Towards an Irish Joint Register

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A dissertation submitted to the University of Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics

Declaration

I declare that the work described in this dissertation is,

except where otherwise stated, entirely my own work,

and has not been submitted as an exercise for a degree

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Signed_____

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Summary

Data repositories which relate to particular health-care domains are used to store precise information specific to the speciality. Numerous examples exist, including renal registers, cancer, childhood illness, screening, adverse drug reaction and many more. This research is concerned with registration of data in relation to joint replacement surgery and its outcome.

Joint replacements have been widely used to treat arthritis in patients since the 1960s. The Scandinavian countries have the longest tradition in collecting data regarding this type of surgery and their registers are widely acknowledged as a valuable source of information. Their success in using this data to improve the outcome of surgery, and achieve cost efficiencies in the delivery of their health services, has been well documented. They have set the precedent for other countries to establish National Joint Registers (NJRs) but Ireland has not yet done so.

The research documents the development of NJRs and evaluates the benefits gained and challenges encountered in implementation. This is achieved through a comparative analysis of the international experience regarding management, technological contribution and information governance. The experience of a local register at Cappagh National Orthopaedic Hospital is presented and used to depict current activity in the unique context in which the Irish health services operate. The outcome of the research suggests that it is now appropriate to initiate a project which will implement an Irish NJR. The findings are used to generate a set of recommendations for its establishment.

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Abbreviations

AOA	Australian Orthopaedic Association
CIS	Clinical Information System
CNM	Clinical Nurse Manager
CNOH	Cappagh National Orthopaedic Hospital
CRR	Cumulative Revision Rate
DOH&C	Department of Health & Children
DVT	Deep Venous Thrombosis
EAR	European Arthroplasty Registry
EFORT	European Federation of Orthopaedics
ESRI	Economic and Social Research Institute
EU	European Union
GP	General Practitioner
HIB	Health Information Bill
HIPE	Hospital In-patient Enquiry System
HIQA	Health Information and Quality Authority
HSE	Health Services Executive
ICT	Information and Communications Technology
IOA	Irish Orthopaedic Association
ISAR	International Society of Arthroplasty Registers
NHIS	National Health Information Strategy
NJR	National Joint Register
OA	Orthopaedic Association

OECDOrgan	isation for Economic Co-operation and Development
OHS	Oxford Hip Score
OMR	Optical Mark Reader
OPD	Out-Patients Department
PACS	Picture Archive and Communications System
PE	Pulmonary Embolism
QOL	Quality of Life
RCT	Randomised Control Trial
ROI	Republic of Ireland
SKAR	Swedish Knee Arthroplasty Register
SOR	Swiss Orthopaedic Register
THR	
TKR	Total Knee Replacement
UPI	Unique Patient Identifier
WOMAC	Western Ontario McMaster Osteoarthritis Index

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1.1 Introduction

Registration of personal data has a long history dating back to the ancient world

Caesar Augustus issued a decree that a census should be taken of the entire Roman world. This was the first census that took place while Quirinius was governor of Syria. And everyone went to his own town to register (Luke 2:1-3).

Many Christians believe that Joseph and Mary travelled from Nazareth to Bethlehem in order to fulfil the requirements of the decree and register. Over the centuries, the tradition of data registration was upheld but it was not until the eighteenth century that the importance of national statistics was recognised, and it was the nineteenth century before any systematic attempts were made to produce moderately reliable data¹. Systems evolved in the twentieth century in response to an inadequacy in the methods of compiling information and in an effort to produce a standard of reference from which meaningful statistics could be derived. The advent of computers facilitated further development and revolutionised methodologies.

Today, Information and Communications Technology (ICT) has provided a multiplicity of means in which to assist in the collection, storage, retrieval and analysis of data, often dispensing with the need to travel. While it is not the intention to speculate on the consequences of that trip to Bethlehem had these ICT infrastructures been in place, the research will provide an insight into the current practice concerning the registration of data in relation to Joint Replacement Surgery. It will evaluate the benefits of establishing a repository of Irish data by examining existing National Joint Registers (NJR), clarify the rationale behind such an initiative and produce a set of recommendations for its establishment based on international best practice.

¹ (Pollock A, Evans M., 1993)

1.2 Motivation

This researcher has been involved in elective orthopaedic nursing for several years having broad experience across various clinical areas at Cappagh National Orthopaedic Hospital (CNOH). In 2004, a pilot study that endeavoured to ascertain the feasibility of developing a local register of data in relation to hip and knee replacement surgery was established at the hospital. ICT infrastructures were created to support anticipated requirements and existing clinical information systems were adapted to accommodate data collection. The researcher had cultivated an interest in healthcare ICT during the course of a Bachelor degree in Health Services Management, therefore was particularly attracted to any new developments within the hospital. In 2005, she was appointed as the clinician concerned with the review process at specially designated, Nurse-led, post-operative clinics.

Following the success of the pilot study, registration of data concerning all Total Hip (THR) and Total Knee Replacements (TKR) performed at CNOH commenced in January 2006. Review of patients at regular intervals was initiated so that clinical data regarding disease specific adverse outcomes and quality of life information could be recorded. This practice of prospective monitoring had been well established in the international orthopaedic arena, but no such efforts had been undertaken on such a scale in the Republic of Ireland (ROI). It was hoped that the register would form the basis for the development of a NJR, which would consider prevailing cultural and epidemiological conditions, in the particular context of the nature and structure of the Irish health services.

It is now almost five years since the inception of the Joint Register at CNOH and many of the initial difficulties have been overcome. However, the dynamic nature of the endeavour, and its quest to collect meaningful, complete and high quality data, implies that new challenges are frequently encountered. While the researcher's role has been enhanced in response to the register's expansion, the initial interest has been sustained and any opportunity to augment its development through the research process is embraced. It is against this background that the study is undertaken.

1.3 The Research Question and Objectives

The aim of the study is to provide an insight into the benefits to be gained, and the challenges to be overcome, through the establishment of a NJR. It is expected that by evaluating the experience of other countries, a body of evidence based on best-practice regarding exactly what type of information to collect, and how to collect it, will be produced. This will provide the framework from which to derive a set of recommendations for the establishment of an Irish NJR.

In order to achieve its aim the following research question was formulated

Would the establishment of a NJR add value to the Irish health services and if so, how should its development be approached?

This poses a subsidiary question

Are the necessary infrastructures in place to support its development?

The focus of this research is to address these questions thereby generating a convincing argument in support of the answers.

1.4 Outline of the Research

The researcher is aware of the existence of registers both within the European Union (EU) and beyond. An historical chronology of the development of these will be presented and a comparative analysis of how they operate will be undertaken. Issues such as structure, funding, consent, privacy & security of data, methods of data collection, dataset, regulation, funding and publication of findings will be explored. Benefits gained and challenges encountered by the existing registers will be evaluated through a comprehensive review of the literature. The current Irish position regarding data collection in relation to joint replacements will be explored so that this practice can be assessed for suitability when making recommendations for a NJR. Activity levels amongst individual surgeons will be analysed with a view to establishing the level of interest in contributing to a collective database, which would form the basis on which to develop a NJR. The national strategy for ICT development will be examined to determine whether

government policies are in place to provide the required infrastructures.

1.5 Outline of the Dissertation

Chapter 1 has introduced the research, its motivation and objectives, and conceptualised the notion of a NJR. The research question has been presented and an overview of how it will be addressed has been given. The following chapters will provide the specific detail of that which has been introduced.

The historical background and development of registers in general, and Joint Registers in particular is considered in chapter 2. The pioneering registers of Scandinavia are reviewed and the benefits conferred upon its populations as a result of implementation are discussed. The precedent set here stimulated the establishment of NJRs in many modern healthcare systems. These are explored in chapter 3 and the literature pertaining to the specifics of individual registers are examined. The benefits and challenges encountered in the establishment of a NJR are evaluated, and considered for transferability to the unique Irish context. An overview of current orthopaedic practice in the ROI is presented in chapter 4 and the features specific to the Irish perspective are evaluated. Current policy is examined with a particular emphasis on strategies in relation to healthcare ICT. Chapter 5 presents the methodology engaged in addressing the research question. A comparative analysis of existing registers, examined in chapter 3, is considered the most suitable approach to devising an effective strategy for the establishment of an Irish NJR. This forms the actual research, which is presented in chapter 6, its outcome is discussed and the evidence generated in addressing the research question is analysed.

The final chapter will conclude the study, summarise its findings, and assess its value. The limitations of the study will be presented and recommendations for further analysis in relation to the study will be made.

Chapter 2: Background & Development

2.1 Introduction

Arthroplasty is a synonym for joint replacement and is derived from the Greek words '*arthro*' meaning joint, and '*plastos*', meaning to reshape. Joint Replacement surgery has successfully alleviated pain and disability in patients with debilitating joint disease for almost half a century and remains the most effective healthcare intervention for improving quality of life (QOL)². Sir John Charnley, an English orthopaedic surgeon is widely acknowledged as a pioneer in his field having invented, in 1962, the low friction arthroplasty. No other hip implant has been tested by longer use and it is reported to have survivorship of approximately 90% in the over sixty age group³. In the younger age group, however, long-term outcomes are less certain.

The Charnley, while still widely regarded today as the gold standard⁴, has been extensively modified to adapt to changing conditions. New models are regularly introduced, so that the choice of prosthesis available to the surgeon is now vast. Furthermore, the surgical technique used to insert the prosthesis has been adapted over the years to suit individual surgeons and to take into consideration issues concerning type of metal, use of cement, surgical approach, instrumentation and various bearing surfaces. This has resulted in the generation of an even greater selection from which to choose a suitable prosthesis.

In 1996 there were 62 different hip joints marketed in the UK⁵. A decade later the Annual report of the NJR of England & Wales, documented that 155 different brands of acetabular cups, and 176 femoral components were in use. This represented an increase of 36% over the previous year for both stems and cups, which was attributed to the introduction of new brands by existing suppliers and/or improved reporting⁶. This rate of increase in the introduction of new implants affords opportunities to market prostheses without long-term performance evaluation. Where

² (Street J., Lenehen B., Flavin R., Bale E., Murray P., 2005)

³ (Curtin P., Harty J., Sheehan E., Nicholson P., Rice J., McElwaine P., 2005)

⁴ (Furnes O., Espehaug B., Lie S.A., 2002)

⁵ (Sochart D.H., Long A.J., Porter M.L., 1996)

⁶ (National Joint Registry for England and Wales 4th Annual report., 2006)

NJRs exist this has been overcome because of the evidence they provide regarding implant survival.

2.2 Anatomy of the Hip

In order to clarify the clinical context, Figure 1 illustrates the anatomy of both a normal hip joint and a diseased joint portraying degeneration of the articular surfaces. The most common cause of disease of the hip is osteoarthritis. The hip joint is a ball-in-socket joint where the ball or head of the femur (thigh bone) joins the pelvis at the socket called the acetabulum. A Total Hip Replacement is a surgical procedure which replaces all or part of the hip joint with an artificial device (prosthesis) in order to restore joint movement.







⁷(US National Library of Medicine, 2008)

The total hip prosthesis consists of three parts:

- a plastic cup that replaces the hip socket
- a metal ball that replaces the femoral head
- a metal stem that is attached to the shaft of the bone to add stability to the prosthesis

If a hemi-arthroplasty is performed, either the femoral head or the acetabulum is replaced with prosthesis. The first time a joint is replaced it is referred to as a primary, any further surgery on the same joint is called a revision.

Figure 2 THR Procedure⁷

The head of the femur and a layer of the hip socket are removed





*ADAM

A metal ball and stem are inserted in the femur and a plastic socket is placed in the enlarged pelvis cup





⁷ (US National Library of Medicine, 2008)

2.3 Background

Changing trends have resulted in improved implant technology often focusing on longer implant survival so that surgery is now performed on a more diverse patient age profile. Consequently, there is no longer a typical candidate for joint replacement surgery but a selection of implants from which to choose the most appropriate for a given patient. As new designs become available, there is a growing need to assess their performance prospectively; a NJR has been widely acknowledged as the most appropriate forum for such evaluation⁸. Randomised Controlled Trials (RCT) provide short-term evidence in relation to specific parameters, and subject to certain inclusion criteria, within a given cohort. Prospective studies focus on the longterm performance, and do not aim to replace RCTs, rather complement them. The all-inclusive nature of a register ensures the large population base necessary to provide significant evidence of differences between implants. This would require the impractical undertaking of reviewing almost 4000 patients for at least 10 years in an RCT⁹. Currently all EU member states are required by law to produce documentation necessary to obtain the CE quality mark which indicates that the prosthesis complies with European standards as detailed in the Medical Devices Directive 90/385. Yet, as suggested by Hardoon et al. this can be placed on the implant before medium- and long-term performance has been evaluated as the standards do not absolutely require clinical testing¹⁰. However, in 2008 the EU commissioned stakeholder consultation on the revision of the legal framework regarding medical devices with a view to improving the current infrastructure. This has not yet been implemented and is likely to require further evaluation¹¹.

Scandinavian countries have been collecting data concerning prostheses and technique, along with other relevant information such as age, gender, underlying disease, morbidity and QOL data, since the 1970s. They have proven to be effective in monitoring and evaluating prostheses, and the outcome of THR has improved significantly since the introduction of their NJRs¹². As a result, many other countries, including Hungary, Australia, Canada, New Zealand, UK, Slovenia and Romania have since implemented NJRs. These provide a mechanism for collection, storage, retrieval and analysis of data regarding joint replacements, and allow for dissemination of findings through annual reports, peer-reviewed journals and conferences. In

⁸ (Labek G., 2005)

⁹ (Robertson, 2007)

¹⁰ (Hardoon S.L., Lewsey J.D., Gregg P.J., Reeves B.C., van der Meulan J.H.P., 2006)

¹¹ (Europa, 2009)

¹² (Curtin P., Harty J., Sheehan E., Nicholson P., Rice J., McElwaine P., 2005)

2005, Curtin et al. identified changing trends amongst Irish orthopaedic surgeons in relation to joint replacement surgery and recommended the introduction of a NJR in order to monitor implant safety and improve outcome follow-up. To date this has not been implemented though there are efforts to collect data on a local level; this, however, is not yet documented.

It is essential to emphasise that while similar prostheses are used internationally in arthroplasty surgery, the prevailing cultural and epidemiological conditions of a particular country can influence the outcome of the intervention. Moreover, the nature and structure of the individual healthcare system must be considered when assessing the requirements for establishment of a NJR¹³. Curtin *et al* suggest that this has been demonstrated within the Scandinavian countries, where the Swedish register reported significant outcome differences in relation to the choice of cement and use of contemporary technique, while the Finnish register found differences in relation to uncemented implants.

2.4 Historical Development

Data registration has it origins in ancient times but modern record keeping, as we are familiar with in Ireland, such as registration of births, marriages and deaths, can be traced back to the nineteenth century. Until 1844, when the Registration of Marriages Act was introduced, there was no civil record of this type. The Act was amended in 1863 to include registration of births and deaths, and extended to include Roman Catholics, but has had no major amendments since¹⁴. In 1952 power was transferred to the Minister of Health to compile and publish vital statistics in the public health interest, and the system was improved to allow for the production of meaningful statistics in the Vital Statistics Regulation Act of 1954. Prior to this responsibility for health was shared with the Department of Local Government, but the controversy surrounding Dr. Noel Browne's Mother-and-Child scheme, heightened awareness amongst policy makers with regard to "Urgent problems relating to public health"¹⁵. This would suggest that the State acknowledged the role of data registration within the realm of healthcare, and McKee's reference in 1944 to the infant mortality rate in Dublin of 98 per 1,000, being three times that of the larger cities of Sweden, would imply that the Scandinavian trend towards data collection was impacting in Ireland.

 ¹³ (Labek G., Stoica C.I., Bohler N., 2008)
¹⁴ (Hensey, 1988)
¹⁵ (McKee, 1986)

Denmark has the oldest national register in the world, a cancer register dating back to 1943¹⁶, while the first nation-wide computerised disease register, also a cancer register, was established in Finland in 1952¹⁷. Professor Muller, a Swiss orthopaedic surgeon, commenced local collection of THR data at the University of Berne in 1965, establishing a tradition which ultimately led to the development of the Swiss NJR¹⁸. In 1972 Charnley referred to the need to seriously consider the central registration of implant data in the UK on a national level¹⁹. The awareness of the need to collect clinical information in the interest of healthcare appears to have been most pervasive in the Scandinavian countries where disease specific data registers have the longest history. Population registers there date back to the 16th century and were initially established in Sweden in 1975 and remains the best example of a well-functioning national register was known as the Swedish Knee Arthroplasty Project (SKAR), and commenced inclusion of THRs in 1979. Since then many other countries have established NJRs. Some chronological details of clinical data registers are presented in Figure 3.

2.4.1 SKAR

Because of its pioneering significance an overview of the SKAR project is presented. The Swedish Orthopaedic Society hosted a meeting in 1975, in Uppsala, Sweden. The main objective was to initiate a nationwide project that could prospectively monitor the performance of new knee implants, which were then being introduced prior to proven performance. Members of the society had been experimenting with knee prostheses since the 1950s but the success of Charnley's low friction THR encouraged further evaluation of possibilities for TKR. Professor Goran Bauer advocated the use of a data register in order to give early warning of inferior products based on the experience of an entire nation rather than a specialised centre. He felt

¹⁶ (Rostgaar K., Helle H., Mouridsen H.T, Lynge E., 2000)

¹⁷ (Gissler M., Haukka J., 2004)

¹⁸ (Röder C, El-Kerdi A, Frigg A, Kolling C, Staub LP, Bach B, Müller U., 2005)

¹⁹ (Philipson M.R., Westwood M.J., Geoghegan J.M., Henry A.P.J., Jeffries C.D., 2005)

²⁰ (Sokka, 2007)

Figure 3 Data Registration : Historical Table		
1952	Finland	Cancer Register
		,
1964	Cuba	Cancer Register ²⁷
1966	Finland	Adverse Drug reaction
1969	USA	Mayo Clinic Arthroplasty Register
1975	Sweden	SKAR (expanded to include hips 1979)
1977	Denmark	National Registry of Patients
1980	Finland	Orthopaedic Implant Register
1982	Finland	Drug Surveillance Register
1987	Norway	Hip Register (expanded to all joints 1994)
1995	Denmark	Hip Register (expanded to include knees 1997)
1998	Hungary, Australia	Hip and Knee Register
1998	New Zealand	Multiple Joints Register
1999	Scottish Arthroplasty Register	Multiple Joints Register
2000	Canada	Hip and Knee Register
2003	England and Wales	Hip and Knee Register
2003	Romania	Multiple Joints Register
2003	Slovakia	Hip and Knee Register
2004	Switzerland	Hip and Knee Register
2005	Italy, Slovenia, Lithuania, Estonia	National Arthroplasty Register ²²
2006	France	National Arthroplasty Register ²³

.

 ²¹ (Martin A.A., Galan Y.H., Rodriguez A.J., Graupera M., Lorenzo-Luaces P., Fernandez L.M., Camacho R., Lezcano M., 1998)
²² (Appendix 1, EAR)
²³ (Appendix 2, EAR)

that the literature gave little guidance on which to base optimal surgical treatment²⁴. The success of the project led to the establishment of the SKAR.

In 1979, the SKAR was computerised using a terminal connected through a modem to a UNIVAC 1100/80 computer. Until the introduction of the PC, specialist non-clinical technologists were required to operate the system, but in 1990, the database was moved to a PC supported by Paradox, SPSS and Microsoft excel software. This enabled the system to be maintained exclusively by orthopaedic clinicians. An acceptable data-set was devised and adjusted to changing conditions over the years. Failure of an implant was indicated if revision surgery was required suggesting that both the patient and the surgeon were dissatisfied with the outcome. Thus, the revision rate became the indicator of success. Computerisation facilitated the production of graphs representing revision rates and the cumulative revision rate (CRR)²⁵ became the benchmark against which performance was measured. Results were published through annual reports, peer-reviewed journals and conferences, both international and national. Robertson *et al.* considered the benefits of the SKAR after 25 years to be manifold, broadly falling into the categories of research, surgeon advice, patient information, political and economic.

The 2008 SKAR Annual Report records a total of 138,255 TKRs since its foundation, and provides a comprehensive set of epidemiological information describing trends in relation to gender and age distribution, incidences and prevalence, and revision rates²⁶.

2.4.2 European Arthroplasty Registry

The European Federation of Orthopaedics (EFORT) recognises the potential benefit of establishing a NJR and supports their development. In 2002 it implemented the European Arthroplasty Registry (EAR) in response to the growing interest in developing a NJR within the EU. Its basic philosophy is based on the success of the Scandinavian model and it aims to foster co-operation between independent NJRs which have been modified to take into consideration prevailing National circumstances. It acknowledges the individual nature of each participating nation and is not in any way a competitor of NJRs, rather a supranational project which does not aspire to replace a national register but to support the sharing of data through

²⁴ (Robertsson O., Lewold S., Knutson K., Lidgren L., 2000)

²⁵ (Appendix 3)

²⁶ (SKAR, 2008)

conferences and publication²⁷. Collaboration between EFORT, EAR and established European NJRs has resulted in defining the aim of a NJR as²⁸

- (i) registration in a central data-base of all primary and revision operations performed in a defined geographical area
- (ii) follow-up of the implant until it has to be revised, the patient dies, or emigrates
- (iii) failure to be defined as revision of at least one part of the implant

Appendices 1 & 2 illustrate the distribution of NJRs within the EU and provide an overview of their development over the past 4 decades. It is of significant interest to note Ireland's position on the extreme west of the continent, further isolated by the absence of EAR involvement towards NJR development.

Appendix 3 shows the reduction in CRR to 6.4% for THRs since the establishment of the Swedish Hip Arthroplasty Register and compares the rate to that of the USA, where it was estimated in June 2008 to be closer to 20%²⁹.

2.5 The 3M Capital Hip

At the 1995 Annual Conference of the British Orthopaedic Association (BOA) concern was expressed about the performance of the femoral component of a prosthesis marketed since 1991 as the 3M Capital Hip System³⁰. An investigation ensued in 1996, resulting in the issue of a Hazard Notice by the Medical Devices Agency (MDA) advising that all patients with the implant be recalled for review. A total of 4688 systems had been supplied to the UK market of which 706 (15.1%) were untraceable. The study conducted by Hardoon *et al.* suggests that had continuous monitoring methods, such as surveillance through a NJR, been available in the UK an alert would have been fired 3 years and 7 months before the Hazard Notice was issued. This would have substantially reduced the total number of patients for recall. Furthermore, the

²⁷ (Labek G., 2005)

²⁸ (Labek G., Stoica C.I., Bohler N., 2008)

²⁹ (Brockenbrough, 2008)

³⁰ (Hardoon S.L., Lewsey J.D., Gregg P.J., Reeves B.C., van der Meulan J.H.P., 2006)

paucity of information regarding those who had received the implants, and their whereabouts, would have been addressed³¹.

The Royal College of Surgeons conducted an official investigation into the 3M Capital Hip incident. In 2001 it reported the results which suggested that the poor performance of the femoral component would have been highlighted had implant data been systematically registered and analysed³².

The failure of the 3M Capital Hip emphasised the need to provide an early warning system for inferior implants. It resulted in a campaign to enhance arthroplasty surveillance with a view to improving the overall quality of outcome following surgical intervention. It has been acknowledged as a catalyst which contributed to the proliferation of NJRs established over the past decade.

2.6 Summary

The evolution of joint replacement surgery has been presented along with an overview of the anatomy of the hip joint and the arthroplasty procedure. The consequences of the abundance of choice in the range of prostheses and surgical technique, in relation to long-term performance of implants has been offered. The concept of data registration and the rationale for its application as a state governed resource has been introduced. This has been linked to the development of NJRs and their chronology has been tabled. The Scandinavians have been shown to have the longest tradition of data registration regarding arthroplasty, and their success has been universally acknowledged and emulated. EFFORT, through the EAR, has adopted the Scandinavian model and encourages development of NJRs within the EU based on the Scandinavian success. The failure of the 3M Capital Hip has been used as an example to demonstrate the need for prospective monitoring of long-term prosthetic performance.

³¹ (Fender D., Harper W.M., Gregg P.J., 2000)

³² (Joint Approach, 2003)

3.1 Introduction

The Rationale for the development of a NJR has been presented therefore the next step in the research process is to provide an insight into current practice regarding their operation. In order to do this a systematic review of the literature was undertaken with a view to addressing the research question

Would the establishment of a NJR add value to the Irish health services and if so how should its development be approached?

This was formulated based on criteria identified in the literature which would focus the research explicitly on those characteristics of a NJR which have contributed to overall success. The term "value" in this context requires some clarification since the economic value of a healthcare product is not entirely subject to the market forces of supply and demand, but is also concerned with benefit measurement such as QOL improvement³³. It is beyond the scope of this study to get involved with the arguments concerning the minutiae of economic value. However, the concept of value in healthcare economics is based on the maxim that rationing of healthcare is a reality because demand always outstrips available resources. In order to constitute value, the introduction of new practices within a healthcare system can only be justified if proven to be efficient and effective in improving the quality of patient care, defined by the degree to which health services increase the likelihood of desired health outcomes³⁴.

Thus the inclusion criteria for the review were specifically and rigorously set to identify value factors within existing NJRs. If the literature suggested that a register had proven to be a valuable resource within a particular healthcare system, then further analysis was deemed necessary in order to address the latter part of the research question and make recommendations for an Irish NJR based on the positive experience of other nations.

An extensive search of electronic resources was carried out using keywords and Boolean operators in the following databases

³³ (Hailey D., 2005) ³⁴ (IOM)

- CINAHL
- PUBMED
- Science Direct
- Cochrane Library

The results identified the sources of pertinent literature and the printed material was obtained. Websites of established registers, as summarised in figure 3, in the previous chapter provided a wealth of information which was critically examined for compliance with the inclusion criteria. Having thus compiled a substantial collection of literature it was synthesised to produce a subset of themes that consistently emerged amongst the literature. These are used as the headings which provide the structure for this chapter.

3.2.1 Benefits

It has been widely acknowledged that arthroplasty surgery has the potential to improve the lives of people who suffer from arthritis and is the most effective healthcare intervention in terms of improved QOL³⁵. Members of the Australian Orthopaedic Association (AOA) felt that the paucity of information regarding the outcome of arthroplasty surgery was limiting their potential to further enhance results, hence the establishment of the AOA NJR. This has been producing high quality data since 1999 enabling surgeons to make more informed decisions in relation to the type of prosthesis and technique for each patient³⁶. There were 65,000 joints replaced in Australia in 2006, according to their NJR Lay Summary annual report.

The success of Scandinavian registers in identifying poorly performing implants and surgical techniques, resulting in a reduction in the revision burden, is repeatedly reported to have been the reason for wider implementation of NJRs. The reduction in the revision rate in Sweden since the introduction of a NJR, from 18% to 6.4% over 20 years³⁷ is cited as an indicator of its success, evidenced by significant cost savings and improved standards³⁸. The literature

³⁵ (Furnes O., Espehaug B., Lie S.A., 2002) (Street J., Lenehen B., Flavin R., Bale E., Murray P., 2005) (Carr A.J., Morris R.W., Murray D.W., Pynsent P.B., 1993) (Wilson N.A., Schneller E.S., Montgomery K., Bozic K.J., 2008)

³⁶ (AOA Joint Replacement Registry, 2009)

³⁷ (Appendix 3)

³⁸ (Fakler J.K., Robinson Y., Heyde C.E., Thilo J., 2007)

suggests that this has largely been attributed to the early warning system provided by prospective monitoring of implants³⁹.

Furnes, in his thesis on the Norwegian Arthroplasty Register suggests that there is an awareness amongst orthopaedic surgeons that the practice of using prostheses without long-term performance evaluation has had catastrophic results in the past. He refers to a study by Sudmann *et al.* published in 1983, which showed a 31% revision rate for the Christiansen hip prosthesis introduced in Norway in 1969, compared to 4% for the Charnley. However, this occurred prior to the establishment of the Norwegian NJR, therefore it took 10,000 Christiansen hips and 14 years of use to prove it to be inferior to the Charnley. As a result the campaign for the nation-wide registration of arthroplasty data based on the established Swedish and Finnish models was initiated. Within 3-5 years of its establishment the register indicated inferior performance of uncemented implants⁴⁰.

Robertson evaluated the cost benefits of the SKAR and concluded that the documentation provided by a NJR places the service provider in a better position to compete for scarce resources. Length of stay (LOS) in hospital has considerable significance in managing resources⁴¹ since reduced LOS is economically desirable. The Scottish Arthroplasty Project (SAP) used data collected by the register to analyse average LOS over a 12 year period, reporting a reduction.

The multiplicity of benefits associated with the introduction of a NJR that have been cited amongst the literature can be summarised as follows

- Continuous monitoring of the performance of individual prostheses⁴²
- Early identification and elimination of inferior implant products⁴³
- Evaluation of surgical technique and approach⁴⁴
- National record of adverse outcomes related to arthroplasty surgery thereby identifying and eliminating risk factors, and ultimately reducing revision rates⁴⁵

³⁹ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007) (Brockenbrough, 2008) (Fender D., Harper W.M., Gregg P.J., 2000)

⁴⁰ (Furnes O., Espehaug B., Lie S.A., 2002)

⁴¹ (Grant D., Jerome J., 2007)

⁴² (Brockenbrough, 2008) (Furnes O., Espehaug B., Lie S.A., 2002) (Fender D., Harper W.M., Gregg P.J., 2000)

⁴³ (Robertson, 2007) (Brockenbrough, 2008) (Furnes O., Espehaug B., Lie S.A., 2002)

⁴⁴ (Curtin P., Harty J., Sheehan E., Nicholson P., Rice J., McElwaine P., 2005)

⁽AOA Joint Replacement Registry, 2009)

⁴⁵ (Brockenbrough, 2008) (Slovak Arthroplasty Register, 2008)

- Provision of epidemiological and demographic detail which can be used as a budgetary tool for service planning⁴⁶
- Provision of a data repository from which to derive meaningful statistics to be used for research and audit purposes⁴⁷
- International collaboration and comparison of outcome data⁴⁸
- Development of prophylaxis policies and evaluation of their effect ⁴⁹
- Further enhance the outcome of arthroplasty through more informed decision making⁵⁰
- Cost efficiency through improved standards and reduced revision rates⁵¹
- Implants can be easily traced if recall is necessary⁵²
- Development of best-practice evidence base⁵³

3.2.2 Clinical Trials versus Register Studies

Appendix 4 provides an overview of the levels of evidence in addressing primary research questions. RCTs are the gold standard⁵⁴ in medical testing because they produce high level evidence, however they usually have set inclusion criteria therefore cannot test all patients who have had a particular treatment. They are rarely focussed on long-term outcomes because of the financial considerations associated with a prolonged study⁵⁵. Register studies include all patients who have had a similar treatment intervention and provide information in relation to long-term outcomes since the patient remains on the register for life. The very large numbers that a register can include improves the reliability of the information because of statistical significance⁵⁶. Both types of study perform different roles in the research process and are not competitors, rather one should complement the other; the register providing a tool for long-term survival analysis, the RCT more concerned with clinical outcomes within a specific cohort⁵⁷.

Robertson (2007) suggests that RCTs are often undertaken at specialist centres thereby introducing a bias by virtue of the experience of the surgeon and the nature of his interest in a particular field. Furthermore, he refers to the publication bias resulting from non-submission of

⁴⁶ (Gissler M., Haukka J., 2004) (Robertson, 2007)

⁴⁷ (Brockenbrough, 2008)

⁴⁸ (Labek G., Stoica C.I., Bohler N., 2008)

⁴⁹ (Fender D., Harper W.M., ThompsonJ.R., Gregg P.J., 1997)

⁵⁰ (AOA Joint Replacement Registry, 2009)

⁵¹ (Wilson N.A., Schneller E.S., Montgomery K., Bozic K.J., 2008)

⁵² (Brockenbrough, 2008) (Labek G., 2005)

⁵³ (Robertson, 2007)

⁵⁴ (Brockenbrough, 2008)

⁵⁵ (Carr A.J., Morris R.W., Murray D.W., Pynsent P.B., 1993)

⁵⁶ (AOA Joint Replacement Registry, 2009)

⁵⁷ (Labek G., Stoica C.I., Bohler N., 2008)

research which reports a negative outcome. Such biases are avoided by implementing a NJR which includes all of the arthroplasties performed within a defined geographical area, while still allowing evaluation of regional trends. Thus, whilst the specialist centres may indicate greater levels of performance, the evidence needs to be evaluated in the context of the National average provided by the register, while acknowledging any biases.

For various reasons, including the financial challenges and difficulties associated with randomising patients to different procedures, high-level evidence in orthopaedics is not as common as in other medical disciplines⁵⁸. Level IV evidence, produced from case series, case-control studies and retrospective cohort studies, is more frequent in orthopaedic research⁵⁹. Register studies cannot provide detailed analyses but can identify sub-sets which require further evaluation⁶⁰. They provide a crude source on which to build more comprehensive research. The literature strongly suggests that the introduction of a NJR provides such a resource⁶¹.

3.3.1 Structure

The literature suggests that many of the registers used the early Scandinavian models as templates for their establishment⁶². Most NJRs began as pilot studies limited to specific regions or surgeons within a defined area and expanded later to include other criteria such as all joints from all surgeons within the entire country. The time taken for expansion varied considerably – the AOA NJR was implemented in a staged manner over a period of 3 years, from initial establishment to full inclusion of all 300 hospitals where hip and knee replacements are performed. In 2007 the Registry expanded its data collection to include shoulder, elbow, wrist, ankle and spinal disc replacement. This was fully implemented in November 2007 with all hospitals undertaking joint replacement in Australia approving participation in the additional data collection⁶³. Given that Australia represents a sub-continent, much of which is considered to be isolated and remote, it is perhaps not appropriate to compare its implementation with EU registers where, for example, in Sweden there are 80 centres⁶⁴ while Denmark has 45 including

⁵⁸ (Wilson N.A., Schneller E.S., Montgomery K., Bozic K.J., 2008)

⁵⁹ (Obremskey W.T., Pappas N., Attalah-Wasif E., Tornetta P 3rd., Bhandari M., 2005)

⁶⁰ (Robertson, 2007)

 ⁶¹ (Fender D., Harper W.M., Gregg P.J., 2000)
(Curtin P., Harty J.,Sheehan E.,Nicholson P.,Rice J., McElwaine P., 2005)
(Hardoon S.L., Lewsey J.D., Gregg P.J., Reeves B.C.,van der Meulan J.H.P., 2006)
(Brockenbrough, 2008)

⁶² (Robertson, 2007)

⁶³ (AOA Joint Replacement Registry, 2009)

⁶⁴ (Herberts P., Karrholm J., Garellick G., 2006)

5 private facilities⁶⁵. The New Zealand NJR was established in April 1998, and began as a Christchurch based pilot study. A year later it expanded to include all surgical hospitals throughout New Zealand. In January 2000 there was further expansion to include all hip, knee, shoulder, elbow and ankle replacements⁶⁶. The Romanian register began as a pilot study collecting arthroplasty data only on THRs in 2001. From January 2003 TKRs were included. There are currently 75 centres involved in the project⁶⁷.

Only Norway, Finland, Sweden and New Zealand include all major arthroplasties (hip, knee, shoulder, elbow & ankle), and only Finland has been doing so since the outset in 1980⁶⁸. Since 1997 all total ankle replacements performed in Sweden are registered to a database administered by The Swedish Competence Centre for Musculoskeletal Disorders (www.nko.se)⁶⁹. Separate registers exist for each joint in Sweden, and in Denmark where only hip and knee data is registered. In Australia and Romania details pertaining to hemi-arthroplasties are recorded⁷⁰.

3.3.2 Maintenance, Funding and Control

Kolling *et al.* conducted an international survey of current arthroplasty registers which evaluated the requirements for the successful implementation of a national database as a source for scientific analysis. The study focussed on NJRs considered to be fully operational with an established structure therefore the more recent ones, still in the early stages of development were not all suitable for consideration. Preliminary information in relation to the organisation of the register, funding, maintenance, documentation, data-management, and output of findings was obtained from the literature and the web. This was then validated through circulation of a standardised questionnaire to all the registers concerned. The responses were subsequently checked and additional information sought if deemed necessary. Contact was made with 15 registers, all returned the questionnaires. Their findings in relation to the structure of the participating NJRs suggest that the majority are maintained by the national associations of orthopaedic surgeons and funded by government agencies with some financial support from levies and grants. With the exception of Finland, Slovakia and parts of Denmark where hospitals have a statutory requirement to participate in the register, the other countries included in the

⁶⁵ (Johnsen S.P., Sorensen H.T., Lucht U., Soballe K., Overgaard S., Pedersen A.B., 2006)

⁶⁶ (Webmaster;New Zealand National Joint Register, 2004))

⁶⁷ (Stoica, 2008)

⁶⁸ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

⁶⁹ (The Swedish Ankle Register, 2009)

⁷⁰ (Labek G., Stoica C.I., Bohler N., 2008)

study participate voluntarily. The orthopaedic associations (OA) in some cases recommends participation. In Romania there are financial incentives, but no legal obligation, to participate⁷¹.

As a result of the proven efficiency of the Scandinavian model, which incorporates a centrally run NJR, with the public health authorities and the national OAs⁷², the EAR advocates the adoption of these models for developing registers. The more recently established NJRs are largely based on these styles with modifications which account for specific national considerations. The survey undertaken by Kolling *et al.* indicated that maintenance is undertaken solely by government only in Canada, Finland and the UK, all other participants in the study are maintained by the OA. The UK register is managed by a steering committee with stakeholder representation from all parties including patients, however concern has been expressed regarding the relatively few orthopaedic representatives⁷³.

Funding is predominantly provided by government with donation support from the OA in New Zealand, and in the Swedish elbow register which is solely funded by OA membership fees. In the UK funding is derived from a £50 levy on the implant manufacturer. Financial support for the Swiss Orthopaedic Registry (SOR) is obtained from a combination of sponsorship from the implant industry and the OA. The Norwegian NJR is primarily funded by the government but has some supplementary support from Medical Associations and research. It considers it preferable to be financially independent of the implant industry⁷⁴.

There appears to be a mix of control between the funding authority and the OAs, but as suggested by Kolling *et al.*, there must be bilateral support. A NJR cannot be sustained without guaranteed financial support provided by government as evidenced in Germany where funding was derived exclusively from member contributions and the implant industry⁷⁵. The German Arthroplasty Register established in 1997 could not be maintained due to financial difficulties and had to be abandoned⁷⁶. In advocating registration of data and outcome assessment Fender et al.⁷⁷ argue that funding can be justified in view of the high cost of failed arthroplasties, both financially and in terms of the reputation of the orthopaedic profession. Interdependent liaisons between funding agencies and government authorities therefore exist and must be supported. Apart from the SOR where government involvement is not clear-cut, no evidence of

⁷¹ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

⁷² (Labek G., Stoica C.I., Bohler N., 2008)

⁷³ (Philipson M.R., Westwood M.J., Geoghegan J.M., Henry A.P.J., Jeffries C.D., 2005)

⁷⁴ (Furnes O., Espehaug B., Lie S.A., 2002)

⁷⁵ (Pitto R.P.,Lang I., Kienapftel H., Willert H.G., 2002)

⁷⁶ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

⁷⁷ (Fender D., Harper W.M., Gregg P.J., 2000)

a register that is independent of government on both the funding and maintenance aspects, was found in the literature. Robertson (2007) suggests that the orthopaedic community and the administrators have different requirements from a register but that if the correct balance of interests is to be achieved, the principles on which the first registers were based must be considered. The purchasers of medical care can use this data in the planning of future services and can implement policy changes accordingly. Federal involvement can influence enactment of legislation required to make participation statutory, as was the experience in Slovakia where a directive from the Ministry of Health which made reporting to the NJR compulsory, was required to improve on initially poor participation rates⁷⁸. Autonomous control by surgeons without regulation by the public health system is advocated by Labek.

3.4 Data-set

Robertson (2007) suggests that there is scope for selection bias in a data register and that in order to overcome this there must be protocols in place for data collection, minimal data-sets and validation. He states that the value of information depends on the completeness and accuracy of the data, and that in the early years of the SKAR it became apparent that a limited data-set was more likely to ensure this. He advocates that if international comparisons are to be made between NJRs then a standard minimum data-set must be used. He summarises this essential core minimal data-set based on guidelines from the International Society of Arthroplasty Registers (ISAR) as follows

- Patient: National identity number, Name, Address, Age, Gender
- Surgery: Date, Diagnosis, Primary or revision, Site and side (right or left)
- Hospital: Name and Address or identity number
- Surgeon: Name or code number

It would appear from the survey carried out by Kolling *et al.* that this core set of information forms the basic level of data for each register, but individual NJRs collect a range of supplementary data. These include clinical scores such as the Oxford Hip Score (OHS), a joint

⁷⁸ (Slovak Arthroplasty Register, 2008)

specific outcome measurement tool designed to assess disability in patients undergoing total hip replacement⁷⁹, and the Western Ontario McMaster Osteoarthritis Index (WOMAC)⁸⁰ which is a self-administered questionnaire relating to pain, stiffness, and physical function and defining the individual's own perception of their health status. The OHS has been modified for use in New Zealand to relate to hip and knee, and to include questions regarding dislocation, infection, and other associated complications. It has been validated, and is referred to as the "Oxford 12" questionnaire⁸¹. The Euroqol-EQSD is a global health index designed to evaluate cost and outcome aspects of treatment interventions used by the Swedish Hip register, while the Swedish shoulder register circulates the WOMAC 5 years post arthroplasty. These measures are reported to add sensitivity to the register data⁸².

In Switzerland where Picture Archiving and Communication Systems (PACS) are well developed, radiological data is collected. Images are linked to questionnaires and converted to the DICOM (Digital Image and Communication) standard for display. This function is generally not routine but reserved for those presenting with complications. Radiographic data is also collected in Romania.

Data management is achieved both electronically and manually, depending on which method is most suitable for the participating hospitals. The UK NJR is the only one which does not offer a manual option to transfer data to the central repository. Electronic data transfer is not available in all registers but, according to the annual reports, resources which facilitate are increasing⁸³. The AOA Registry continues to use a paper-based system but has established the mechanisms to collect data electronically where this is feasible for contributing hospitals⁸⁴. Patients on the New Zealand register are sent a questionnaire to measure the outcome of their surgery approximately six months post-operatively, this can be answered online. Data collection based on internet technology is widely used in the SOR which uses a multi-tier electronic documentation system within which internet applications are embedded. The online interface is the basic mode of data entry even where collection is manual, since the paper based forms have an optical mark reader (OMR)⁸⁵. In Canada an electronic data submission service (eDSS)

⁷⁹ (Wylde V. , Learmonth I.D., Cavendish V.J., 2005)

⁸⁰ (Appendix 5)

⁸¹ (Appendix 6)

⁸² (Malchau H., Garrellick G., Eisler T., Karrholm J., Herberts P., 2005)

⁸³ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

⁸⁴ (AOA Joint Replacement Registry, 2009)

⁸⁵ (Röder C, El-Kerdi A, Frigg A, Kolling C, Staub LP, Bach B, Müller U., 2005)

was introduced in 2008 in an effort to reduce user omission errors and improve completeness of data collected⁸⁶.

According to Roder *et al.* the most valuable data-set that an arthroplasty register records is that which describes the implant components. These precise details are normally contained in a barcode, on the manufacturer's label, to facilitate registration of the data. The barcode is scanned at the time of surgery and linked to the Clinical Information System (CIS) via a central server. This is the method used in the SOR, the Danish Knee Register and the UK NJR, though others are conducting trials and expect to introduce a facility in the near future. Where barcode scanners are not available manual input is necessary, requiring a substantial investment of clinician's time. For modern data collection systems, manufacturer support provided by barcodes is recommended⁸⁷. Pitto *et al.*, reporting on the now defunct German Arthroplasty register, suggest that the large volume of data generated by registration of implants can only be managed with computer support. This is in contrast to the Australian experience where preference for electronic data transfer was initially indicated, but on implementation, concerns were raised in relation to the expense, increased time and reduced accuracy regarding electronic data management⁸⁸.

3.4.2 Definition of Failure

Stoica et al (2008) define failure of an implant as that set out by the EAR (outlined in 2.4.2): "revision of at least one part of the implant".

Measurement of implant survival is generally determined by the need for revision, though Robertson (2007) suggests that this is a crude measurement used because of lack of consensus regarding the definition of failure. The need for revision ignores those who have unsatisfactory outcomes but do not opt for revision surgery, or are deemed medically unfit. In such cases the use of outcome measurement through self administered questionnaires, such as the WOMAC and SF36, provide "soft data" about those patients who may never present for revision, but may not necessarily have positive outcomes^{89.} Kolling *et al.* consider the aim of a register to be the measurement of the outcome of surgical intervention, which suggests that the

⁸⁶ (Canadian Joint Register, 2008)

⁸⁷ (Labek G., 2005)

⁸⁸ (Graves S.E., Davidson D., Ingerson L., Ryan P., Griffith E.C., McDermott B.F.,McElroy H.J., Pratt N.L., 2004)

⁸⁹ (Robertson, 2007)

crude measurement, using only revision rates is not a true evaluation of outcome⁹⁰. They advocate the use of patient self-evaluation questionnaires in determining outcomes of surgery. The debate concerning the definition of failure is ongoing but until a consensus is reached it seems that the decision to revise the prosthesis is to be considered the end-point. Thus an implant is considered to be performing poorly if its revision rate is unacceptably high⁹¹.

3.5 Consent

Patient consent is mandatory in Canada, the UK, New Zealand, Norway, Romania and in the Danish Knee Register. In Finland where participation in the NJR is statutory, patient consent is not obligatory because statutes exist which give health authorities, both private and public, the right to register relevant information specified in the legislation, thereby exempting data used for scientific and statistical purposes from the need for consent⁹². The Scandinavian tradition of data registration has ensured that registers are regarded as part of the social infrastructure, hence their maintenance are strictly controlled by statute, and operation is facilitated greatly by the use of unique patient identifiers⁹³. Australia has an opt-off system which means consent is assumed except for those who specifically request to be excluded. This conforms to data-protection legislation, and after 5 years of the register's existence only 5 patients out of 140,000 exercised the option⁹⁴. In Switzerland demographic data is anonymised therefore consent is not required, however if additional information such as a social security number is included then consent must be obtained⁹⁵.

In the study conducted by Kolling *et al.* the alternative to obligatory consent for participation in the register is not specified. However, Article 8 of The European Convention for the Protection of Human Rights (ECHR) refers to the explicit right to personal privacy⁹⁶ and since the introduction of the ECHR Act 2003 forms part of domestic Irish law. This act obliges the data controller in relation to consent, to identify their role, to specify the purpose for which the data is to be collected and to give assurance regarding its non-disclosure. EU member states are

⁹⁰ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

⁹¹ (Hardoon S.L., Lewsey J.D., Gregg P.J., Reeves B.C., van der Meulan J.H.P., 2006)

⁹² (Gissler M., Haukka J., 2004)

⁹³ (Sokka, 2007)

⁹⁴ (Graves S.E., Davidson D., Ingerson L., Ryan P., Griffith E.C., McDermott B.F.,McElroy H.J., Pratt N.L., 2004)

⁹⁵ (Röder C, El-Kerdi A, Frigg A, Kolling C, Staub LP, Bach B, Müller U., 2005)

⁹⁶ (ECHR, 2009)
subject to directives regarding consent and privacy but exceptions may be made for medical research allowing implementation of local legislation accordingly⁹⁷.

Where patient consent is obligatory those who do not consent to submit their data cannot be registered therefore data completeness can be compromised⁹⁸. In the first year of the UK NJR consent was obtained from only 68% of patients, while in Canada 10% of patients do not give their consent for inclusion. As a result of poor recording of patient consent in the UK the Department of Health approved a shorter text in March 2008 in an effort to ensure greater compliance⁹⁹.

Galpottage and Norris (2005) researched international best practice regarding e-consent and report a comprehensive infrastructure of considerations for its implementation. No evidence of a register which obtained consent electronically was identified in the literature.

3.5.1 Privacy and Security

Gissler and Haukka suggest that the use of sensitive information in research can only be justified when widely accepted aims are served. Security is therefore a major consideration wherever identifiable clinical data is subject to electronic transfer. Data Protection legislation places specific obligations on organisations concerned with the processing of sensitive personal information and applies to any data that is processed including paper, telephone and digital. All NJRs encountered manage data according to the prevailing data protection legislation and apply various methods of anonymising sensitive information. Within the EU the European Data Protection Directive (Directive 94/46 EC) provides the framework from which local legislation has been derived. As outlined in relation to consent, the Scandinavian infrastructure allows for management of registry data by organisations which operate under the supervision of government. This historical association of social responsibility for healthcare may have extricated the citizens of these counties from major concerns regarding privacy of health information, which elsewhere have resulted in legislation which makes health registers almost illegal¹⁰⁰.

⁹⁷ (Sokka, 2007)

⁹⁸ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

⁹⁹ (Joint Approach, 2003)

¹⁰⁰ (Sokka, 2007)

Nonetheless, patients concerns regarding privacy have been shown to influence their willingness to participate in registers¹⁰¹. The failed German Arthroplasty Register operated under such strict data protection legislation that highly complicated encryption algorithms had to be applied to data, rendering tracing of patients almost impossible¹⁰².

Security issues also arise in relation to surgeon confidentiality, these are discussed in 3.6.

3.5.2 Unique Patient Identifier

Registration of health data is greatly facilitated by the use of a Unique Patient Identifier (UPI) because data quality is improved and available information augmented¹⁰³. These unique identifiers are used in Scandinavia and have been acknowledged as a key factor in contributing to the success of their registers¹⁰⁴. Scandinavian nationals are issued at birth with a personal identification code which allows linkage of data through various population databases, an extremely important factor when validating data¹⁰⁵. The lack of UPI in Switzerland is cited as a factor inhibiting the SOR from reaching the Scandinavian standard in terms of data validation¹⁰⁶.

Prior to the establishment of the UK NJR Fender advocated the universal use of a UPI within the NHS, this is currently in use, and many of the registers participating in the study undertaken by Kolling *et al.* reported the use of nationwide identifiers.

However, introduction of such identifiers is surrounded by controversy in relation to privacy, security and data-protection as outlined in 3.5.1. The argument continues and despite the attractions of a national identifier implementation is met with great resistance as evidenced in both Switzerland and Germany. In Ireland, a survey commissioned by the data protection office in 2005 revealed that privacy in relation to medical records was second only to financial records, and that 89% of Irish people considered personal privacy to be very important¹⁰⁷. This has implications for consideration in the introduction of an Irish NJR.

¹⁰¹ (Terry A.L., Chesworth B.M., Bourne R.B., Speechley M., 2008)

¹⁰² (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

¹⁰³ (Gissler M., Haukka J., 2004)

¹⁰⁴ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

¹⁰⁵ (Sokka, 2007)

⁽Röder C, El-Kerdi A, Frigg A, Kolling C, Staub LP, Bach B, Müller U., 2005)

¹⁰⁷ (Press Release - 12th January 2006)

3.6 Publication of Results

Presentation of register data is most commonly done through publication of annual reports, meetings of the OA, and peer-reviewed journal articles. Regular feedback is necessary to sustain involvement of the clinical stakeholders and this is facilitated by statistical analyses¹⁰⁸. In Sweden statisticians have been employed by the register since 1993, and most of the registers established in the past decade have followed this practice. Confidentiality regarding the performance of individual surgeons and hospitals should be guaranteed when publishing results¹⁰⁹. In the USA where a NJR has not yet been implemented, potential misuse of information for the purpose of litigation has been cited as a barrier to implementation¹¹⁰. This was also found to be a significant concern amongst Irish orthopaedic surgeons surveyed in 2008 for their opinions regarding the establishment of a NJR¹¹¹ and in the UK¹¹².

Most registers report results anonymously, with an option to further analyse on request subject to certain terms and conditions¹¹³. No patient, surgeon or hospital is identified in the reports and publications of the AOA NJR, a surgeon code may be used but this is not compulsory¹¹⁴, therefore it is not always possible to identify the surgeon. The minimal data-set referred to in 3.4 suggests coding of sensitive information as an alternative to identify at the point of data entry.

Publications and annual reports are available from many of the NJR websites, with the exception of New Zealand and Switzerland¹¹⁵. The AOA NJR introduced a Lay Summary in 2007 in order to present the findings in a clear, easily understood, manner which would satisfy community interest. This is available on their website and it is hoped that the information presented will promote informed discussion between patients and their surgeons.

The use of Kaplein-Meier graphs is widespread amongst the NJRs encountered in the literature. They are used to calculate the survival of an implant presented as CRRs for given variables thereby allowing for comparisons to be made between different implant components.

¹⁰⁸ (Labek G., 2005)

¹⁰⁹ (Labek G., Stoica C.I., Bohler N., 2008)

¹¹⁰ (Wilson N.A., Schneller E.S., Montgomery K., Bozic K.J., 2008)

¹¹¹ (Oduwole K.O., Codd M.B., Byrne F., O'Byrne J., Kenny P.J., 2008)

¹¹² (Philipson M.R., Westwood M.J., Geoghegan J.M., Henry A.P.J., Jeffries C.D., 2005)

¹¹³ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

¹¹⁴ (Graves S.E., Davidson D., Ingerson L., Ryan P., Griffith E.C., McDermott B.F.,McElroy H.J., Pratt N.L., 2004)

¹¹⁵ (Oduwole K.O., Codd M.B., Byrne F., O'Byrne J., Kenny P.J., 2008)

3.7 Challenges

An abundance of evidence has been presented which suggests that numerous benefits can be gained through implementation of a NJR. Nonetheless, in spite of the documented evidence of these benefits, many modern healthcare systems, both within the EU and most notably the USA, have yet to embark on implementation. A search of the literature for barriers to successful implementation revealed that challenges broadly fall into 3 categories, ethical, financial and technical, with obvious inter-relationships arising from the cost and ethical implications of healthcare technology.

- Ethico-legal considerations in relation to privacy, security and confidentiality of patient, surgeon and hospital identity. Many of the studies indicated that these concerns were hindering progress¹¹⁶, while of particular note is the Irish study undertaken in 2008 by Oduwole *et al.*, which reported that 58% of respondents expressed medico-legal concerns in relation to publication of NJR reports. Similar fears have been voiced in the UK regarding the potential use of NJR data for the publication of league tables, this could discourage surgeons from operating on high-risk patients thereby becoming deskilled¹¹⁷. In contrast, the severity of data protection legislation has been noted to be an inhibiting factor in the failed German register¹¹⁸, while in the USA failure to reach a consensus on data protection legislation is considered to be a prohibitive factor in establishing a NJR¹¹⁹. It would therefore appear that achieving the correct balance between data protection, regulation, participation, compliance and confidence of all stakeholders in the system, presents a significant challenge.
- **Over enthusiastic definition of data-set** documentation should be minimised and focused on objective data-sets since completeness is fundamental to the data quality of the register¹²⁰. It has been demonstrated that a NJR is essentially all-inclusive therefore its goals must be realistic when defining precisely what data it needs to collect so that 100% stakeholder participation is achievable. Efforts should be made to minimise the time taken to register data by careful selection of the variables required¹²¹. Participation

¹¹⁶ (Labek G., 2005) (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007) (Oduwole K.O., Codd M.B., Byrne F., O'Byrne J., Kenny P.J., 2008)
(Wilson N.A., Schneller E.S., Montgomery K., Bozic K.J., 2008)

¹¹⁷ (Philipson M.R., Westwood M.J., Geoghegan J.M., Henry A.P.J., Jeffries C.D., 2005)

¹¹⁸ (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

¹¹⁹ (Wilson N.A., Schneller E.S., Montgomery K., Bozic K.J., 2008)

¹²⁰ (Labek G., Stoica C.I., Bohler N., 2008)

¹²¹ (Robertson, 2007)

has been shown to be potentially compromised where consent is obligatory¹²². The use of self-administered questionnaires such as the WOMAC & SF36 add sensitivity to the data in terms of outcome but add another dimension to the data collection process, possibly explaining why their use is limited. Arriving at the most balanced decision regarding data-set which does not discourage participation, and optimum use of the opportunity to collect quality data, therefore poses a challenge to those involved in developing strategies for new registers.

- IT Infrastructure the establishment of a NJR presents practical challenges in terms of data management and selective access to the database¹²³. The failed German Arthroplasty Register is reported to have struggled with identification of revision cases not only because of encoding in the absence of a UPI, but also as a result of poor IT infrastructures such as separate networks making web-based data exchange impossible. Roder et al. describe a comprehensive web-based data management system, in which all technical servicing is centralised, and can facilitate the set-up of any register. This can be demonstrated at www.memdoc.org. However the system incurs substantial initial expenditure while ongoing support and service is payable monthly. The Slovakian NJR considered these technical standards to be in excess of requirements when setting up their register resulting in lack of consensus which delayed establishment¹²⁴. Where there is manufacturer support in the form of bar-coding data management is facilitated, and where standardised, constant and life-long social security numbers exist the IT challenge regarding linkage and validation of data is more easily surmounted¹²⁵. In order to ensure success protocols for validation of data need to be in place¹²⁶.
- **Financial Considerations** Furnes reported that in spite of the interest demonstrated by health authorities financial support is not always forthcoming. Insufficient funding was cited by Kolling *et al.* as a major contributing factor regarding the failure of the German Arthroplasty Register. In the early stages of the Canadian NJR and the Danish hip register lack of funding was reported, this was addressed by national authorities only when the potential benefits of continued funding for the registers were recognised. The

¹²² (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

¹²³ (Roder C., El-Kerdi A., Eggli S., Aebi M., 2004)

¹²⁴ (Slovak Arthroplasty Register, 2008)

¹²⁵ (Labek G., 2005) (Pitto R.P.,Lang I., Kienapftel H., Willert H.G., 2002) (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007)

¹²⁶ (Robertson, 2007)

potential savings associated with a well-established NJR have been recognised by the Scandinavian health insurers¹²⁷. Financial support, either from a federal or professional source, is widely recommended as a key to success and justified in terms of returns¹²⁸.

3.8 Summary

This chapter has presented the findings in the literature regarding successful implementation of a NJR. The infrastructure of many of the established registers has been examined in terms of maintenance, control, organisation, funding, governance, data-set, consent and regulation. Issues impacting on privacy, security, publication and participation have been considered. All of the factors presented will form the basis for discussion and evaluation in a later chapter which will culminate in the development of a set of recommendations for an Irish NJR.

¹²⁷ (Pitto R.P.,Lang I., Kienapftel H., Willert H.G., 2002)

 ¹²⁸ (Graves S.E., Davidson D., Ingerson L., Ryan P., Griffith E.C., McDermott B.F.,McElroy H.J., Pratt N.L., 2004) (Fender D., Harper W.M., Gregg P.J., 2000) (Labek G., 2005) (Kolling C., Simmen B.R., Labek G., Goldhahn J., 2007) (Pitto R.P.,Lang I., Kienapftel H., Willert H.G., 2002)

Chapter 4: Current Practice in Ireland

4.1 Introduction

The Irish health system has been described as "mixed" in terms of funding and provision of services because it has been derived from a number of healthcare models. Its structure has evolved since the enactment in 1970 of the Health Act, which established the now defunct regional health boards. The current situation whereby the HSE is responsible for the execution of health policy as prescribed by the DOH&C was established by the Health Act 2004. The system has been classified by the OECD as a social assistance model because of the categories (1 & 2) which determine eligibility to the service depending on the individual's income¹²⁹. This system has features in common with other healthcare systems but also unique elements which require consideration when making international comparisons. NJR data reflects the prevailing standards within a particular public health system¹³⁰, therefore Ireland's unique structure and access to the services, and the distribution of public and private healthcare resources cannot be excluded from the evaluation process. Ireland's 51 public hospitals provide a range of emergency, assessment, diagnosis, treatment, rehabilitation and specialist services to all citizens¹³¹. Services are provided free of charge at the point of delivery to category 1 patients, while there is limited eligibility to those in category 2. In 2005 half of the population had private health insurance.

4.2 Orthopaedics in Ireland

There are an estimated 40,000 people in Ireland who have arthritis¹³², 90% of these suffer from osteoarthritis, and 30% of all visits to General Practitioners (GP) are related to arthritis¹³³. Joint replacement surgery has been shown to be the most effective intervention in alleviating pain and disability in those who present with osteoarthritis, the primary indication for both THR and TKR¹³⁴. There are 126 consultant orthopaedic surgeons registered in the 2008-2009 Irish

¹²⁹ (Wiley, 2005)

¹³⁰ (Labek G., Stoica C.I., Bohler N., 2008)

¹³¹ (Public Hospitals in Ireland, 2007)

¹³² (McGreevy, 2009)

¹³³ (McCann, 2009)

¹³⁴ (Street J., Lenehen B., Flavin R., Bale E., Murray P., 2005)

Medical Directory¹³⁵, 89 of these operate within the public health system which provides elective orthopaedic surgery facilities at 12 centres nationally. The remaining 37 are either retired or provide a private service only, in one or more of the 16 listed private hospitals. Those who are appointed to the public health service may also operate within a private service.

HIPE (Hospital In-patient Enquiry System) is a computer system which collects demographic, clinical and administrative data in relation to patients discharged from all public hospitals. It is managed by the Economic and Social Research Institute (ESRI) in association with the DOH&C and the HSE. It provides the only source of morbidity data for acute hospital services but does not take account of surgery performed in private hospitals¹³⁶. The most recent data available is for the year 2007 when a total of 5,235 primary and revision hip and knee replacements were reported, representing a very marginal decrease on the previous year when the total was 5,257¹³⁷.

There is no national mechanism for the registration of data in relation to joint replacement surgery in Ireland, but CNOH has been registering its arthroplasty data since 2005.

4.2.1 Cappagh National Orthopaedic Hospital Joint Register

CNOH is the largest centre for elective orthopaedic surgery in the ROI. 22 Consultant Orthopaedic Surgeons, all of whom have shared contracts with 7 acute Dublin hospitals, perform approximately 1,200 primary and revision hip and knee replacements at CNOH annually. The CNOH Joint Register was established in 2005 in response to international developments, in particular the Scandinavian successes, regarding the registration of arthroplasty data. It was the first Irish endeavour to undertake such a project. Its main objective was to monitor the performance of joint replacements through outcome measurement and to develop a local data-base from which to derive meaningful statistics so that ultimately the overall quality of patient care would be enhanced.

4.2.2 Background and Development

The register began in 2005 as a pilot study, led by a project team comprised of one Consultant Surgeon, the Clinical Nurse Manager (CNM) involved in research and audit, the IT manager and an orthopaedic NCHD (non-consultant hospital doctor). The initial study included all primary and

¹³⁵ (Irish Medical Directory)
¹³⁶ (ESRI, 2009)
¹³⁷ (Hipe Data Requests, 2009)

revision hip and knee arthroplasties performed by 5 participating orthopaedic surgeons. The team explored the implications of the project and set targets and objectives based on the experience of other registers but taking into consideration the nature and structure of the Irish healthcare system and its epidemiological conditions. The time frame for the study was set at one year. The ICT infrastructure required to support the administration of the project was developed at CNOH and the existing CIS was adapted to accommodate data entry in relation to clinical outcomes. Consequent to the success of the pilot study the project expanded in January 2006 to include all 22 surgeons who operate at CNOH.

4.2.3 Structure

Data is collected at designated nurse-led clinics which are held daily. All patients who have had a primary or revision TKR or THR are reviewed at intervals of 6 months, 2 years and every following 5 years. Review is life-long or until revision is required, which if performed at CNOH will be every 2 years. Baseline data is collected pre-operatively. The WOMAC and SF36¹³⁸ self administered QOL questionnaires are used to ascertain the patients' perception of their pain, function, disability and emotional status concerning their arthritis. At the time of surgery implant details contained in the manufacturers label are recorded. All implants used at the hospital contain this data in a barcode. Data in relation to anaesthetic, surgical technique, antibiotic therapy and thromboprophylaxis are recorded electronically. The CIS and the PAS interface enables the data recorded at the time of operation to generate the post-operative review date. At this review post-discharge complications are documented in the CIS so that an electronic record of adverse outcomes is available. The WOMAC and SF36 are again completed by the patient to reflect their perception of the effect of surgical intervention¹³⁹, and an x-ray is performed.

All patients who do not attend are contacted by telephone and the review is done remotely, necessitating attendance for x-ray at a local radiological ¹⁴⁰imaging centre. Patients who persistently fail to keep appointments, and are difficult to trace, are actively pursued through their surgeon or GP.

¹³⁸ (Appendix 5) ¹³⁹ (Appendix 8)

4.2.4 Benefits

A data-base regarding the outcome of surgery performed specifically at CNOH has been built and it is now possible to make comparisons between rates of revision and infection, with those experienced elsewhere. The incidence of adverse outcomes associated with arthroplasty surgery, such as pulmonary embolism (PE) and deep venous thrombosis (DVT), can now be highlighted. All data relating to revision rates, infection, PE, DVT and QOL outcomes, are presented at bi-annual clinical audit meetings¹⁴¹.

Risk assessment policies are being developed as a result of the register findings in relation to peri-operative mortality and morbidity associated with PE and DVT. Chemical thromboprophylaxis is a preventative measure which aims to eliminate or minimise the risk of DVT through anticoagulant drug therapy. However, surgeons have differing opinions regarding the need for this in routine arthroplasty¹⁴². The incidence and prevalence of PE and DVT in CNOH can now be precisely determined, and a thromboprophylaxis policy has been developed. Outcomes recorded at the register will be used to evaluate the effects of the policy.

Prior to the introduction of the register patients were reviewed at the Out-Patient Department (OPD) following surgery depending on the individual surgeon's protocol. This varied from one initial review at 6 weeks post surgery to multiple reviews in the first year. Now that all patients are reviewed at the joint register it is no longer necessary to arrange repeat OPD reviews unless it is deemed appropriate by the register nurse to refer back to the surgeon. This is expected to result in greater efficiencies in relation to OPD appointment management, ultimately leading to cost reduction, though this has yet to be analysed. It also complies with the HSE Transformation Programme 2007-2010, which issued guidelines in 2008 aimed at reductions in repeat OPD visits to allow more reviews of new patients¹⁴³.

Many of the potential benefits of a register will not be perceived in the short term since a minimum follow up period of 10 years is normally required to judge the success of an arthroplasty¹⁴⁴. However, the benefits realised to date have provided the hospital with valuable data which heretofore had not been systematically documented. It is expected that this will ultimately result in improvements in the overall quality of the delivery of patient care.

¹⁴³ (HSE, 2008)

¹⁴¹ (Appendix 8)

¹⁴² (Fender et al)

¹⁴⁴ (Sochart D.H., Long A.J., Porter M.L.,, 1996)

4.2.5 Governance and Funding

The funding for the register is derived from the hospital budget allocation decided by the HSE and supplemented by donations from the hospital benevolent trust. The Joint Register was considered by the board of management to be an initiative with the potential to enhance patient care hence there was little resistance to the project in terms of funding. The annual cost has been estimated by the CEO to be in the region of €120,000. These costs relate predominantly to payroll costs, other expenditure arising from postage, printing, telephone charges and basic operating costs. Capital expenditure has been minimal, the clinics are held in areas of the hospital which were surplus to requirements therefore no building costs were incurred. The management of the register lies within the remit of the research and audit CNM under the direction of the Consultant Surgeon involved in the initial project. Participation of all surgeons who operate at the hospital is mandatory by corporate decision. At present one full-time nurse runs the review clinics and one part-time secretary provides administrative support. Technical support is derived from the hospital IT department with supplementary remote support from the CIS provider. There are currently 5715¹⁴⁵ patients on the register and approximately 200 reviews per month are conducted. The first 5 year reviews will commence in January 2010, resulting in an increase in activity levels as anticipated from the outset. Figure 4. shows the attendances for each year since its establishment, and the predictions until 2011. These take into account the increased numbers arising from

- 6 months and 2 year review of all patients
- 2 year review of all revisions
- 5 year review in 2010 of the original pilot study participants
- 5 year review in 2011 of all patients since 2006

These figures have implications for a review of planned staffing levels.

¹⁴⁵ (August 2009)



Figure 4 Attendance and predicted increase in activity

4.2.6 Consent, Privacy and Security

Informed consent is obtained from all patients at the earliest point of contact. This is facilitated by the attendance at the pre-operative assessment clinic where combined consent to acquire clinical notes from other hospitals and for participation in the joint register is obtained¹⁴⁶. Patients are assured that data is used to produce anonymous reports of clinically important information. There is an opt-out facility which to date has been exercised by less than 1% of patients. Data for clinical studies is only available to clinical staff who have sought permission from the professor of surgery and, if necessary, the ethics committee. It may only be used anonymously. Public access to data is limited to the annual report and no data which identifies the surgeon is published.

¹⁴⁶ (Appendix 7)

4.2.7 Challenges

The aim of the register is to collect data on all THRs and TKRs performed at CNOH so that prospective total population studies can be undertaken. This requires 100% follow-up which presents a challenge in the absence of remote consultation technology. Not all patients who have had surgery are willing to attend for life-long review in spite of the benefits. Some patients consider it to be an onerous commitment and either, persistently fail to attend, or choose to opt-out. A substantial amount of time is spent trying to obtain data from these patients. This process could be enhanced through the use of web-based technologies, such as on-line questionnaires combined with remote consultation. Many patients are quite happy to submit information but for a variety of reasons are unable or unwilling to attend the hospital.

It is the policy of the register to do a radiological assessment at each review unless this has been recently performed elsewhere. In this case it is sufficient to record that the radiograph is available if required. Many hospitals are now using digital imaging and send a CD-rom of the film on request. If a national PACS was available remote consultation would be further facilitated as x-rays could be performed at the nearest facility and obtained digitally as required, dispensing with the need for the patient to attend for review.

The data-set for the register is somewhat more substantial than that found in the literature. As presented in chapter 3, the use of self administered QOL questionnaires undoubtedly adds sensitivity to the data, and provides clinicians with valuable information from the patient's perspective. However, there is a challenge in attaining an appropriate balance between minimum data-set and collection of detail which may potentially deter participation because of the tedium involved in submission. Many patients report difficulty in compliance with the WOMAC and SF36 because of complexity and time consumed in completion. Alternative methods of data submission have been explored. It is planned to pilot a project which will evaluate the effect of having touch-screens available at review for patients who opt to input QOL data directly onto the system.

Many of the revisions performed at CNOH have had the primary surgery done elsewhere. Without national patient identifiers and in the absence of a NJR it is often difficult to trace the details of the primary operation, resulting in reliance on the patient's account of the event. This can lead to distortion of the true revision rates at CNOH and it has been necessary to add the details of the primary to the record at the time of revision surgery. All of this information requires manual input and incurs extra effort on behalf of the NCHD who inputs the data at the time of surgery.

Endeavours to enhance the data collection process through improved technology are ongoing but constrained because of limited resources. IT support specifically dedicated to the register would facilitate progress towards the required level of infrastructure such as that encountered in the literature.

4.3 Discussion

The CNOH Joint Register has been shown to have many parallels with the established NJRs presented in chapter 3 albeit on a much smaller scale. The fundamental principles of a NJR are applied in terms of structure, governance, maintenance and control, with certain modifications which take account of the scale and nature of the register within its unique Irish healthcare context. There are however some features, particularly in relation to documentation and technological support which have not been encountered in other NJRs. No register collects QOL data at such regular intervals or to such an extent, therefore it is considered appropriate to evaluate the benefit of continuing this practice, particularly in view of the poor level of IT infrastructure and the difficulty in attaining 100% participation.

Another aspect of the register which differs somewhat from the majority of those identified in the literature is the collection of radiographic data. At CNOH all patients attending for review routinely have an x-ray which is reported on by a radiologist. Any abnormal reports are brought to the attention of the surgical team. Radiological evidence of asymptomatic complications can be used to determine which patients might require closer review. This practice is considered central to the early detection of abnormality but there is some scope for modification in the future if a nationwide PACS becomes available.

Regarding technological infrastructure the register would appear to lag behind that identified in the literature hence requires substantial development. The absence of a web-based data-entry facility in an information age that is heavily reliant on internet technology is considered unacceptable. All NJRs have web-sites designed to enhance communication between the various stakeholders, and encourage patient involvement through publication of their data. CNOH lacks such an amenity and, while there is anecdotal evidence only, it is suggested that this has contributed to some of the difficulties regarding participation.

The literature could not be expected to provide evidence of what constitutes the correct level of staffing since this depends on a number of variables. The surgical activity depends on population needs which are not met uniformly across different nations therefore guidelines are

difficult to apply when determining staffing. Many of the NJRs employ statisticians and dedicated IT personnel, but this is not feasible at CNOH because of financial constraints. As the register develops and expands the current levels of activity cannot be sustained, consequently a review of human resources is recommended.

A study which would evaluate the patient's perception of the register as a routine part of their treatment is also recommended. This would scientifically identify the reasons for poor attendance and determine precisely what aspects of the register require modification. It would also provide an insight, from the patient perspective, of how much clinicians can expect from patients in terms of compliance with data submission.

4.4 IT Policy in Ireland

The DOH&C Statement of Strategy 2008-2010 declares that all healthcare systems depend on good information which is essential to evaluate their performance so that improvements can be made. New technologies require strategic development in order to capitalise on the data generated within the system to support needs assessment, service planning and evaluation. The statement pledges to ensure coherence in the implementation of ICT solutions which support the objectives of health information policy.

The National Health Information Strategy 2004 (NHIS)¹⁴⁷ acknowledges the potential of ICT to achieve value for money through the delivery of a more integrated health service. It recognises that the low level of investment in ICT is central to "difficulties in meeting the complex information requirements of a modern health service".

The then Minister for Health, Micheal Martin, TD, in his introduction, states that its primary aim is

"to recommend the necessary actions to rectify present deficiencies in health information systems and to put in place the frameworks to ensure the optimal development and utilisation of health information"

The principles of the Strategy are to:

- Safeguard the privacy and confidentiality of personal health information
- Ensure that health information systems are efficient and effective
- Promote the optimal use of health information
- Ensure the high quality of health information.

¹⁴⁷ (http://www.dohc.ie NHIS 2004)

Its objectives include the establishment of processes and structures that ensure the fuller use of health information in policy making and the exploitation of technologies in the collection, processing, analysis and dissemination of health information.

The implementation process of the strategy was set over 3 phases, the first covering years 1-2, the second years 3-5, and the final phase from 5 years onwards. Priority in Phase 1 was given to the establishment of the Health Information and Quality Authority (HIQA) and the introduction of the Health Information Bill (HIB), while phases 2 and 3 would build on further development of infrastructures with particular focus on procedures in relation to security, the electronic record and the unique patient identifier.

In May 2007 HIQA was formally established by the 2007 Health Act which conferred on it responsibility for setting and monitoring standards regarding safety and quality of healthcare within the public health system. Its information related functions include evaluation of the clinical and cost effectiveness of health technology, in line with international practice, so that health service resources are optimised to ensure the best outcomes. HIQA therefore plays a pivotal role in the implementation of the NHIS.

The HIB has been proposed, by the current Minister for health, Mary Harney, TD, who states

"Its central objective is to facilitate the more effective use of information to improve healthcare outcomes while ensuring that the privacy of personal health information is appropriately respected".

Considerable consultation regarding the bill has been commissioned, with both members of the public and the healthcare profession¹⁴⁸. It is a component of the Health Reform Programme and reflects its core principles which are based on the critical need for improved ICT within the health services. Discussion of the HIB continues in Dáil Éireann and according to the Department of the Taoiseach its publication date has not been announced¹⁴⁹.

4.5 Conclusion

The context within which a NJR will be proposed and the rationale behind the development of the only Irish Joint Register has been presented. The evolution and current operation of the CNOH Joint Register has been summarised including the benefits and challenges entailed in

¹⁴⁸ <u>http://www.dohc.ie/closed/hib/draft_audit_paper.pdf June 2008Accessed1/5/09</u> <u>http://www.taoiseach.gov.ie</u>

undertaking such a project. Comparisons have been made with international practices encountered in chapter 3, and contrasting features highlighted. Where appropriate, arguments which support justification of these have been offered. Recommendations for review of practices, protocols and procedures in relation to IT infrastructure, patient participation and future operation of the register have been made. Section 4 has sought to provide an insight into the contemporary values and priorities of the Irish policy makers in relation to health information and the legal basis on which these are prescribed. The depiction of current practice in the ROI through the CNOH register will be used in a later chapter to apply an Irish experience to the process of making recommendations for the establishment of a NJR.

Chapter 5: Methodology

5.1 Introduction

The research objective is to provide an insight into the experience of other countries where a NJR has been established in order to ascertain if the Irish health services would benefit from the introduction of a NJR, and if so to devise the most effective strategy for implementation. Chapter 4 has portrayed the experience of a local Irish register and will provide a useful understanding of certain aspects peculiar to the Irish context. This chapter provides the context for the methodology engaged to address the research question. A comparative analysis of the structure and practices of the registers identified in the literature is considered the most appropriate approach in this context. By evaluating and comparing these experiences, evidence of best-practice is used to generate a set of recommendations for the establishment of an Irish NJR.

5.2 Rationale

The strategy of enquiry into current practice has been presented through the literature and web review. This provides a collection of theories which form the underlying philosophies on which the research is based. A comparative study which critiques these different approaches provides the most appropriate methodology for the research. Alternative methodologies were explored, and the survey as a research instrument was considered. However the literature search provided the comprehensive survey undertaken by Kolling et al. which supplied the information that the planned survey would have sought. A second survey of the Irish orthopaedic community was also considered with a view to determining the level of interest in establishing a NJR. The study undertaken by Oduwole et al. in 2008 surveyed all of the orthopaedic surgeons listed as members of the IOA, and to ensure completeness, included those who were not members but listed as specialist orthopaedic surgeons in the Irish medical directory. This methodology was considered to address that which the researcher had intended to determine, consequently any efforts to conduct a similar survey were deemed superfluous since identical data had been collected from the same source during the past year. Essentially the literature review became the survey as no other method of data collection was deemed suitable for this particular study.

The debate surrounding qualitative and quantitative methodologies has polarised both paradigms suggesting that research represents a dichotomy of choices rather than a systematic process of, in the case of this research, validating or refuting existing knowledge¹⁵⁰. In advocating a mixed approach to research methodologies Onwuegbuzie and Leech designed a framework of 7 steps to be followed in the research process. In the absence of a convincing argument regarding the qualitative or quantitative nature of the study, these steps have been deemed appropriate and form the rationale for methodology selection. The steps are as follows

- 1. formulating a research problem and research objective;
- 2. develop research purpose, research questions, and hypotheses;
- 3. select a research design / method;
- 4. collect data;
- 5. analyse data;
- 6. interpret / validate data;
- 7. communicate findings.

Steps 1 and 2 have been addressed, the research is considered to be exploratory in nature. This has been taken into consideration in selecting an appropriate research design, or overall plan for data collection and analysis. The theory on which the research is based is used to examine existing knowledge for consistency in the explanation of the sustained use of NJRs. This will later form the fundamentals of discussion in the next chapter.

5.3 Data Collection

The introduction to chapter 3 specifies the precise criteria used to identify pertinent literature. This systematic approach to the review has been taken so that the most rigorous knowledge of developments regarding the establishment of a NJR has been used to provide a comprehensive summary of the evidence available. The web searches were set to include only peer-reviewed journal articles so that the literature would reflect current practices and theories deemed satisfactory to professional curiosity. In this way existing knowledge has been used to make suggestions for future development of similar theories. The EAR provided a valuable resource in directing the researcher to literature and web-sites directly concerned with the research. This

¹⁵⁰ (Onwuegbuzie A.J., Leech N., 2005)

helped to avoid selection bias, ensure that the sample was sufficient and representative, and to facilitate the collection of valid, reliable and replicable information.

Existing knowledge regarding the Irish situation has been derived from a variety of sources. In relation to the structure of the Irish health services and the formulation of policy within them, many of the statutory bodies responsible for healthcare in the ROI were consulted. Statistics regarding the quantity of orthopaedic surgeons and the hospitals from which they operate were difficult to obtain from these sources, consequently much of this information was obtained from the Irish Medical Directory which provides health service information and is updated annually. All of the data was validated against the number of posts listed within each hospital and, as much as was possible, through information found while searching the statutory bodies. Data regarding the number of arthroplasty procedures performed were obtained from the ESRI. The development of the CNOH Joint Register and its current operations has been depicted through the researcher's experience. It is acknowledged that this is a subjective account but nonetheless necessary in the absence of alternative documentation of the Irish experience.

5.4 Data Analysis, Interpretation and Validation.

The process of interpreting data which has been collected begins with the synthesis of research data so that a concise summary of existing knowledge can be portrayed. The theoretical basis of this knowledge and the methods used to generate it is then critically evaluated¹⁵¹ so that estimations of uncertainty and error measurement in reporting will be taken into account. Thus the data analysis process culminates in eliciting meaning from the research data.

This provides the framework for the comparative analysis of the registers presented by the study in the broader context. By comparing and contrasting the features and commonalities which contribute to the success of each register, and highlighting the challenges encountered in implementation, a descriptive theory of the phenomenon of Joint Registers is built. From this theory a proposal for a set of recommendations for the establishment of an Irish NJR is devised.

5.5 Communication of Findings

The results of the analyses of the research data generated in addressing the research question is reported in the final chapter. This provides a synopsis of the main features of the study, the

¹⁵¹ (Crookes A., Davies Sue, 1998)

methods which it employed, and the interpretation and implications of its findings. It addresses criteria such as credibility, reliability and dependability and the techniques used to ensure the quality of the data¹⁵². Since the researcher is the data collecting instrument and the creator of the analytical process, professional qualification and experience in the field are documented in order to further assure credibility.

¹⁵² (Polit D., Beck C.T., Hungler B.P., 2001)

Chapter 6: The Research Findings

6.1 Introduction

The previous chapters have sought to address the research question through the collection of relevant data. The outcome of this process is a body of information which provides the basis for the comparative analysis that will be used to produce a definitive answer to the research question. This chapter presents the research findings, gives an insight into the significance of specific findings and examines the implications from the Irish perspective. The features of the registers, and the main issues presented in the research are assessed and their significance in relation to the critical success of the overall project is evaluated. Adaptation to the explicit environment in which the Irish health services operate is considered, culminating in the most effective strategy for the establishment of an Irish NJR, thus realising the objectives of the research.

6.2 Core Issues

The key structural, operational and ethical parameters on which NJRs are established have been presented comprehensively in chapter 3. These are now considered on a scale of significance in terms of what was expected, unexpected and that which is deemed to have specific implications for the establishment of an Irish register.

6.2.1 Benefits

An abundance of evidence supporting the concept of a NJR was generated by the research. No evidence which refuted the theoretical basis for the establishment of a register was found. This was as expected since NJRs are founded on proven principles and paradigms, therefore only exist where these are accepted and adopted. They are generally advocated by members of the orthopaedic community who are avidly in favour of development. However, the rate of establishment of new registers in the past decade would strongly suggest that there are valuable benefits to be gained for the individual nation which implements a register.

The economic benefits have particular significance to the Irish context since any innovations within the health services are expected to be cost efficient and based on the existing quantum of

public funding for health ¹⁵³. The national data-base which constitutes a register has been shown to be a useful budgetary tool for service planning. The data in relation to age profile and population diversity generated by a NJR has the potential to assist in planning the type of orthopaedic service which will satisfy the needs of a changing population. Traditionally the average arthroplasty patient was aged approximately 70 and of Irish ethnicity, but there is no longer a typical candidate. 21st century data reflect a much more diverse age and demographic profile¹⁵⁴. According to Dunbar in his address to CNOH, the past decade has seen huge increases in arthroplasty performed on the 45-55 year olds as well as the over 85 age group. This is complicated by the likelihood that the patient is now more obese therefore more at risk of adverse outcome. Appendix 9 illustrates the current age profile from the CNOH joint register. The significance of this data lies in its potential to predict the future orthopaedic needs of the population in contrast to those of the earlier decades of joint replacement surgery. Dunbar goes on to point out that data from the Scandinavian registers reflect patients who generally do not have the same obesity levels as countries such as the USA, therefore cannot be used to plan services for unique national circumstances.

The average price for THR increased by 132% in the USA during the 10 year period to 2006, while there was a 70% increase in demand for arthroplasty over the 5 years to 2005¹⁵⁵. A 2% decrease in US revision rates is estimated to yield \$652 million savings per annum¹⁵⁶. Those implants with proven success through NJR outcome monitoring are more likely to be adapted to meet new demands, therefore provide a potential to reduce costs in relation to innovation. Nations with long-standing register data are cautious about innovation because they have the proof of successful implants in their CRR rates. The Swedish NJR reported that by the year 2000 six implants captured 70% of the market, and its revision burden was reduced to 7%. Dunbar considers the sustained reduction in CRR in Scandinavia to be related to product standardisation since the most popular implants, which have been proven through joint registry studies to be highly successful in their particular populations, are the most frequently used. The converse to this argument is that NJRs may hinder innovation but Robertson (2007) alleges that there is little scientific evidence to suggest that this is a major concern. It is therefore suggested that the introduction of an Irish NJR will enhance the value in the health service through the use of implants proven to be the most cost efficient for the specific population it serves.

¹⁵³ (Harney, 2008)

¹⁵⁴ (Dunbar, 2009)

¹⁵⁵ (Wilson N.A., Schneller E.S., Montgomery K., Bozic K.J., 2008)

¹⁵⁶ (AAOS, 2009)

It has been demonstrated that the accepted benchmark against which success of an implant is measured is its CRR. Revision surgery costs more in terms of outcome and financial expense therefore a reduction in CRR inevitably means lower costs. In the absence of a national mechanism for recording arthroplasty data the accurate calculation of CRR is not possible since no data in relation to primary surgery is available. Estimates can be made but accuracy cannot be assured such as is the case in the USA where data is derived from Medicare statistics which are not complete, and do not account for other surgery performed outside of Medicare. If we are to provide a true reflection of arthroplasty activity in the ROI and produce meaningful information on which decisions regarding Irish patients are made, then it would appear prudent to proceed towards a NJR.

6.2.2 Challenges

The research identified the German register as the only evidence of a failed NJR. It foundered on a lack of resources mainly as a result of poor strategic planning. This finding is significant for the Irish context since the prevailing economic climate calls for rationing of already scarce resources, hence any funding allocated to the development of a NJR must be justified in advance. The strategic oversights which failed to take account of the future sustenance of the German NJR at the time of its development must not be repeated by the Irish. Kolling's study demonstrated that the newer registers in Romania and Slovakia were cautious from the outset regarding financial support because of the failure of the German register, and the experience in Canada and Denmark, where both encountered difficulties due to lack of funding in the first year. Therefore, in order to ensure successful implementation of an Irish NJR, financial support must be guaranteed before embarking on the project.

The majority of registers were funded by government, supplemented in some cases by levies and professional contributions. It is clear from the literature that both policy-makers and the orthopaedic professional community are stakeholders who will benefit from the introduction of a NJR, therefore financial support derived primarily from government, and administered according to consensus from the IOA, is suggested. The literature did not produce any significant evidence either in favour of, or against, the involvement of the implant industry. However, because of the relatively small Irish population, and consequently the smaller amount of arthroplasty surgery, it is suggested that an implant levy would not generate as much revenue as in the UK. Furthermore, it is likely that this added cost would be passed on to the consumer, ultimately being the tax-payer, and could be counter-productive. It is therefore not considered a viable option for an Irish NJR. The EAR advocates the adoption of the Scandinavian model as a result of proven efficiency through the incorporation of government and the national OAs, consequently this is the model recommended for an Irish NJR.

The literature demonstrated diversity in the range of ICT contribution towards successful implementation of NJRs, but leaves no doubt with regard to its potential to increase efficiency in relation to data management. Facilities such as web-based technologies for data entry have been shown to enhance patient participation therefore would appear to be essential if 100% participation is to be achieved. More complex systems, such as that advocated by Roder and used in Switzerland, can potentially address the documentation needs of nations in the process of establishing registers through centralised data management and evaluation. The experience of the CNOH register suggests that ICT infrastructure poses a substantial challenge to successful implementation and that for successful expansion, increased resources are essential. The importance of healthcare ICT and its potential to improve clinical effectiveness has been acknowledged in a number of DOH&C policy documents as outlined in 4.4. Its adoption however of lags behind that of other sectors, and is perceived as a low priority when competing with other service delivery¹⁵⁷. If a NJR is to provide accurate and meaningful information which is accessible to all stakeholders then it is imperative that the technological developments required to enable and sustain it are in place.

Challenging issues in relation to participation have been dealt with in a variety of ways by different nations. Statutory participation has been demonstrated to require comprehensive legislation regarding security and confidentiality and would appear to be feasible only where data registration has a long tradition and is well enshrined in the legal framework. For this reason it is not considered viable to impose statutory participation in the ROI particularly in advance of the publication of the HIB. Privacy, security, confidentiality and integrity of patient information is discussed in greater detail in a later section.

The ICT objective of a NJR is to coordinate techniques for data collection and dissemination through the use of interoperable electronic systems. It has been demonstrated that the ROI legislature widely acknowledges the potential of ICT to improve the delivery of healthcare. However, the challenge lies in the allocation of adequate human and financial resources which is central to successful implementation. It is therefore considered vital to attach significance to this when making recommendations for an Irish register.

¹⁵⁷ (NCMN, 2009)

6.2.3 Data-set

The minimum data-set as discussed in section 3.4 satisfies the basic information requirement of a register. This has been supplemented to various degrees depending on the specific national circumstances, but it has been explicated that a balance must be sought between collection of essential data and that which is deemed to add sensitivity. This is in the interest of both participation and ease of data entry which must be considered in the light of scarce resources. The Irish health services are delivered within an economic climate which is compromised by limited availability of all resources required to ensure success therefore data-set requirements merit considerable assessment if the project is to justify consumption of these resources.

The New Zealand NJR uses the Oxford 12 Questionnaire¹⁵⁸ for the post-operative monitoring of arthroplasty patients, and have found it useful in deciding which patients require more regular review¹⁵⁹. Furthermore, they have noted that there is little significant change between the 6 month and the 5 year scores, from which they have deduced that the 6 month score is indicative of the medium-term outcome. Interestingly, they select a random sample of patients to complete the questionnaire in order to achieve a response rate of 20%, which their statisticians have deemed ample to provide powerful statistical analysis. This finding was unexpected as it appears to contravene the ISAR maxim that for a national registry to be effective it has to have as close to 100% coverage as possible and ideally no less than 95%. In New Zealand it was justified because of the large number of patients on the register after 3 years of operation. However, it is not recommended that an Irish NJR should randomly select a sample of patients because of the risk of under-representation. This could be re-assessed after some years in operation, and following further evaluation of the statistical validity of proportional representation. Because of its concise nature the Oxford 12 questionnaire is advocated for use by an Irish NJR.

It is clear from the research that data-collection forms should be concise and user-friendly. It is therefore suggested that the forms should be completed at the time of surgery by the operating theatre staff. Bar-code labels from the manufacturers should be either scanned into the CIS if a facility is available, or attached to the form. It would seem logical to suggest that where there is no facility to scan the label that a small investment would procure the necessary equipment, and provide returns in terms of reduced staff time used in manual data entry and increased data accuracy. Appendix 10 is a sample of the minimum data-set form recommended by the ISAR

 ¹⁵⁸ (Appendix 6)
 ¹⁵⁹ (Rothwell A., Hobbs T., Frampton C., 2007)

and is advocated for use by the Irish NJR, with an additional field to include Body Mass Indicators (BMI) of obesity. In light of increased risk to the obese patient as discussed in 6.2.1. it is considered beneficial to record BMI at the time of pre-operative assessment. This should be included in the minimum data-set so that adverse outcomes are intuitively associated with a preexisting risk factor. With the exception of prosthesis details, the data fields should be prepopulated from the PAS, and defaulted to reflect the scheduled procedure with an option to amend if necessary.

It was surprising to find that electronic data management was not pandemic, however where manual systems are in use the research suggests that the transition to electronic transfer of data is in progress. The CNOH register is almost paperless, with the exception of written consent all data is recorded electronically. If a NJR were to be established it would therefore appear reasonable to continue this practice and establish a similar system in the other participating centres. This would facilitate transfer of data to the central repository and eliminate the need to access the paper patient record. Regarding patient questionnaires that are manually completed the use of an OMR is recommended, and an on-line option to submit answers should be available.

Many of the registers began with data relating to a single joint and later expanded to include others. While shoulder, elbow and ankle replacements do not account for a large percentage of joint replacement surgery, it is suggested that a NJR should reflect all arthroplasty activity within a given population therefore implementation plans should include the necessary infrastructure to support the collection of data from all major arthroplasties. Whether inclusion from the outset is to be recommended is unclear, but the majority of NJRs at some point after implementation expanded to include all major joints therefore this should be accounted for in the development of a strategy for implementation.

6.2.4 Ethico-legal Considerations

Issues in relation to consent, confidentiality and regulation, present additional challenges in health related projects¹⁶⁰. The ethical principles of autonomy, justice, beneficence and non-maleficence, common to all clinical practice, must be adhered to regardless of the method of consultation or data collection. Inter-net technology services are relatively new methods of

¹⁶⁰ (McCubbin C.N., 2006)

patient consultation falling into the domain of eHealth or telemedicine. According to McCubbin, this new approach to healthcare requires further analytical review in relation to legal and ethical issues with particular regard to the following

- Consent & privacy
- Transfer of medical data across international boundaries
- Legal acceptance of electronic documentation
- Research ethics guidelines and regulations
- Standards and accreditation
- Ownership issues in relation to medical data
- Security Data protection legislation
- Licensing and exploitation

The HIB, relevant details of which has been presented in chapter 4, appears to aspire to address some of these issues. The bill is still in the discussion stage in Dáil Éireann and a publication date has not been issued. It is hoped that it will clarify uncertainties in relation to electronic documentation and interpretation of legal requirements. In making recommendations for an Irish NJR issues such as consent, UPI, security and anonymity of data must be considered. Current legislation which impacts on patient information for use outside of treatment includes the Data Protection Act 1988, 2003, the Freedom of Information Act 1997 and the European Data Protection Directive. Until the HIB is enacted this legislation will govern any decisions relating to data security. It is unlikely that a UPI will be available in the ROI prior to the completion of this research therefore measures must be taken to anonymise all data used in a NJR. A unique identifier will have to be devised in order to achieve this, since data will be transferred across different healthcare institution boundaries. It is however essential to be aware of the experience of the failed German Arthroplasty Register regarding data encryption and pay particular attention to careful anonymisation of data so that decryption is uncomplicated, while also addressing patient's concerns regarding confidentiality.

In light of the findings of the survey conducted by the Irish Data Protection Office in relation to privacy of personal data, referred to in 3.5.2, and because of the absence of exempting legislation, it is considered necessary to obtain informed patient consent for inclusion in the NJR. Because this has been shown to potentially compromise participation a facility for

electronic consent should be embedded in the system. It is expected that any legislative changes required to support this will be addressed by the HIB.

6.3 The Irish Dimension

The research has highlighted the predominant themes in relation to the development of a NJR and much of the analysis surrounding these has been done. What remains for discussion are the opinions and values of the orthopaedic community. As referred to in 5.2, Oduwole *et al.* surveyed the Irish orthopaedic surgeons with the objective of determining their level of interest in establishing a NJR. This was the first Irish study to address the subject and they hoped to discover the possible reasons why an Irish register has yet to be established. A questionnaire, which addressed many of the issues discussed in this research, was used as the research instrument. The questions related to funding, outcome measurement, and dissemination of information, medico-legal concerns, political issues and specific surgical matters. These were presented as statements with a 5 scale Likert response range from strong agreement to strong disagreement.

The most significant of the findings demonstrated that 97% believed it was time to establish a NJR, while 94% were willing to enrol their patients and 81% considered that participation should be compulsory. In relation to funding a majority of 82% were of the opinion that government should bear the cost, 24% were in favour of the implant industry involvement in funding, while 14% believed that costs should be shared by the government, the IOA and the industry. As regards privacy and liability 58% believe that public access to reports could have medico-legal implications.

The findings suggest that there is overwhelming support in favour of the immediate establishment of a NJR.

6.4 Recommendations

The research question has been addressed and its outcome suggests that the establishment of a NJR would define the epidemiology of arthroplasty in the ROI, thus potentially adding value to the Irish health services. Having considered all of the implications it is now appropriate to make the recommendations for its establishment. These are presented using the research findings as the basis for the terms of reference which will define the scope of the project, outline the various roles and responsibilities of the stakeholders and document the constraints within which it must operate.

It is clear from the research that establishment of a NJR based on the Scandinavian model is the objective of the project. The stakeholders involved include the government, the orthopaedic community, the implant industry and the arthroplasty patients. In order to focus the project and achieve a sense of common purpose and direction the goals and objectives of these stakeholders should be harmonised. The research has provided the appropriate indicators for practice on which to build the project. The following recommendations are formulated to facilitate their translation into action.

- 1. The first recommendation for an Irish NJR is a meeting with representation from the stakeholders. The objective of this meeting is to clarify who will participate in the project, how it will achieve its goals and what constraints will impact on its execution. The outcome of this collaboration should provide a clear vision of how the register will be established, the terms of reference under which it will operate and the timeframe over which the targets will be reached. These will be used to generate a project proposal document which will detail the following.
 - Project title, proposer and sponsor
 - Rationale for development and description of the project
 - Aims, objectives and scope
 - Implementation timeframe and project organisation
 - Stakeholders
 - Cost-benefit analysis
 - Performance measurement
 - Constraints and dependencies
 - Risks and assumptions

The document will provide the basis for assessment in order to obtain project approval

2. The organisational structure of the register should reflect the Scandinavian model which incorporates a centrally run NJR with the orthopaedic profession and the health services authorities. Clinical decisions and issues in relation to data publication and ownership will be made by members of the IOA, while organisational and political matters such as allocation of resources will be managed by the funding agency, which will be the government. An agreed budgetary allocation will be set out based on a needs analysis

undertaken by the financing authority, having considered the required skill mix and technological infrastructure. Commitment to financial support from the government will be guaranteed at the outset.

- 3. A team comprised of clinical, administrative, technological and statistical personnel will be required for successful implementation. The country will be divided into five geographic regions broadly representing the capital and the four provinces. The existing elective orthopaedic centres will be set up to model the register at the National Orthopaedic Hospital. Each centre will supply the registry data to the regional elective centre effectively creating four regional registers which in turn will feed composite data to the central data repository. An orthopaedic surgeon will be designated to each region and will act as the Regional Coordinator responsible for maintaining the register. The data collection network will be managed centrally by the NJR team.
- 4. The minimum data-set form prescribed by the ISAR and modified to record BMI, as shown in Appendix 10, is recommended. This data must be collected at the time of surgery in the operating theatre. A designated member of the clinical staff will be assigned responsibility for NJR data reporting at each participating hospital. The implant component details should be scanned into the CIS at each centre, however, in order to ensure that all arthroplasties are registered manual data entry is acceptable. The data from each centre will be forwarded to the regional centre, where the Regional Coordinator will ensure that it is sent to the NJR.
- 5. The use of the Oxford 12 questionnaire, as validated by the New Zealand NJR, is advocated for patient outcome self-assessment. This data will be collected pre-operatively so that a baseline against which outcome can be measured is recorded. One year post surgery the Oxford 12 will be administered to all patients and any adverse surgical outcomes will be recorded. An on-line facility for patient data-entry will be provided through the register's website which will actively encourage participation. The patient will be requested to attend a local radiology facility for x-ray, details of which will be recorded should a copy be required. Patients with poor outcomes, determined by the Oxford 12 score, will be followed-up and referred to the orthopaedic surgeon if necessary. This process will be repeated every 5 years for life or until revision is required.

- 6. All patients who have primary and revision THR and TKR at all public hospitals, will be included on the register. Participation of all public hospitals will be voluntary. It is suggested that the IOA will determine whether inclusion of all arthroplasty surgery should be advised from the outset. The data collection system will be designed so that it is adaptable to include all joints at a later stage without further development of the system. The regional centres will operate nurse-led joint register review clinics based on the current CNOH model. These will provide the primary review mode aimed at patient attendance at the centre, but will incorporate a facility for remote consultation.
- 7. The ICT infrastructure for the central database will be developed and maintained by the ICT professional on the NJR team. Local modification of existing systems will be evaluated prior to launching the register. Standardisation of these must be achieved and any systems which are not interoperable with the proposed infrastructure cannot be considered. The data-base must have powerful query and reporting functions, with the ability to meet the registry requirements well into the future and the capacity to be interoperable with other systems, such as a national PACS. Remote consultation will be an optional method of review, therefore the system must provide an interface to the web. The data collection instruments will be adapted to accommodate electronic data entry through the use of OMR paper questionnaires and mobile barcode readers. All internet applications should be embedded within a web content management system as prescribed by Roder, to facilitate use by non-technical operators. The system will be continuously monitored to detect functionality deficiencies so that documentation management will be optimised.
- 8. The NJR will operate within the existing legal framework which impacts upon data protection, security and publication. Assurance will be given to patients regarding confidentiality of their data, and all data which is submitted to the central server will be anonymised. No data will be reproduced for any purpose other than that for which it was collected. Publication of outcomes will not be related to any individual surgeon. Data will at all times be subject to prevailing legislation and the participants will be informed of any new statutory requirements. An opt-out facility will exist for those unwilling to participate.
- 9. The patient will be advised of the life-long review process at the first consultation with the healthcare delivery service, and informed consent to participate will be sought. Emphasis will be placed on the potential need to trace the patient in the event of implant

recall, hence the importance of their data registration. Baseline patient demographics will include an email address where applicable. The philosophical motivation for the existence of the register will be asserted from the outset and reaffirmed throughout the patient journey.

10. The project group will meet regularly in the early stages so that targets can be assessed and issues set out in the terms of reference reiterated. Once approval for the project is obtained these meetings will continue, providing a forum for continual assessment of progress, and an opportunity to redress any shortfalls. Following implementation the group will support and maintain the register and provide a continuous assessment of its development. When firmly established the activities of the register will be documented in an Annual Report. This will be available for publication.

6.5 Discussion

Critical success factors have been considered in light of the evidence generated by the research. Each factor contributes an individual element but success is inter-dependent on a composite, holistic approach therefore no factor can be considered in isolation. However, in the interest of continuity and coherence, the following paragraphs discuss their individual contribution.

The significance of agreed funding at the outset of the project cannot be over-stated if the hazards experienced by other registers are to be avoided. It is essential to achieve stakeholder agreement on the correct level of financial support having considered all of the requirements. Human resources will form a large proportion of the operational costs and it is clear from the research that the skill-mix of the project team is fundamental to success hence the inclusion of a statistician. Technological development will also require considerable financial commitment at the outset, but once implemented, maintenance costs should not be excessive.

The rationale for the regional divisions is to allow decentralised responsibility for data management. This should enhance data quality and completeness while utilising established regional networks. All of the hospitals in the ROI which perform arthroplasty surgery will be responsible for submission of data to the regional register. All surgical procedures are routinely recorded by the operating theatre staff for theatre registration purposes, the NJR data-set can easily be incorporated into this process.

There was little evidence to support the frequency of review undertaken by the CNOH register hence the decision to compromise and review patients one year post-operatively and every five years thereafter. The Oxford 12 questionnaire is chosen for its user-friendly nature in the interest of obtaining a patient perspective of outcome. The research was inconclusive regarding what arthroplasties to include at the outset, but it was quite clear that over time many became all-inclusive, hence the decision is to be made by the IOA. Voluntary participation is recommended in light of the research findings which did not reflect the need to make it statutory. The on-line facility for data submission is recommended for those who are willing to provide data, but unwilling to travel for review.

The documentation technology advocated by Roder (MEMdoc) and used in the SOR has been trialled by emerging registers but there was no evidence to suggest that its substantial implementation and maintenance costs could be justified. It is therefore recommended that the project team evaluate the system through cost-benefit analysis, prior to making a final decision on its suitability for an Irish NJR.

The research has demonstrated that there is widespread political acknowledgement of the potential of ICT to enhance the delivery of the Irish health services. Many of the issues surrounding privacy, security and confidentiality are expected to be addressed by the HIB. It remains to be seen whether the recognition of the effective use of information can be translated into action through the commitment of the required resources.

6.6 Summary

The findings of the research have been presented in this chapter and the outcome confirms that which was intended to disclose. It is clear from the evidence that in the interest of providing a quality service and improving patient care it is appropriate to establish an Irish NJR. The data generated by the research has highlighted the critical factors which contributed to the successful implementation of other registers while also emphasising failure factors which must be avoided if the research is to be of benefit. These have been considered in detail and analysed from the unique perspective of the Irish health services. They have provided the blueprint for the development of a NJR. A proposal based on the outcome of the research, which sets out the corporate objectives and makes recommendations for implementation, has been devised.

Chapter 7: Conclusion

7.1 Introduction

The rationale for the development of joint registers and their historical chronology has been documented. The literature has been used to generate an evaluation of the theoretical basis of knowledge on which NJRs are founded. The unique circumstances within which the Irish health services are delivered have been presented and the research findings have been applied to form of a set of recommendations for the development of an Irish NJR.

The final chapter summarises the main features of the study and assesses its contribution. A methodological critique of the research is offered, and the implications of the research findings for the provision of healthcare in Ireland are discussed. The limitations of the study are considered and suggestions are made for further evaluation and future research in this field.

7.2 Synopsis Report

Figure 5 summarises the historical development and the findings of the study in relation to information governance and management of NJRs.

The main points of the research can be summarised as follows:

- For almost half a century arthroplasty has restored mobility and eliminated pain in countless patients who suffer from arthritis.
- The Scandinavians were the first to collect data in relation to the outcome of arthroplasty. As a result of their success in using this information to improve outcomes other countries began to develop their own data registers.
- The benefits of implementing a NJR are numerous, these have been well documented in the literature and are summarised in section 3.2.1 of the research.

Figure 5 Summary of International Practice and Chronology

			nimum Data- +	cumentation	a Output	guibr	intenance	ient Consent	ltutory ticipation
Year	Country	Туре	Mir set	typ t	Dat	Fur	Ма	Pat	Sta Paı
1975	Sweden	SKAR- expanded to include hips 1979)	Patient Questionn aires	Paper, web & Data file	Public Report & Access to Database	Govt & OA	Govt & OA	NO	NO
1980	Finland	Orthopaedic Implant Register	Patient Questionn aires	Paper	Public Report	Govt	Govt	NO	YES
1987	Norway	Hip Register (expanded to all joints 1994)		Paper & data file	local & Public Report	Govt	OA	YES	NO
1995	Denmark	Hip Register- expanded to include knees 1997	Clinical Scores	Paper & data file	local & Public Report	Govt	Govt & OA	NO	YES
1998	Hungary	Hip and Knee Register							
	Australia	Hip and Knee Register		Paper & web	Public Report	Govt	OA	Opt out option	NO
	New Zealand	Multiple Joints Register	Patient Questionn aires	Paper & web	local & Public Report	Govt & OA	OA	YES	NO
1999	Scotland	Multiple Joints Register					OA		
2000	Canada	Hip and Knee Register		Paper & data file	local & Public Report	Govt	Govt	YES	NO
2003	England and Wales	Hip and Knee Register			Public Report & Access to Database	Implant Levy	Govt	YES	YES
	Pomonio	Multiple Joints	Radiograp	Papar & web	Public Report & Access to	Govt	0.0	VES	NO
	Slovakia	Hip and Knee Register		Web & Data	Access to Database	Govt	OA	NO	YES
2004	Switzerland	Hip and Knee Register	Patient Questionn aires & Clinical scores & Radiograp hic detail	Paper , Web & OMR	Access to Database	OA	OA	NO	NO
	Italy Slovenia Lithuania Estonia	National Arthroplasty Registers							~
2006	France	Arthroplasty Register							
- The main challenges associated with introduction of a NJR fall broadly into 3 interdependent categories
 - 1. Ethico-legal data security and confidentiality which if not adequately addressed can result in compromised participation.
 - 2. Finance underfunding has resulted in failure, finance must be agreed in the early stages of the project.
 - Technical optimum infrastructure requires commitment of resources from the outset. Data encryption must ensure anonymity while simultaneously needing to be easily decoded. Consensus on minimum data-set is essential.
- Ireland does not have any such National Register, however the researcher's experience of a local register at CNOH is documented. This provides an insight into register practice operating within the unique setting of the Irish Health Services.
- A comparative analysis of existing registers provided a body of evidence on which to base recommendations for the development of an Irish NJR, thereby attaining the objective of the study and addressing the research question.

7.3 Assessment of the Research

Through evaluating the experience of other countries in establishing a NJR the research has generated an evidence-base of how best to approach development. It has identified the practices that have been proven effective in the establishment of a NJR, and highlighted the obstacles to be avoided. The results suggest that the implementation of a NJR provides an opportunity to improve the delivery of service to the arthroplasty patient, and have been used to develop recommendations for an Irish NJR. The findings are consistent with the external evidence provided by the body of prior research, thus enhancing the credibility of the results. Some outstanding aspects of the research are now considered.

7.3.1 Methodology Critique

The methods of inquiry were chosen with a view to providing the most appropriate means of addressing the research question. No single study was relied upon in isolation, rather every endeavour was made to consult with numerous pertinent sources. The decision to rely solely on the literature was made when it became evident that there was a wealth of information to be gleaned from that focus. An alternative approach, such as a survey of the registers identified, may have produced a different answer to the research question but the author considered this unlikely because of the convincing evidence provided by the existing body of research. Furthermore, it was considered superfluous to replicate recently conducted studies within the same sample.

The professional qualification and clinical experience of the researcher was relied upon to ensure the quality of the data. This was supplemented where possible with advice and counsel from peer members of the profession in an effort to enhance credibility. This is acknowledged as a potential bias because of the reliance on subjective experience, but nonetheless it was considered appropriate to document the CNOH experience since it had not previously been undertaken.

Some difficulty was encountered in obtaining reliable data in relation to the location of operative centres, the precise number of arthroplasties performed, and the number of surgeons operating in Ireland. Every effort was made to ensure the reliability of this data through validation with official sources, but its stability cannot be guaranteed because of the fluctuating nature of current activity within the Irish health services. For example, it is known within the orthopaedic profession that some surgery is performed in the acute hospital sector when high-risk patients require specialist intensive care, while a number of patients have surgery through the National Treatment Purchase Fund; these could not be accounted for.

7.3.2 Implications for Practice

The results demonstrate that there is nothing to be gained by delaying the establishment of an Irish NJR. The findings imply that the consequences of not implementing a NJR are significant in terms of missed opportunity to improve the cost-effective delivery of the Irish health services. To ignore the outcome of the research could be viewed as failure to keep abreast of best practice evidence.

The statement of strategy published by the DOH&C (May 2008) acknowledges the increasing Irish population, the elderly proportion of which is expected to reach 35% by 2050. The research findings have considerable implications for the planning of services and anticipation of the needs of this population profile.

The researcher's difficulty in obtaining reliable data regarding orthopaedic activity is considered a noteworthy incidental finding because of the implications for future research. While the valuable data provided by the ESRI is acknowledged, it is suggested that a comprehensive approach to systematic collection of health service activity across all specialities be introduced.

7.4 Limitations of the Study

Appropriate steps have been taken to ensure that the research accurately reflects practice. Each attribute has been measured consistently and repeatedly across a sample of several registers in an effort to ensure reliability and stability. However, the paucity of literature from the unique context of the Irish health services presents a limitation regarding the transferability and generalisation of the findings. This provides justification for the documentation of the CNOH register experience, albeit from an acknowledged subjective bias.

The research design was chosen as the most appropriate approach to address the research question. Other designs were eschewed because of the existing body of knowledge therefore no alternative methodology was available. This intrinsically poses a limitation.

7.5 Recommendations for Further Research

The paucity of Irish literature poses a forum for multidimensional further studies which could be used to inform practice. The CNOH register has the potential to analyse aspects such as the reasons for non-attendance and participation. The outcome of such a study could be used to determine optimum data-set for the particular population which will form the NJR, and assist in reaching consensus on the most appropriate review format.

The impending publication of the HIB should clarify legislative obscurities in relation to governance. This will provide a basis for the strategy in relation to consent, security and confidentiality. However, further analysis of these issues from the patient perspective, is recommended so that a NJR, unique to the population it serves, can be developed.

There is a perception that elderly patients are not compliant with advancing technology therefore would not be amenable to data submission over the internet. It is suggested that the ICT literacy of arthroplasty patients be examined so that remote consultation can be optimised.

It was beyond the scope of the study to examine arthroplasty activity in the private Irish hospitals. This was due to several reasons, not least because of set parameters regarding the magnitude and time-frame of the study, but also because of the lack of consistency in statutory reporting from this sector. Particularly in view of the public/private structure of the Irish health services, it is recommended that further research be undertaken to examine private sector practice and evaluate the outcomes of surgery for comparative analysis.

7.7 Summary

In conclusion, the research has been summarised and its value assessed within the context of its scope and methodological limitations. The implications of its outcome have been presented and can be used to inform practice for planning, implementing and evaluating the benefits of establishing an Irish NJR. It is clearly evident that not only is this appropriate, rather, that failure to do so may well be interpreted as disregard for the rights of the consumer of Irish healthcare, with consequent implications for negligence.

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Appendices

Appendix 1	Register Development
Appendix 2	Register Activities in Europe
Appendix 3	Cumulative Frequency of Revision
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Appendix 6	Oxford 12 Questionnaire
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Appendix 11	ESRI Response to Data Request

Appendices 1-4

Adapted from: Labek G. (2005) *Results of Arthroplasty Registers and Benefit for a country or national Society running an Arthroplasty Register* (<u>www.ear.efort.org</u>)







Levels o	evels of Evidence for Primary Research Question			
		Types	of Studies	
	Therapeutic Studies— Investigating the Results of Treatment	Prognostic Studies— Investigating the Outcome of Disease	Diagnostic Studies— Investigating a Diagnostic Test	Economic and Decision Analyses— Developing an Economic or Decision Model
Level	 Randomized controlled trial Significant difference No significant difference but narrow confidence intervals Systematic review² of Level-I randomized con- trolled trials (studies were homogeneous) 	 Prospective study¹ Systematic review² of Level-I studies 	 Testing of previously devel- oped diagnostic criteria in series of consecutive pa- tients (with universally applied reference "gold" standard) Systematic review² of Level-I studies 	 Clinically sensible costs and alternatives; values obtained from many stud- ies; multiway sensitivity analyses Systematic review² of Level-I studies
Level II	 Prospective cohort study³ Poor-quality randomized controlled trial (e.g., <80% follow-up) Systematic review² Level-II studies Nonhomogeneous Level-I studies 	 Retrospective study⁴ Study of untreated controls from a previous random- ized controlled trial Systematic review² of Level-II studies 	 Development of diagnostic criteria on basis of consec- utive patients (with univer- sally applied reference "gold" standard) Systematic review² of Level-II studies 	 Clinically sensible costs and alternatives; values obtained from limited stu ies; multiway sensitivity analyses Systematic review² of Level-II studies
Level III	 Case-control study⁵ Retrospective cohort study⁴ Systematic review² of Level-III studies 	e	THE JOURNAL OF BONE &	JOINT SURGERY s and
Level IV	Case series (no, or historical control group)	Case series	J .	IS

WOMAC & SF 36 Questionnaire

Oxford 12 Hip Score

1. During the past 4 weeks, how would you describe the pain you usually had from your hip?

None	Very mild ²	Mild ³	Moderate ⁴	Severe ⁵

2. During the past 4 weeks, have you had any trouble with washing and drying yourself (all over) because of your hip?

	No trouble at all ¹	Very little trouble ²	Moderate trouble ³	Extreme difficulty ⁴	Impossible to do ⁵
Γ					

3. During the past 4 weeks, have you had any trouble getting in and out of a car or using public transport because of your hip?

1	No trouble at all ¹	Very little trouble ²	Moderate trouble ³	Extreme difficulty ⁴	Impossible to do ⁵

4. During the past 4 weeks, have you been able to put on a pair of socks, stocking or tights?

Yes, easily ¹	With little difficulty ²	With moderate difficulty ³	With extreme difficulty ⁴	No, impossible ⁵

5. During the past 4 weeks, could you do the household shopping on your own?

Yes, easily	With little difficulty ²	With moderate difficulty ³	With extreme difficulty ⁴	No, impossible ⁵

6. During the past 4 weeks, for how long have you been able to walk before pain from your hip becomes severe (with or without a stick)?

[No pain/more than 30 minutes ¹	16 – 30 minutes ²	5 – 15 minutes ³	Around the house only ⁴	Not at all – pain severe on walking ⁵
[

7. During the past 4 weeks, have you been able to climb a flight of stairs?

Yes, easily ¹	With little difficulty ²	With moderate difficulty ³	With extreme difficulty ⁴	No, impossible ⁵

8. During the past 4 weeks, after a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?

Not at all painful ¹	Slightly painful ²	Moderately painful ³	Very painful ⁴	Unbearable ⁵

9. During the past 4 weeks, have you been limping when walking because of your hip?

Rarely/never ¹	Sometimes, or just at first ²	Often, not just at first ³	Most of the time ⁴	All of the time ⁵

10. During the past 4 weeks, have you had any sudden or severe pain - 'shooting', 'stabbing', or 'spasms' - from the affected hip?

No days ¹	Only 1 or 2 days ²	Some days 3	Most days ⁴	Every day ⁵
			N	

11. During the past 4 weeks, how much has pain from your hip interfered with your usual work (including housework)?

	tery	Moderately	A little bit	Not at all
_	tety	stoderately	 on	A intue
_			 	

12. During the past 4 weeks, have you been troubled by pain from your hip in bed at night?

No nights ¹	Only 1 or 2 nights ²	Some nights 3	Most nights ⁴	Every night ⁵
		1000		

Joint Register Consent Form

This form should be kept in the patient record chart

Patient addressograph

I CONSENT to my details being recorded within the Cappagh Hospital Joint Register. I am aware that relevant clinical information will be stored In the hospital. This information will be reproduced on a non-named basis, for analysis in furthering the hospital's goal of improving patient care

Signature of patient:

Date

Signature of witness:

Date



Average Outcomes for 3 Hip Implants

Age & Gender Profile of THRs at CNOH 2009



Summary of Minimum Dataset

Recommended National Arthroplasty Registry Essential Minimum Dataset					
SECTION	DATA				
-					
Prosthesis Details	Catalogue number				
	Lot number				
Patient Details					
	Full name				
	Age				
	Gender				
	Address				
	Operative Hospital Patient Identifier				
	BMI				
Surgery Details	Date				
	Site/Side				
	Diagnosis				
	Primary or Revision				
·					
Hospital Details	Identity Number (or name and address)				
·					
Surgeon Details	Name or code number				



Health Research and Information Division, ESRI

CONDITIONS OF USE OF HOSPITAL IN-PATIENT ENQUIRY DATA

- The tables/data provided outlined below are provided exclusively to Fionnuala Walsh
- These data should not be passed to any third parties.
- HIPE data are not to be presented in either written or oral form that could directly or indirectly identify an individual patient, doctor or health care institution.
- HIPE data should not be used to identify patients or to contact patients for the purposes of research or other purposes.
- Linking record level HIPE data with any other data source(s) is prohibited.
- Tables containing HIPE data should not be published where any individual cells contain less than 5 cases.
- The responsibility for all interpretations of the data lies fully with the data user.
- The Health Research and Information Division in the ESRI should be clearly acknowledged as the source of the data in any publication or presentation in which HIPE data are used.
- The Health Research and Information Division in the ESRI should be provided with a copy of any published paper in which HIPE data are used.

Data provided: H09023_FionnualaWalsh(1)