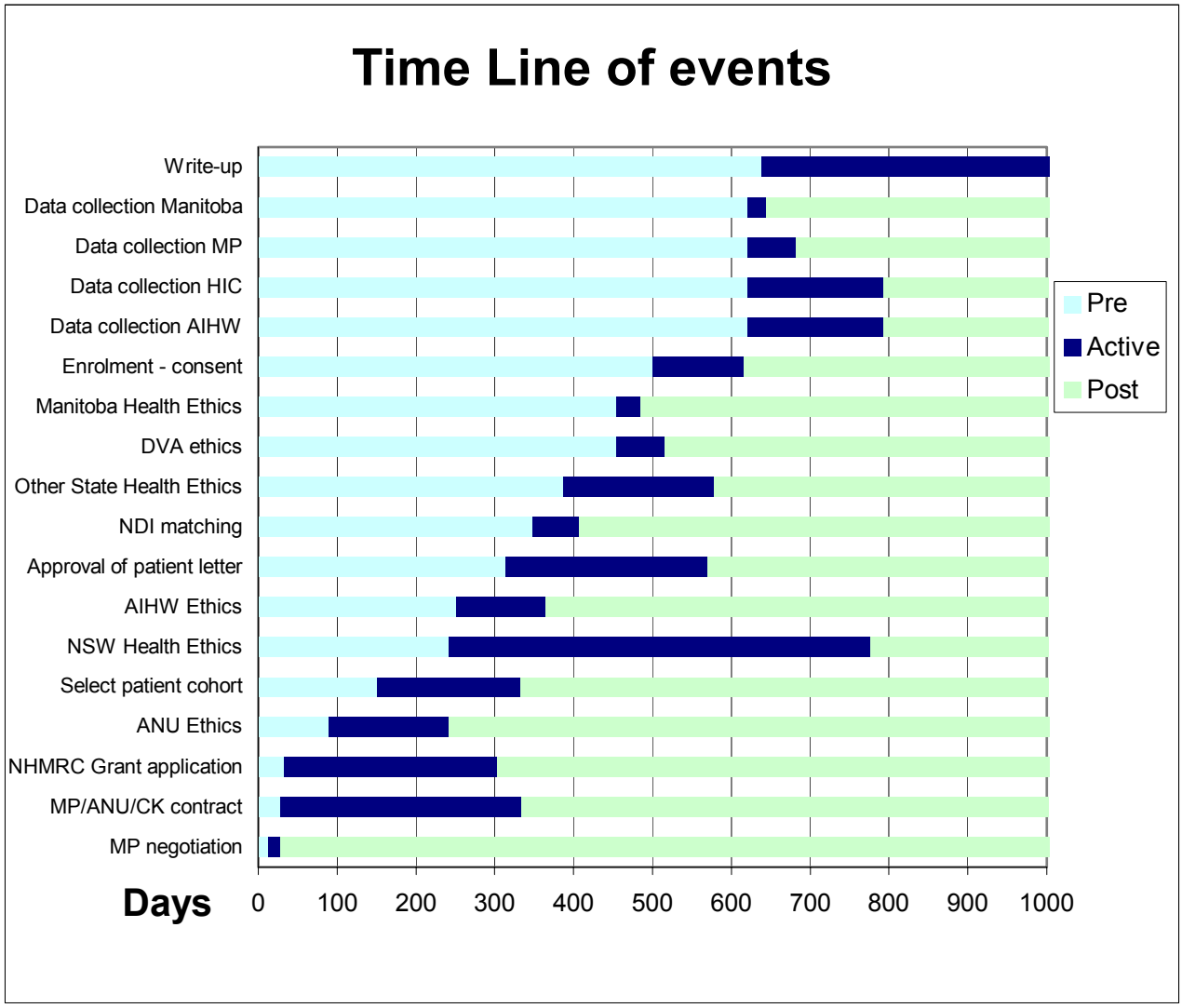
Appendix 7: Flow charts

Figure A7-1 Gathering the cohort, sets and subsets of Australians:



This figure shows the links between the various groups of persons some of whom eventually comprised the Australian Medical Devices Study cohort.

Figure A7-2 The Medical Devices Study time line



This figure demonstrates the relative amounts of time expended on the various stages of the studies. It shows that for health research using the Australian administrative data, the majority of researcher time is spent in mastering a series of bureaucratic requirements. The situation in Manitoba is quite different.

Appendix 8: Data Fields

A: Data fields requested and received from the various institutions

Data fields submitted to the AIHW, DVA and HIC for matching.
Fields are from the claims archive of
Medibank private

PATIENT ID number
DATE OF SERVICE
TYPE OF SERVICE
HOSPITAL
PROVIDER
REFERRING PROVIDER
TYPE OF IMPLANT
CLAIM
BENEFIT
OP_TOTAL
HIC_COST

After identification of the patients, the following fields were requested from the various collections:

MBS/DVA:

MEDICARE/DVA #
DATE OF SERVICE
BENEFIT
HOSPITAL
ITEM #
PROVIDER #
REFERRING PROVIDER
REFERRAL DATE
PROVIDER SPECIALTY (or table for decode)

PBS dataset:

MEDICARE/DVA #
DATE OF SCRIPT
DRUGS PRESCRIBED
PHARMACY CODE (+ location decode)

NHMDS:

RECORD ID
STATE
DATASET YEAR
SECTOR
SEX
DOB
COUNTRY OF BIRTH
MARITAL STATUS
PATIENT ACCOM STATUS
INSURANCE STATUS
ADMISSION DATE
SEPARATION DATE
REFERRAL SOURCE
SEPARATION MODE
EXTERNAL CAUSE
DRG
PRINCIPAL DIAGNOSIS
PRINCIPAL PROCEDURE

B: National Data Collections: Contents

National Death Index core data items
State of registration
Registration number
Year of registration
Full name including aliases where applicable
Maiden name if female
Sex
Date of birth
Date of death
Aboriginality
Marital status
Cause of death code (ICD Ninth Revision)

HIC Medicare data available:
Personal Identification Number (PIN)
Date of Service
MBS item number
Annual report category of MBS item number (Pathology, Radiology etc)
Hospital flag
Number of services
Benefit (rebate)
Schedule fee
Charge

PBS data available to the Medical Devices study:
Medicare number
Doctor ID
Supply date
Drug identifier (DIN)
Pharmacy ID

Medibank Private Claims Archive contents

Variable	description
book	membership number.,
cover	represents level of cover the member holds
state	state where members joined (not necessarily address state)
clmtype	type of hospital claim ,
pin	member identification number
proys	provider (hospital/medical) and last digit represents location
prgrp	provider group/ type of facility where service provided (R=private, U=public, M=medical, 0=other) ;
type	type of service provided and associated with claimtype
acmtype	accommodation room type (P=private, S=shared)
acmlevel	accommodation stepdown level
age 1	patient's age at the start of the service date
age2	patient's age at the end of the service date ;
length	length of membership with Medibank at the time of service
dosf	service start date/ admission period
dost	service end date 1 discharge period
dop	the date the claim was processed by Medibank staff
benefit	dollar amount of benefit paid to member
fed	front end deductible excess amount member is liable to pay
charge	the amount actually charged by provider to the patient
services	number of items provided by the medical provider of that type code;
bed days	the number of bed days the patient spent in hospital
scale	scale of membership cover (F=family, S=single)

The Extras claims history includes the following variables:

trrntid	unique number allocated to each treatment claim
lntype	0 refers to original line, R is for reversing entry;
book	membership number;
cover	represents level of cover
state	state where members joined (not necessarily address state)
clmtype	'E'xtras claim type ;
pin	member identification number
proys	ancillary provider number ;
item	type of service provided
dos	the actual date the service was provided
dop	the date the claim was processed by Medibank staff
benefit	dollar amount of benefit paid to member
services	number of items provided by the provider on that type code
charge	the amount actually charged by provider to the patient
length	length of membership with Medibank at the time of service
scale	scale of membership cover (F=family, S=single)

Appendix 9: Sample case history for a typical hip patient with poor outcome

As an example of the type of case that was detected using a search of procedure codes potentially related to adverse outcomes following a hip implant, a case history has been compiled from all data relating to this patient. Individual procedure codes were decoded with text descriptions to allow the record to be interpreted.

This patient was aged 77 when she was admitted for the 'index' procedure (arthroplasty) in January 1993, she received a Zimmer hip prosthesis. Nine days later she required a CT brain scan, presumably for a suspected CVA. She remained in hospital for 13 days on this occasion.

In July 1993 she was admitted again for 49 days for implantation of a knee prosthesis

In February 96, she was admitted for an Osteonics hip prosthesis; this procedure was noted to be a revision. She then had a series of complications, two attempts were made to reduce a hip dislocation with closed reduction, then six weeks later another attempt was made using an Osteonics revision. After this procedure, she was again treated with a closed reduction for hip dislocation and then remained in a private room in a public hospital for another month. The total time in hospital on this occasion was around six months. Total costs for the first hip implant procedure was around $16,000, however to perform the revisions an additional $95,000 was spent.

In responding to the mailed questionnaire, this lady assessed her current and previous health as 'good' and in answer to the question about how her medical implant had affected her health she judged that it had made it 'worse' rather than 'much worse'. However in spite of these experiences, she returned 15 months later for implantation of an Acrylic Intra Optic Lens. At the end of the study she was alive and still a member of Medibank Private.

Total costs and bed-days for these admissions are noted below in Table 1. A condensed case history is shown Table 2. Services suspected to be 'related' to her index operation are noted in the columns entitled early (complication), late (complication) or revision. Providers are coded with letters A to M.

Table A9-1 Duration and costs of orthopaedic admissions

Admission date	bed-days	$ total	Reason
05-Jan-93	9	16,066.80	Zimmer prosthesis
14-Jan-93	4	2,157.00	Complications
14-Jul-93	50	40,563.25	Knee prosthesis
05-Feb-96	180	95,541.60	Hip revision
	248	154,328.65	Total costs

Table A9-2 Service record for patient with poor outcome following hip replacement

Case History for Pt 2976, Hip replacement poor outcome.

					'Related' procedure?			
Date	**Fee**	**Provider**	**Provider**	**Beddays**	**Early**	**Late**	**Revision**	**Description**
05-01-93			A	9				Zimmer prosthesis (index procedure)
14.01.93	172.5	56006	D		**1**			CTscan brain
18.01.93	2060	ASP2	A	4	**1**			ADVANCED SURGICAL PRIVATE ROOM LEVEL 2
14.07.93	5280	MDP1	A	12				MEDICAL PRIVATE ROOM LEVEL 1
26.07.93	1080	ASP1	A	2				ADVANCED SURGICAL PRIVATE ROOM LEVEL 1
28.07.93	3750	ICU1	A	2				INTENSIVE CARE LEVEL 1
30.07.93	4860	ASP1	A	9				ADVANCED SURGICAL PRIVATE ROOM LEVEL 1
08.08.93	540	ASP1	A	1				ADVANCED SURGICAL PRIVATE ROOM LEVEL 1
09.08.93	4635	ASP2	A	9				ADVANCED SURGICAL PRIVATE ROOM LEVEL 2
18.08.93	3090	ASP2	A	6				ADVANCED SURGICAL PRIVATE ROOM LEVEL 2
24.08.93	4635	ASP2	A	9				ADVANCED SURGICAL PRIVATE ROOM LEVEL 2
22.01.96	440	MDP1	A	1				MEDICAL PRIVATE ROOM LEVEL 1
23.01.96	64.6	13815	B					Central vein catheterisation (via jugular,
23.01.96	1875	ICU1	A	1				INTENSIVE CARE LEVEL 1
23.01.96	46.95	13815	C					Central vein catheterisation (via jugular,
24.01.96	5280	MDP1	A	12				MEDICAL PRIVATE ROOM LEVEL 1
05.02.96	52.5	11600	B					Blood pressure monitoring (central venous,
05.02.96	64.6	13815	B					Central vein catheterisation (via jugular,
05.02.96	52.5	13842	B					Intra-arterial cannulisation for the purpos
05.02.96	85	SRP1	A	1				SURGICAL PRIVATE ROOM LEVEL 1
05.02.96	76.3	11600	C					Blood pressure monitoring (central venous,
05.02.96	46.95	13815	C					Central vein catheterisation (via jugular,
05.02.96	38.15	13842	C					Intra-arterial cannulisation for the purpos
06.02.96	642.3	49346	E				**1**	Hip, revision arthroplasty with replacement head or liner
06.02.96	33.25	66225	F					Quantitation of: (a) blood gases (including pO2, oxy
06.02.96	3750	ICU1	A	2				INTENSIVE CARE LEVEL 1
06.02.96	466.7	49346	G				**1**	Hip, revision arthroplasty with replacement head or liner
06.02.96	24.95	66225	H					Quantitation of: (a) blood gases (including pO2, oxy
08.02.96	935	SRP1	A	11				SURGICAL PRIVATE ROOM LEVEL 1
19.02.96	2975	MDP2	A	7				MEDICAL PRIVATE ROOM LEVEL 2
26.02.96	4250	MDP2	A	10				MEDICAL PRIVATE ROOM LEVEL 2
10.03.96	246.2	47048	M			**1**		Hip, treatment of dislocation of, by closed
10.03.96	850	SRP1	A	10				SURGICAL PRIVATE ROOM LEVEL 1
10.03.96	178.9	47048	I			**1**		Hip, treatment of dislocation of, by closed
20.03.96	1760	MDP1	A	4				MEDICAL PRIVATE ROOM LEVEL 1
21.03.96	246.2	47048	M			**1**		Hip, treatment of dislocation of, by closed
24.03.96	85	SRP1	A	1				SURGICAL PRIVATE ROOM LEVEL 1
25.03.96	52.5	11600	J					Blood pressure monitoring (central venous,
25.03.96	64.6	13815	J					Central vein catheterisation (via jugular,
25.03.96	52.5	13842	J					Intra-arterial cannulisation for the purpos
25.03.96	1641	49327	E				**1**	Hip, total replacement arthroplasty of, revision with bone graft
25.03.96	33.25	66225	F					Quantitation of: (a) blood gases (including pO2, oxy
25.03.96	7560	ASP1	A	14				ADVANCED SURGICAL PRIVATE ROOM LEVEL 1
25.03.96	76.3	11600	K					Blood pressure monitoring (central venous,
25.03.96	46.95	13815	K					Central vein catheterisation (via jugular,
25.03.96	38.15	13842	K					Intra-arterial cannulisation for the purpos
25.03.96	1193	49327	G				**1**	Hip, total replacement arthroplasty of, revision with bone graft

25.03.96	24.95	66225	H			Quantitation of: (a) blood gases (including pO2, oxy
26.03.96	33.25	66225	F			Quantitation of: (a) blood gases (including pO2, oxy
27.03.96	246.2	47048	M		**1**	Hip, treatment of dislocation of, by closed
08.04.96	3605	ASP2	A	7		ADVANCED SURGICAL PRIVATE ROOM LEVEL 2
15.04.96	3605	ASP2	A	7		ADVANCED SURGICAL PRIVATE ROOM LEVEL 2
22.04.96	11845	ASP2	A	23		ADVANCED SURGICAL PRIVATE ROOM LEVEL 2
15.05.96	3080	MDP1	A	7		MEDICAL PRIVATE ROOM LEVEL 1
22.05.96	4727	PBP1	L	29		PUBLIC HOSPITAL PRIVATE ROOM
20.06.96	1141	PBP1	L	7		PUBLIC HOSPITAL PRIVATE ROOM
27.06.96	652	PBP1	L	4		PUBLIC HOSPITAL PRIVATE ROOM
01.07.96	2934	PBP1	L	18		PUBLIC HOSPITAL PRIVATE ROOM
26.11.97	540	ASP1	A	1		ADVANCED SURGICAL PRIVATE ROOM LEVEL 1

Appendix 10: SPSS syntax file

To examine utilisation by monthly fees paid. All patient services are synchronised relative to the date of their index operation. (Condensed)

```
* ENTER EXCLUSION PERIODS IN DAYS: X = PRE-OP, Y= POST-OP
Z=POST-OP DEATHS PERIOD, FOLLOW UP PERIOD IS 60 MONTHS.
COMPUTE csecs = 86400.
COMPUTE x=  60*csecs.
COMPUTE y= 60*csecs.
COMPUTE z= 30 *csecs.
COMPUTE timeobs = 60*(30.4375*csecs).
FORMATS date  dod clsedate (edate8).
NUMERIC popdeath preop fpostop (F1.0).

*FLAG PRE AND POST OP ENTRIES.
IF date <=indxdate preop=1.
IF date > indxdate fpostop=1.
IF dod < indxdate + z popdeath =1.
DO IF preop=1.
COMPUTE fee1=fee.
COMPUTE beddays1= beddays.
END IF.
DO IF fpostop=1.
COMPUTE fee2=fee.
COMPUTE beddays2= beddays.
END IF.

*SET UP CONSTANTS AND START/FINISH DATES.
COMPUTE cmonths = 12/(365.25*csecs).
COMPUTE obs1=(indxdate - date.dmy(01,01,1993) - x)*cmonths.
COMPUTE endobs = (indxdate + y + timeobs).
DO IF (endobs > date.dmy(31,12,1997)).
COMPUTE endobs = date.dmy(31,12,1997).
END IF.
COMPUTE start =(indxdate + y).
FORMATS start endobs (edate8).

DO IF (sysmis(dod) AND sysmis(clsedate)).
COMPUTE obs2 = (date.dmy(31,12,1997) - (indxdate + y))*cmonths.
ELSE IF (dod <= endobs).
COMPUTE obs2=(dod - start)*cmonths.
COMPUTE endobs = dod.
END IF.

DO IF  (sysmis(dod) AND (clsedate <= endobs)).
COMPUTE obs2=(clsedate - start)*cmonths.
COMPUTE endobs = clsedate.
END IF.

* SET UP MONTHLY OBS PERIODS EACH OF 30 DAYS.
```

```
DO IF (date < (indxdate - 360*csecs) AND (indxdate - 360*csecs) >
date.dmy(01,01,1993)).
COMPUTE pre13 = 1.
ELSE IF (date < (indxdate - 330*csecs) AND (indxdate - 330*csecs) >
date.dmy(01,01,1993)).
.
.(REPEAT FOR INTERVENING PERIODS)
.
ELSE IF (date < (indxdate - 30*csecs) AND (indxdate - 30*csecs) >
date.dmy(01,01,1993)).
COMPUTE pre2 = 1.
ELSE IF (date <= indxdate).
COMPUTE pre1 = 1.
END IF.
EXECUTE.

*FLAG ENTRIES ACCORDING TO WHERE THEY FALL IN THE OBS PERIOD.
DO IF  (date > (indxdate + 1770*csecs) AND (indxdate + 1770*csecs) <= endobs).
COMPUTE fpost60= 1.
ELSE IF (date > (indxdate + 1740*csecs) AND (indxdate + 1740*csecs) <= endobs).
COMPUTE fpost59= 1.
ELSE IF (date > (indxdate + 1710*csecs) AND (indxdate + 1710*csecs) <= endobs).
COMPUTE fpost58= 1.
.
.(REPEAT FOR INTERVEING PERIODS)
.
ELSE IF (date > (indxdate + 30*csecs) AND (indxdate + 30*csecs) <= endobs).
COMPUTE fpost2 = 1.
ELSE IF (date > indxdate).
COMPUTE fpost1 = 1.
END IF.
EXECUTE.

* TAG THOSE SERVICES THAT FALL WITHIN THE OBSERVATION PERIOD,
BEFORE DEATH OR CLSEDATE.
SELECT IF (date <= endobs).

*COLLECT ALL CORRELATED SERVICE MEASURES AND SUM.
do repeat
  #v=pre13 pre12 pre11 pre10 pre9 pre8 pre7 pre6 pre5 pre4 pre3 pre2 pre1 fpost60
…….. fpost3 fpost2 fpost1.
if #v=1 #f=fee.
end repeat.
execute.

AGGREGATE
  /OUTFILE=*
  /BREAK=id obs1 obs2
 /fpre13 fpre12 fpre11 fpre10 fpre9 fpre8 fpre7 fpre6 fpre5 fpre4 fpre3 fpre2 fpre1
fpost60….. fpost3 fpost2 fpost1
```

```
  =sum(  fpre13 fpre12 fpre11 fpre10 fpre9 fpre8 fpre7 fpre6 fpre5 fpre4 fpre3 fpre2
fpre1
  fpost60 …. fpost3 fpost2 fpost1).
EXECUTE.

*WEED OUT THOSE AGGREGATES THAT REFER TO SUMS BEFORE THE
OBSERVATION PERIOD.
DO IF (obs1 < 1).
RECODE fpre2 fpre3 fpre4 fpre5 fpre6 fpre7 fpre8 fpre9 fpre10 fpre11 fpre12 fpre13
(0=SYSMIS).
.
. (REPEAT FOR INTERVENING PERIODS)
.
ELSE IF (obs1 < 12).
RECODE  fpre13 (0=SYSMIS).
END IF.

*AND THOSE AFTER THE OBS PERIOD.
DO IF (obs2 < 1).
RECODE  fpost2 fpost3 fpost4 fpost5 fpost6 fpost7 fpost8 fpost9
 fpost10 fpost11 fpost12 fpost13 fpost14 fpost15 fpost16 fpost17 fpost18 fpost19
 fpost20 fpost21 fpost22 fpost23 fpost24 fpost25 fpost26 fpost27 fpost28 fpost29
 fpost30 fpost31 fpost32 fpost33 fpost34 fpost35 fpost36 fpost37 fpost38 fpost39
 fpost40 fpost41 fpost42 fpost43 fpost44 fpost45 fpost46 fpost47 fpost48 fpost49
 fpost50 fpost51 fpost52 fpost53 fpost54 fpost55 fpost56 fpost57 fpost58 fpost59
 fpost60 (0=SYSMIS).
.
. (REPEAT FOR INTERVENING PERIODS)
.
ELSE IF (obs2 < 58).
RECODE  fpost59
 fpost60 (0=SYSMIS).
ELSE IF (obs2 < 59).
RECODE  fpost60 (0=SYSMIS).
END IF.
EXECUTE.

FREQUENCIES
  VARIABLES= fpre13 fpre12 fpre11 fpre10 fpre9 fpre8 fpre7 fpre6 fpre5 fpre4
  fpre3 fpre2 fpre1 fpost1 fpost2 fpost3 fpost4 fpost5 fpost6 fpost7
  fpost8 fpost9 fpost10 fpost11 fpost12 fpost13 fpost14 fpost15
  fpost16 fpost17 fpost18 fpost19 fpost20 fpost21 fpost22 fpost23
  fpost24 fpost25 fpost26 fpost27 fpost28 fpost29 fpost30 fpost31
  fpost32 fpost33 fpost34 fpost35 fpost36 fpost37 fpost38 fpost39
  fpost40 fpost41 fpost42 fpost43 fpost44 fpost45 fpost46 fpost47
  fpost48 fpost49 fpost50 fpost51 fpost52 fpost53 fpost54 fpost55
  fpost56 fpost57 fpost58 fpost59 fpost60  /FORMAT=NOTABLE
  /STATISTICS=MEAN    /ORDER  ANALYSIS .
```

Appendix 11: "Related" events for post-operative complications of Arthroplasty

Table A11-1 'Related'events for post-op complications

Degree[1]	Code[2]	Brief Description	$	Condition suspected
1	11503	Measurement of the mechanical or gas exchange	105.05	DVT, ICU care
1	11600	Blood pressure monitoring (central venous,	52.50	DVT, ICU care
1	11701	Twelve-lead electrocardiography, report only	11.80	DVT
1	13815	Central vein catheterisation (via jugular,	64.60	ICU care
1	13839	Arterial puncture and collection of blood	17.45	ICU care
1	13842	Intra-arterial cannulisation	52.50	ICU care
1	13918	Chemotherapy, administration of, by IV	74.20	ICU care
1	13921	Chemotherapy, administration of, by IV	83.95	ICU care
1	13924	Chemotherapy, administration of, by IV	49.50	ICU care
1	13927	Chemotherapy, administration of,	64.00	ICU care
1	13930	Chemotherapy, administration of, by intra-a	89.25	ICU care
1	13933	Chemotherapy, administration of, by intra-a	99.00	ICU care
1	13936	Chemotherapy, administration of, by intra-a	64.50	ICU care
1	49303	Hip, arthrotomy of, including lavage, drain	413.85	Infection
1	55244	Duplex scanning, unilateral, involving B mode	172.90	DVT
1	55245	Duplex scanning, unilateral, involving B mode	201.00	DVT
1	55262	Duplex scanning, bilateral, involving B mode	172.90	DVT
1	55263	Duplex scanning, bilateral, involving B mode	201.00	DVT
1	56001	Computerised tomography - scan of brain	201.45	DVT, embolus, stroke
1	56003	CTscan brain	198.00	DVT, embolus, stroke
1	56006	CTscan brain	234.60	DVT, embolus, stroke
1	56007	Computerised tomography - scan of brain	257.25	DVT, embolus, stroke
1	56301	Computerised tomography - scan of chest,	305.05	DVT, embolus, stroke
1	56303	CTscan chest	294.60	DVT, embolus, stroke
1	56306	CTscan chest	371.00	DVT, embolus, stroke
1	56307	Computerised tomography - scan of chest,	412.70	DVT, embolus, stroke
1	61328	Lung perfusion study, with planar imaging	189.40	DVT, embolus, stroke
1	61348	Lung perfusion study and lung ventilation	388.95	DVT, embolus, stroke
1	66225	Quantitation of: (a) blood gases (including pO2,	33.25	DVT, embolus, stroke
1	69293	Blood culture for pathogenic micro-organisms	30.00	Infection
2	47048	Hip, treatment of dislocation of, by closed	246.20	Fracture/dislocation
2	47051	Hip, treatment of dislocation of, by open r	328.20	Fracture/dislocation
2	47492	Acetabulum, treatment of fracture of, and	178.45	Fracture/dislocation
2	47495	Acetabulum, treatment of fracture of, and	356.75	Fracture/dislocation
2	47498	Acetabulum, treatment of fracture of, and	535.15	Fracture/dislocation
2	47501	Acetabulum, treatment of single column #	713.55	Fracture/dislocation
2	47504	Acetabulum, treatment of T-shape #	1070.35	Fracture/dislocation
2	47507	Acetabulum, treatment of transverse #	1070.35	Fracture/dislocation
2	47510	Acetabulum, treatment of double column #	1070.35	Fracture/dislocation
2	47516	Femur, treatment of fracture of, by closed	328.20	Fracture/dislocation
2	47519	Femur, treatment of trochanteric or subcapital	656.50	Fracture/dislocation
2	47522	Femur, treatment of subcapital fracture	570.90	Fracture/dislocation
2	47528	Femur, treatment of fracture of, by interna	570.90	Fracture/dislocation
2	47531	Femur, treatment of fracture of shaft,	727.85	Fracture/dislocation
2	47534	Femur, condylar region of, treatment of int	820.60	Fracture/dislocation

2	47537	Femur, condylar region of, treatment of #	328.20	Fracture/dislocation
2	49306	Hip - arthrodesis of (Assist.)	820.60	Implant failure
2	49315	Hip, arthroplasty of, unipolar or bipolar	642.25	Implant other side
	2 49318	Hip, total replacement arthroplasty of,	998.95	Implant other side
	2 49319	Hip, total replacement arthroplasty of,	1754.85	Implant other side
	2 49321	Hip, total replacement arthroplasty of,	1213.15	Implant other side
	3 49309	Hip, arthrectomy or excision arthroplasty	570.90	Revision of implant
	3 49312	Hip, arthrectomy or excision arthroplasty	713.55	Revision of implant
	3 49324	Hip, total replacement arthroplasty of, rev	1427.20	Revision of implant
	3 49327	Hip, total replacement arthroplasty of, rev	1641.25	Revision of implant
	3 49330	Hip, total replacement arthroplasty of, rev	1641.25	Revision of implant
	3 49333	Hip, total replacement arthroplasty of, rev	1855.30	Revision of implant
	3 49336	Hip, treatment of a fracture of the femur w	271.15	Revision of implant
	3 49339	Hip, revision total replacement of,	2105.00	Revision of implant
	3 49342	Hip, revision total replacement of,	2105.00	Revision of implant
	3 49345	Hip, revision total replacement of,	2497.55	Revision of implant
	3 49346	Hip, revision arthroplasty with replacement	642.25	Revision of implant

1 Degree indicates closeness of possible relationship to index procedure
2 MBS codes