

A National Renal Registry – An Irish Perspective.

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requirements for the degree of Master of Science in Health Informatics

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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 at this or any other university.

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For Grace, thank you for making me smile along the way.

And finally, for Norah, without you none of this would be possible.

Summary

The purpose of this dissertation is to examine current renal data collection methods from a national and international view point and to explore the process of implementing a National Renal Registry in Ireland.

The background to the dissertation is that a renal registry currently does not exist in the country and its development is critically required. There is a lack of accessible quality information on the epidemiology of renal disease and on renal services in Ireland. Management of Chronic Kidney Disease patients is becoming increasingly complex in today's modern healthcare system. Over the last 10 years an increasing number of patients worldwide have started dialysis or received renal transplantation. With the renal population in Ireland increasing there is a need for a quality data repository to be created and implemented, thus providing comparative data for auditing, planning, clinical governance and research on a national level.

A state of the art literature review was conducted to examine how other international registries are organised and operate. The advantages and disadvantages of such systems are considered. Following this review a proposal for an Irish registry is suggested. A registry would allow the retrospective annual review of renal replacement treatments and to give a more accurate reflection of renal disease in Ireland. The proposal further suggests that a robust electronic registry a renal measures disease outcomes and is a viable concept as an administrative, research and report generating tool.

A survey questionnaire of one hundred and thirty four renal clinicians was undertaken to investigate current understanding of how familiar the respondents were in relation to their exposure to IT in their place of work. The purpose of the study was to investigate IT utilisation and current knowledge of a renal registry amongst specialist nephrology staff from the largest nephrology unit in Ireland. The questionnaire yielded a response rate of 66%. Also further research was preformed by interviewing a target group of Nephrologists from around the country to gain a national understanding as to why there is no renal registry and further understanding of how to move the implementation process forward.

This dissertation has outlined the process of implementing a national renal registry. Having looked at the current challenges and potential barriers to this process working, the case has been put forward to indicate that the benefits to patients, hospitals and the country would far outweigh the challenges in its implementation.

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Abbreviations

ADR	Annual Data Report
AES	Advanced Encryption Standard
ANZDATA	Australian and New Zealand Dialysis and Transplant Registry
ANCSR	Australian National Cardiac Surgery Register
CNM	Clinical Nurse Manager
CAPD	Continuous Ambulatory Peritoneal Dialysis
CF	Cystic Fibrosis
CFRI	Cystic Fibrosis Registry of Ireland
CIA	Confidentiality Integrity Availability
CKD	Chronic Kidney Disease
CSO	Central Statistics Office
DAME	Distributed Application Middleware Engine
DBMS	Database Management System
DES	Data Encryption Standard
EAS	Electronic Administration System
EDTA	European Dialysis and Transplantation Association
EfG-TS	Etablissement francis des Greffess TS
EHR	Electronic Health Record
ERA	European Renal Association
ESKD	End Stage Kidney Disease
gVPN	Government Virtual Private Network
HIS	Hospital Information System
HIV	Human Immunodeficiency Virus
HL7	Health Level Seven

HSE	Health Services Executive
ICD	International Classification of Disease
ICT	Information Communication Technology
IKA	Irish Kidney Association
INCR	Irish National Cancer Registry
IT	Information Technology
KDIGO	Kidney Disease Improving Global Outcomes
KDOQI	Kidney Dialysis Outcome Quality Initiative
MDT	Multi-Disciplinary Team
NCHD	Non-Consultant Hospital Doctor
NHF	National Service Framework
NHIS	National Health Information Strategy
NHS	National Health Service
NRSR	National Renal Strategy Review
PDMS	Patients Data Management System
pmp	Per Million Populations
RRT	Renal Replacement Therapy
SQL	Structured Query Language
SSL	Secure Socket Layer
TCP/IP	Transmission Control Protocol and Internet Protocol
UKRR	United Kingdom Renal Registry
USRDS	United States Renal Disease System
WHO	World Health Organisation
XML	Extensible Mark-up Language

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1. Introduction

1. Introduction

1.1 Introduction

This dissertation examines the need for a national renal registry; it reviews existing renal registries and proposes the implementation of a national renal registry. Currently a renal registry does not exist in Ireland, nor is there participation in any international registry. Therefore there is a lack of accessible quality information on the epidemiology of renal disease and on renal services in Ireland. Renal Registries provide a focus for the collection and analysis of standardised data relating to the incidence, clinical management and outcomes of renal diseases. The aim of any health service is the delivery of the highest standard of care to its patients. The collection of renal data and the storage and analysis of this data will be discussed in detail throughout in this dissertation.

1.2 Background

Management of Chronic Kidney Disease (CKD) patients is becoming increasingly complex in today's modern healthcare system. Over the last 10 years an increasing number of patients worldwide have started dialysis or received renal transplantation. Many are elderly with complex comorbidity conditions. Registries across the world all show a rapid and dramatic increase in the number of older patients accepted for renal replacement. Patients are being identified earlier, and there is an increasing array of therapeutic options available to combat the effects of the disease and to provide renal replacement therapy ie, dialysis.

In the last twenty years, computerised data collection systems have been widely adapted to the healthcare setting. There are now evidence-based guidelines on all aspects of renal care including the K-DOQI (Dialysis Outcome Quality Initiative) Guidelines and the Renal Association Guidelines. National data systems such as the United States Renal Data System (USRDS), the European Registry (ERA-EDTA) and the United Kingdom Registry have provided much useful information on trends in the management of Chronic Kidney Disease (CKD) and have facilitated clinical audit and quality improvement across renal centres.

At present, auditing of this disease is actively done by most renal units in Ireland. However this valuable data is collected locally and is not submitted to a central renal registry. Such a registry is required so that renal patients can be tracked and managed from first diagnosis through early chronic kidney disease and on to haemodialysis, peritoneal dialysis and transplantation.

1.3 Motivation

In Ireland there is a vast amount of information, obtained by the renal units, and this information is of significant value to service planning, bench marking, quality assurance and research for CKD patients or for patients who require renal replacement therapies and also for the institutions that deliver the care. If this data was submitted to a data repository such as a renal registry the ability to provide comparative data for auditing, planning, clinical governance and research on a national level would be possible. The current IT system in place fails to meet the demands of the Irish renal service. A robust, reliable and efficient IT service which both significantly upgrades the patient experience and promotes Irish renal services is required.

This dissertation examines and discusses the key requirements for a national renal registry. These will include but are not inclusive to:

- Monitoring the quality and quantity of renal care in Ireland.
- Show patients that they should expect a level of quality and professionalism as standard.
- Determine the level of burden of chronic kidney disease on a national basis.
- Be able to generate its own consistent national figures from a reliable source, rather than relying upon sporadic and possibly inaccurate and erroneous data.
- Improve accountability in the provision of renal services and ensure equality in the delivery of care on a national basis.
- Integrate electronic data transfer techniques and information communication technologies (ICT) to reduce error.
- Develop an IT friendly environment within the renal population to ensure that accurate data collection is considered good clinical practice.

- Create a standard within all the renal units in Ireland for the collection of data.
- Stimulate research.
- The Registry should also identify patients not receiving appropriate clinical and laboratory screening for renal complications.
- Enhance and preserve confidence in Irish nephrology among patients, clinicians and society by providing accurate and up-to-date data.

It maybe argued as to which of the above is deemed to be of the most important, however it cannot be denied that if any of the above are implemented the benefactor would unquestionably be the patients suffering from kidney disease.

1.4 Author's Interest

The author's interest in the area of renal registries stems from a nursing background. The author has worked in the acute hospital settings for 15 years and has experienced clinical settings of many hospitals in Ireland and Australia. Whilst overseas the author witnessed technological advances that had yet been implemented in Ireland. Where by an interest in information communication technology, in the healthcare setting, was developed.

The author currently works as Renal IT Nurse Manager in a major Dublin acute hospital and has been a part of renal nursing and the delivery of renal replacement therapies for many years. Currently it is the responsibility of the author to record and produce the statistics for the Renal Unit on a monthly, quarterly and annual basis. This is done by gathering and correlating these statistics thus enabling the renal unit to produce an accurate and timely report for the Hospital and HSE when required and also provides the unit with the appropriate information to plan the service for the future.

Furthermore, the author is a clinical systems manager of a renal database management system. This system captures all relevant information for the delivery of optimum care to the patients. The development of the computer data system for the management of renal services has further enhanced the author's interest in the area of renal registries and renal data management.

1.5 Research Objectives

A questionnaire of Nurse/Non-Consultant Hospital Doctor (NCHD) has been designed to determine the knowledge levels of Nurses and Doctors in relation to a national renal registry. Such questions have been asked, what is their knowledge of renal registries? What benefits they would bring to patients? Have any of these health professional been directly involved with the submission of data to a registry previously? And if so, what experience did they have? ie, did they find it increased their work load or was their role passive were somebody else obtained the data? Did they feel they got any benefit from such a registry? Also, the questionnaire is designed to support the literature review and to highlight any skills deficit present amongst the renal health professionals, which in turn will identify possible difficulties of implementing a national renal registry in the future.

For the purpose of the dissertation interviews with Nephrologists from the main renal centres in Ireland have been conducted. The main reason for interviewing these healthcare professionals is to determine what, in their opinion, is required from a national perspective for a renal registry to be implemented? What barriers exist? How to move the implementation of such a registry forward? These interviews were conducted face to face in the specific clinical area of each of the nephrologists. The interviews were invaluable in gaining the knowledge and opinions of the most senior professionals in the field of renal care.

1.6 Literature Review

The literature review mainly concentrated on the current state of practices outside of Ireland, with specific focus on the United States, United Kingdom and other large data repositories. Renal registration and renal databases was determined and discussed at length. As these countries have highly evolved and advanced registries. Also, how these countries manage their national renal databases was reviewed and for what purposes this data is utilised by the registries.

The author reviewed the basic minimum datasets required by each registry to successfully function at a beneficial level. Comparing the datasets of each registry was significant for the author to set a benchmark for which an Irish system can be measured. Some datasets may not be as relevant to an Irish registry whilst others may hold a higher importance and relevance to the Irish population.

Proven benefits were also needed to be determined. Since the inception of each registry has the overall care and treatment of patients outcomes improved, and if so, how significant is this improvement? The author demonstrates that the implementation of a registry will be of benefit to patients suffering from kidney disease.

Barriers and risk to registries were also reviewed. Previous experiences of other registries will be observed and the barriers encountered commented on. This will enable the dissertation to give a complete critique of registries from both a positive and negative angle.

Transferring of data from one site to another was needed to be considered. How much data is required? And how much data sharing can be considered a violation of data protection? Data protection was reviewed as each territory will have their own data protection laws and ethical beliefs in relation to handling and sharing of patients data.

1.7 Implementation

The dissertation examines what is required for the successful implementation of an Irish National Renal Registry. An implementation proposal was designed incorporating a proposed state of the art renal information system for the whole country. Issues of regulations and governance were considered and discussed in full. Ethical issues such as consent and data protection were explored to determine which solution would be most appropriate to the Irish health system. A major remit of the implementation of an Irish National Renal Registry is the consideration of appropriate datasets for the registry; also this dissertation examines the issues of data standardisation whether it is the main key to comparing quality and performance.

Furthermore interfaces were explored for the proposed registry to determine which are the most utilised and effective options available. Security is a vital aspect for the use of

healthcare information systems and was commented on in the body of work of this dissertation. Other areas such as connectivity and transfer of data were examined and also financial considerations were evaluated.

And finally to complete the dissertation a prototype of an Irish renal registry with the appropriate dataset and information required to give an overall understanding and summarisation of an Irish renal registry will be created. The Microsoft Access 2003 and Microsoft Visio 2003 applications will be utilised for this section of the dissertation.

2. Renal Disease in Ireland

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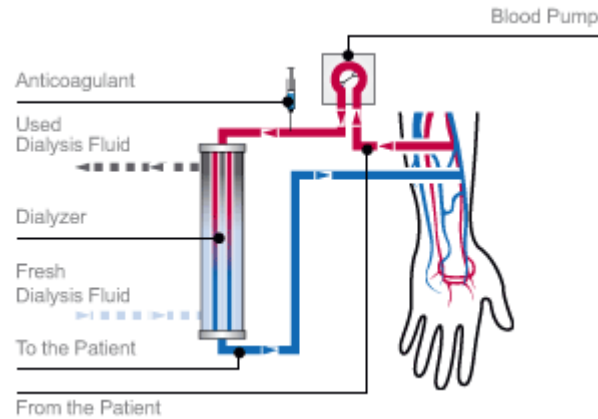
2.1 Introduction

The primary function of the kidneys is to rid the body of the waste produced through the breakdown (metabolism) of protein to an energy form. The main waste product is urea, which is normally excreted out of the body via the bladder. The term renal disease typically refers to diseases of the kidney and nephrology is the branch of medicine concerned with the kidney - its development and anatomy and physiology and disorders. Conditions of the kidneys have different presentations and treatments. If your kidneys present with malfunction or Chronic Kidney Disease (CKD), urea builds up in your body, accumulating in the kidneys, bloodstream and elsewhere. When the kidneys malfunction, problems frequently encountered are abnormal fluid levels in the body, anaemia, and abnormal levels of potassium, calcium, and phosphate. Long-term kidney problems have significant repercussions on other organs, such as cardiovascular disease and diabetes. Others diseases such as anaemia, bone disease and heart failure are the consequences of renal failure itself. If the condition of CKD continues untreated and symptoms persist then the condition develops into End Stage Kidney Disease (ESKD) and the requirement of Renal Transplantation or Renal Replacement Therapy (RRT) must be initiated or the condition will be fatal for the patient.

There are three main forms of RRT; transplantation, haemodialysis and peritoneal dialysis. The goal of treatment is to control symptoms, reduce complications, and slow the progression of the disease. Diseases that cause or result from chronic kidney failure must be controlled and treated as appropriate.

2.2 Haemodialysis

Haemodialysis is the process in which blood is sent through a machine that filters away waste products. The cleansed blood is returned to the body. Haemodialysis is usually performed at a dialysis centre three times per week for 3 to 4 hours. Haemodialysis is a complicated and inconvenient therapy that requires a coordinated effort from the patient's whole health care team, including the nephrologist, dialysis nurse, dialysis technician, dietitian, and social worker. Hemodialysis can be an outpatient or inpatient therapy. This necessary life saving treatment each week can disrupt the patient's working, social and family life. An example of haemodialysis is represented in Figure 1 below.

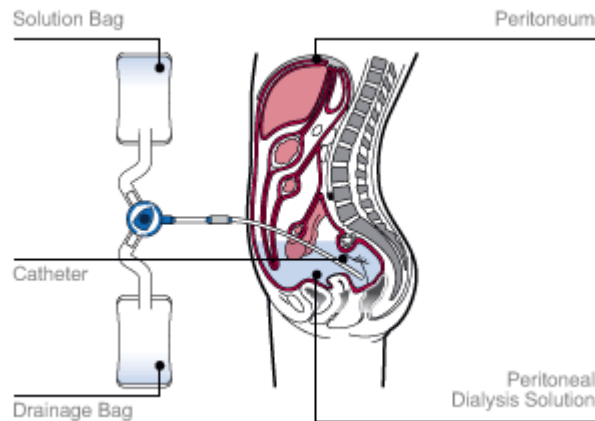


Ref: Fresenius Medical Care 2006.

Figure 1. Haemodialysis

2.3 Peritoneal Dialysis

In peritoneal dialysis, a high sugar concentrate fluid is infused into the abdomen. This dialysis fluid captures the waste products from blood using the principle of diffusion. After a few hours, the dialysate containing the body's wastes is drained away. Then, a fresh bag of dialysis fluid is infused into the abdomen. Patients using continuous ambulatory peritoneal dialysis (CAPD), the most common form of peritoneal dialysis, require changing the dialysate four times a day. Patients can perform peritoneal dialysis themselves at home. Since the advent of dialysis, studies have shown that a diagnosis of ESKD/CKD can lead to severe psychological stress (Cameron, 1996). The impact of the illness is not confined to the psychological; it also affects the patient physically, socially and financially. An example of peritoneal dialysis can be seen in Figure 2 on page 9.



Ref: Fresenius Medical Care 2006.

Figure 2. Peritoneal Dialysis

2.4 Transplantation

Kidney transplants are the most commonly performed transplant procedure. A kidney is removed from a human donor and then placed inside the recipient's body. It is connected up to the blood vessels as well as the bladder and takes over the function of the failing kidneys. Individuals with CKD who have a living donor available often elect to undergo transplantation before RRT is required. A donated kidney may come from an anonymous donor who has recently died or from a living person, usually a relative. The kidney that the recipient receives must be a good match for the body to prevent the immune system from rejecting the new organ. Appropriate drugs are used to suppress the immune system from rejecting the donor kidney. Transplantation is the ideal outcome for any patient who requires RRT or who diagnosed CKD.

2.5 Epidemiology of Renal Disease in Ireland

It is difficult to ascertain the prevalence and incidence of CKD and RRT in the Republic of Ireland as there is no national renal registry. Also there is no population based study on which to base estimates. In Northern Ireland data is obtained via a sophisticated patient data management system and this data is routinely submitted to the United Kingdom Renal Registry (UKRR). It is therefore relatively easy to make comparisons on data within the United Kingdom. There is no requirement currently to maintain a mandatory register

of patients with chronic kidney disease in Ireland. Although it is possible to identify patients who are currently on dialysis, or have had a renal transplant, it is almost impossible to track patients with less severe, but ultimately progressive, levels of the disease who fall into the category of Chronic Kidney Disease or End Stage Kidney Disease.

Due to unavailable integrated data from renal units around the country, there is a reliance on nationally obtained demographic data obtained by the Health Services Executive (HSE). This in combination with attendance and admission figures from renal units nationwide allow an estimate to be made of the number of persons who currently have CKD.

Preliminary results from the 2006 Census indicate that the population has increased to 4,234,925. Based on these figures, it is reasonable to assume that significant CKD afflicts 120,000 -140,000 Irish people (CSO, 2006). The prevalence of ESKD in Ireland for the years 2003-2005 shows there are almost 3000 patients currently alive with ESKD in Ireland. It is estimated that about half of these have a functioning renal transplant. This increasing prevalence of ESKD reflects the fact that more patients develop ESKD each year than die with the condition.

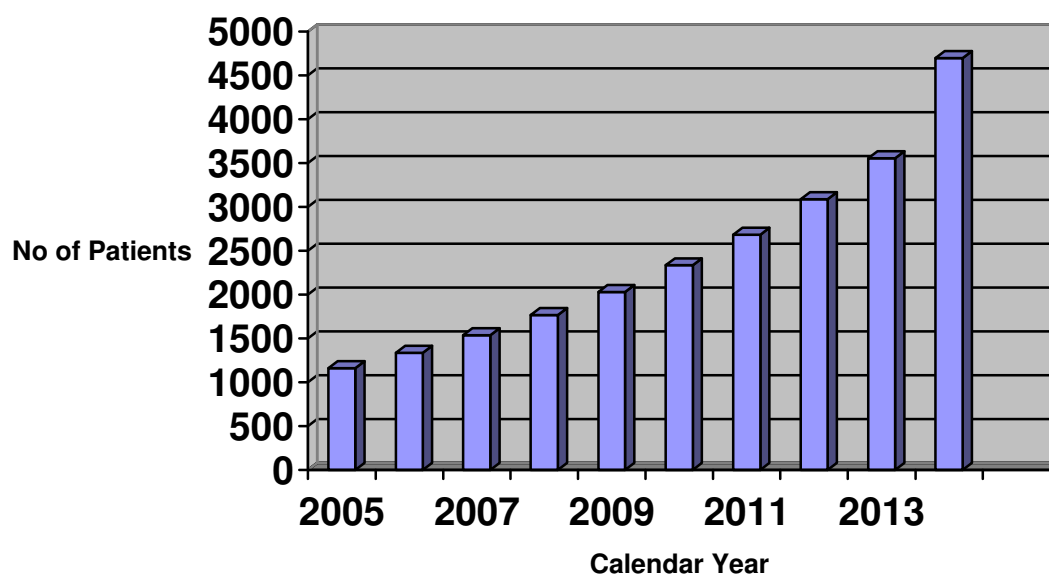
	<i>Haemodialysis</i>	<i>Peritoneal Dialysis</i>	<i>Total Dialysis</i>	<i>Transplant</i>	<i>Total</i>
2005	1146	197	1343	1505	2848
2004	978	213	1191	1379	2570
2003	826	187	1013	1391	2404

Ref: Health Services Executive Renal Survey 2003-2005

Figure 3. Number of ESKD patients in Ireland over last 3 years.

Without a national renal registry, it is difficult to assess the detailed rates needed to accurately model future needs (Davis, 1997). However estimations have been made by

the Irish Kidney Association (IKA) and other government report groups based on cross sectional audits of activity and units, thus also examining previous trends. As can be seen on Figure 4, below, there is significant growth predictions for ESKD patients who will be requiring haemodialysis. The main reason for the increase in the numbers of patients with kidney disease is the increase in the number of patients suffering from diabetes and hypertension. The incidence of these diseases also rises sharply with advancing age and given Ireland's increasing ageing population, this has obvious implications on the planning and delivery of future renal services in Ireland.



Ref: Health Service Executive 2006.

Figure 4. Predicted Growth of Haemodialysis Population in ROI 2005-2015.

3. Literature Review

3. Literature Review

3.1 Introduction

The literature review will concentrate on the current state of practices inside and outside of Ireland, with specific focus on the United States, United Kingdom and other large data repositories in relation to renal registration and renal databases, will be examined and discussed at length. Also, how these countries manage their national renal databases will be reviewed and for what purposes this data is utilised. The rationale for having a renal registry and also the barriers associated with administering a registry will also be discussed.

3.2 Data Collection in Ireland.

At present there are several registries in Ireland. For the propose of this dissertation the author will concentrate on two Irish registries, 'The Cystic Fibrosis Registry of Ireland (CFRI)' and 'Irish National Cancer Registry'. Both these registries are well established, and similar to Chronic Kidney Disease (CKD) as they are singular diseases that effect patients on a national basis.

The creation of Cystic Fibrosis (CF) Registries began in the US and Canada in the early 1980's. Europe followed suit in the 1990's with registries in the UK, Germany, Denmark, France, etc. To date, many studies about CF treatments have been carried out by analysis of information stored in these registries and some very important findings have been published. In Ireland the CFRI was established in the summer of 2001, with a rigorous set of aims and objectives in place (Foley, L. 2003). It was felt that it was necessary to create a useful and relevant registry system to enhance CF suffers outcomes. The CFRI identified three stages of knowledge management: 1) collecting facts and data; 2) relating those facts to produce information; and 3) 'mining' that information for reliable knowledge. Also the CRFI has certain strategic aims to ensure that the registry is utilised to its optimum. These are, to record genetic information of all CF sufferers in Ireland, to ensure that the data is accurate and collected affectively, to provide annual reports on its findings and to initiate research into the ontology and treatment of CF.

On a much a larger scale is the Irish National Cancer Registry (INCR). According to the World Health Organisation (WHO) in 2006 Cancer accounts for 13% of global deaths therefore it is no surprise that for a disease that accounts for such a high level of mortality, there was an obvious need to collect this data from an Irish perspective. The INCR was set up in 1991 and began registering cancers nationwide in January 1994. The information collected is used to research into the causes of cancer, in education and information programmes, and in the planning of a national cancer strategy to deliver the best cancer care to the whole population. The Registry is set up by statute, and wholly funded by the Department of Health and Children.

There has been under development of information systems throughout all aspects of the Irish health service from policy-making through to implementation (Brennan Report 2003). The report goes further by stating that clinicians need to have access to cost, performance and clinical outcome information in order to provide quality health care in an efficient and effective manner. The HSE has the largest ICT infrastructure of any other organisation in Ireland. In 2004 the publication "Embedding the e in Health" set out a strategic perspective for building an ICT framework for the Irish Health System. However, Takeda and Endoh 2002 state, that health care has gone from a relatively stable service industry to a dynamic one since a decade ago, and this based on the Japanese healthcare system, which is considered by many to be further evolved technologically than the Irish healthcare system.

While recognising the two existing registries discussed above, it can be observed, that the value of implementation of an Irish registry for a specific disease is invaluable for the care of the patients suffering from these specific disorders. However as pointed out by the Brennan Report there exists a deficit within the Information Communication Technology (ICT) and the expertise in the Irish healthcare system, substantial expenditure is required within this area in order to facilitate any successful implementation of a national renal registry. Specific organisational change would be necessary for the successful implementation of this registry.

3.3 Renal Data Collection in Ireland.

To date we do not have a renal registry in Ireland, nor do we participate in any international registry. There is a lack of accessible quality information on the epidemiology of renal disease and on renal services in Ireland. The current practice of renal data collection in Ireland is carried out by the Health Services Executive (HSE). This is carried out at the beginning of the calendar year and then at the mid-point of the year. All nephrology centres in Ireland are harvested for explicit data. The data is gathered via a questionnaire (see Appendix A.) it is then sent via an email to department heads and/or specialised data managers in each nephrology centre. Although all units gather data manually, information is not readily available on how renal services perform either in terms of patient outcome, patient satisfaction, inter-unit comparison or international norms.

The questionnaire consists of four main sections concentrating on Haemodialysis, Peritoneal Dialysis and Transplantation. Demographics and age profiling of the patients are gathered, however specific details such as name and address are not required. Virology (HIV, Hepatitis) status is sought. Also financial estimation of travel costs is submitted to the HSE.

The requirement of renal units in Ireland to undertake a regular audit of the service that is provided to deliver an efficient and appropriate response to any quality issues that arise, and to continuously improve the standard of care delivered to patients is absent. For the delivery of care to be of the highest standard, patients require a renal service that can offer good quality information and deliver evidence-based service planning with national and international comparisons.

Clinical data on all patients with CKD, requiring RRT will enable individual renal units to observe standards of care and performance against evidence-based guidelines, engage in clinical audit, integrate with and supply data to a National Renal Registry, and inform strategic planning of renal services. This can be achieved with a common ICT platform for patient management and data extraction, with automatic downloading of core data items to a Renal Registry. Such a system would facilitate rapid individual patient feedback with clinical information and also enable reports to be generated on a regular basis to ensure a dynamic and timely response to any quality issues that might arise in order to continuously improve the standard of care offered to patients. If this core data is collated nationally to a Renal Registry, it will facilitate the Registry to monitor the quality and

quantity of renal care in Ireland, estimate the burden of CKD on a population basis, stimulate research and provide an evidence base for service planning.

3.4 Renal Data Collection Outside of Ireland.

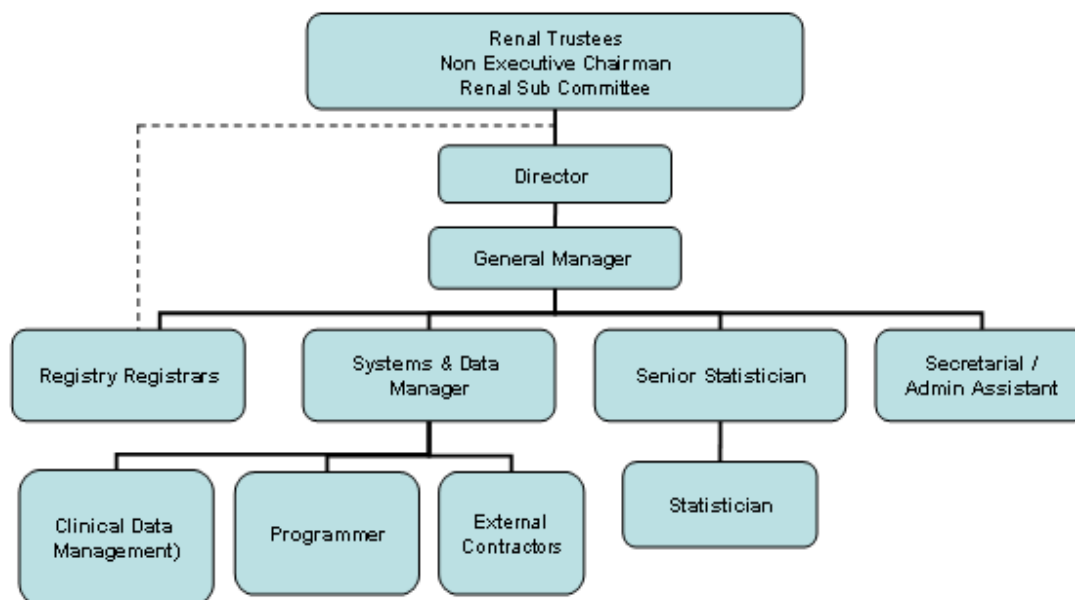
The development of registries can be traced back at least as far as 1086 to the preparation of England's 'Domesday Book' (Weddell 1973). At present there are over 40 existing renal registries/databases internationally (IFRR, 2002). They contain information in relation to renal data collection practices outside of Ireland with specific focus on the United States, United Kingdom and other large data deposits in relation to renal registration and renal databases. This literature review is vital in order to gain a good understanding of how large and well established registries collect and utilise their renal data.

The common thread in the formation of renal registries may be summarized "At the earliest meetings of nephrologists and registrars . . . clinicians perceived the value of pooling their patient data for research and arming themselves with demographic information for financial and political debates which were anticipated" (Wing & Brunner, 1989). The central role of clinicians rather than government in the management and content of the Registry was apparent in Europe, and countries such as United States, Australia, Canada and France. Undue reliance on government for funds brought undue interference, inappropriate data collection, some lack of co-operation and many other faults. Again Wing & Brunner make the point that, "Run by physicians for physicians, the European Dialysis and Transplant Association (EDTA) Registry always aimed to be of service to the clinical community and in those services lie the seeds of compliance. . . . data collected from willing collaborators for scientific study are always likely to be of superior quality to those surrendered for obligatory audits. Good auditing is a by-product of proper clinical documentation". This can be said of today's modern registries, were the majority of them are part or wholly funded by government sources, they still have mission statements stating that they are independent of outside interference and are subject to their own agenda and ethos and are beyond the sphere of external interference. As is stated but by CFRI, 'the Registry shall stand on its own, as a satellite to the hospitals, patients and associations from which it receives its information.' The initiation of the Registry was financed by grants from the Department of Health and Pharma industry. However other registries and continuing activity is self-funded by a charge annual to participating renal units of an annual fee per renal replacement therapy

(RRT) patient registered. In this way the Registry is able to remain an independent source of data providing analysis on national activity in renal disease.

3.5 United Kingdom Renal Registry.

"In the UK the incidence of End Stage Renal Disease has doubled over the last ten years and has now reached 101 patients per million population." UK Renal Registry Annual Report 2004. The UK Renal Registry was established by the Renal Association with support from the Department of Health, the British Association of Paediatric Nephrologists, and the British Transplant Society as a resource for the development of patient care in renal disease. The UK Renal Registry (UKRR) is part of the UK Renal Association and provides independent, professionally led, audit and analysis of renal replacement therapy (RRT) in the UK. The Registry provides a focus for the collection and analysis of standardised data relating to the incidence, clinical management and outcome of renal disease. It thus acts as a source of comparative data, for audit/benchmarking, planning, clinical governance and research. The UK Renal Registry monitors indicators of the quality as well as quantity of care, with the aim of improving the standard of care. There is currently a concentration on data concerning renal replacement therapy, including transplantation (Department of Health UK, 2004).



Ref: UK Renal Registry.

Figure 5. UK Renal Registry Staff Structure.

Individual renal units across the UK, comprising of England, Scotland, Wales and Northern Ireland, have been collecting population-based renal data for the last 40 years. However it was not until the mid 1990's that these specialised units amalgamated their data to form what is now known as the UK Renal Registry. Only in 1996 was the registry a functional organisation and producing its first annual report in 1998. To date there are over 200 renal centres in the UK which contribute data to the UK Renal Registry. The UK is increasingly well covered with participation now approaching 100%, although there are differences in data completeness and quality that are being worked on. Units not involved are mostly limited by ICT difficulties, although a lack of willingness is not attributed as a reason (The Renal Association, 2008).

There is no nationally agreed dataset for nephrology in the UK. The data obtained by different renal units is determined by certain factors, not all units offer the same services, not all units use standardise care pathways. The Clinical Practice Guidelines Committee prepares guidelines for the renal community in the UK. The guidelines provide a template for the management of patients with kidney disease in the UK and define the data collected by the Renal Registry. The current guidelines are the 4th edition and are being published in modular form, these consist of:

- Chronic Kidney Disease
- Complications
- Peritoneal/Haemodialysis
- Transplantation
- Acute Renal Failure

Each module comprises of a series of guideline statements with accompanying text to explain how these are derived. The supporting evidence is referenced and audit measures clearly defined. The current UK standards can be compared with those recently produced by other organisations across the world on the kidney disease as set out by Kidney Disease Improving Global Outcomes (KDIGO), an independently incorporated non-profit foundation governed by an international Board with the stated mission, "improve the care and outcomes of kidney disease patients worldwide by promoting coordination, collaboration, and integration of initiatives to develop and implement clinical practices guidelines." Eknoyan, et al. The National Health Service (NHS) has recently developed a National Renal Dataset. The requirement for an improved infrastructure to support the care of and service delivery to patients with renal disease has as one of its key components, the need to establish a National Renal Dataset as a core element of

secondary uses data to support the National Service Framework for Renal Services. The National Renal Dataset has been developed to build upon existing collections by the UK Renal Registry, UK Transplant and the British Association of Paediatric Nephrologists. This will enable the National Datasets Service to apply to the NHS Information Standards Board for the dataset to be approved as a Full Operational Standard, after which the collection will be mandated by the Department of Health. (Department of Health UK, 2008).

At present, there are 13 different computerised data management systems in use by UK renal centres, some of them commercially obtained from vendor companies and some in-house development, (UKRR, 2007). As new data are defined and the need for collection by the Registry accepted, there will be a continuing requirement that these companies provide the necessary enhancements to their systems to permit collection of these items and maintenance of an interface with the Registry for the new items.

As can be seen, data from the UK registry is of the utmost importance in the fight against renal disease. The UK Renal Registry is a resource for the development of patient care in renal disease, and other medical specialities within the UK enjoy this facility which makes renal medicine unique in its suitability for automated audit and setting standards of care.



Ref: United Kingdom Renal Registry.

Figure 6. UK National Renal Registries Map

3.6 United States Renal Registry.

The United States Renal Data System (USRDS) is a national data system that collects, analyzes, and distributes information about end-stage renal disease (ESRD) in the United States. USRDS presented its first report in 1989 and subsequently made innumerable contributions on a broad range of clinical, administrative and economic issues. Five central goals define the mission of the USRDS:

- To characterise the CKD population.
- To describe the prevalence and incidence of CKD along with trends in mortality and disease rates.
- To investigate relationships among patient demographics, treatment modalities, and morbidity.
- To identify new areas for special renal studies and support investigator-initiated research.
- To provide data sets and samples of national data to support research by the Special Studies Centres.

The USRDS database, designed to serve as a resource to the academic and clinical medicine communities, has been operational since 1988 (NIH Guide, 1992). Along with producing the Annual Data Report on Chronic Kidney Disease in the United States, the USRDS also produces the Researcher's Guide, fulfils data requests, provides standard analysis files and specialized datasets to researchers, and presents the results of its research at national conferences and in peer-reviewed journals.

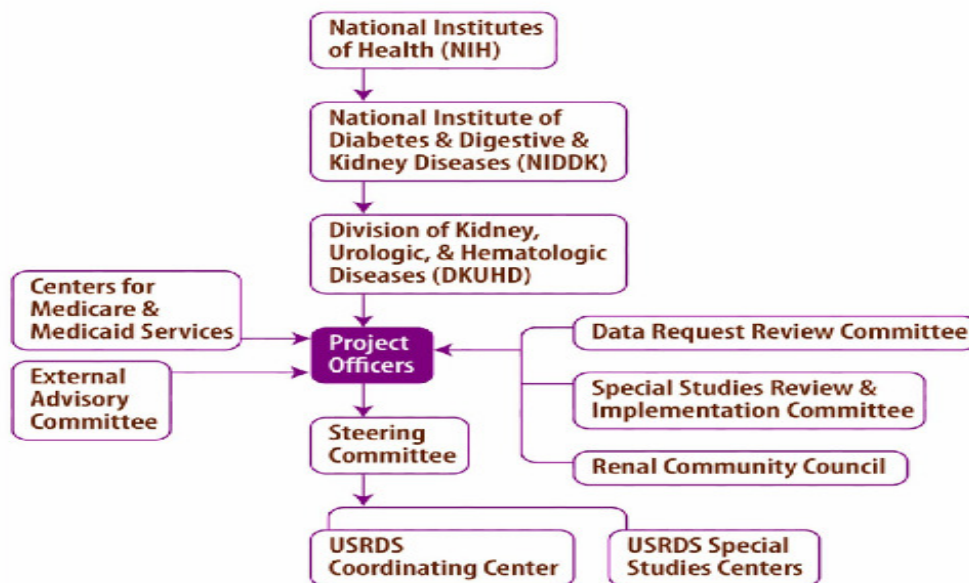
The establishment of the USRDS has greatly facilitated retrospective analyses of outcomes in CKD patients. The USRDS database contains patient-specific and centre-specific data on essentially all CKD patients treated in the United States, including demographic and medical information and CKD treatment history (Bethesda, 1998). The USRDS presents summary statistics of these data annually and makes data files available to researchers who wish to test specific hypotheses. One example of an analysis of the USRDS database is the comparison between outcomes in peritoneal dialysis and haemodialysis reported by Vonesh & Moran 1999.

In the case of the USRDS database, the data is collected in the same manner for all patients. One important source of these data is the regional CKD units and clinics. The renal centres then compile this data and forward it on to the USRDS. Some centres may

be more precise than others in collecting and reporting data. Unlike other data collecting registries, such as controlled clinical trials, there is very little, if any, validation of the data submitted to the USRDS database (Ward & Brier, 1999). Thus, in spite of uniform methods of data collection, the quality of the data in the USRDS database may be variable, but must be said of all national renal registries that do not have a correct validation process in place.

The USRDS website provides users with access to PDF files of the printed Annual Data Report (ADR), Excel files of the Reference Tables and the data underlying the graphs and state maps, and PowerPoint slides of USRDS presentations and ADR figures. The USRDS has a primary objective of making data available to the renal community. One of the important means of making data available is through timely response to data requests made by researchers, practitioners, and other members of the renal community. In many cases these requests can be answered by providing data published in the ADR.

The USRDS dataset is a living record of CKD care in the U.S., continually updated with new data on the CKD population. Delays in data reporting are unavoidable, and late information is added to the dataset as soon as it becomes available.



Ref: United States Renal Data System.

Figure 5. Administration Oversight of the USRDS

3.7 Other National Renal Registries

The European Renal Association (ERA) and European Dialysis and Transplant Association (EDTA) Registry is a European Registry collecting data on renal replacement therapy via the national and regional renal registries in Europe. It analyses the data and distributes the resulting information through registry reports presented at the yearly ERA-EDTA congresses, publications in nephrology journals and through the ERA-EDTA website. The EDTA was the first international Registry and to date is an amalgamation of 29 different territories registries to form a concise and in-depth bank of European data (ERA-EDTA Annual Report 2005). It developed a template adopted by several other Registries, and was generous in sharing experience with newcomers (Druukker, 1989).

The ERA-EDTA Registry differs significantly from the registries discussed previously in this dissertation. Rather than being the primary source to collect clinical data from a specific region it acts as a sorting-housing for renal data from different European regions. It also has different aims than a regional registry. In the setting of an increasing number of National Registries in Europe, the aim of the ERA-EDTA Registry is to complement and build on the analyses which the National Registries themselves can carry out. In particular comparison of disease patterns and their treatment in the various member regions, study treatment outcomes, carry out analyses where patient numbers in individual National Registries are small and build up a demographic picture of renal failure within the member countries. An example of data collected can be seen in Figure 8 below.

	Population (in thousands)	Renal Units (n)	Renal Units (p.m.p)
Greece	11061	129	11.7
Austria	8104	69	8.5
Sweden	8993	65	7.2
Catalonia	6726	43	6.4
Finland	5228	28	5.4
Netherlands	16281	55	3.4
Denmark	5401	15	2.8
Ireland	3917	11	2.8
Scotland	5078	11	2.2
England & Wales	53045	56	1.1

Ref: European Renal Association - European Dialysis Transplant Association 2005.

Figure 8. CKD and Ratio of Renal Units per million populations (pmp) in Europe.

For the ERA-EDTA to be relevant it must gather data by establishing links with National and/or large Regional Registries in the countries within or bordering Europe. By means of these links, transfer of data can take place to the Registry and transfer of the information arising from completed analyses can also be communicated back to the National Registries. The ERA-EDTA Registry will validate and then use for analysis, data it receives from the National/Regional Registries. This analysis will fall into two broad categories. Firstly, core data will be used to provide an epidemiological and demographic picture of renal replacement therapy (RRT) in Europe. Secondly, more focused studies using data from a segment of the catchment population will be carried out with the aim of answering specific questions.

The ERA- EDTA Registry will collaborate with Renal Replacement Therapy (RRT) registries based in other continents around the world. The objects of this collaboration will be to carry out joint analyses, and to participate in Registry sessions at international meetings. Thus, creating the International Federation of Renal Registries (IFRR).

Although the ERA-EDTA Registry collects data on RRT on an annual basis via the national and regional renal registries in Europe, it must be understood that with the comparison of data between registries there may be small differences between registries in definitions and in the collection of their data. For example, the different registries do not collect data at the same level of detail, especially with regard to the different subtypes of the treatment modalities. The dataset the ERA-EDTA obtains can be considered to be narrow and focused, however with a collection of data across the European continent of such geographical size and with such a diversity of languages and customs, it can only be agreed that the registry is a huge accomplishment and an asset to the individuals who care for the sufferers of CKD. This data includes the patient's date of birth, gender, cause of renal failure, date of first RRT, history of RRT with dates and changes of modality, treatment centre, date and cause of death and information concerning transfer from or to other renal registries.

The gathered data by the national/regional registries are imported into a MS-SQL-server database. The data is stored in a fixed format: all translations and uniformisation-steps

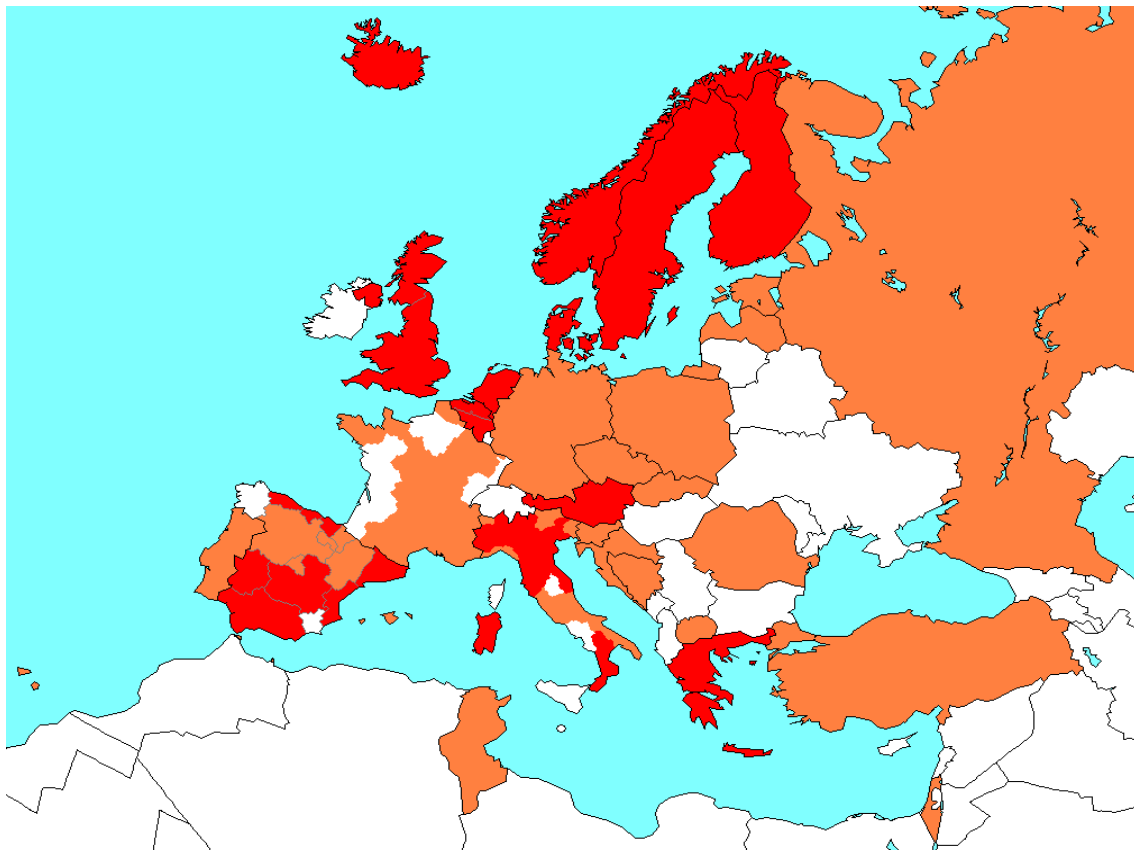
are performed during the import-steps. This guarantees a consistent view of the data for each country.

The data model that has been used is quite simple: basically, there are five entities:

- Patients: A table which contains data on individual patients.
- Transactions: Data regarding treatments and other events.
- Transfer In: Origins of patients transferred into the reporting registries
- Transfer Out: Origins of patients transferred out of the reporting registries
- Death: In this table the date and cause of death are recorded.

The registry-data is imported using a locally developed import-utility. This program first uniformes the data, then translates any non-standard codes. After the translations, the data is checked and finally imported into the database. The program performs extensive logging and the logging-results can be used for feedback to the registries highlighting inconsistencies, or other problems in the data.

ERA-EDTA Registries



Registries contributing individual data to the ERA-EDTA Registry



Registries contributing aggregated data to be included in the annual report



No contribution / No registry / Data not eligible for analysis

Ref: European Renal Association (ERA) and European Dialysis and Transplant Association (EDTA) Registry.

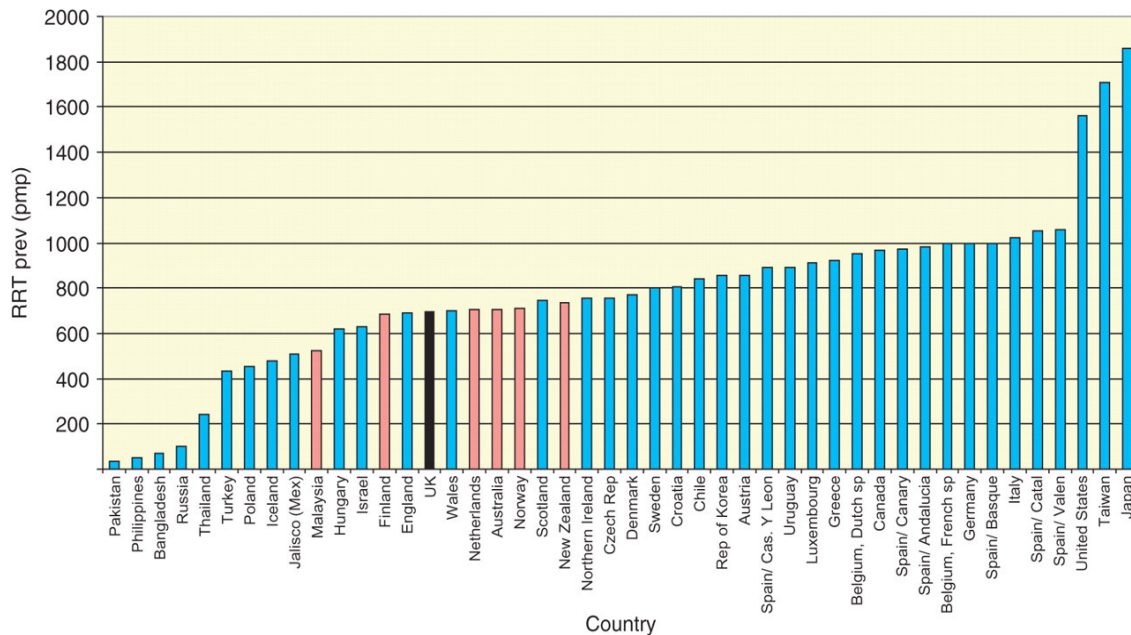
Figure. 9 The following national and regional registries contributed data as of June 2007.

3.8 Benefits of Registries

The benefits of renal registries are far reaching and sometimes understated, as is the case in the benefits attained from the data from registries for research purposes. Renal registries create a mechanism to gather data on the entire journey through renal disease, from first visit and medical history, through diagnosis and treatment and including follow-up work. Renal Registries provide a focus for the collection and analysis of standardised data relating to the incidence, clinical management and outcomes of renal diseases. These registries provide comparative data for auditing, planning, clinical governance and research. A unified registry utilises advantages of information technology and gives physicians better insight into disease and case details, simplifies data retrieval and further analysis (Kostic, 2008).

There are many renal registries globally which provide data on the acceptance rate of patients for renal replacement therapy (RRT), the total number of patients being treated, treatment modalities and, causes and rates of mortalities. The best possible medical treatment can only be achieved if complete medical data is collected and compared with data from other units/regions that also collect the same standardised data.

International renal registry comparisons provide an opportunity for benchmarking between countries, providing reassurance when data is consistent and driving further research when differences are seen. Such comparisons are important in generating hypotheses—defining the research questions for future epidemiological research (Casey et. al 2007). With the benefit of data comparison we are able to observe forming patterns of renal disease, plan for future demands on renal services and observe Renal Replacement Therapy (RRT). As can be seen in the diagram below (Figure. 10), the RRT prevalence rate of 694 per million people in the UK can be identified and compared with other regions. A Renal Registry is invaluable in providing data for statistical analysis and data comparison.



Ref: United Kingdom Renal Registry 2007.

Figure. 10 Incidence of Renal Replacement Therapy (RRT) in different countries

Renal Registries can provide data for studying the etiology and natural history of renal disease in populations. They have been identified as an important approach in providing simultaneous opportunity for research, evaluation and planning of health care services, and clinical audit across different centres (Black 1997). Renal registry data is particularly useful for public health and healthcare management. Its uses for such purposes have amply demonstrated that a renal registry serves a need for information that could not otherwise be met.

3.9 Barriers/Risks to Renal Registries.

Data in a medical registry must be of good quality, however in practice, frequently incorrect patients are registered or data items can be inaccurately recorded or not recorded at all (Goldhill and Sumner, 1998). For clinical registries to have value for health services researchers, care providers and policymakers, the collected data must be complete, accurate and representative of patients with the disease (Silver et al. 2006). Data quality is an important issue for renal registries. Unlike data collection for clinical trials, the number of patients per centre can be large, and data is generally not audited to ensure accuracy. This can also be confounded further by language and culture

differences between regions and territories. No two registries are alike and their evolution is dependent upon the ethical and political status of the registries country of origin.

Another common barrier is the lack of dedicated professionals to carry out complete data entry. The duty of data entry usually falls on nursing staff, increasing their workload even further. This commonly leads to incomplete data entry, especially in non-mandatory fields, making data interpretation more difficult (Ho, 2008). The level of accuracy of complete data in registries has not commonly been studied. In a comparison of local renal registry data with health records, Maitre et al. (2007) reported inaccurate registry entries concerning cause of death.

Multi-centred clinical databases remain underused, partly because of scepticism about their quality (Black 2004), also it was noted that more work is needed to help hospitals and clinicians for audit and research (Rowen & Black 2000). Developing a comprehensive clinical database relying solely on physician data entry will result in poor compliance, also database relying solely on data analysts may suffer in quality and will always be entirely retrospective (Fallis et al. 2007). This is mainly due to time constraints on behalf of the physician and inaccessibility to the data for the data analysts. It is advised that data should be submitted as soon as is realistically possible to ensure less errors and more accuracy. Figure 11 below represents potential barriers to setting up and running a successful renal registry.

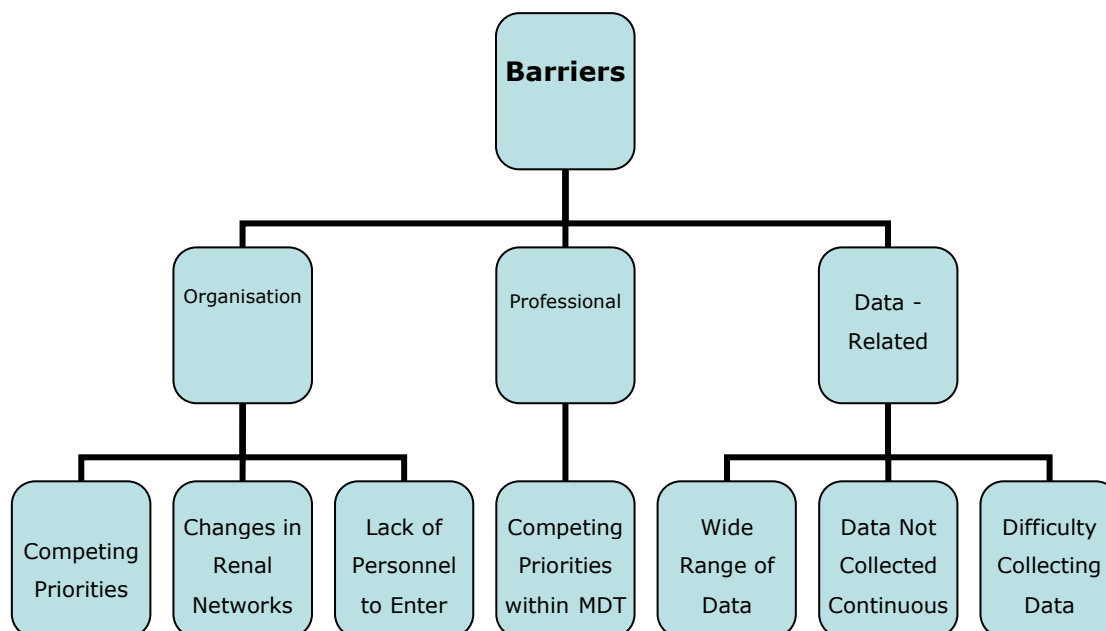


Figure 11. Potential Barriers to Implementation of a National Renal Registry.

A lack of standardisation of data amongst renal registries is also another barrier to completion of accurate data collection. Without such a standard it is not possible to determine the reliability of the registry (Capuzzo et al. 2005). It was also noted by the author that the findings of an audit, in 2003, of the French Renal Registry – Etablissement français des Greffes TS (EfG-TS), showed that the data collected was not referring to medical standards such as Health Level Seven (HL7) or International Classification of Disease 10 (ICD 10), but in fact terms used for kidney diseases inspired from those of the ERA-EDTA, although not as a standard (Jacquelinet et al. 2003). The audit also revealed that the lists of available medical terms were lacking of completeness. The qualitative analysis showed 25% of the terms proposed for initial diseases had at least one defect among the following: ambiguity, incompleteness, implicit and inconsistency. (As can be seen from Figure 3 above, the French Renal Registry – Etablissement français des Greffes TS (EfG-TS) contributes aggregated data to be included in the annual report of the ERA-EDTA).

Security is an area of concern, which arises when several public databases are indexed with the same common identifier i.e, Social Security Number to identify a patient on the registry. Some registries do create a link between national insurance, health care and social security but usually the data that can be viewed is restricted to name and address and only authorised personnel with appropriate security privileges have access to such information.

The gathering of data, whether for statistical analysis, workflow measurement tool or audit of care delivered, is essential to the proper management of each regions healthcare system. However there are strong arguments for this data to be anonymised. Statistics are intrinsically not about individuals, but about communities (Neame, 2004). He further goes on to say, that if the identity of the patient is included with the data from the registry for analysis, it is inevitable that the individuals identity will be revealed. Personalised data is clearly essential for the accuracy and validity of a registry and it can be considered that individual identities may be necessary for audit to be effective. Neame suggests that unless the registers are required by statute or some other legal instrument, individuals should be able to choose whether or not their identity should be added to the register.

Common problems associated with the development of a clinical database are cost, high error rate and poor compliance from clinicians (Salenius et al. 1992). Furthermore,

design approaches centred on the technology without recognising the dynamics of an institution may result in unwanted outcomes (Eason 2001).

Information costs are especially high for data captured by health professionals in the structured, coded representation often required by computerised record systems (Wyatt 2005). The most recently published Irish ICT Strategy discusses major under investment in IT in the health sector. Without adequate funding a registry would be at risk of poor data collection thus leading to a lack of confidence in the registry.

The barriers and risks identified have raised a number of issues but for each of them there is a trade-off between cost, effectiveness, efficiency, risk, national benefit and personal privacy. However it is undeniable that the benefits a national renal registry can bring to a healthcare system by far out way the risks associated with not having a renal registry in place.

3.10 Summary

A registry can provide a powerful argument for greater standardization of treatment and a best practice approach to management. The main objectives for establishing a renal registry appears to have a common ideology amongst all registries highlighted by the author, (i) to determine the relative incidence, aetiology and natural history of different types of renal disease; (ii) to assist in planning and implementation of preventive and therapeutic measures; (iii) to serve as a centralised information database for individual patients medical history.

Good quality health information is required to plan, monitor and evaluate health services. 'Quality and Fairness: A health System for You' (DOHC 2001), emphasises an urgent requirement to apply a strategic approach to the development of health information. Current deficiencies in Irish health information were recognised by the National Health Information Strategy (NHIS), 2004. NHIS recommends action to rectify present deficiencies and put in place frameworks to ensure optimal development and utilisation of the current health service reform programme.

Renal registry data is particularly useful for public health and healthcare management. Its uses for such purposes have amply demonstrated that renal registry does serve a need for information that could not otherwise be met.

In the last twenty years, computerised data collection systems have increasingly been used in the healthcare setting. There are now evidence-based guidelines on all aspects of renal care including the K-DOQI (Dialysis Outcome Quality Initiative), Guidelines and the Renal Association Guidelines (Levey, 2003). National renal registries such as the USRDS, the ERA-EDTA and the United Kingdom Registry have provided much useful information on trends in the management of Chronic Kidney Disease (CKD) and have facilitated clinical audit and quality improvement across renal centres.

The future role of Registries for renal failure treatment depends on the interest and influence of the clinicians (medical, nursing and others). To maintain Registries such as EDTA, UK Renal Registry and the United States Data System there must be involvement of active clinicians in the determination of the content of data collected, its distribution, and the interpretation of analyses. While the developing world of CKD treatment currently needs Registries for all the reasons that spawned EDTA, however those countries/regions with large dialysis populations may find that such centralized national basic descriptive data should be supplemented by selected group analyses of more detailed data. The role of a Registry should be regularly revised and tailored both to changes in practice and to the needs of clinicians, the community, government and not least the patients, (Disney APS, 1998).

4. Implementation of an Irish National Renal Registry

4. Implementation of an Irish National Renal Registry

4.1 Introduction

The National Renal Strategy Review (NRSR) was commissioned by the Department of Health and Children (DOHC), following the publication of the Health Strategy, 'Quality and Fairness – A Health System for You' in 2001. Following this, the then Minister for Health and Children, Mr Michael Martin, T.D, appointed Dr Liam Plant, Consultant Renal Physician, as chairperson of the National Renal Strategy Review. The NRSR has comprehensive representation from the major stakeholders of the renal services, including medical and nursing personnel, professions allied to medicine, health planners and administrators, the Irish Kidney Association (IKA), general practitioners and a patient representative. One of the key observations of NRSR was that future information system development is required to plan, monitor and evaluate renal health services. Current deficiencies in Irish health information were recognised by the National Health Information Strategy (NHIS, 2004). The NRSR proposed the development of a computerised renal health intelligence system for Ireland and this would consist of a Renal Registry.

As previously stated by the author, a national renal registry does not exist in Ireland to date, nor do we participate in any international registry. Data collection is gathered by the Health Services Executive (HSE) on a bi-annual basis. This data is obtained via an e-mailed/posted survey to each renal unit. The survey consists of demographic, modality types and age profile on all patients in each local renal unit. Although this information is invaluable to the planning and development of renal conservative treatment and renal replacement therapy within the Irish health system, the information is not readily available on how renal services perform either in terms of patient outcomes, patient satisfaction, renal unit comparison or benchmarked against international standards.

It has been identified that clinicians are conscious of and adhering to Best Practice and without adequate data collection their ability to deliver optimum care may be compromised without having the necessary data to gauge the success of their administered treatment. The submission of collated data to registries is now a fundamental part of practice and is common work practices in nephrology centres across Europe, Australia and United States.

4.2 Requirements of a National Renal Registry

An ideal data collection system would be easy to use, applicable to various types of studies, allow simple and efficient data entry with minimal errors and require inexpensive equipment (Shapiro et al. 2004). Renal services in Ireland would best benefit from a centralised common IT platform for patient management and data extraction, with automatic downloading of core data items to a renal registry. Patients need a renal service that provides good quality information to enable evidence based service planning with national and international comparisons. The registry needs to have the ability to collect, analyse, organise and present data that enables patient and nephrology long term management within Ireland. The system should become an essential resource in clinical, financial and research/audit practice. The Renal multi-disciplinary team (MDT) should view it as an integral part of the delivery of optimum care and utilise it as an excellent bank of data to support local and regional research. An Irish renal registry should allow quality and performances' benchmarking that enables an improvement in the provision of services for all, it should also provide a basis for instilling IT acceptance among the renal population.

4.3 A National Renal Registry Requirements:

- Monitor the quality and quantity of renal care in Ireland.
- Show patients that they should expect a level of quality and professionalism as standard.
- Determine the level of burden of chronic kidney disease on a national basis.
- Be able to generate its own consistent national figures from a reliable source, rather than relying upon sporadic and possibly inaccurate and erroneous data.
- Improve accountability in the provision of renal services and ensure equality in the delivery of care on a national basis.
- Integrate electronic data transfer techniques and information communication technologies (ICT) to reduce error.
- Develop an IT friendly environment within the renal population to ensure that accurate data collection is considered good clinical practice.
- Create a standard within all the renal units in Ireland for the collection of data.
- Stimulate research.

- The Registry should also identify patients not receiving appropriate clinical and laboratory screening for renal complications.
- Enhance and preserve confidence in Irish nephrology among patients, clinicians and society by providing accurate and up-to-date data.

Patient demographics, causes of chronic kidney disease, co morbidities, and nutritional and functional status all contribute to survival predictions for dialysis (renal) patients (Held et al. 1994). It is essential that an Irish standardised approach is taken when the requirements and implementation of a national renal registry are being decided upon, whilst also adhering to international experience and good clinical practice standards. The best possible medical treatment can only be achieved if complete data is collected and comparisons are made. In chronic kidney disease, this comparison should be continued over a long period of time. Only then is it possible to derive the positive and negative effects of the influences of medication, treatment, surgical interventions and other therapies. Also, the collection of accurate and timely information is an essential prerequisite for effective clinical audit, (McKee 1993). Traditionally, one of the main reasons for the failure to use routine data has been concern over its quality. McKee further states that data quality covers three measures: completeness, accuracy and precision. These are three paramount issues to be addressed when developing an Irish National Renal Registry.

4.4 Implementation Proposal

An Irish National Renal Registry must be easy to set up, low-cost, low maintenance and units must feel that they do not have to contribute large amounts of time to collate the required data. A foundation of data monitoring should be created from the onset as an integral part of any registry. Most existing national registries were developed from paper based systems whereby units completed paper forms which were then sent to the registry and entered. This created a large volume of work and also created more potential for error for both unit and registry. The proposed national renal registry would have to be based on a software solution that all units in Ireland could implement. Although, according to many software vendors, the use of information technology has the potential to save time in documentation and retrieval of patient information, (Marasovic et al. 1997).

However, creating a registry is a considerable undertaking and a complex process. Healthcare projects have failed in the past when the needs and views of users, the tasks they need to perform and their ranges of technical abilities have been ignored (McManus, 2000). It has been identified that technical and organisational skills are required for a registry to be successfully implemented. Eight requirements have been highlighted as crucial for the successful development of a registry (Solomon et al. 1991). These include; an implementation plan, quality control procedures, adequate documentation, case definitions and case finding procedures, determination of datasets, data collection and processing procedures, data access policy, and a framework for dissemination of registry data and findings.

The future success of a registry depends on the development of a business plan for its funding, management and operation. The business plan should be developed to include the following components:

- Executive Summary
- Business mission and objectives
- Database development
- Compliance and risk management
- Database market assessment
- Staffing and infrastructure
- Structure and governance
- Funding and financial projections

4.5 Renal Information System

The design of a responsive renal information system is a key requirement for a registry at the implementation stage. Purpose designed registry reporter software allow users to collect and review data in an iterative fashion in support of units' formal obligations to submit data to a national renal registry. When the user is satisfied with the quality and completeness of the data, the registry reporting software should create a file in the format specified by the registry for transmission. Of course, many hospitals have units

with distinct characteristics and needs. There are three potential software models which could be utilised for a national registry. A centralised model, a distributed model and a hybrid model:

- The Centralised Model is based around the concept of a single database and single system servicing the needs of the whole of all the users. The server/database would typically reside in a data centre and would be accessed by each individual nephrology department across the country. This model can lead to the total harmonisation of data. The integration of local solutions should not become an issue. Tracking of patients across units will be enhanced. The system management and control should be easier thus creating less expense and, most importantly, a single interface would be required by all units to complete a national renal registry. However this may take longer to get agreement on statement of requirement. It would require all hospitals to commit fully to be successful. Historically this system does not build upon or really recognise any work already done in each individual hospital. Centralises cost issues and puts onus for funding in single place which in turn may inhibit local investment initiatives. Will lead to restricted market environment. And, user access controls across multiple agencies against a single database are more technically complex implementation issues for considerations.
- The Distributed Model is based on the publication and endorsement of a set of standards, which would be adopted into each local implementation. Each local hospital would be responsible for its own choice of software and the adoption of the standards into that software. Each system would need to have its own individual interface to the renal registry in order to transmit data to it. There would need to be agreement with the funding authority that only projects which supported the renal register and the implementation of the standards would receive funding. The advantages of this system is that it could be easier to get local buy-in as it allows some autonomy in decision making and preference of choice. It does not involve the national body in local issues such as, prioritisation, funding, implementing, etc. However the disadvantages are depending on local implementation teams to fulfil national requirements. Unlike the centralised method this system does not support patient tracking across units. It can be difficult to get an overall implementation within a specified time frame. The fragmentation of budget allocation can lead to inequalities such as financial and IT inequalities. It creates a more complicated interface requirement to the renal

registry. And, there is always the danger of people modifying the 'standard' to meet some local requirement.

- The Hybrid Model takes elements of both of the above models in that it allows freedom of choice at hospital level but involves some additional functionality in the units to facilitate the exchange of patient data between hospitals and to facilitate patient tracking across hospitals. This would typically be seen as a compromise solution. The advantages of this may be easier to get local buy-in as it allows some autonomy in decision-making and preferences. It does not involve the national body in local issues such as, prioritisation, funding, implementation, etc. It supports a competitive market place and it also supports patient tracking across units. The disadvantages of this are that it is dependent on local implementation teams to fulfil national requirements. It can be difficult to get overall implementation programme within a specified timeframe. Like the distributed model, it can cause fragmentation of budget allocation and lead to inequalities. It could be considered a more complicated interface than the centralised and distributed models.

The centralised and distributed software models each have their strengths and weaknesses. Organisations that provide IT services locally have fewer performance issues, but are vulnerable to high support costs. Given that current development of renal information systems is minimal in most units and a renal registry does not exist in Ireland, then most units may well prefer a centralised method. This system would also be consistent with the ongoing development of an Electronic Health Record (EHR) and would facilitate the development of a smart card system to facilitate transfer of individual patient data between units.

At present renal information systems vary between units. For example, the renal unit at Beaumont Hospital utilises a different system than Cork or Galway. Some hospitals have procured 'off the rack' systems from renal specialists companies, whilst others have acquired tailor made systems. The three hospitals in the north west, Sligo General Hospital, Letterkenny General Hospital and Cavan General Hospital have installed a system on a joint cross border initiative with the North of Ireland. These developments have taken place at individual unit level and with little reference to developments in other units. The National Health Information Strategy recommends that the migration towards

a set of common systems for similar functions throughout the health service and the need for standardised information will force some standardisation of procedures.

A report by Deloitte and Touche states, 'Audit of the Irish Health System for Value for Money' (2001), major and sustained investment in information systems is required. Otherwise it will not be possible to provide the necessary scope and depth of information that is necessary to meet the complex requirements of the health sector.

4.6 Regulations and Governance

Registries can get units to provide data either voluntary or a regulatory authority can make it a mandatory process. A voluntary system will work well but only if all units provide data, otherwise the data becomes nationally incomplete, thus making the data incomparable and unusable. For example, the UK Registry is increasingly well covered with participation now approaching 100%, although there are differences in data completeness and quality. Units not involved are mostly limited by IT difficulties, not lack of willingness. It is a requirement of the National Service Framework (NSF) that all centres submit data to the Registry. All Registry data is obtained by electronic download from information systems in individual Trusts or renal centres. It was stated in the publication of the UK Renal Registry 10th Annual Report (2007) that there are only 3 renal centres in England who are still not in a position to send data to the Registry.

The proposed registry should be registered as a data controller under the 2003 Data Protection Act. The registry should regard the lawful and correct treatment of personal information as very important to successful operations, and to maintain confidence between those with whom it deals and itself. The registry should develop and implement procedures and controls to ensure that it treats personal information lawfully and correctly. To this end the registry will fully endorse and adhere to the Principles of Data Protection, as enumerated in the Data Protection Act 1988 and 2003.

Specifically, the Principles require that personal information:

- Shall be processed fairly and lawfully and, in particular, shall not be processed unless specific conditions are met.

- Shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
- Shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
- Shall be accurate and, where necessary, kept up to date.
- Shall not be kept for longer than is necessary for that purpose or those purposes.
- Shall be processed in accordance with the rights of data subjects under the Act.
- Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

However, controversy about cancer registries and patient privacy in the United Kingdom highlighted the need for more debate about the governance of medical registries (Illman, 2002). A long term proposal would be the requirement of regulations indicating the mandatory monitoring and publishing of quality and performance data by all units.

Good registry governance involves developing a structure that includes stakeholders in management of institutions that analyse personal medical information (Williamson et. al 2004). They go further to recommend that a registry should have a management independent of the institutions that provide healthcare, provides a research environment that maximises scientific benefit to patients and the wider community and receives adequate funding to ensure continuity of data collection and quality assurance.

4.7 Consent

In order to promote and to develop the recruitment of participants for a renal registry, which is essential to the success of such a registry, it is imperative that the highest ethical standards regarding consent is maintained and, at the same time, remain aware of the practicalities of obtaining informed consent from current patients, previous patients and deceased patients. Informed consent rests upon the principle of autonomy and the right to self determination (Kegley, 2004). However, Kegley also states that informed consent is already perceived to be an imperfect instrument of protection, even in regular medicine, and some have proposed abandoning the concept.

Government legislators and research ethics boards in some regions require all patients to give written informed consent before participation in clinical registries. However, the effect of such a requirement on the use of clinical registries and the extent to which a registry data can be generalised remain uncertain. In Ireland this would be a huge undertaking and must be considered fully before the commencement of obtaining written informed consent from all participants for an Irish National Renal Registry. It is estimated that there is 140,000 potential participants by the Central Statistics Office (CSO 2006), who would be requiring consent.

The UK Registry has been granted temporary exemption by the Secretary of State to hold patient identifiable data. This exemption allows the registration of identifiable patient information from renal units without first asking the consent of each individual patient, avoiding a breach of the common law on confidentiality. This exemption is temporary and is reviewed annually. However renal registries such as the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA) require a vigorous informed and written consent procedure for all participants of the registry. (Examples of information leaflet and consent can be noted in Appendix I).

An 'opt-out consent' should also be considered, where by a patient must explicitly state that they do not wish for have their personnel data stored in a registry. Prior to setting up of certain registries brochures and posters are circulated in clinics explaining the existence of the registry, its uses and the fact that patients have the ability to opt out of having their private health information used for data collection and research purposes. As is the case with the Australian National Cardiac Surgery Register (ANCSR) and which is also applied by the Australian Orthopaedic Association's 'Joint Register'.

With the development of large, electronic health record systems and technical developments that have facilitated data collection and record linkage have caused increasing concern among the public about the privacy of personal health information (Upshur, 2001). The creations of registries pose ethical and legal questions regarding the collection, analysis and ownership of data. However a study by Grey et al. (1991) showed 88% of patients not only agreed to their medical records being used for the purpose of medical research, but actually thought that this was the case without their consent been obtained. Determining the right balance between the need for both individual privacy in a

society and the benefits gained from a limited loss of privacy will pose a difficult challenge.

4.8 Prototype Database

A database is a compilation of information, often a group of variables with their definitions and values, that is stored electronically (Wolfe, 1995). More specifically a database is a persistent collection of related data supporting several different applications within an organisation. A database management system (DBMS) is the software used to organise and maintain the database. Specifically databases are dedicated to capture, organise, sort, and analyse patient data. The data it contains is stored in a logical and precise manner (Elmasri, 1999). For the purpose of this prototype a relational database is used.

Microsoft Access 2003 and Microsoft Visio 2003 are the software applications chosen to support this project. It is a conceptual prototype system only. Its scope is to provide a means of storing renal data in such a way as to facilitate the linking of data and also allowing the interrogation of this data.

A relational database is a database that conforms to the relational model, and refers to a database's data and schema. A relation is a table of rows and columns. In fact, the relational database was born in 1970 when E.F. Codd, a researcher at IBM, wrote a paper outlining the process. Microsoft Access is a relational database management system and is a key component to this prototype. Illustrated in Figure 12. is displaying a list of all data types of the prototype in using Access.

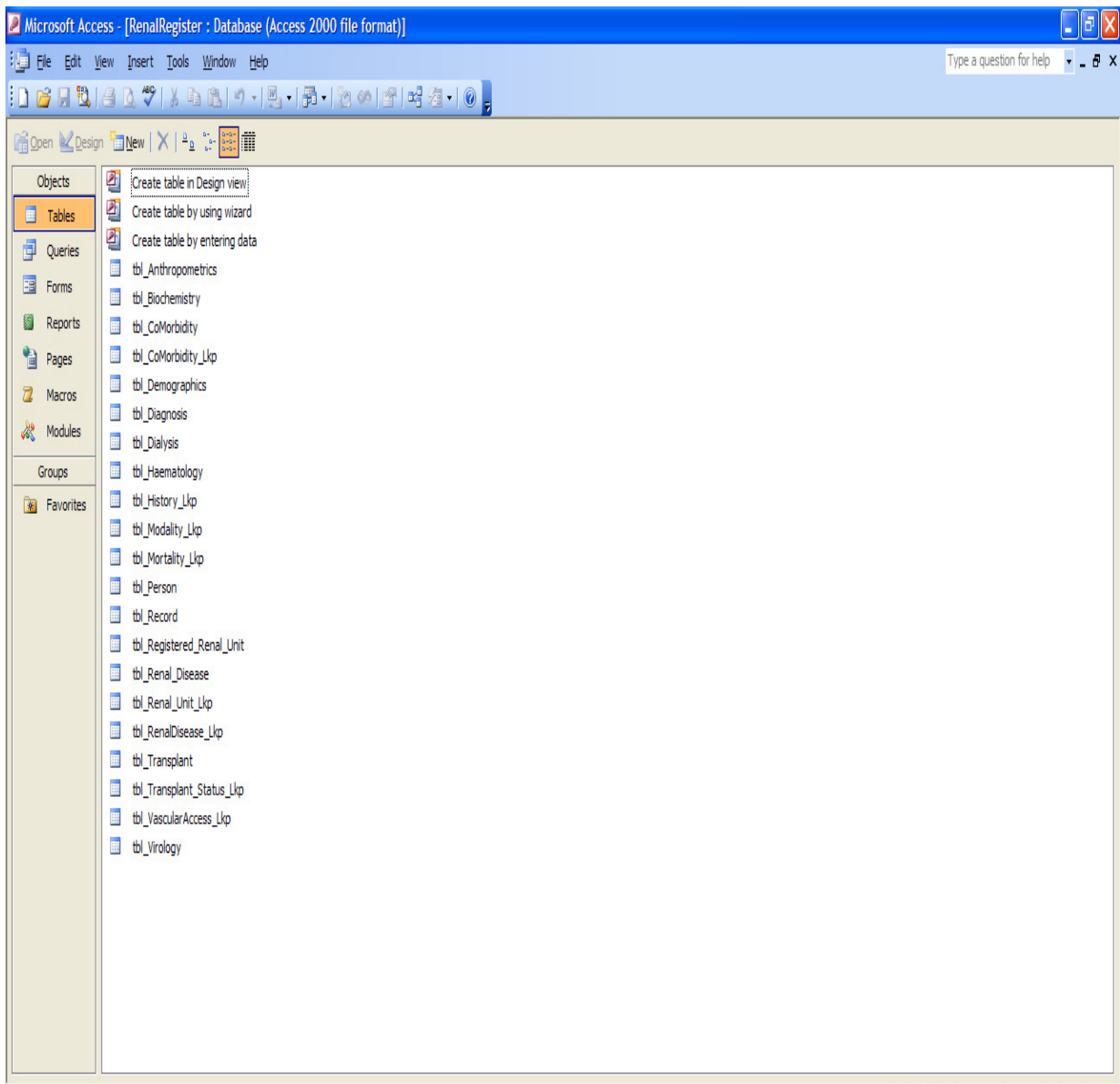


Figure 12. Prototype Database- List of Data Types

Relationships in Access allow queries, forms and reports to display information from several different tables at once. Relationships work by matching data in key fields. These fields are usually the primary key in one table and the equivalent foreign key in another. In most cases the relationship between two tables is one to many. To explain this further, for one record in the first table there are many related records in the second table but for any record in the second table there is exactly one matching record in the first table.

Figure 13 and 14 show relationships of the conceptual prototype database using an entity relation diagram in MS Access and MS Word respectively.

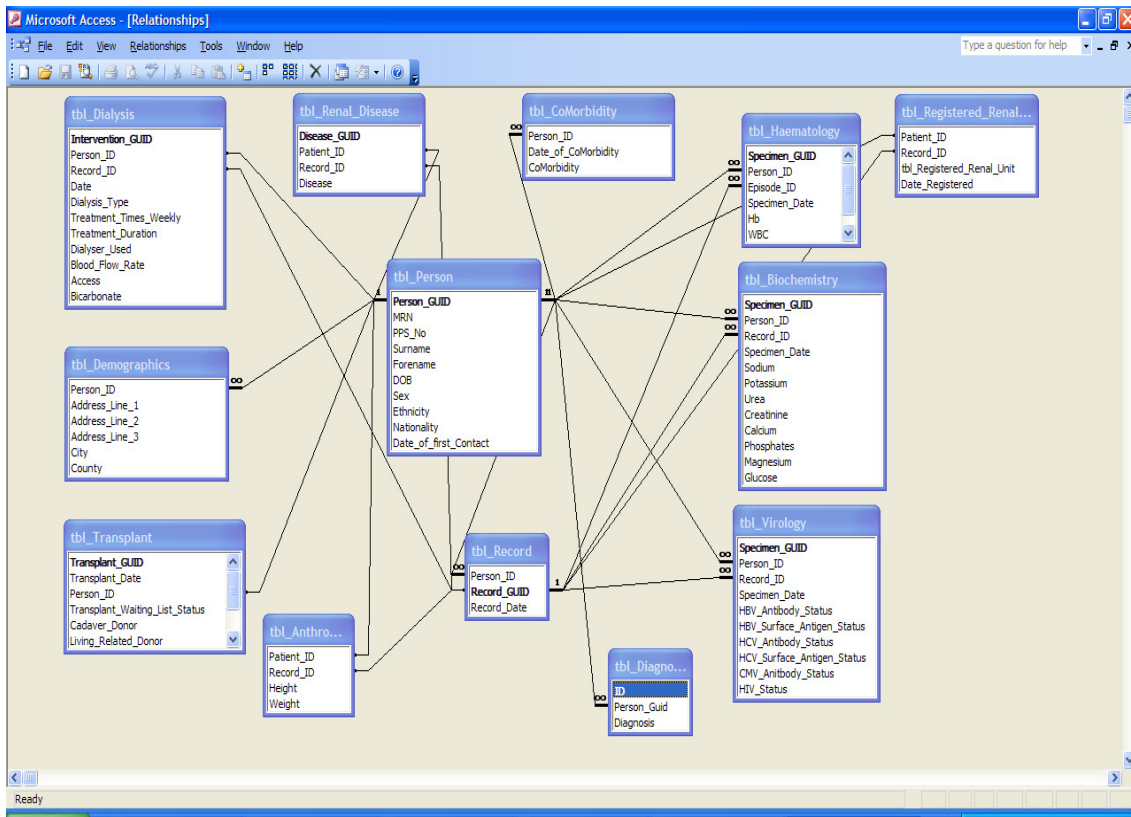


Figure 13. MS Access Prototype Database Entity Relation Diagram

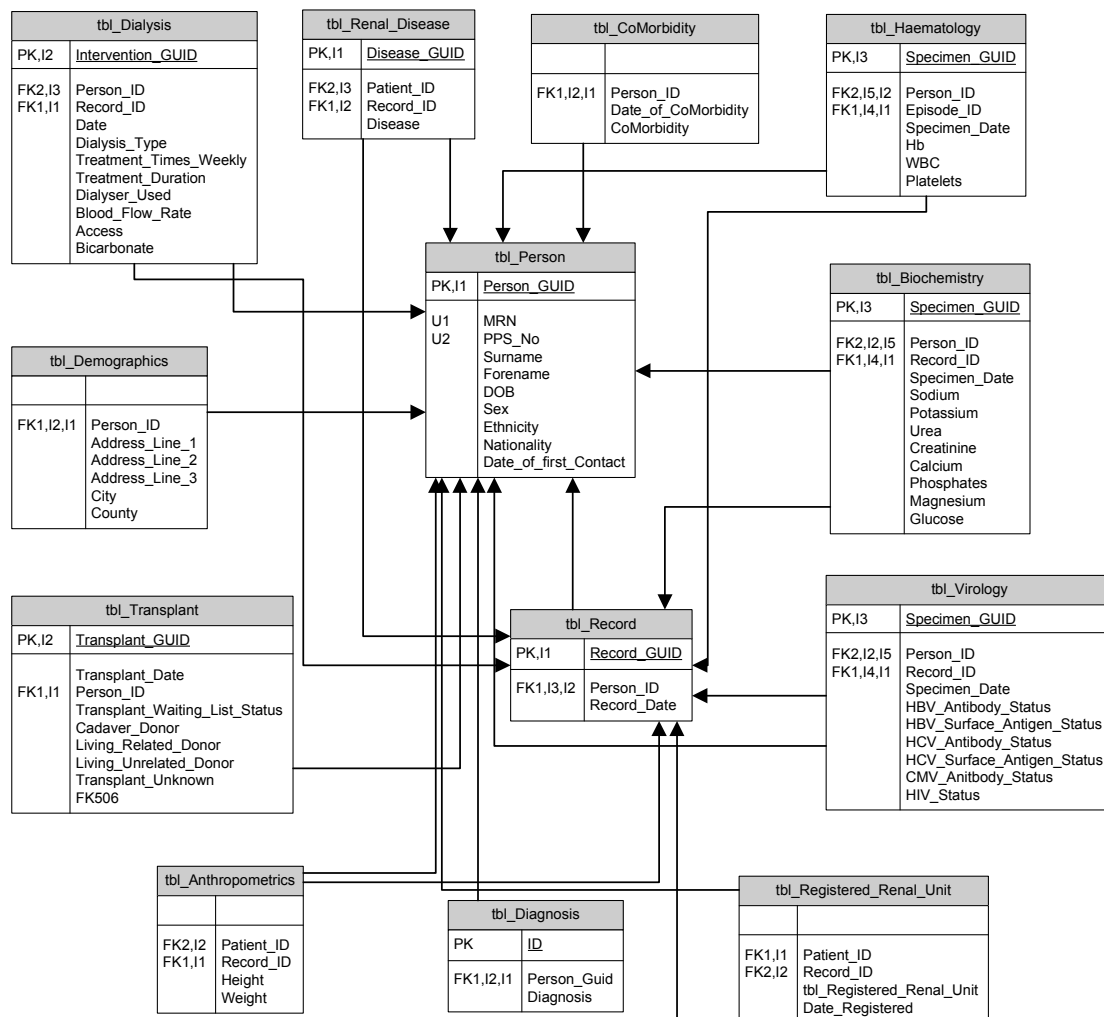
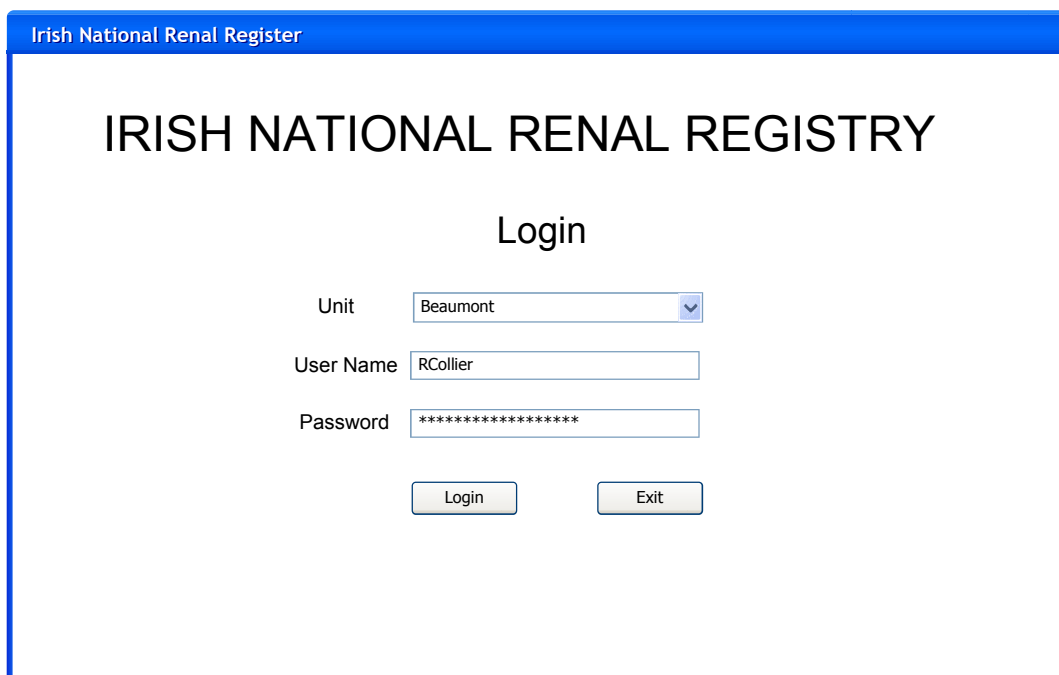


Figure 14. MS Word Prototype Database Entity Relation Diagram

The prototype database was designed to collate information about various aspects of the renal disease from hospitals that specialise in nephrology from all over the country. The emphasis during the database development has been on accessibility and user friendliness. For each reported treatment or data entry specific items are displayed on specially designed forms with a functional graphical user interface. The prototype database features an easy to use patient centred point-of-care interface enabling entry of multiple data. These include patient demographics data and modality, dialysis prescription and related data, primary renal disease data with associated co-morbidity, laboratory studies including – haematology, biochemistry, virology, and transplant information.

In addition to analysis and display of information from a specific patient, the prototype database has the capability to analyse and present data across a defined cohort of patients. Populations can be identified by multiple criteria including modality, consultant or renal unit. The database can be developed to have the function to generate a review of an identified dialysis unit enabling nephrologists to measure disease outcomes and the service on local level. Also, in order to facilitate national analysis, the prototype database has the ability to create aggregated anonymous data, which can then be centrally collated with data from individual renal units.

The database has a username and password access screen to ensure the highest level of security.



Irish National Renal Register

IRISH NATIONAL RENAL REGISTER

Login

Unit

User Name

Password

Figure 15 Prototype Database Security Access Screen

Once access to the registry has been authorised the user will have the given function to register a new patient or to search for a patient. This search will be governed by a hierarchical requirement of access privileges. Only certain individual's users can access information that is relevant to them. The search can be made using the patients name, MRN or search by unit. Figure 16 illustrates the search window.

Irish National Renal Register

IRISH NATIONAL RENAL REGISTRY

Main Menu

Find Patient

Register Patient

Exit

Figure 16. Prototype Database Register and Search Screen

Once the search has been conducted the user will then be prompted with a selection of search results. A list of patients names will appear and user must click on the appropriate one to access or update the patients data. This illustrated in Figure 17.

Irish National Renal Register

IRISH NATIONAL RENAL REGISTRY

Patient MRN PPS Unit

Last Name First Name DOB

PPS No	Patient MRN	First Name	Last Name	DOB	Sex	Date of Registration
12333300H	0987634	Nora	Says	29/07/67	F	01/03/2007
34678888L	1234455	Simon	Says	12/07/1967	M	14/05/2005
67823444H	54789900	Kieran	Says	19/05/1988	M	21/04/2008
144555567H	23466767	Siobhan	Says	21/03/1958	F	13/03/2003

Search Exit

Figure 17. Prototype Database Search Screen

Once the patient has been selected a window with five tabs will appear showing renal disease, dialysis, transplantation, medical history and pathology. When the dialysis tab is selected a screen will appear with the patients current haemodialysis prescription. Figure 18.

Irish National Renal Register

IRISH NATIONAL RENAL REGISTRY

Patient MRN Hospital DOB Age

First Name Address

Last Name

Renal Disease | **Dialysis** | Transplant | Medical History | Pathology

Dialysis Details

Dialysis Type

Dialyser Type

Dialysate Type

Vascular Access

☒ Bicarbonate

Treatment Schedule

Treatment Days

☒ Monday

☐ Tuesday

☒ Wednesday

☐ Thursday

☒ Friday

☐ Saturday

☐ Sunday

Treatment Times

☒ 1

☐ 1.5

☐ 2

☐ 2.5

☐ 3

☐ 3.5

☐ 4

Figure 18. Prototype Database Dialysis Screen

The user also has the ability to navigate through any of the tabs once they have the sufficient access. Figure 19 highlights the pathology screen displaying the haematology and biochemistry bloods.

Irish National Renal Register

IRISH NATIONAL RENAL REGISTRY

Patient MRN Hospital DOB Age

First Name Address

Last Name

Renal Disease | Dialysis | Transplant | Medical History | **Pathology**

Specimen ID	Specimen Date	Hb	WBC	Platelets	Urea	Creatinine	Na	K
123876009	01/01/2008	14.2	5.3	376	9.5	221	144	4.7
432224444	23/01/2008	13.1	5.8	365	8.6	257	139	4.9
789665555	29/02/2008	12.7	6.1	341	8.1	211	143	6.7
234444444	02/03/2008	11.5	5.0	350	7.9	260	135	4.5
234987652	07/03/2008	13.5	5.9	358	8.0	255	139	3.8
345678883	10/03/2008	13.9	6.2	345	10.0	236	140	6.2
234566666	21/03/2008	12.8	5.7	362	7.6	215	145	6.1
456333333	05/04/2008	13.0	5.2	359	7.8	281	137	5.0
234591882	12/05/2008	13.8	6.1	354	7.0	291	139	4.6
675443232	25/05/2008	13.1	5.3	372	8.0	267	142	4.8

Figure 19. Prototype Database Pathology Screen

4.9 Datasets for Proposed Registry

“What data should be recorded? The golden rule here is to keep it as simple as possible” (Brooke, 1974). Even though this was stated over thirty years ago, it can be seen that keeping the amount of data to a minimum, results in lower costs, increases compliance and reduces the amount of time it takes to get data into the registry. Although it is desirable to avoid collecting unnecessary data, it is equally important to try to ensure that all the essential datasets are collected from the inception of the registry.

A major remit of the proposal of an Irish National Renal Registry is the consideration of appropriate datasets for the registry. A dataset is a collection of data usually in tabular form and there is usually only one variable and this is often represented as a list.

The datasets can be broken down into six main groups:

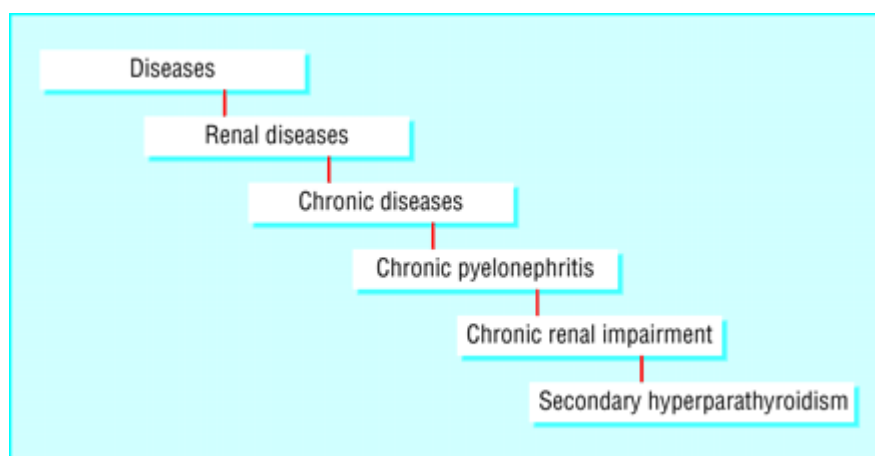
- General demographic data on renal patients
- Chronic Kidney Disease
- Peritoneal Dialysis

- Haemodialysis
- Other Renal Replacement Therapies
- Laboratory Results

The establishment of a fully comprehensive dataset must be co-ordinated by all stakeholders of a national renal registry. To date almost all Irish units have some form of a standalone database. This has arisen out of a need for data to be used on a local level. However with the creation of a registry, an overhaul of current datasets would be required to reflect standardisation and current practice, as well as the need to facilitate main system development in the future. Creation of an information group with a representative from each renal unit submitting data should be established to define an Irish Renal Dataset. This dataset should contain sufficient data fields to enable registry returns, facilitate the practice and management of the renal units and also allow audit of the key data.

4.10 Data Standardisation

A standard is a set of technical specifications that adhere to a particular technology, and standardisation is the process of developing, ratifying and implementing the standard (Gerst et al. 2005). Data standardisation is the key to comparing quality and performance. Standardisation and classification is represented in Figure 20. below.



Ref: ABC of Health Informatics 2005.

Figure 20. Partial Hierarchy of Disease Classification

Adoption of a current standard classification is recommended to be able to compare data quality among registries or within a registry at different points in time. Most standards developing organisations produce standards for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance transactions. There are two main health classification indicators that should be considered in which patients and their conditions can be grouped. Kidney Disease Outcomes Quality Initiative (KDOQI) Guidelines and International Classification of Diseases 10-AM (ICD-10) are the standards, which support renal clinical practice and the management, delivery, and evaluation of health services, are the most commonly used in the world.

- KDOQI provides evidence-based clinical practice guidelines developed by volunteer physicians and health care providers for all stages of chronic kidney disease and related complications, from diagnosis to monitoring and management. Guidelines have become an integral part of nephrology practice in many parts of the world. It is widely acknowledged that the KDOQI Guidelines have had an impact in improving quality of care and outcomes of patients treated by dialysis. The guideline, Chronic Kidney Disease: Evaluation, Classification and Stratification (2002), will serve as the foundation for future guidelines by standardizing the definition and classification of stages of chronic kidney disease, laboratory evaluation of kidney disease, association of the level of kidney function with complications, and stratification of risk for adverse outcomes of kidney disease.
- ICD is the International Classification of Diseases published annually by the World Health Organisation (WHO) for the classification of morbidity and mortality information for statistical purposes this assists health organisations world-wide, to speak the same language. It has become the international standard diagnostic classification for all general epidemiological and many health management purposes. ICD-10 was endorsed by the Forty-third World Health Assembly in May 1990 and came into use in WHO Member States as from 1994. ICD-10-AM is the Australian Modification of the tenth version of the International Classification of Disease. ICD-10 is currently the most comprehensive statistical classification of diseases and related health problems in the world.

(See Appendix G)

Health classification indicators are tools that can turn complicated data into relevant and easily understandable information. They create measurements that are indicative of the impacts of diseases on communities and regions. Also they reflect the result of efforts both of health service provision and intervention. Information collated helps policy makers and others identify trends and patterns of renal disease, provide evidence for decision making and support evaluation of progress towards addressing health issues. It can also be used to emphasize areas for possible intervention action. These classification indicators can be used to assist the regular surveillance and monitoring of the occurrence and development of diseases. They support strategies aimed at prevention and management of diseases and their risk factors.

4.11 Interfaces

An interface defines the communication boundary between two entities, such as a piece of software, a hardware device, or a user (Babylon, 2007). For it to be possible to interface with other databases, an on-line database requires an application that can communicate and translate data in a format that is compatible across many data storage formats. This is known as "middleware" technology. A novel middleware application known as the "distributed application middleware engine" (DAME) has been designed and specifically for used with health-care registries. This modular JAVA application can interface with virtually any other data system using both the specific standard health communication protocol Health Level 7 (HL7) and other general industry standard communication protocols including extensible mark-up Language (XML) (Nesrallah et al. 2004). It will then be possible that the Registry will eventually be able to link with other electronic databases such as the ERA-EDTA to submit data to the European registry.

HL7 is a non-profit organisation which has produced a family of standards for exchange, management and integration of data in the healthcare domain (Muller, 2005). HL7 enables hospitals and other healthcare provider organisations that typically have many different computer systems to interface with each other. HL7 specifies a number of flexible standards, guidelines, and methodologies by which various healthcare systems can understand. Such guidelines or data standards are a set of rules that allow information to be shared and processed in a uniform and consistent manner. These data

standards are meant to allow healthcare organisations to easily share clinical information. As would be a priority when submitting data to a registry.

4.12 Information Security

Although it is not difficult to send information between organisations, the Data Protection Acts 1988 and 2003 indicates that all individuals involved with data must be aware that they have a key responsibility in relation to the information they process. Security is a vital aspect of the use of healthcare information systems and with healthcare data appropriate security measures must be taken against "unauthorised access to, or alteration, disclosure or destruction of, the data and against their accidental loss or destruction." (Data Protection Commissioner, 2005). When determining measures, a number of factors need be taken into account including the nature of the data concerned and the harm that might result from unauthorised or unlawful processing. There is a greater duty of care relating to the processing of sensitive personal data. (Data Protection Commissioner, 2005). The ethics of confidentiality and the keeping and disclosure of electronic data are complex and frequently misunderstood. Invasion of privacy is a public concern in relation to the establishment of computer databases (Peterson, 2005).

Although the potential benefits of health information systems are widely accepted, the potential threats to confidentiality with its implications for patient privacy are more controversial (Carter, 2000). Various legal, physical and system security measures must be in place to protect the integrity of the registries database and to ensure the highest standards of confidentiality and privacy are maintained. Patient's data should be collected utilising a secure socket layer (SSL) technology, a protocol that transmits data over the Internet in an encrypted form so that it can not be accessed or modified by unintended parties. This high level security feature will ensure patient confidentiality. Also data sent through the network Transmission Control Protocol (TCP) and the Internet Protocol (IP) (TCP/IP) protocols should be encrypted using a private data key such as Advanced Encryption Standard (AES).

Confidentiality, integrity and availability, known as the CIA Triad, are the core principles of information security (Represented by Figure. 21 below). This principle is applicable across the whole subject of information security, from a user's access to a database to security of encrypted data across the internet. If confidentiality, integrity or availability can be breached it can have serious consequences for the systems concerned.

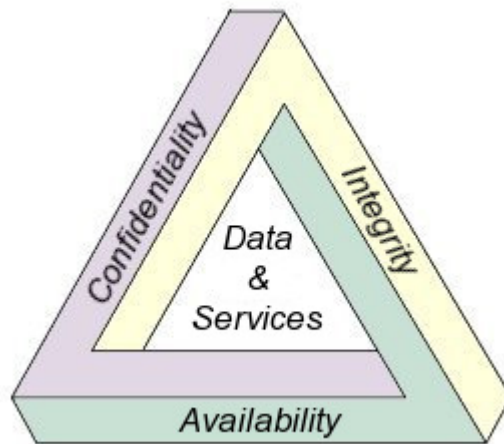


Figure 21. Confidentiality, Integrity and Availability Triad.

- Confidentiality is the ability to hide information from those people unauthorised to view it. It is perhaps the most obvious aspect of the CIA triad when it comes to security; but correspondingly, it is also the one which is attacked most often. Cryptography and Encryption methods are an example of an attempt to ensure confidentiality of data transferred from one computer to another.
- Integrity is the ability to ensure that data is an accurate and unchanged representation of the original secure information. One type of security attack is to intercept some important data and make changes to it before sending it on to the intended receiver.
- Availability it is important to ensure that the information concerned is readily accessible to the authorised viewer at all times. Some types of security attack attempt to deny access to the appropriate user, either for the sake of inconveniencing them, or because there is some secondary effect. For example, by

breaking the web site for a particular search engine, a rival may become more popular.

4.13 Electronic Health Record

The electronic health record (EHR) is increasingly being deployed within health care organisations to improve the safety and quality of care. Health professionals have been using information systems to improve the efficiency and effectiveness of their delivery of patients care via Hospital Information Systems (HIS), Patient Data Management Systems (PDMS) and Electronic Administration Systems (EAS).

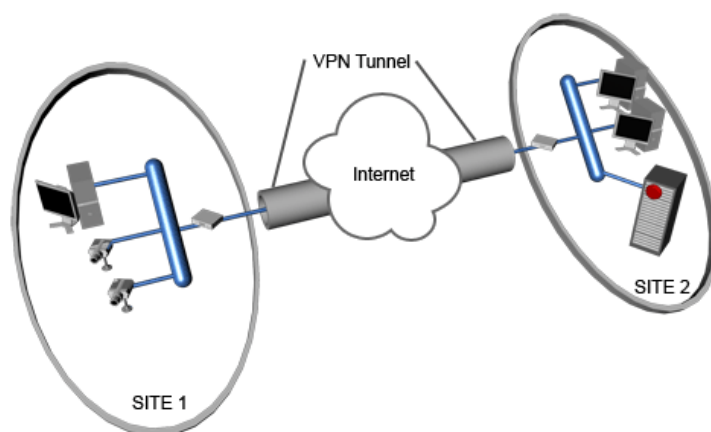
4.14 Connectivity and Transmission of Data

In order for the proposed registry to work efficiently and effectively, the Irish national renal dataset must be transmitted electronically on a routine basis to the national renal database.

Most registries collect paper returns and transfer data to their computer systems. This slows retrieval and analysis - for example, the renal registries in the United States, Australia, and Italy are at least two years behind in analysing and reporting on the collected data (Ansell et al. 1998). The UK Renal Registry is the only national or international renal registry that utilises full electronic data extraction and transmission. The registry collates sequential quarterly data on patients and also tracks patients as they move between treatments and centres. Data is collected by software links to existing clinical computer systems in renal units.

The most advanced renal health network in Ireland at present is used by the patient data management system of Cavan, Letterkenny and Sligo Hospitals. The data is stored on servers installed in Kells and is administered by an ICT Project Manager with the HSE who has overall ICT responsibility for the region. Users access the system via Citrix Metaframe Presentation Server across the government virtual private network (gVPN) (See Figure 22. below). The government VPN is a private network that uses a public network (in this the internet) to connect healthcare facilities and users together. Renal patient records for all

three hospitals are held and managed within a single database. The system is an integral part of patient care in the recording of information at each dialysis session. It collates data and provides accurate and timely results and reports allowing for comparison of data across sites. This VPN will provide the underlying technology to enable the real time and secure exchange of information and is a key requirement for supporting the functionality of a fast and secure communications infrastructure to support the implementation of a national renal registry.



Ref: Iveda Solutions, 2008.

Figure 22. Illustration of government Virtual Private Network (gVPN)

4.15 Financial Considerations

The foremost problem in the establishment and maintenance of a registry is cost (Goldberg, 1980). The most recently published Irish ICT Strategy discusses major under investment in IT in the health sector. Without adequate funding a registry would be at risk of poor data collection thus leading to a lack of confidence in the registry. It is hard to conceptualize the implementation of a national renal registry of such complexity, and involving such a level of commitment, being managed effectively with the current level of funding of information systems. As stated in the report by Deloitte and Touche, an Audit of the Irish Health System for Value for Money (2001), the legacy of under-investment in ICT is an inadequate infrastructure to support the complex information requirements of a modern health service. And this report concluded that significantly increased and

sustained investment in human resources and in the overall health information infrastructure is urgently required.

There would appear to be a great discrepancy in the amount of funding allocated to each hospital for renal IT systems. Certainly to date, research funding has been used for the development of IT systems in hospitals. However there is indeed a different amount of spending on IT from hospital to hospital, and from health authority to health authority. Hospitals within the same health authorities have different levels of spending in the area of IT.

Information costs are especially high for data captured by health professionals in the structured, coded representation often required by computerised record systems as previously stated by Wyatt. However, the potential benefits of the proposed registry should be evaluated in light of what the registry will cost to develop and maintain. Although registry data is expensive to collect, when registries are organized well the data can provide an excellent resource for the community (Cameron et al. 2004). Initially the Registry should be part financed by grants from outside bodies and funding from the Department of Health and Children. However, its overall aim is to eventually be able to self-fund, this can be brought about by a charge to participating renal units of an annual fee per RRT patient registered. In this way the Registry will be able to remain an independent source of data providing analysis on national activity in renal disease. Other registries such as the German Renal Registry (Quasi – Niere) have secured agreement between ESKD therapy providers, insurance companies and their government authorities to fund and support the registry office and its electronic data base.

5. Renal Unit Questionnaire

5. Renal Unit Questionnaire

5.1 Introduction

A structured questionnaire involving clinical staff of the renal unit in Beaumont Hospitals was carried out, in order to accurately determine the current state of IT usage and registry awareness in the acute renal setting. This questionnaire required the participation of doctors and nurses who specialise in the area of haemodialysis, peritoneal dialysis and transplantation. The questionnaire has being designed to identify the qualification of the participant, assess their skills and level of usage of IT and finally to get an understanding of their knowledge and utilization of renal registries. The questionnaire is also designed to support the literature review and to highlight any skills deficit present amongst the renal health professionals, which in turn will identify possible difficulties of implementing a national renal registry in the future. Part of the questionnaire is to identify the qualification of participants completing the questionnaire, the rationale to this is to compare if certain health professional have utilised IT or have being exposed to a renal registry in a different territory, and then to compare these findings with other health professionals who have not had exposure to a national renal registry.

5.2 Overview

In the context of the study, emphasis was placed on gaining an understanding of how familiar the respondents were in relation to their exposure to IT in their place of work. The purpose of the study was to investigate IT utilisation and current knowledge of a renal registry amongst specialist nephrology staff from the largest nephrology unit in Ireland.

Specific objectives included:

- To determine which professional body and what the grade of the participant was included in the survey.
- To gain a historical view of computer usage.
- To gain a current view of computer usage.
- To ascertain the level of appreciation of overall computer usage.
- To identify the accessibility of computers within the work area.
- To observe the interactions with a renal registry.

A cross-sectional, non-experimental, self-completion survey design tool was used. A cross-sectional study is extremely simple in design, where the researcher decides what they want to find out, identifies the study population, selects a sample and contacts the respondents to find out the required information (Kumar, 2005). A questionnaire was designed to capture this information as it was deemed the most appropriate tool to obtain the necessary information from the participants concerned. This chapter outlines the steps that were followed to design and administer the questionnaire in addition to the subsequent analysis of the data. Questionnaires offer an objective means of collecting information about people's knowledge, beliefs, attitudes, and behaviour (Oppenheim, 1992).

5.3 Questionnaire Planning

The questionnaire was carried out in the country's largest provider of nephrology care. The target population of the study generally represents all specialists in nephrology comprising of Registrars in Nephrology, Senior House Officers, Medical Interns, Clinical Nurse Managers, Clinical Nurse Specialists, Patient Care Coordinators, Nurse Counsellors, Clinical Practice Support Nurses and Staff Nurses. This was to ensure that the results of the questionnaire represented the different a broad range of specialities.

5.4 Questionnaire Design

Keeping in mind study design recommendations from Boynton (2004), questions must be phrased appropriately for the target audience and information required, also good explanations and design will improve response rates. The questionnaire contained 10 questions (see Appendix C). All ten questions invited the respondent to tick the most relevant answer that was most appropriate to the participant. However question 7 (b) required a free text answer if the question was answered in the positive context. The questionnaire was completely anonymous.

The most common approach to collecting information is to send the questionnaire to prospective respondents by mail. Each questionnaire was sent to the potential individual

respondent utilising the internal mailing system of the hospital and individually addressing each questionnaire which was accompanied with an information section.

The study was also accompanied by a poster campaign to highlight the study (see Appendix D). This was to give further information about the study; posters were placed in all clinical and staff areas in the Department of Nephrology. Furthermore the study was also submitted to the homepage of the units own specialised intranet website to ensure that the questionnaire was fully publicised to all staff members.

5.5 Ethical Approval

It was deemed necessary to obtain ethical approval when undertaking the questionnaire within the hospital. Voluntary completion of the questionnaire by renal professionals was indicative of their consent to partake, and therefore written consent was not required. Ethical approval was sought by the hospital to undertake the staff study. A letter and submission documents was completed and written to the chairperson of the ethics committee (see Appendix B), outlining the reason for the study, and requesting permission to undertake the study in the Department of Nephrology over the stated four week period. A copy of the proposed questionnaire and the authors' curriculum vitae was also included. The ethics committee gave ethical approval (see Appendix E).

5.6 Pilot Study

A pilot questionnaire was conducted with support of nursing colleagues and certain IT staff members, this provided useful information about the robustness of the questionnaire tool. The aim was to detect any flaws in the questioning and correct these prior to the main survey. By piloting the questionnaire with clinical and technical staff also aided in refining the questionnaire to be pitched at the appropriate level. However in general, the questionnaire itself was deemed to be suitable, and consequently both the format and the range of questions were carried forward into the main survey.

5.7 Data Collection

The questionnaire was individually addressed to each staff member via the internal postal system of the hospital. This ensured that all members of staff received a questionnaire. A total of one hundred and thirty four staff members were included in the study population. A cover letter was attached to the front of the questionnaire (outlined in Appendix C), to explain fully the objectives of the dissertation and the purpose of the questionnaire. Respondents were asked to return the completed questionnaire via a 'ballot' box strategically placed in the clinical environment. The study ran for duration of four weeks and the end date adhered to.

A Microsoft Excel spreadsheet was developed to collate and analyse the information extracted from the questionnaire. This spreadsheet also gave the ability to generate graphs and further detailed analysis. The primary reason to use Excel for statistical data analysis is because it is widely available and the author has had previous experience with this application.

6. Questionnaire Results and Discussion

6. Questionnaire Results and Discussion

6.1 Introduction

This chapter describes in detail the results of the study. Analysis of data was done in accordance with the objectives of the study. The reply to each question will be analysed and the findings represented in graph format. One hundred and thirty four questionnaires were circulated. A total of eighty eight questionnaires were returned within the set time frame laid down. This indicated that an overall response rate of 66% was achieved.

6.2 Response Rate per Profession

Participants were requested to indicate to which professional group they were associated. Of the total of 134 questionnaire circulated there was a return rate of 66%. Breaking down each profession by return rate equates to 50% of doctors replied to the questionnaire, 96.4% of Clinical Nurse Managers (CNM) completed and returned the questionnaire and 58.6% of Staff Nurses returned the questionnaire

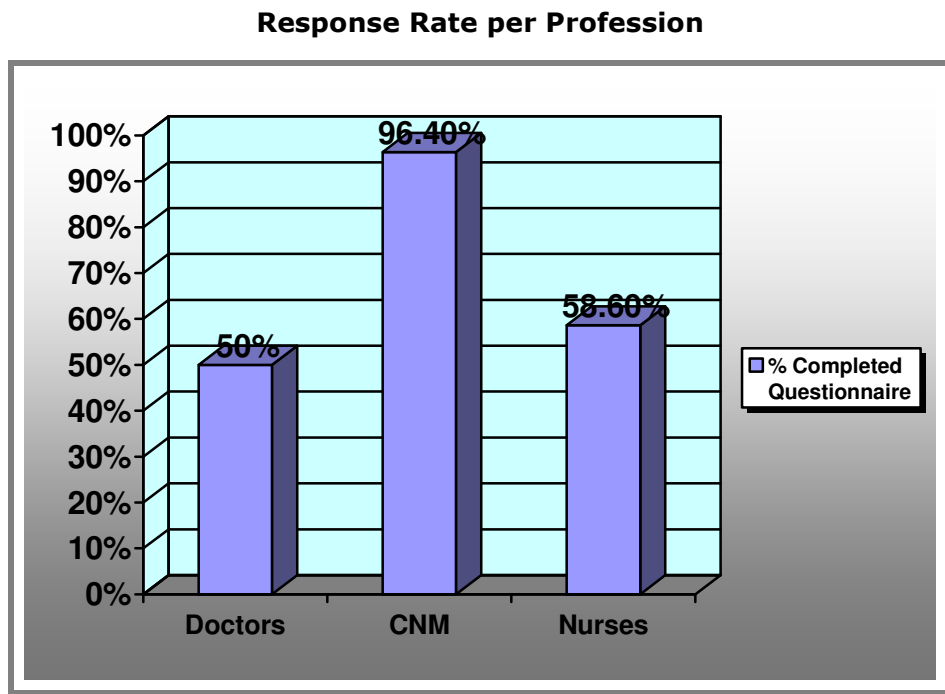


Figure 23. Response Rate per Profession.

6.3 Information Technology Utilisation

In order to gain an understanding of computer utilisation, respondents were asked how long have they been using a computer? The responses were limited to, less than a year, one to two years, two to five years, five to ten years and more than ten years.

The returned questionnaire had a breakdown of 1% of participants had less than one year IT experience, 3% had one to two years experience, 14% had two to five years experience, 34% had five to ten years experience and finally 48% had more than ten years experience with using computers.

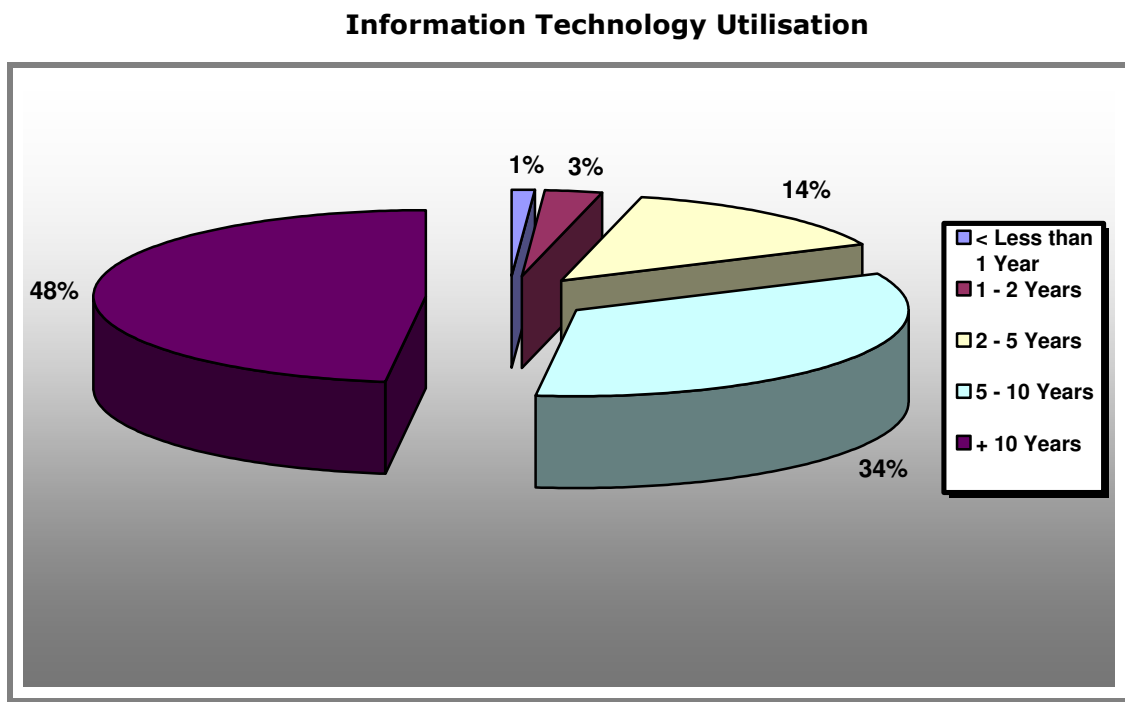


Figure 24 Information Technology Utilisation.

6.4 Computer Usage Within the Work Environment

The respondents were asked to indicate the number of hours of computer usage within the confines of work? The answers were limited to four possible answers, less than an hour, one to two hours, two to five hour and five or more hours.

The results of the surveyed showed, 7% of respondents indicated that their computer usage is less than one hour per week, 27% stated that they used computers one to two hours per week, 41% indicated that their usage is two to five hours per week and 25% confirmed that they use computers more than five hours per week.

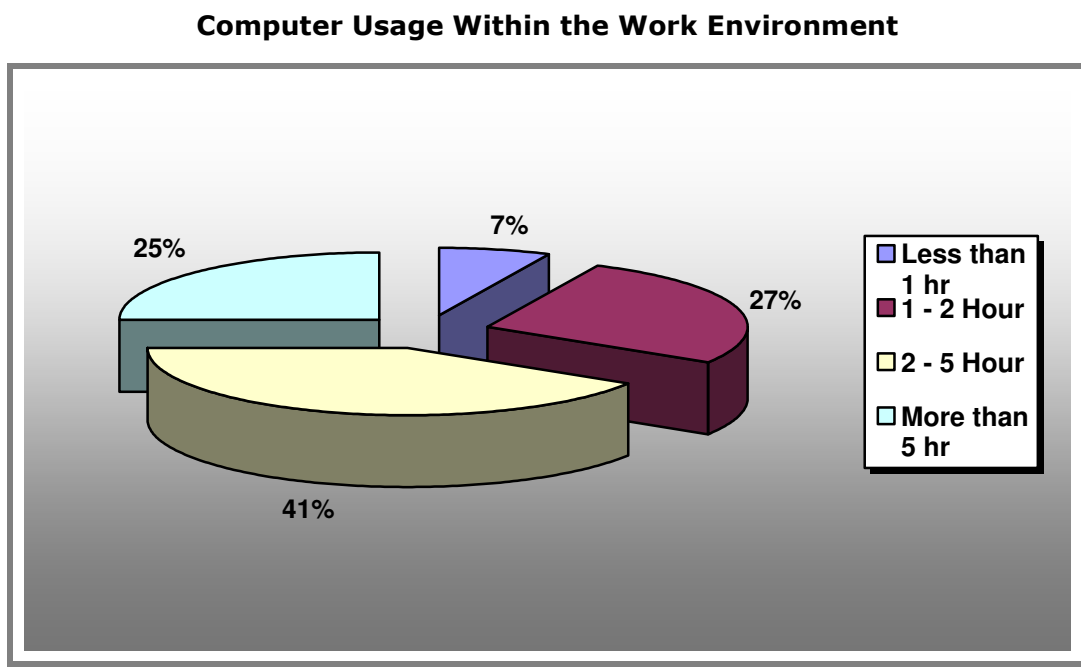


Figure 25 Computer Usage Within the Work Environment

6.5 Overall Computer Use Status

To reveal how respondents would like to interact with IT in their place of work, they were asked if they would like to use computers in their place of work more often, less often and not at all.

All 88 respondents replied to whether they would like to use computers more often less often and not at all. The following responded; 64% indicated that they wished to use computers more often in their place of work and 36% indicated that they would like to use less often in work. However, when the statistics were analysed even further it showed that 70% of Staff Nurses stated they would like to use computers more in the work place, whilst 52% of Nurse Managers indicated they would like to use computers less, and 71% of doctors expressed a desire to use computers more often in the work place.

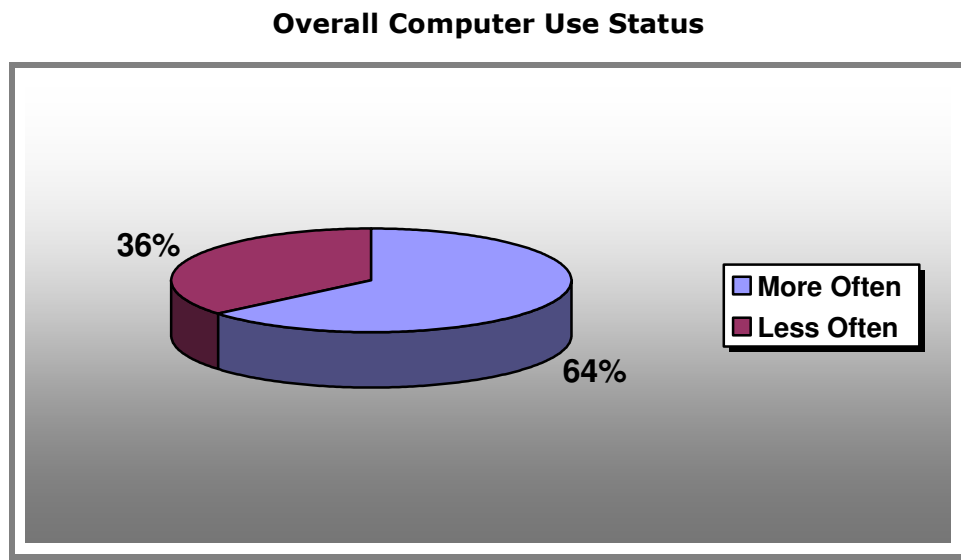


Figure 26 Overall Computer Use Status

Breakdown By Profession – Computer Use More Often

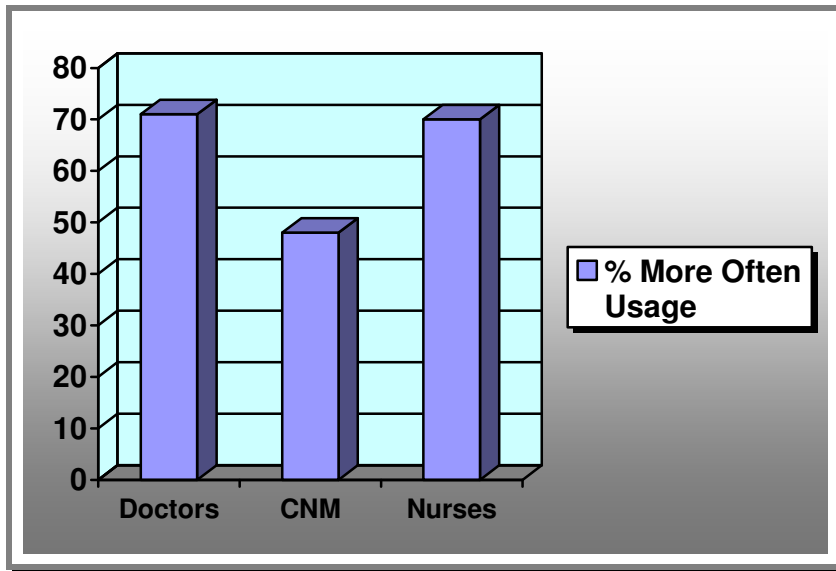


Figure 27 Breakdown By Profession – Computer Use More Often

Breakdown By Profession – Computer Use Less Often

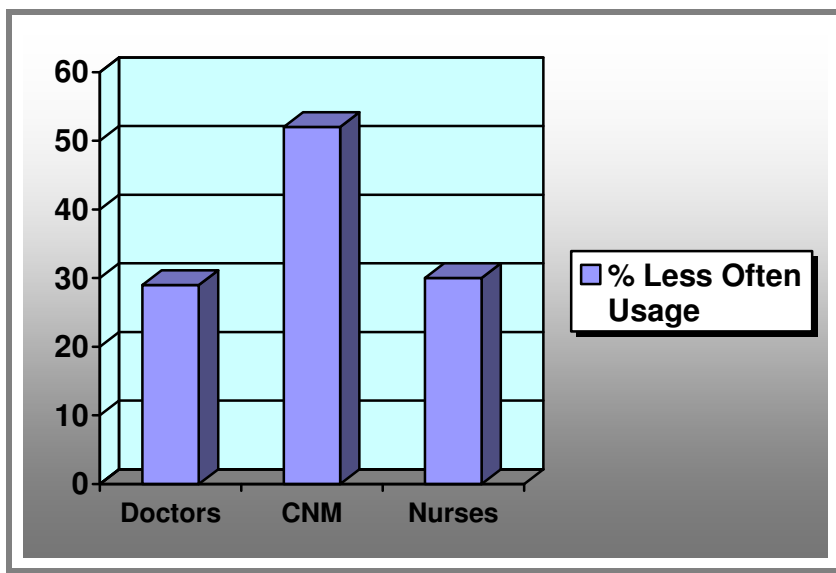


Figure 28 Breakdown By Profession – Computer Use Less Often

6.6 Overall Internet Usage

Participants were questioned on their overall internet usage. As can be seen in the Figure 29 below; 49 of all respondents indicated that they used the internet once a day, this equates to 56% of all respondents. Whilst 31 responded to usage of at least once a week, this is represented by 35% of all respondents.

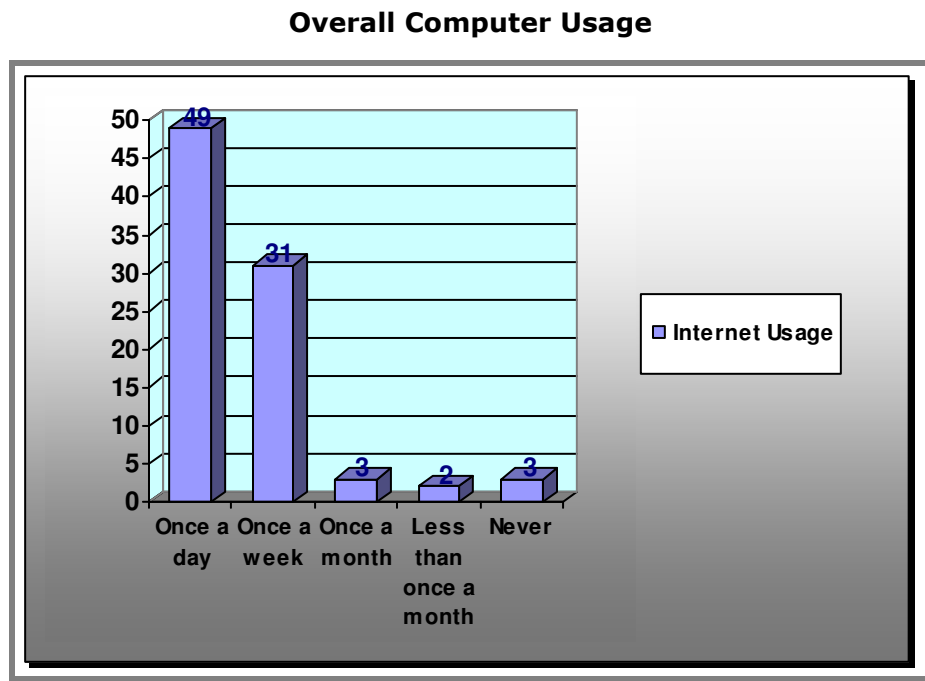


Figure 29 Overall Internet Usage.

6.7 Accessibility of Computers in the Work Area

The location dependency of information technology regionalises its users' time into specific areas where information technology is accessible (Shen, 2006). To determine how accessible a computer is in their work area, respondents were asked. The results showed 35% of respondents indicated that the accessibility of computers in their area of work was very good, 48% stated that accessibility was good, whilst 17% felt that

accessibility to computers was poor in their place of work. It is worthy to note that no respondents indicated that their accessibility is very poor.

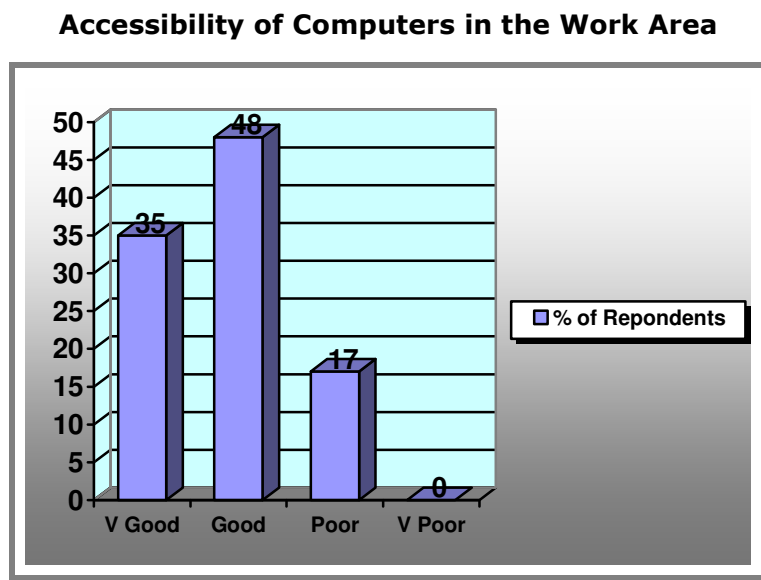


Figure 30 Accessibility of Computers in the Work Area.

6.8 Previous Interactions with a National Renal Registry

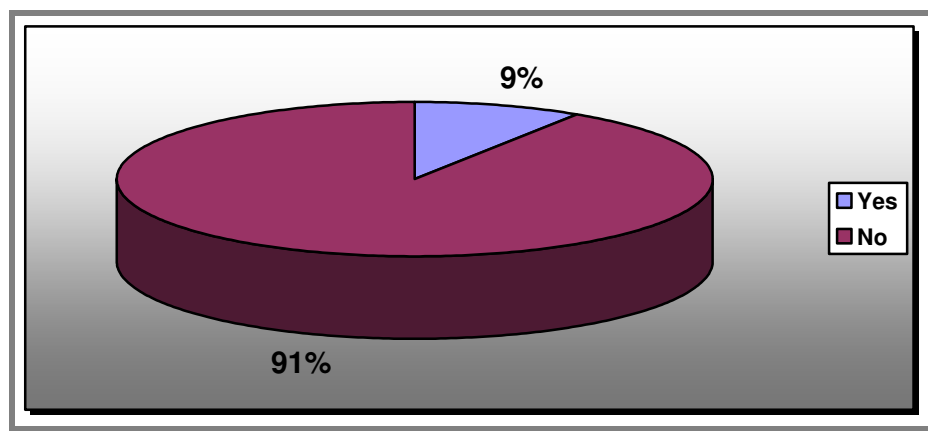


Figure 31 Previous Interactions with a National Renal Registry

International renal registry comparisons provide an opportunity for benchmarking between countries, providing reassurance when data are consistent and driving further research when differences are seen. When questioned on previous interactions with renal registries, the results were as follows; 9% indicated that they previously utilised a

national renal registry in another territory and 91% stated that they have never had any interaction with a registry before. Of the 9% positive responses, 8 respondents in total, 50% of them had interacted with more than one registry. The UK Renal Registry was utilised the most frequent, whilst the American Renal Registry (USRDS) was the second most utilised.

Different Registries Utilised

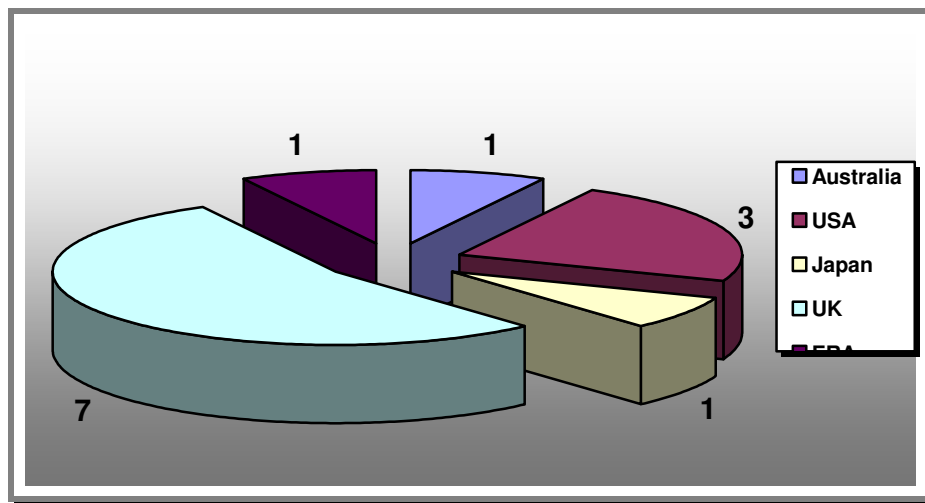


Figure 32 Different Registries Utilised

6.9 Functionality Utilised

Of the 8 participants who had previous interactions with renal registries, they were questioned on what role they had when utilising these registries; 2 actively inputted data, 1 analysed data and 10 used the registries to look up data, keeping in mind that many respondents had dual functions.

Furthermore the respondents were asked to rate their experience of utilising a renal registry. This was graded from Excellent, Good, Fair and Poor. Percentage breakdown is as follows; 62.5% felt it was an excellent clinical guide, whilst 37.5% felt it was a good

clinical guide. Noting that 0% rated it of fair or poor use to them clinically. These two findings are represented in the graphs below (Figures 33 & 34 respectively).

Functionality Utilised

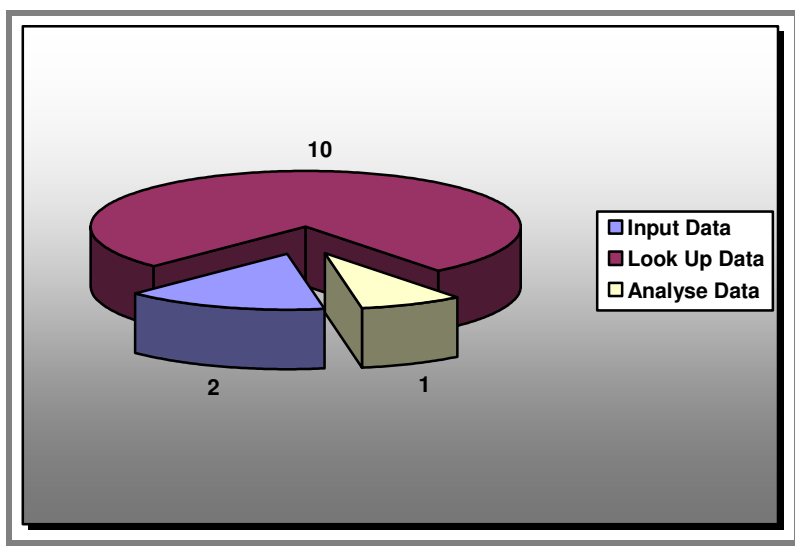


Figure 33 Functionality Utilised.

Clinically Beneficial

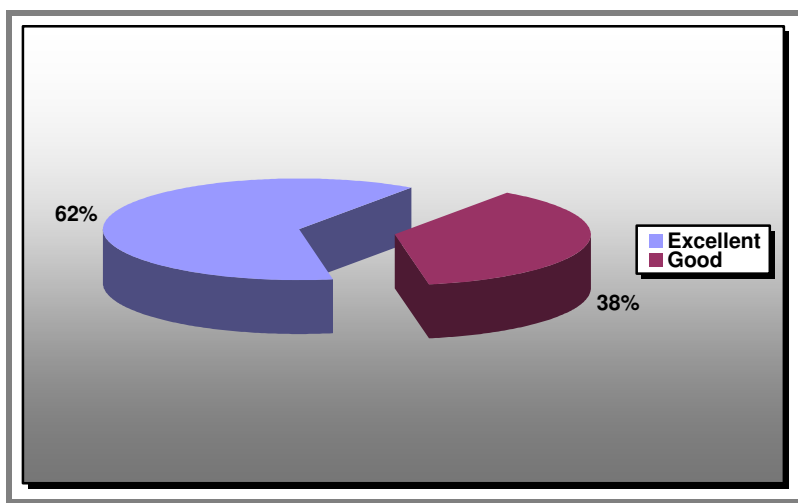


Figure 34 Clinically Beneficial.

6.10 Registries Improvement to Delivery of Care

With respect to the overall delivery of care and the benefits that a renal registry can offer, all 88 respondents were asked would the implementation of a national renal registry improve delivery of care. The results are as follows; the overall return was 100% (88 respondents), 74% indicated that they believed that a national renal registry would be of benefit to patients, 0% was the response to no it would not be of benefit and 26% didn't know whether it was of benefits or it was not.

The analysis of this by profession highlighted that 63% of Staff Nurse thought it would be benefit to have a national renal registry, leaving 37% who didn't know if it was of benefit, 89% of CNMs believed that it would be of benefit, the remaining 11% indicated that they did not know. And 100% of doctors all stated that they felt it would be of benefit. The representations of these findings are in Figures 35, 36 & 37 below.

Registries Improvement to Delivery of Care

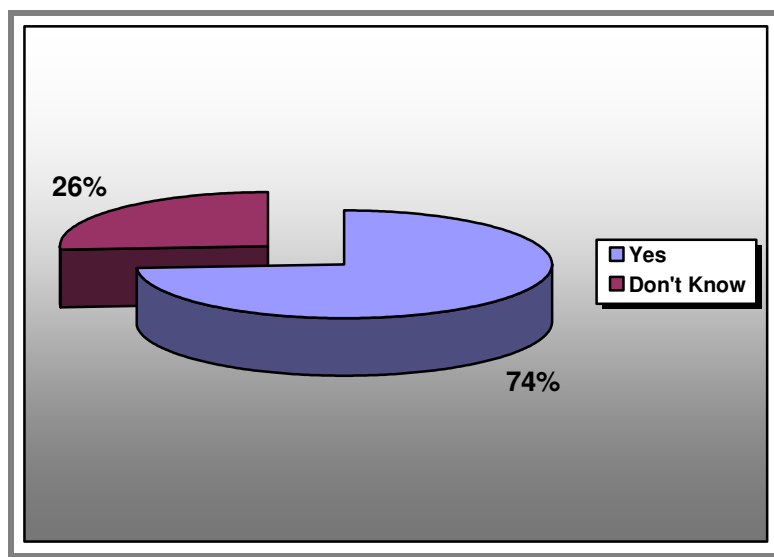


Figure 35 Registries Improvement to Delivery of Care

Registries Improvement to Delivery of Care – Staff Nurses

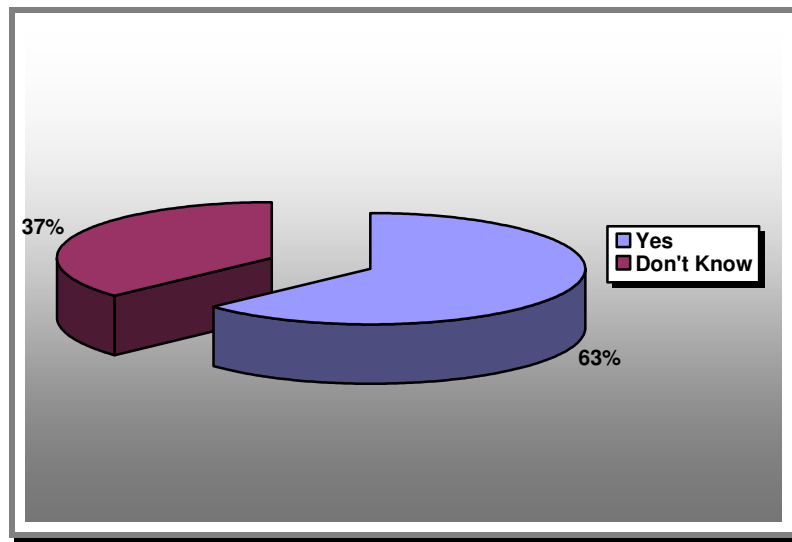


Figure 36 Registries Improvement to Delivery of Care – Staff Nurses

Registries Improvement to Delivery of Care – Clinical Nurse Managers

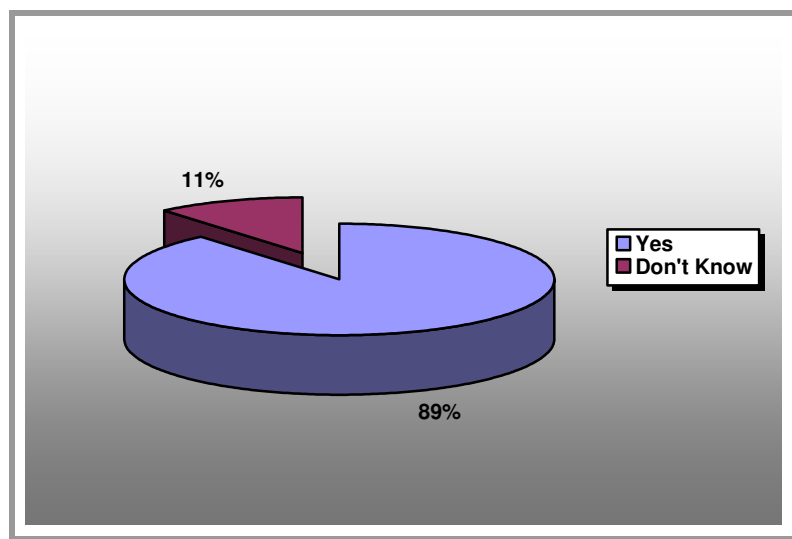


Figure 37 Registries Improvement to Delivery of Care – Clinical Nurse Managers

6.11 Data Analysis and Discussion

Data analysis was conducted to look at and to summarise the data collected with the intention of extracting useful information and to develop conclusions. Data analysis was conducted after all data had been collected for this study. The study was carried out in June 2008 and completed questionnaires were returned within the appointed time stated.

As previously discussed, a total of one hundred and thirty four questionnaires were sent to each potential participant via the internal mail. Eighty eight questionnaires were returned; this represented 66% of all returns. Non-response to postal questionnaires reduces the effective sample size and can introduce bias (Armstrong, 1995). However, since only 34% did not respond, thus a return rate of 66% can be considered adequate to ascertain certain findings. Boek and Lade considered a return rate of 88% to be unusually high to a questionnaire but attributed this high return rate to the intense interest the respondents had on the subject matter of the questionnaire. This can be attributed to the high return of CNMs within the study questionnaire with a response rate of 96.4%. Most CNMs are highly skilled in their specific area and also have years of experience to rely upon, thus giving them a greater interest within sphere of renal registries.

In response to the question of computer utilisation just under half of all respondents (48%) have been using computers for more than ten years. Whilst only 1% of returns equated to less than one year experience of computers. Renal healthcare specialists are clearly well experienced in the field of IT utilisation with a further 34% stating they had five to ten years IT exposure. This is reinforced further when participants were questioned on their overall weekly computer usage in their place of work, which is illustrated in Figure 17. A quarter of all respondents asked, estimated they use computers more than five hours weekly and 41% used the computer for two to five hours per week. The ability to use information systems is important in nursing practice, and accordingly it is an important area of nurse education (Saranto, 1996). It is also agreed that all health professionals should be able to use Hospital Information Systems and have be IT literate to enable the delivery of optimum care. The ability of renal specialists to use computers to an appropriately proficient level would assist the implementation of a renal registry by lack of IT educational needs, greater understanding of IT from previous experience and also a higher level of acceptance of new IT applications.

The respondents were asked if they would like to use a computer more or less often in their work area. As seen in the results, overall majority of respondents (64%) indicated

that they would like to use computers more often in the execution of their duty. This indicates that an overall positive response to the utilisation of IT. However the 34% who indicated they would like to use a computer less often showed a dichotomy of opinion on the issue and also raises awareness of the some respondent's resistance to use more IT in their work area. Understanding resistance is part of understanding the design and implementation of most IT based projects (Timmons, 2003). However, when the statistics were analysed even further it showed that 70% of Staff Nurses stated they would like to use computers more in the work place, and 71% of doctors expressed a desire to use computers more often in the work place. Whilst 52% of Nurse Managers indicated they would like to use computers less.

Participants were questioned on their overall internet usage. Since its widespread introduction into the public sphere in the early 1990s, the Internet has grown rapidly. Internet use has the potential to overcome problems of distance, status, time and personal schedules that other means of communication cannot (Norris, 1999). Nurses and other health professionals are challenged to improve their literacy in the field of information technology to keep pace with patients, who are turning to the 'web' in search of health-related information at ever-increasing rates (Jadad, 1999). With the Internet growing at a rate of 1–2 million new users per month (Benjamin et al. 1996), nurses will be ill-equipped to deal with patients who have armed themselves with information from the Internet, unless they have the capability to stay abreast of new health evidence. In response to this 56% indicated that they accessed the internet on a daily basis and 35% access the internet on a weekly basis. This shows that there exists a culture of high level internet activity amongst renal specialists. However the questionnaire showed that 9% of respondents were only logging on to the internet on a monthly basis. Barriers to internet use in the clinical setting include; lack of administrative support, negative attitude towards computer technology, lack of expertise, and also time constraints within the workplace were highlighted (Estabrooks, 2003).

Another important consideration of this, is the accessibility of a computer within the place of work. The results showed 35% of respondents indicated that the accessibility of computers in there area of work was very good, 48% stated that accessibility was good. This shows that 83% stated a positive response to accessibility of computers. For a renal registry to be adequately utilised and developed, access to state of the art hardware for all users would be a priority for the success of the implementation of such a registry.

Likewise, not to have accessibility to adequate computer hardware must be deemed as a serious risk to the project.

The next section of the questionnaire deals mainly with renal registries, the respondents were asked if they had previously interacted with a renal registry. In response to this, 9% of all respondents have previously interacted with a renal registry. The availability of appropriately skilled and trained staff to support the potential of information within health agencies, together with providing the skills-base and training programmes to support the roll-out and full use of major ICT solutions throughout the sector, are critical for the implementation of IT projects (DoHC, 2004). It is crucial to ensure that the usage of a renal registry will yield immediate benefits for primary users, and this can be realised with previous experience of registries. Also, essentially the enthusiasm and understanding of the need for the system must be diffused down to clinicians and nurses from the users who have previous experience with registries. Examining the opinions of registry users is one way to begin to evaluate registry success at the clinic level (Wells, 2000).

When questioned what registries have previously been used, 50% of all respondents have utilised more than one registry. The UK Renal Registry was the registry most used by the respondents; this is of some geographical significance. However this is also of historical significance, for years Ireland produced more nurses than it could employ, and Irish nurses were highly sought after by other developed countries, including the United Kingdom and the United States. Also from an Irish nursing context, the recent Irish economic boom resulted in the expansion of jobs for nurses in Ireland, so much so that the number of jobs exceeded the domestic supply of employed nurses. Ireland has become a major host rather than a source country and now recruits actively overseas. Long-standing nurse migratory patterns between the United Kingdom and Ireland have totally reversed: Ireland is now a major destination for U.K. nurses instead of vice versa (Aiken, 2004). This will have an overall affect on the numbers of renal health professionals who have had previous experience with other territories national registries.

The survey results showed a positive response when the respondents were asked to rate their previous experience of utilising a renal registry. Not only did 62% indicate that they thought a renal registry would be 'excellent' with reference to clinical benefits, 38% felt the addition of such a database would be of 'good' benefit from a clinical point of view. None of the respondents indicated that a renal registry was either 'fair' or 'poor', the other two possible options available to them on the questionnaire. By having such a

positive response from all surveyed should enhance the buy-in by users for the proposed registry. A sophisticated, integrated information system will only positively affect patient care and financial performance if it is used by all members of the health care team (Treister, 1998). Also, as proposals for information technology systems increasingly seek to produce improvements in patient care, clinicians have a greater part to play in these decisions, which compete for resources directly with investments in treatment and clinical facilities (Lock, 1996).

With respect to the overall delivery of care that the benefits of a renal registry can offer, all respondents were asked, in their opinion, would the implementation of a national renal registry improve overall delivery of care? As can be seen in the results of the questionnaire, 74% indicated that they believed that a national renal registry would be of benefit to patients. With such a positive response to the expected overall benefits of a renal registry, is very encouraging to have so many specialists in the field of renal healthcare agreeing that a registry would improve the already high standard of care delivered. As has been previously stated in the literature review, the benefits of renal registries are far reaching and sometimes understated, as is the case in the benefits attained from the data from registries.

7. Interview Questionnaire

7. Interview Questionnaire

7.1 Introduction

The aim of the personal interview questionnaire was to interact with a chosen target group, to establish a high level discussion of a proposed renal registry from an Irish context. Open or unstructured interviews figure amongst the most common data gathering techniques (Price, 2001). This is mainly because it is a very resourceful research tool to be utilised when collecting data. The major advantage of this type of research is that valuable data can be obtained quickly and cheaply.

7.2 Methodology

Qualitative data was collected by interviewing nephrologists from a cross section of acute hospitals from around the country, thus making them broadly representative of the population of interest. Invitations were sent to seventeen nephrologists in total. The total sample size of the chosen target group was five, though the response was less than had been expected, eight key nephrologists in an already small specialist population was sufficient to augment a survey style interview with closed and open ended questions. Recording equipment was used during the interviews and all interviews were later fully transcribed from the master tapes (Appendix J).

The purpose of the interviews was to obtain an appreciation of the main issues covered in the literature review from an Irish perspective, such as international renal registries, setting up an Irish registry, governance of a proposed registry, potential ethical issues associated with this and perceived barriers to the implementation of an Irish National Renal Registry. With all of this in mind the interview questions were designed (Appendix F).

All interviews were carried out face-to-face with the respondents. The open discussion encouraged the interviewees to discuss in depth their vision of an appropriate data capturing tool and at the same time sharing their knowledge, experience and reservations on such issues as ethics, governance and financial considerations involved in the creation of a renal registry.

7.3 Pilot Study

Pilot interviews were carried with two senior Registrars working in the speciality area of nephrology. Feedback was obtained on interview style and clarity of topic. The design, wording and interview technique was then further refined.

7.4 Data Collection and Analysis

This section describes the results from the interviews. In the data presented below Nephrologist# is the respective participant from the chosen target group, the consultants name has been omitted for the purposes of confidentiality. The participants' own comments are highlighted in italics.

Question 1:

Have you ever utilised a renal registry before?

All the participants had previously used a renal registry directly or indirectly. The registry most used by the nephrologists was the UK and US renal registries. This would mainly be attributed to the period in the participants' career where they gain invaluable experience in other nephrology units outside of Ireland.

Nephrologist 1 – *'.....not directly. Obviously I'm familiar with the USRDS, the European Renal Association, The British Renal Association, and certainly I have looked up the website every year for the US Renal Association and the British Renal Association but we don't have one in Ireland.....'*

Nephrologist 2 – *'.....The Renal Registry in the U.K. Well basically every year you would get a copy of the previous year's Renal Registry. So you would read through that and use that as a standard to compare with our local audit.....'*

Nephrologist 3 – *'.....Yes in the U.K. It was compiled by the Renal Association U.K. I worked for a number of years in London.....'*

Nephrologist 4 – *'.....Yes I did in the U.S.A and found it very helpful.....'*

Nephrologist 5 – *'.....Yes I'm familiar with the U.S Registry having worked in the United States for 15years. I also was exposed to the Transplant Registry there. I found it extremely useful. Also about 10years I contributed to the European Renal Registry.....'*

Nephrologist 6 – *'.....Yes. When I worked in North America, they had the U.S.R.D.S for all end stage renal disease patients and so I was indirectly involved in using the data but I would also be very au fait with the information system per say.....'*

Nephrologist 7 – *'.....Yes directly and indirectly I suppose. The biggest Registry I would have used was in the United States.....'*

Nephrologist 8 – *'.....Well I actually set up one in 1998. What we did was, we got everybody to write in with the names and addresses of all the patients in the units. Just to give us a snapshot of points presence of dialysis.....'*

Question 2:

Do you feel there is a requirement for a renal registry in Ireland?

All the participants viewed the requirement of a renal registry favourably. And when asked to explain why there is a requirement for a national renal registry in Ireland, there was a similar theme for all the answers, the key points were bench marking standards of care, statistical analysis of local data, financial implications of not having a register in place and frustration at not been able to access renal information on a national basis. But overwhelmingly there was there agreement that the patients would benefit from the introduction of a registry.

Nephrologist 1 – *'.....it costs about €60,000 or €70,000 per annum to keep somebody on dialysis and the least you would do in terms of determining quality, quality of access or effectiveness of treatment, or proper use of State resources, we would have some measurement of how much dialysis you are doing, how much transplants and the outcome.....'*

Nephrologist 2 – *'.....You want to know if there is variability between the centres, and if so why is there variability. That's one great thing the Registry will show up for you.....'*

Nephrologist 3 – *'.....I think it is very important to know that in your individual unit, from an individual patient's point of view and also from the dialysis's units point of view, that you are achieving the standards set out either by the renal association or KDOQI.....'*

Nephrologist 4 – *'.....a Registry would give us very useful information about the demographics of kidney disease in Ireland, which would be important for planning of resources, staff etc.....'*

Nephrologist 5 – *'.....for the optimal delivery of care, there should be a Registry in the country.....'*

Nephrologist 6 – *'.....it would help provide a huge amount of research data which could be very important, and perhaps highlight issues which are specific to Ireland.....'*

Nephrologist 7 – *'.....in predicting how the service needs to be delivered and improved, and the only way this can absolutely be done is by using the Renal Registry.....'*

Nephrologist 8 – *'.....Well I think the model in the U.K and particularly the model in Northern Ireland has shown that only with knowledge can we plan the future.....'*

Question 3:

What barriers would you foresee to the setting up of a National Renal Registry?

Again a similar theme was noted when the participants answered this question, there appeared to be two main barriers stated, firstly lack of a robust IT system was the key barrier and secondly insufficient financial backing. Also a lack of buy-in from users was also suggested. One nephrologist felt that there was a lack of a strong unified argument to be put forward by the main stakeholders (nephrologists, renal nurses, allied personnel) to the HSE.

Nephrologist 1 – *'.....it is partly our fault that we did not provide sufficient robust arguments to the HSE, although we are tired banging our heads against the wall.....'*

Nephrologist 2 – *'.....main barrier is you need to have an IT system that is accessible throughout the country or an IT system that can link directly to each other.....'*

Nephrologist 3 – *'.....well one of the main barriers is the significant lack of IT..... I guess Finance is always going to be a bit of a barrier. The other barrier, you see all these barriers are surmountable, is who will manage the Renal Registry.....'*

Nephrologist 4 – *'.....No barriers, but skilled staff would be needed to input the data and analyse it.....'*

Nephrologist 5 – *'.....Appropriate funding could potential be a barrier. Also a lack of will on behalf of those concerned.....'*

Nephrologist 6 – *'.....I suppose the practicalities especially the money would be the main issue in providing the infrastructure and data managers and putting in the proper programmes.....'*

Nephrologist 7 – *'.....firstly buying the IT Systems and secondly 'manning it'. Manning would be a big issue.....'*

Nephrologist 8 – *'.....Firstly funding. It cost a lot of money and effort. Secondly there has got to be a certain amount of paperless transactions.....'*

Question 4:

Who should have governance over the proposed registry?

The replies varied to this question, it was felt that overall buy-in from all renal units in the country, to The Irish Nephrology Society should have overall governance, also the DoHC and the HSE should be considered. However there appeared to be agreement that the nephrologists themselves should have an active role in the governance of registry

Nephrologist 1 – *'.....Committee that would be consisting of renal consultants, senior nursing personnel and probably some advocacies for patients who would have some say in the governance.....'*

Nephrologist 2 – *'.....I would have thought that the people who are going to be using the Registry are the doctors and the nurses, who are in the Irish Nephrology Society and the nurses organisation, along with the relative skill mix in those forums of people.....'*

Nephrologist 3 – *'.....I mean the governance would be very important. I would probably suggest some role for the Irish Nephrology Society in it.....'*

Nephrologist 4 – *'.....a Consultant Nephrologist, perhaps a patient representative, it might be worth looking at the U.K model of governance and adopting what's good from that.....'*

Nephrologist 5 – *'.....The Nephrologists should have governance over it, in the form of the Irish Nephrologists Society and the HSE should also play a role.....'*

Nephrologist 6 – *'.....the primary carers, and that would be the Nephrologists who would have governance.....'*

Nephrologist 7 – *'.....I think it should be shared between the Government and the Nephrologists.....'*

Nephrologist 8 – *'.....I think the HSE has the responsibility to see that patients' records are correct...'*

Question 5:

In your opinion where should funding for a registry come from?

There was varied responses amongst the participants interviewed, about who should infact fund the registry. It was pointed out by one nephrologist that there is a lack of willingness in capital investment from the government. But other felt the HSE were the only appropriate body to raise adequate funds. One nephrologist suggested that the Parma Industry should finance a registry once there was no direct involvement from the pharmaceutical company. Furthermore consideration of losing governance of the registry to whoever provides funding was also raised.

Nephrologist 1 – *'.....short sightedness, inertia, lack of willingness to make capital investment. That's the biggest reason; lack of willingness to do capital investment.....'*

Nephrologist 2 – *'.....concerned that you'll lose governance of your Registry, if it's privately funded. So if you could trust the HSE to fund it, really it would benefit the patients, if they did, it would actually save money for the HSE in terms of improved*

outcomes, but pragmatically and in the real world, if you fund it by charitable associations etc that would certainly mean it would be more autonomous.....'

Nephrologist 3 - *'.....the Health Service Executive should fund it.....'*

Nephrologist 4 - *'.....I would suggest the HSE....'*

Nephrologist 5 - *'.....the HSE being the paymaster should fund the Registry.....'*

Nephrologist 6 - *'.....It would have to come from the HSE, on an ongoing basis.....'*

Nephrologist 7 - *'.....the government if they provide the bulk of the money should have responsibility for how the money is being spent and what it is being spent on.....'*

Nephrologist 8 - *'.....The HSE - it's in their own interest.....'*

Question 6:

Do you feel that all potential participants should be consented to be part of a renal registry?

There was overall consensus amongst the nephrologists when answering this question. It was widely felt that to undertake the task of consenting all patients would be too labour intensive, and also from an ethical point of view it was not deemed pertinent as the patient's privacy and confidentiality was not considered to be compromised.

Nephrologist 1 - *'.....their records are going to be stored in an electronic format whether they want it not, that's just the modern way.....'*

s

Nephrologist 2 - *'.....so at the thought that you are going to anonymise the data, then patients don't need to be consented. Obviously if the data can in any way be traced back to an individual patient, that is a confidentiality issue.....'*

Nephrologist 3 - *'.....No. This is an audit. I mean I do not consent people to take a Hb.....'*

Nephrologist 4 – *'.....I believe the precedent internally is that you don't need consent, that would make the whole process unnecessarily cumbersome.....'*

Nephrologist 5 – *'.....No I do not think so, as I feel this would be a waste of time, as I do not foresee any ethical issues arising.....'*

Nephrologist 6 – *'.....It would also be very labour intensive. If the HSE is running it and funding it, and providing all the patients treatment, I don't see the need for consent.....'*

Nephrologist 7 – *'.....I don't see any reason why patients should have to be consented.....'*

Nephrologist 8 – *'.....I think it should be part of your consent when you start to go on dialysis, there should be a general consent form.....'*

7.5 Summary

The participants were unanimous in their endorsement of the proposed renal registry with no respondent voicing any feelings of dissent. As was uncovered in the interviews all nephrologists have previously discussed the implementation of a registry amongst themselves at the annual meetings of Irish nephrologists and the formation of a registry has been a key area of discussion for many years. There does not appear to be a lack of focus among the participants when asked why there is no registry in place to date, it was strongly suggested that the nephrologists have been pushing the issue for at least ten years and have even attempted to start a registry amongst themselves on a small scale. Again all respondents were in agreement as to what benefits a registry has to offer, stating that a useful database would help plan the renal services into the future and would also assist in benchmarking the care delivered measured against other territories.

One area of concern expressed by the participants was in relation to the lack of a robust IT system in place across the country. The participants felt that for a registry to be successful an appropriate IT system would have to be adopted with adequate personnel to manage and administer the system and also to take responsibility for the data captured in the registry.

On issues such as governance and funding the nephrologists varied very little in their opinions as to who should fund and who should look after the registry. The respondents

declared that the nephrologists themselves should have overall governance of the registry and they should also be supported by senior nurses and allied health personnel in the day-to-day running of the registry. The response to funding was unanimous that the HSE should be the provider of adequate funds to set up and run a registry. Some nephrologists stressed that the pharmaceutical industry should have no financial role in the registry what-so-ever, as this maybe construed as a conflict of interest. However it was also suggested that voluntary contributions should be considered as another form of generating finance.

The participants pointed out that there would be unnecessary levels of work created if every patient was to be consented as part of a renal registry. The respondents also pointed out that this would in no way compromise the patients' ethical rights as far as they were concerned. They argued that to start consenting for a registry would create an environment where the patient would have to be consented for every interaction with the health system.

The interviews were an invaluable source of information from the key individuals who head-up the nephrology services in Ireland. Most notably was the unified stance all the nephrologists held when the issue of there been no registry in place to date. Also the interviews uncovered the efforts to which the nephrologists have actively lobbied the government to assist in creating a registry and even to go as far as setting up a registry amongst themselves with minor input from the HSE. This further highlights the pressing need for a registry in Ireland.

8. Summary & Conclusion

8. Conclusion

The following recommendations and conclusions were formulated in the light of the literature review and the detailed analysis of the information received from the questionnaire and the interviews. The dissertations main objectives were to examine how renal data is currently gathered and analysed on a national and international basis, to determine the benefits and limitations of renal registries and to design a set of proposals for the implementation of an Irish National Renal Registry. Potential challenges and problems that may arise to prevent the realisation of an Irish registry have also been discussed.

At present, auditing of chronic kidney disease is actively done by most renal units in Ireland. However this valuable data is collected locally and is not submitted to a central renal registry. Such a registry is required so that renal patients can be tracked and managed from first diagnosis through early chronic kidney disease and on to haemodialysis, peritoneal dialysis and transplantation. To date, a national renal registry does not exist in Ireland. The dissertation has identified that without such a registry in place the ability for a modern healthcare system to deliver optimum care to its patients is compromised.

The dissertation shows that a renal database measures disease outcomes and is a viable concept as an administrative, research and report generating tool. Within the body of the text, it was necessary to present information relating to clinical performance data, what indicators renal registries are currently monitoring and reporting on from an Irish and an international context. Also this dissertation highlights that using renal data provides comparative data for auditing, planning, clinical governance and research on a national level. With each hospital benchmarking against a national standard, comparisons can be drawn and areas of improvement can be identified.

It is noted in the dissertation that there is a diverse range of indicators and methodology in which registries monitor and report on. No two registries are the same and their creation and implementation is dependent upon the medical, ethical and political status of the registries country of origin. From funding to consenting, each registry deals with these issues uniquely and in a tailored fashion to best suit the culture and identity of each region on a local basis.

Close attention must be paid to the key areas discussed in the implementation section of this dissertation (Chapter 4). Clearly defined proposal and requirements suited best to the Irish renal health system, procurement of a unified patient data management system that can integrate successfully with hospital information systems, suitable governance and regulations that work to the highest level of fairness and integrity, ethical issues such as consent to be debated fully whilst keeping in mind the rights of the patient and the practicalities of operating a registry, agreement of an appropriate dataset and standardisation of all information across the participating units, the necessary level of information security to comply with current legislation to ensure the patient is protected at all times, organised transmission of data across utilising existing ICT infrastructure and finally, ensuring adequate financial backing for a registry. If all of these requirements can be met then creation of a renal registry will undoubtedly be realised.

The questionnaire highlighted that renal health carers are using computers as part of their daily work and the participants surveyed would embrace the opportunity to use ICT more frequently to support them in the delivery of care. Similarly, as could be seen with the interviews of the nephrologist, there was overall support for the implementation of a renal registry amongst the respondents surveyed. Having buy-in from the clinicians surveyed would be of paramount benefit to the overall success of a registry.

The literature also suggests that at present an inadequate IT system exists in the Irish healthcare system and this is reflected in the renal units around the country. It has been identified that there is a need for a reliable, robust and unified IT system within the renal sector and this is to be installed if the success of the registry is to be realised. An efficient IT service would significantly upgrade the patients experience and assist in the delivery of optimum care. This was strongly reinforced in the interviews by the nephrologists when discussing possible barriers to a renal registry.

Significantly the interviews highlighted that there was general consensus amongst the nephrologists in relation to the need for a registry. It was felt that there is no political or geographical barrier created by the nephrologists and that they were completely cohesive on the issue of the implementation of a registry. The transcripts from the interviews support this fully (Appendix J). Also, previously there have been efforts made to create a renal registry driven by key individuals from the Irish Nephrology Association. However, the main issue expressed by the nephrologists is that the HSE would need to assume responsibility for there been no renal registry in Ireland to date as this body of

professionals have requested for the HSE to assist in setting up a national registry on numerous occasions.

The future success of a registry depends on the development of a business plan for its funding, management and operation. The business plan should be developed to include the following components, executive summary, project mission and objectives, database development, compliance and risk management, database market assessment, staffing and infrastructure, structure and governance, funding and financial projections.

With an uncertain economic future ahead, it may be argued that finances should be best allocated elsewhere as opposed to a renal registry or ICT in general. The Brennan Report (2003) strongly highlights that there has been under development of information systems throughout all aspects of the Irish health service from policy making through to implementation. However, as the literature review supports that the initial cost of setting up of a registry can be considered costly, but by not having an appropriate ICT system in place, this could incur an even greater cost to the health system in the future. Ultimately it will be the renal patients who will benefit from a renal registry. This dissertation has outlined the process of implementing a national renal registry. Having looked at the current challenges and potential barriers to this process working, the case has been put forward to indicate that the benefits to patients, hospitals and the country would far outweigh the challenges in its implementation. This process could not work without electronic data collection and electronic transmittal of data, as stated in the Brennan Report technology is essential in health care evolution. It is only through the use of technology that the Irish health system will benefit and evolve. The use of a national electronic renal database, would ensure that accurate and timely data be collected, analysed and distributed to best plan and provide a state of the art renal service for Ireland.

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Appendix A

HSE Data Collection Forms

PROFILE OF EXISTING SERVICES FOR PATIENTS WITH END STAGE KIDNEY DISEASE (ESKD) 31/12/07 – PARENT RENAL UNIT

Hospital :-

Date completed:

SECTION A: PATIENT INFORMATION

1. HAEMODIALYSIS FOR END STAGE/CHRONIC KIDNEY DISEASE

Total number of ESKD/chronic patients on haemodialysis in your unit as of 31st December 2007:-

Please indicate numbers of adult patients by age, and gender, according to county of residence as set out in the table below, receiving treatment on 31/12/07.

	18-55		56-65		66+	
	M	F	M	F	M	F
DUBLIN NORTH EAST						
North Co. Dublin (inc. all city north side patients)						
Meath						
Louth						
Monaghan						
Cavan						
DUBLIN MID LEINSTER						
S. Co. Dublin (inc. all city south side patients)						
Longford						
Westmeath						
Offaly						
Laois						
Wicklow						
Kildare						
SOUTHERN						

Kilkenny						
Waterford						
Wexford						
Carlow						
Cork						
Kerry						
South Tipperary						
WESTERN						
Limerick						
North Tipperary						
Clare						
Galway						
Mayo						
Roscommon						
Sligo						
Leitrim						
Donegal						

Number of Non EU National included above on Haemodialysis:_____

Do you/unit consultant(s) have clinical responsibility for any additional patients whose haemodialysis is provided in a commercial satellite unit?

If so how many patients attend & at what unit(s)

2. PERITONEAL DIALYSIS

Does your unit provide a service for peritoneal dialysis Yes /No:

If yes please complete the section below. If no, skip to next section..

Total number of ESKD patients on peritoneal dialysis (PD) as at 31st December 2007 _____

Number of these patients using automated cyclers _____

Please indicate adult numbers of PD patients by age, and gender, according to county of residence as set out in the table below, **receiving treatment on 31/12/07.**

	18-55		56-65		66+	
DUBLIN NORTH EAST	M	F	M	F	M	F
North Co. Dublin (inc. all city north side patients)						
Meath						
Louth						
Monaghan						
Cavan						
DUBLIN MID LEINSTER						
S. Co. Dublin (inc. all city south side patients)						
Longford						
Westmeath						
Offaly						
Laois						
Wicklow						
Kildare						
SOUTHERN						
Kilkenny						
Waterford						
Wexford						
Carlow						
Cork						
Kerry						
South Tipperary						
WESTERN						
Limerick						
North Tipperary						
Clare						
Galway						
Mayo						

Roscommon						
Sligo						
Leitrim						
Donegal						

Number of Non EU National included above on PD: _____

SECTION B: UNIT FACILITIES

Please provide information on the following as at 31st December 2007

Number of dialysis spaces in your unit to routinely deliver a treatment per shift (**excluding** spaces for isolation*) :

Please provide information on number of treatments per shift, per day of the week in grid.
See example of grid below:

The grid set out below is an example of how to enter data based on the following information

EXAMPLE

No. of dialysis spaces in use = 12

Operational hours of unit = 7 days, 24 hours – except Saturday/Sunday 20.00-08.00 closed for maintenance/water cleaning

No. of shifts for dialysis per week = 4

	Shifts			
	1 st	2 nd	3 rd	4 th
Days of week				
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

PLEASE COMPLETE THE FOLLOWING GRID FOR YOUR UNIT

*No. of dialysis spaces in use = **24***

*Operational hours of unit = **7 days, 24 hours – except Sunday 08.00- 12:00 closed for maintenance/water cleaning***

No. of shifts for dialysis per week = 4 to 4.5

	Shifts				
	1 st	2 nd	3 rd	4 th	5 th
Monday					
Tuesday					
Wednesday					
Thursday					

Friday					
Saturday					
Sunday					

Please also supply the following information:

Total number of haemodialysis treatments per week:-

Number of patients on dialysis twice a week:-

Number of inpatient beds explicitly allocated to renal services:

(Two Bedrooms used for isolation haemodialysis)

***ISOLATION FACILITIES**

How many spaces (compliant with the DOHC 2005 guidelines) are reserved/available for isolating patients with BBVIs?:

What has been the usage of these isolation units in 2007

2007 Treatments					
Month		Hep B	Hep C	Other	Total
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					

SECTION C: OUTPATIENT CLINICS AND ATTENDANCEClinics

Number of nephrology outpatient clinics per month _____

Are clinics held in other hospitals which do not have chronic dialysis units ____

If so where _____

Are General Medical (GIM) patients also seen at this clinic: Yes/No _____

Are ESKD patients seen at a separate clinic: Yes/No _____

What proportion of workload is devoted to GIM patients _____

Patient attendance (Jan 2007 – Dec 2007)

(Please **exclude** GIM patients from these numbers)

No. of NEW patients _____

No. of FOLLOW-UP patients (attendances) _____

No. _____ of _____ attendances _____ to _____ nephrology _____ out-patients _____ 2007:

SECTION D: NEW PATIENTS

1. NEW HAEMODIALYSIS PATIENTS

Total **new*** ESKD patients starting haemodialysis between January 1st and December 31st 2007 _____

*Please note definition of '**new**' refers to patients newly diagnosed/not previously treated.

(**PLEASE DO NOT INCLUDE:** Patients formerly treated for ESKD, and alternating between treatment type or transferred in from another service for ESKD)

Please indicate numbers of **new** haemodialysis patients by age, and gender, according to county of residence as set out in the table below.

	18-55		56-65		66+	
DUBLIN NORTH EAST	M	F	M	F	M	F
North Co. Dublin (inc. all city north side patients)						
Meath						
Louth						
Monaghan						
Cavan						
DUBLIN MID LEINSTER						
S. Co. Dublin (inc. all city south side patients)						
Longford						
Westmeath						
Offaly						
Laois						
Wicklow						
Kildare						
SOUTHERN						

Kilkenny						
Waterford						
Wexford						
Carlow						
Cork						
Kerry						
South Tipperary						
WESTERN						
Limerick						
North Tipperary						
Clare						
Galway						
Mayo						
Roscommon						
Sligo						
Leitrim						
Donegal						

2. NEW PERITONEAL DIALYSIS PATIENTS

Total new* ESKD patients starting peritoneal dialysis between January 1st and December 31st 2007 _____

*Please note definition of 'new' refers to patients newly diagnosed/not previously treated. (**PLEASE DO NOT INCLUDE:** Patients formerly treated for ESKD, and alternating between treatment type or transferred in from another service for ESKD)

Please indicate numbers of new peritoneal dialysis patients by age, and gender, according to county of residence as set out in the table below.

	18-55		56-65		66+	
DUBLIN NORTH EAST	M	F	M	F	M	F

North Co. Dublin (inc. all city north side patients)						
Meath						
Louth						
Monaghan						
Cavan						
DUBLIN MID LEINSTER						
S. Co. Dublin (inc. all city south side patients)						
Longford						
Westmeath						
Offaly						
Laois						
Wicklow						
Kildare						

SOUTHERN						
Kilkenny						
Waterford						
Wexford						
Carlow						
Cork						
Kerry						
South Tipperary						
WESTERN						
Limerick						
North Tipperary						
Clare						
Galway						
Mayo						
Roscommon						
Sligo						
Leitrim						
Donegal						

3. NEW TRANSPLANT PATIENTS

Total new* ESKD patients starting with transplant between January 1st and December 31st 2007 _____

*Please note definition of '**new**' refers to patients newly diagnosed/not previously treated. (**PLEASE DO NOT INCLUDE:** Patients formerly treated for ESKD, and alternating between treatment type or transferred in from another service for ESKD) Essentially this relates only to those patients whose FIRST ESKD treatment is with a transplant (i.e. pre-emptive transplants)

Please indicate numbers of **new** transplant patients by age, and gender, according to county of residence as set out in the table below.

	18-55		56-65		66+	
DUBLIN NORTH EAST	M	F	M	F	M	F

North Co. Dublin (inc. all city north side patients)						
Meath						
Louth						
Monaghan						
Cavan						
DUBLIN MID LEINSTER						
S. Co. Dublin (inc. all city south side patients)						
Longford						
Westmeath						
Offaly						
Laois						
Wicklow						
Kildare						
SOUTHERN						
Kilkenny						
Waterford						
Wexford						
Carlow						
Cork						
Kerry						
South Tipperary						
WESTERN						
Limerick						
North Tipperary						
Clare						
Galway						
Mayo						
Roscommon						
Sligo						
Leitrim						
Donegal						

Section E: Additional Information

1. Renal Transplants

- I. Number of patients currently on the transplant list (31/12/07)
 - a. Active _____
 - b. Suspended _____
- II. Total number of transplants performed on patients from the unit during 2007

- III. Were any of these transplants undertaken outside of Ireland? _____

If so how many and where _____
- IV. How many patients with a functioning renal transplant are under active follow-up by your Unit? _____
- V. Are any of these also under follow-up at another renal centre?

If so, how many and at what centre? _____

2. Vascular Access

Of patients currently receiving haemodialysis, how many fall into the following categories:

1. Functioning native AV fistula _____
2. Functioning PTFE AV fistula _____
3. Tunneled access line with maturing AV fistula (any type) _____
4. Tunneled access line awaiting creation of AV fistula _____
5. Tunneled access line not suitable for creation of/unwilling to consent to AV fistula _____
6. Other temporary access _____

3.

Pati

ents with BBVIs

Numbers of patient with Hep B on Haemodialysis _____ on PD _____

All Hep B Haemodialysis Pts treated at Northern Cross & are not included above.

Numbers of patient with Hep C on Haemodialysis:- _____ on PD _____

Numbers of patient with HIV on Haemodialysis _____ on PD _____

Numbers of patient with HIV and Hep B on Haemodialysis _____ on PD _____

Numbers of patient with HIV and Hep C on Haemodialysis _____ on PD _____

(Patients with Hep C & Hep B & HIV or combination of these should only be counted once)

4.

Tran

sport Transport Costs

Please provide general description of hospital's policy with regard to transport of patients to units and assistance, financial or other, offered, whether by the hospital or relevant HSE region.

Number of Renal Service Patients availing of HSE patient transport service	
Number of Renal Service Patients availing of taxi transport service funded by the hospital (applicable Dublin only)	
Number of Patients using own transport	

Annual Costs incurred directly by hospital/HSE Area for renal service patient transport
 € _____

The above cost relates to the hospital provided patient transport service for only haemodialysis patients. There have been until recently, administration difficulties relating to separating the entire renal service from the rest of the hospital. It is hoped that it will be improved upon for 2008. It is not possible to obtain the cost of HSE provided transport and Eastern Region Ambulance Services costs and any other non-dialysis renal patient transport.

Questionnaire completed by _____ Contact number: _____

Thank-you for taking the time to complete this questionnaire.

Please return the attached form by 31/1/08 by email to:

*****@hse.ie

Appendix B

Ethics Committee Application Forms

21st May 2008

Professor Kieran Murphy
Convenor
Ethics (Medical Research) Committee

Dear Professor Murphy,

Cathal Collier: A National Renal Registry - An Irish Perspective

I have decided to write my dissertation on a national renal registry (or the lack of one). At present I'm the Renal IT Nurse Manager in Beaumont Hospital and have a considerable amount of renal contacts and experience, which I believe will assist me in writing my dissertation. The reason I picked this topic is because I have an interest in this area and I'm aware that the publication of such a thesis maybe of interest to others.

The direction I'm thinking of taking is to look at why we do not have a registry in place already and identify the barriers and resistance to having one. Then to have a look at other countries (ie, NHS, US Registry and Australia) to see how they went about implementing their registries and the benefits and pitfalls encountered in implementing a registry. Also, creating a questionnaire for all Clinical staff within the renal unit, Beaumont Hospital to find out their levels of knowledge an understanding of a national renal registry.

And then finely I'll propose how to implement such a system within the current Irish healthcare system and how to operate and organise such a registry, highlighting the benefits to people with End Stage Kidney Disease, Dialysis Dependent and Acute Renal Failure patients.

With best regards

Yours sincerely

Cathal Collier

**Beaumont Hospital - Ethics (Medical Research)
Committee**

APPLICATION FORM

1. Title of the Research Project:

A National Renal Registry – An Irish Perspective

Is this study a clinical trial of a medicine or a clinical investigation of a medical device? **No**

If No, please delete Box A and move to Box B. If yes, and your trial relates to medicinal products for human use, please do not use this application form. Please fill in the standard Department of Health and Children Application Form:

http://www.dohc.ie/issues/clinical_trials_2004/forms2007

If yes, and your study is a clinical investigation of a medical device for human use, please reply to the questions in box A. Do not fill in Box A if your study is a Registry of a Medical Device!

Box B:

Is Beaumont Hospital the only site in which it is proposed that this research will take place? Yes		
Is this a multi-centre study? No		
If so, give a listing of all proposed sites in Ireland and the proposed Principal Investigators?		
	Principal Investigator at each site:	Site:
1		
2		
3		
4		

2. Principal Investigator: The person who takes primary responsibility for the conduct of the research.

For research involving patients, it is essential that a Beaumont Hospital Consultant be named as a co-investigator.

Name:	Present Appointment:	Title: (Dr. / Mr. / Ms)	Qualifications
Cathal Collier	CNM 2	Mr	RGN, Grad .Dip (Health Informatics)
Address:	Direct Telephone No.	Mobile	E-Mail

Renal Unit, Beaumont Hospital	8092758	086-8675995	cathalcollier@beaumont.ie
----------------------------------	---------	-------------	---------------------------

3. Please indicate whether any payments, monetary or otherwise, are to be made to a person for conducting this research project or any part of the project.

None.

Give details of the value of the funding obtained or sought and the source of that funding.

None.

Do not leave any question unanswered. As far as possible, type an answer to each question and do not use 'non-applicable' or 'as above.'

It is important that the language used in this application is clear and understandable to lay members. Do not use acronyms.

DETAILS OF THE RESEARCH PROJECT
--

4. Has this or a similar application been previously submitted for review to this or No

any other Ethics Committee in Ireland or the EU and, if so, what was the outcome?

Has similar research on this topic been done before in this country or elsewhere? No

If Yes, please elaborate and justify this proposed research.

5.

Proposed Commencement Date:	June 2008	
Proposed Duration:	0 Years	1 Month
Proposed Completion Date:	July 2008	

6 (a) What is the principal research objective of the proposed study?

The proposed study is attempting to determine the qualification of the participant, access their Information Technology (IT) skills and level of usage and finally to get an understanding of their knowledge and utilization of renal registries.

6 (b) What are the secondary research objectives?

None

6 (c) What is the scientific justification for this research?

The aim is to examine the absence of a renal registry in Ireland and identify the barriers and resistance to the development of one. Then to further examine other countries (ie, NHS, US Registry and Australia) to see how development and implementation of their registries and the benefits and pitfalls encountered in

creation of a registry. The dissertation will also involve the creation of a questionnaire for all Beaumont Hospital clinical staff.

7. Give a full summary of the purpose, design and methodology of the planned research, including explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the participant, how many times and in what order.

It is proposed that the study will be conducted using a questionnaire design. All clinical staff in the renal unit (doctors and nurses) will be invited to participate in the study. Data will be collected using a self-administered questionnaire with no identifier of the participant. Containing 10 questions to evaluate the skill levels of staff members and also to enable the researcher to compare between the different health professionals who work solely in the speciality of nephrology. It is estimated to take no more than 5 minutes to complete. The participant will then be asked to place the completed questionnaire in a collection box in their area of work.

8(a) Does the design of the study allow a statistically significant conclusion to be reached?

Yes. There is significant numbers in the study populations to support a comparative study to examine

8(b) What method(s) of analysis will be used?

Chi-squared tests would be used to compare categories of skills between the different professions.

9. Please name the medical device that it is proposed to investigate in the course of the study? (ONLY RESPOND TO THIS QUESTION IF YOU RESPONDED TO BOX A, Question 1)

10(a) State all possible risks to be incurred by PARTICIPANTS in the proposed clinical trial or research study? (Indicate the nature, probability and magnitude of risk, whether physical, psychological, psychosocial or other)

Nature of Risk:	Probability of Risk:	Magnitude of Risk:	Physical / Psychological / Psychosocial
------------------------	-----------------------------	---------------------------	--

			or other
<i>(e.g. bruising due to blood sample)</i>	<i>(e.g. Very High Risk)</i>	<i>(e.g. not serious)</i>	<i>(e.g. physical)</i>
None	None	None	None

10(b) State all possible risks to be incurred by CONTROLS in the proposed clinical trial or research study?

(Indicate the nature, probability and magnitude of risk, whether physical, psychological, psychosocial or other)

(You may Delete Question 10 (b) and Table 10 (b) if your study does not involve CONTROLS.)

Nature of Risk:	Probability of Risk:	Magnitude of Risk:	Physical / Psychological / Psychosocial or other
<i>(e.g. bruising due to blood sample)</i>	<i>(e.g. Very High Risk)</i>	<i>(e.g. not serious)</i>	<i>(e.g. physical)</i>
None	None	None	None

11(a) Please list those procedures in the study to which SUBJECTS will be exposed indicating those which will be part of Normal care and those that will be Additional. (If your participants are staff members, normal is the normal working day, additional is your research i.e. questionnaires, interviews and focus groups.)

Normal Care:	Additional Care:
Normal working day	Completing questionnaire

12. Please indicate if any treatment is withheld as a result of taking part in the study.

No treatment is being withheld as a result of taking part in this study.

13(a) What is the potential for pain, discomfort, distress, inconvenience or change to lifestyle for RESEARCH PARTICIPANTS?

Pain (e.g. skin biopsy, lumbar puncture):	Discomfort (e.g. while giving a blood sample):	Inconvenience (e.g. attending a clinic/filling in a questionnaire):	Change to lifestyle (e.g. results of genetic testing / risk of surgery impacting on participant lifestyle etc):
None	None	None	None

14. (a) What is the potential for benefit for RESEARCH PARTICIPANTS who agree to take part in this research, if any?

Although there are no specific direct benefits to individual participants of the study, it is anticipated that by completing this study, results of this study will be useful for renal clinicians to identify and access a body work on renal registries.

15 (a) How will the health of the participants be monitored both *during* and *after* the study?

N/A

15 (b) What criteria exist for withdrawing individual participants prematurely?

Participants are assured that they can opt not to partake in the study or withdraw from the study at any point in time for whatever reason without having to justify their decision and without having any negative impact on them.

15 (c) What steps will be followed if participants decide to withdraw during the course of the study? (Participants who withdraw have the right to expect the destruction of identifiable data and samples, and that their data/samples/results will not be used in the final research)

As data collection is completely anonymous there is no identifiable data and therefore individual participants cannot be identified from the data.

16. What criteria exist for stopping or prematurely ending the research study?

None.

17. (a) What arrangements are in place for monitoring, recording and reporting and evaluating adverse events? Please state who has overall responsibility in this area and what protocols are in place to monitor any unforeseen events. (Please name the person with overall responsibility.)

There are no anticipated physical or psychosocial risks to be incurred by the participants in this study beyond the inconvenience of completing the questionnaire, which contains 10 questions in total, and is estimated to take no more than 5 minutes to complete.

17. (b) Will a data monitoring committee be convened?

Yes/

No

(ONLY RESPOND TO THIS QUESTION IF YOU RESPONDED TO BOX A, Question 1)

If Yes, please give details.

18. Does the Principal Investigator or any of the key investigators have any direct or indirect involvement in the outcome of the study that could in any way be regarded as a conflict of interest?

No

Detail of Participants /

19. How many Subjects and Controls are expected to participate at each named site?

Principal Investigator:	Site:	Number of Subjects:	Number of Controls:
Cathal Collier	Renal Unit, Beaumont Hospital	148	N/A
		Total: 148	Total:

20. (a) How will Subjects be identified, approached, recruited and selected?
(Please be clear on whether you are approaching subjects in person in a clinic / on

a ward, or in writing via letter at home, and how you are identifying patients e.g. from clinic lists etc. Also, be clear on how you are recruiting e.g. by poster, by website advertisement.)

Identified	Approached	Selected	Recruited
Identified via work placement rosters	Internal post	All willing participants will be selected.	Posters will be placed around the renal unit making potential aware of the questionnaire.

21. What are the principal inclusion criteria? (Please be careful not to contradict your replies to Question 29)

1	Clinical staff member of renal unit, Beaumont Hospital.
2	
3	
4	
5	
6	
7	
8	

22. What are the principal exclusion criteria? (Please be careful not to contradict your replies to Question 29)

1	Not a clinical staff member of renal unit, Beaumont Hospital
2	
3	
4	
5	
6	
7	
8	

23. Will any of the participants be simultaneously involved in any other research investigation?

No, not to my knowledge.

24. Will participants receive reimbursement of expenses (travel costs, loss of earnings) or any other incentive or benefits for taking part in this research? **No**

If so please provide details.

25 (a) Will the participant's family Doctor be notified of the proposed study?¹ No

25 (b) Does the Information Leaflet inform the participant that their GP will be contacted? No

25 (c) Have you included a copy of the letter to the General Practitioner for review? No

¹ If you replied 'yes' to Question 25 (a), *please enclose the letter of notification to the GP for review.*

PATIENT INFORMED CONSENT

26 (a) Will written informed consent be obtained? **No**

26 (b) Have you enclosed a copy of the Consent Form for Review? **No**

26 (c) Which **named person(s)** will be responsible for obtaining consent?
(qualifications and experience)

	Name:	Qualification	Experience
1	N/A	N/A	N/A
2			
3			
4			

26 (c) Give details of how this will be done. (Be careful to ensure your replies are consistent with Questions 20 (a) and 20 (b))

27 (a) Will the participants be provided with an Information Sheet and Consent Form?

Information will be provided on the questionnaire itself

28. Will the participant be given as much time as they require in which to make a decision regarding participation in this research study? **Yes**

29 (a) Are any of the following groups included:

	Yes	No
Pregnant Women	Yes	
Women of Child bearing potential	Yes	
Children or Minors (≤ 16 years)²		No
Cognitively impaired persons³		No
Comatose patients		No
Elderly/aged persons (> 65 years)		No
Hospital Employees⁴	Yes	
Students in the Hospital e.g. NCHD students⁵		No

29 (b) If so, please justify outlining how the study is expected to benefit the individual who participates.

Risk Group to be included in the study:	Benefit to individuals in that risk group:
---	--

2

3

⁴ Hospital staff are excluded from participating in Beaumont Hospital studies, where a supervisory or dependent relationship exists with the Principal Investigator or any of the co-investigators listed in response to Question 2.

⁵ Medical Students and NCHDs are excluded on ethical grounds from participating in Beaumont Hospital studies.

Due to the nature of the study, there are no risks to the above mentioned patients.	
---	--

29 (c) State the manner in which consent will be obtained paying particular attention to the role of parents, legal representatives, witness etc

Minors & the role of parents /guardians:	Adults without capacity and the role of legal representatives:	Will the consent form include a witness signature?
N/A	N/A	N/A

HUMAN BIOLOGICAL TISSUE:

(You may Delete Questions 30 (a) – (h) if your study does not involved HUMAN BIOLOGICAL TISSUE)

31. What arrangements exist to ensure participants are informed of any new information that becomes available during the course of the study? (Particularly information that could impact on their initial consent.)

N/A

32 (a) How will the results of this study be reported and disseminated?

The researcher plans to disseminate the research in dissertation form within Trinity College Dublin, including a presentation to postgraduate colleagues also undertaking the Masters in Health Informatics and lecturers from the Computer Science Department. Staff within the field of nephrology have expressed great interest in the study. Following this, the researcher hopes to have the study published in a peer reviewed nursing journal, such as the Nephrology Nursing Journal.

32 (b) Will results be made available to research participants? Yes

A copy of dissertation can be made on request.

If so, how will this be done?

INDEMNITY

33. What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for negligent harm?⁶ *(Employees of Beaumont Hospital Board are covered by the Clinical Indemnity Scheme. Non-hospital employees will need to provide proof of indemnity.)*

The researcher is an employee of Beaumont Hospital and thus is covered by the Clinical Indemnity Scheme

34. What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for non-negligent harm?⁷ *(Employees of Beaumont Hospital Board are covered by the Clinical Indemnity Scheme. Non-hospital employees will need to provide proof of indemnity.)*

The researcher is an employee of Beaumont Hospital and thus is covered by the Clinical Indemnity Scheme

35 (a) Have all medical practitioners involved in this study current medical malpractice insurance? N/A

35 (b) Is each member of the investigative team insured? Yes

⁶ **NB** Sponsors must comply with the Association of British Pharmaceuticals Industry (ABPI) compensation guidelines and Irish law

⁷ **NB** Sponsors must comply with the Association of British Pharmaceuticals Industry (ABPI) compensation guidelines and Irish law

36. (a) Who is the custodian of the data generated? (This may be the same custodian as for the human biological material – see Question 30 (c), or may be a different custodian)

The investigator, Cathal Collier will be the custodian of the data collected during the course of the study

36 (b) Who has access to this data? Access to the data will be confined to the named researcher only

		Hospital Employee?	
1	C. Collier	Yes	
2		Yes	No
3		Yes	No
4		Yes	No
5		Yes	No
6		Yes	No
7		Yes	No
8		Yes	No
9		Yes	No

36 (c) Does the Information Leaflet inform participants who is going to have access to their data? N/A

36 (d) How is security of data maintained?

In order to maintain confidentiality, data and all identifying information will be kept in separate locked filing cabinets within the department and access to computer files will be password protected which are to be available to the named researchers only.

⁸ **NB. Investigators should be aware of the provisions of the data Protection Acts 1988 and 2003 and their obligations as set out in those Acts.**

37 (a) How will the data be stored AND for how long?

Data will be kept securely for five years from the date of publication of the research

37 (b) How will the data be disposed of?

Data will be shredded and disposed of in a confidential document bin by the researcher five years following the date of publication of the research.

37 (c) Does the Information Leaflet inform participants how long data will be stored for, and how data will be destroyed? N/A

38 (a) What action will be taken to ensure that the identity of each participant remains confidential?

In order to uphold the participants' right to confidentiality, the research will be conducted with complete anonymity of participants. To ensure anonymity will exist, the researchers will not know the identity of participants as participants are part of a random sample and are required to return responses with no form of personal identification. This study will not require access to participants personnel records. Data will be analysed as group data so that individuals cannot be identified by their responses.

38 (b) Would you class the data as anonymous, identifiable or coded? (Be careful: data is only anonymous if you have no idea who the data belongs to and have no way of finding out who it belongs to. Most data in research is coded, and the code can be broken by the custodian of the data, so that the identity of the participant is known.)

Anonymous

39 (a) Will the participant's medical records be examined? No

39 (b) Will any medical records be examined by research workers No

If Yes, please justify.

39 (c) Does the Participant Information Leaflet inform participants that their medical records will be examined, and by whom?

Yes/No

N/A

ETHICAL CONSIDERATIONS:

40. Does the Chief Investigator consider that there are any specific ethical issues that this study might present and how would these be dealt with? Please identify and evaluate.

The researcher does not feel that any specific ethical issues will arise during the course of this study. **Title of the Research Project:**

A National Renal Registry – An Irish Perspective

PLEASE ENSURE THAT YOU COMPLETE THE CHECKLIST ON THE FRONT COVER OF THE APPLICATION FORM AND ENCLOSE ALL RELEVANT ADDITIONAL DOCUMENTS.

DECLARATION:

- **I certify the information in this form is accurate to the best of my knowledge and belief and I understand my ethical and legal responsibilities as Principal Investigator of this study.**

- **I confirm that the protocol and research will comply with all relevant Irish legislative requirements and will abide by the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice.**
- **If the study receives a *favourable opinion* I agree to supply Annual Progress Reports, a Final report, and to seek prior approval from the Ethics Committee of any proposed changes/amendments to this protocol.**
- **All relevant information about serious adverse reactions and new events likely to affect the safety of the subjects will be reported to the Ethics (Medical Research) Committee in writing.**

Name _____ of _____ Principal Investigator:

Signature _____ of _____ Principal Investigator:

Date: _____

The Principal Investigator who signs the Ethics Committee Application takes responsibility for the standard and quality of this application. Substandard application forms, and substandard accompanying documentation will not be accepted for review by the committee.

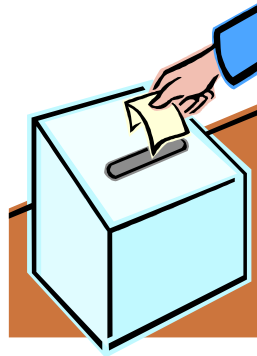
Appendix C

Questionnaire

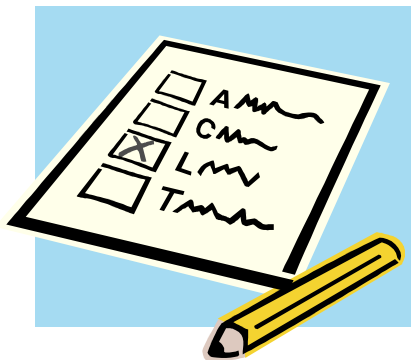
Appendix D

Questionnaire Poster

RENAL REGISTRY QUESTIONNAIRE



AS PART OF MY ON GOING DISSERTATION FOR A MASTERS IN HEALTH
INFORMATICS ENTITLED
'A NATIONAL RENAL REGISTRY - AN IRISH PERSPECTIVE', I WILL BE REQUESTING
FOR ALL CLINICAL PERSONNEL IN THE RENAL UNIT TO COMPLETE THE
QUESTIONNAIRE SENT OUT TO YOU IN THE INTERNAL POST.



CAN ALL COMPLETED QUESTIONNAIRES BE RETURNED TO THE
APPROPRIATE BOXES AT YOUR NURSES STATION. CLOSING DATE
27TH JUNE2008.

THANKING YOU IN ADVANCE FOR YOUR SUPPORT AND
COOPERATION

ANY QUERIES PLEASE DO NOT HESITATE TO CONTACT ME. TEL:
8092758 BLEEP:338
cathalcollier@beaumont.ie

Appendix E

Ethics Approval Letter

Appendix F

Interview Questions

Interview Questions

- Have you ever utilised a renal registry before?
- If yes, where did you use this registry?
- Do you feel there is a requirement for a renal registry in Ireland?
Why?
- What barriers would you foresee to the setting up of a National Renal Registry?
- Who should have governance over the registry?
- In your opinion where should funding for a registry come from?
- Do you feel that all potential participants should be consented to be part of a renal registry?

Appendix G

ICD-10 Renal Disease Classification

Appendix H

Sample Reports from the ANZDATA Renal Registry

Appendix I

ANZDATA Renal Registry Information Leaflet and Consent Form

Appendix J

Transcription of Interviews

Interview with Nephrologist 1 Beaumont Hospital
In relation to MSc in Health Informatics
3.30pm 22nd July 2008

Q.1 Have you ever utilised the Renal Registry?

A. Not directly. Obviously I'm familiar with the US RDS, the European Renal Association, The British Renal Association, and certainly I have looked up the website every year for the US Renal Association and the British Renal Association but we don't have one in Ireland. But what we do have is a Transplant Registry, which is pretty good! An Irish Renal Transplant Registry, which is largely operated by *****. You know all 3400 and something transplants that have already been carried out, have detailed information, but it doesn't have dialysis information.

Q.2 Do you feel there is a requirement for a Renal Registry in Ireland?

A. Definitely!

Q.3 Why do you feel there is a requirement?

A. Well I think, you know we get on to the HSE and say we need more dialysis patients and they say well how many patients are on dialysis in Ireland. Up till recently, the only way we could know that is to go to some person in the Kidney Association, who because of the absence of a Renal Registry, would write to all the Units (Dialysis) every six months and try and get these figures.

But you know it costs about €60,000 or €70,000 per annum to keep somebody on dialysis and the least you would do in terms of determining quality, quality of access or effectiveness of treatment, or proper use of State resources, we would have some measurement of how much dialysis you are doing, how much transplants and the outcome! I mean we don't know whether people live as long when they come to Beaumont (Hospital) Cork or Galway. It seems to me you know that a lot of effort is being put in to discuss the outcomes of patients with cancer. There is a Centre of Excellence. Well the same thing should apply to renal disease, which is maybe less common, but just as expensive and just as horrendous from the affect it has on the quality of life of the patient.

If I had kidney failure, I would like to know that somebody is checking out to see that standards are being maintained and that my chances of surviving and being well looked after, are as good in Dublin, Cork or Galway as they are in Belfast. And

the only way you can do that is if you have somebody looking at the Data and comparing how one sector does compared to the other. And if one falls out, that they can come back and say, you know, the mortality in Galway is twice that of Dublin. Maybe there is a reason for it. It may be because you know, that things aren't being done right. So for all those reasons, I would see it as being more than just a Registry, but indeed a kind of a Database where to get the full benefit of a Registry, you want to include a lot of factors. You want adjust the co-morbidity for instance. The more information you can have on the database, the more powerful, it is then to analyse. For example EPO, we don't have a proper rugged information system. We can't really tell you what proportion of our patients are on Aranesp, Neorecorman, EPO or the other different forms. There is one needing more...., more units of EPO, you know, to be treated than other preparations. All sorts of answers that would be useful.

Q.4 Who should have governance over the Renal Registry?

A. I think for it to work well, it needs to be a National Renal Registry. So it means buying from all the renal units in the country, and therefore an over.... Committee that would be consisting of renal consultants, senior nursing personnel and probably some advocacies for patients who would have some say in the governance. Obviously confidentiality has to be maintained, but Health Officials, planners and financial people should have access. But with a proper governance structure there should not be any difficulty in resolving this.

Q.5 On that same note and related to it; do you feel that all potential participants should be consented to be part of the Renal Registry?

A.5 Do you mean patients?

Q. Yes patients. Should patients give a written consent or given that they are a renal patient should they automatically be included in the Registry. This is an issue as there are 140,000 listed in the CSO in 2005, as potential chronic renal patients.

A. Well of course, it depends. The patients probably should be consented or informed that the information is going to be collected. But then what do you do, if patients opt out? Their records are going to be stored in an electronic format whether they want it not, that's just the modern way. It's not practical to say No I'm not going to be included electronically, you may only have my details on paper.

You may call it research but you may also call it audit. And I think it needs to be complete. I think it's unlikely that patients, as long as they are reassured that appropriate safeguards are put in place. (will object). But I mean all medical data in this hospital and every hospital in the country are maintained on an electronic format and are all subject to audit. That's part of you know necessary day to day medical practice. So yes they should be informed that if you are opting for dialysis, this is what you are going to have. But now the other issue then is, so it's a renal registry primarily of end stage renal failure patient; ie transplant and dialysis, so whether it may also be very good to have a registry of patients with chronic kidney disease, as you say there are a couple of hundred thousand of those in the country. So in fact what I think is that a proper modern way of doing this is that you have a National Electronic Medical Database, so that whether you go in to Beaumont or the Mater / Galway, with a toenail to be removed or kidney failure, you could call up Cathal Collier from Galway and not have to repeat tests such as Xrays or blood tests. So if you operate that way, it could be far down the road, maybe 10 or 20 years, maybe it would never happen, but why people find it easier to just repeat the blood test for eg, rather than try and get it(previous result) from the Mater, is very wasteful, completely wasteful in terms of resources and what not.

So I think what should happen with regard to consent is that patients come in to hospital and it should be standardised across the country, they should be told that they consent to medical treatment in the hospital and as part of that, it automatically means they consent to their records being stored in an electronic fashion, and their records being used for audit in order to improve.

I don't think patients will have a particular difficulty with that. What is really important is that as you say proper governance is done and that proper confidentiality is maintained, that not just anybody can look up information eg. You see your neighbour in the hospital and you can look up the computer and say ' oh look she had a tubal ligation done ' or that sort of thing. These sort of things are done very poorly in this country.

Q.6 In your opinion where should the main funding for the Registry come from?

A. Well I mean all renal care in Ireland is paid for by Brendan Drumm/ Mary Harny / Brian Cowen. It's a public health system. The only people who pay for dialysis is the state. There are private providers but it's the behest of the state. So the funding should come from some budget under the health service.

Q.7 And would you feel that if the funding came from the government coffers, that the data would be protected better and be free of individual interference?

A. Well it depends on your philosophy in life. I am not paranoid about the state to be honest. If the state is providing the cost of the health care, and they have an interest in ensuring the appropriate people are treated, there should be a government structure , probably independent of the providers, although it doesn't have to be. There should be an overall government structure I suppose, created off the providers, but the governors need to be able to look at individual providers like Cork or Beaumont or whatever and see how they are doing. I actually think that electronic medical records would actually save the health system a fortune. I mean when you look at the medical records department, there are probably hundreds of people employed in the hospital, moving charts around.

I go to clinic on a Wednesday afternoon, the secretary brings along probably about 40charts. 9.99% of the contents of these charts are never looked at. Really what you want to be able to see are the recent diagnosis, medications etc. If there was one Master Server, on the scale of things it would cost very little to run, compared to having to store all the paper, protect it from fire, deal with lost charts, deal with lost results. It's a no brainer really. It requires an upfront capital organisation, but after that I think it would save a lot of money.

Q.8 Why do you feel there is not a Registry already in existence in Ireland at the moment?

A. Short sightedness, inertia, lack of willingness to make capital investment. That's the biggest reason; lack of willingness to do capital investment.

Q.9 Do you see any other barriers to the creation of a Renal Registry in Ireland. Do you think there is enough will there from all concerned?

A. Well If the doctors and nurses would all see the benefit of it, but the fact that it hasn't happened, it certainly is not just 'the piper's', it is partly our fault that we did not provide sufficient robust arguments to the HSE, although we are tired banging our heads against the wall. I don't think we can just say 'oh its all Brian Cowen or whoever's fault.' But to do it properly, I'm not certain that for example,

why should there be a Renal Registry, a Cancer Registry, a Cardiovascular Registry. Having all separate Registry's doesn't really make sense when the one patient gets kidney disease from cancer, it should really be an all encompassing medical record.

Q.10 That's all my questions, is there anything you would like to add?

A. No just implement it.

Interview with Nephrologist 2 Beaumont Hospital
Re: MSc in Health Informatics
11.45pm 29th July 2008

Q.1 Have you ever utilised the Renal Registry?

A. Yeah. The Renal Registry in the U.K

Q.2 Can you tell me exactly how you interacted with it?

A. Well basically every year you would get copy of the previous year's Renal Registry. So you would read through that and use that as a standard to compare with our local audit. In the north of Ireland we would have had an IT set -up whereby all the centres were connected with the one Renal IT system, so we had a Northern Ireland wide renal forum, where we would be able to compare our data, in terms of biochemical parameters particularly. We would compare that with the national standards in the Renal Registry.

Q.3 Would you make local comparison's with your previous year's figures or would you look at the whole national picture?

A. Yes. So in Daisy Hill for example, they would have done an annual review of their data and outcomes.. They would have looked at mortality figures, in-patient admission figures etc. as well as biochemical parameters and compared that year on, to see how they were progressing. Most of the units in the north of Ireland then fed back into the U.K Renal Registry. You were able to view your own results in the setting of the Renal Registry in the U.K.

Q.4 By benchmarking, did that promote higher standards in the delivery of care?

A. I think it is very important, that if you see yourself doing well, it is a real positive thing for the staff. You know you can say, we are actually doing a very good job here, in comparison to our peers. And if you are not doing so well, it can sometimes highlight an area which previously might have had a blind spot, where you knew there were deficiencies in your system that you needed to work on.

Q.5 As you are aware there is no Renal Registry in Ireland at present ,do you see where there would be a need for one?

A.Yes.

Why?

Q.5 I mean in terms of the Republic of Ireland, without a Renal Registry, you have no idea as regards outcomes across the whole of the country, which is a much bigger country than Northern Ireland, which has its own Renal Registry, and the Republic has a lot more dialysis patients. You want to standardise your patient outcomes. You want to know if there is variability between the centres, and if so why is there variability. That's one great thing the Registry will show up for you.

If you feature down at the bottom of the list of access eg, in the Renal Registry, in fact it gives you strength, you can go back to your hospital / Trust and say eg we have 50% fistulas compared to Beaumont that have 80% fistulas, because we have only one vascular surgeon session per week, and we need to have 80%. It is very useful for benchmarking and give all the centres feedback as to what is the best practice. Then whatbecause the patient theoretically. So they should not confine their results....

Q.6 What barriers could you see to setting up a National Renal Registry in Ireland?

A. Well the main barrier is you need to have an IT system that is accessible throughout the country or an IT system , that can link directly to each other. That also requires the Registry to be driven from a National perspective. It cannot be driven from a local hospital, trying to co-ordinate it all.

That won't happen. You need someone to be nationally driving a Renal Registry.

In which case the people driving it nationally need to see the benefits the Renal Registry for patient outcomes. No doubt that every time you have a Registry, patient outcomes will improve. Staff morale, I imagine will improve. You will see how well you are doing. I have reviewed the Beaumont findings and I find they compare very very favourably with findings in the U.K., that is across Northern Ireland, England, Scotland and Wales. So that means the quality of care is very good already but it would just be nice to have that nationally. It sort of needs a national approach.

Q.7 Who should have Governance over the Registry?

A. It really should be The Irish Nephrology Society. I would have thought that the people who are going to be using the Registry are the doctors and the nurses, who are in the Irish Nephrology Society and the nurses organisation, along with the relative skill mix in those forums of people. They are IT savvy and they are not people, doctors and nurses working down here have an awful lot of knowledge on Epidemiology and how to use a Registry. Of course you want it to be used with purpose rather than just to be used for reasons that you don't want to control. You want to get out of it what you feel is going to best match your needs.

Q.8 Following on from that on a funding issue, in your opinion where should the funds for the Registry come from?

I've heard that the U.K is virtually self funded, that it is industry assisted, as opposed to HSE assisted. It is probably indirectly funded. There are issues over funding and results and some people feel, that if the ... funded it, it could

A. So I think that question fits in nicely with the Governance question. Your concerned that you'll lose governance of you Registry, if its privately funded. So if you could trust the HSE to fund it, really it would benefit the patients, if they did, it would actually save money for the HSE in terms of improved outcomes, but pragmatically and in the real world, if you fund it by charitable associations etc that would certainly mean it would be more autonomous. You would just have concerns with the HSE that there maybe ulterior motives, as there usually area.....

Q.9 Do you feel that all potential participants should be consented to be part of a Renal Registry? Past and present.

A. This was certainly a problem now in the Belfast City Hospital whereby the legislative background of the North of Ireland would be different to the U.K in terms of releasing data to a national registry. It took quite a while actually for the Northern Ireland centres to return data for a renal registry because of that problem. I from memory ,don't think the patients were consented for their data to be returned, because the data was returned in an completely anonymous fashion. So it was just returned en masse. So it couldn't' in many ways be fed back to an individual patient.

So at the thought that you are going to anonymise the data, then patients don't need to be consented. Obviously if the data can in any way be traced back to an individual patient, that is a confidentiality issue. Otherwise if you are returning data on 200 dialysis patients, and you are looking at your averages etc then I would prefer to consent.

Cathal: The problem with that is that in Ireland there are 140,000 patients with kidney conditions ranging from theAnd trying to consent all them would be a

A.I think the difficulty with trying to, this comes under your IT infrastructure, you need to have one unique identifier number for the transfer of data seamlessly around the IT unit. And provided that the unique number is in a way they can be traced back to a patient but only through strict security. So once that's in place, but I think you'll find getting that in place is a bit of an undertaking in the current infrastructure.

Q.10 What barriers do you see in place preventing the creation of an Irish Renal Registry?

A. I would say the main barrier is going to be the IT infrastructure. There's a lack of political money at the moment and nothing that costs money is going to be done. So this comes back to the need for it to be funded by Charitable organisations, even money from somepeople, again in the U.K, there are few pharmaceutical companies who give some money, but to make sure.

Interview with Nephrologist 3 Cavan General Hospital
Re: MSc in Health Informatics
12.30 at 19th August 2008

Q.1 Dr *** did you ever use the Renal Registry?**

A. Yes in the U.K. It was compiled by the Renal Association U.K. I worked for a number of years in London.

Q.2 Do you feel there is a requirement for a renal registry in Ireland?

A. Yes I do.

Q.3 Why?

A. I think it is very important to know that in your individual unit, from an individual patients point of view and also from the dialysis's units point of view, that you are achieving the standards set out either by the renal association or KDOKI. I suppose dialysis or renal disease is one of the few specialities that has one of the guidelines of standards; so its very important that you know where you are , and if you know where you are from an individual patient point of view or from a unit point of view, then you know what you need to do to reach those standards. Also a Renal Registry,

Ireland is an extremely small country, so there shouldn't be a huge amount of difficulty in setting up a Registry. A Registry will give you hard facts when you want to talk to purchasers about development; at least you can talk about the hard facts behind what you are saying.

Q.4 What barriers would you see to creating a National Renal Registry?

A. Well one of the main barriers is the significant lack of IT. I guess it's the whole health structure in the whole of Ireland, its not just restricted to renal, but the main driver would be, and would make it so much easier is that if we all had a common kind of platform, an IT platform that would allow us to talk to each other. For instance we have EMed here in Cavan General. It was developed really by a Co... which is a co-operation working together project, which is a cross border project. All of the dialysis units in Northern Ireland have EMed and in Letterkenny and Sligo, my colleague Dr Stack uses it there, so we can do a comparative audit and

compare KT/V, Calcium/ Phosphate, PTH's, all the regular kind of standards, markers for quality, with our colleagues in Northern Ireland. And I must say it gives some very interesting results. But the main thing that allows us do that was a very upto date IT platform. The data is always there but it is retrieving it and using it, and if you have a system that simplifies that then people will use it.

So that would be the first barrier that I would see to be quite honest with you. I know at the moment the HSE are going down the road exploring (Are you aware of that?) , they have about €500,000 to spend before the end of the year, and I met somebody, one of the chiefs in the HSE came up here to have a look at it (Emed). They are going down that road and they are exploring it. So I think the drive is coming also from the HSE as well as us.

I guess Finance is always going to be a bit of a barrier. The other barrier, you see all these barriers are surmountable, is who will manage the Renal Registry. That would have to be kind of thought out.

I would not feel there are too many barriers around it. I mean most other countries, in Europe, and certainly in Western Europe, have registries', so I guess we're just playing catch up. There are no insurmountable barriers, to the Registry. There are loads of reasons why not but you can get over them, if you want to.

Q. 5 Who would have Governance of the Registry?

A. That's a good question. I know in the U.K, its run out of Bristol. They have one person who is in charge of it and they have a team and that kinda stuff. But they have an awful lot more units and a lot more data to input. I suppose the day-to-day running of it would have to have some funding. Because one of the functions of a registry is obviously to produce a report. It would just show you where you fit in. I mean the governance would be very important. I would probably suggest some role for the Irish Nephrology Society in it, which I am sure you are aware is a body mainly made up of Nephrologists and people who have interest in research in Nephrology and I think that would kinda make it a communal ownership, not just owned by one person, but everybody could feel they are important stake holders, which they are, because without their data, the system would not be complete. I think you would want some completeness. Collection of data would be very important. So if you capture everybody then you know whats going on.

Q.6 Where should funding for the Registry come from?

A. That's very easy, The Health Service, should fund it. I mean to be honest, they would have a big interest in funding it too, because dialysis is quite an expensive treatment, so the more information and analysis you have about what's going on, the easier it is to plan events. I don't think they will have any issue regarding funding it, and I think there are other Registeries set up, there is a Cancer Registry, (Cathal – a Transplant Registry), yeah so I mean they fund all those.

Q.7 Do you feel that all potential participants should be consented prior to the Renal Registry being set up?

A. Consent patients ? No This is an audit, audit. I mean I do not consent people to take a Hb. I think to do that, a person would have to have no life, no work to do, to go around consenting people first. Should we consent them before we put in the needles, consent them before we take them out. ' read that form and consent them for monthly bloods'? No its audit not research. Obviously you would anonymise the data. You don't want to see that Kieran Hannon's Hb was 12.8 and all that kinda stuff.

There are 1400-1500 people on dialysis so you would go consenting them once a year? How many transplants are there? 2,600, so you are going to be doing that once a year? I mean NO. If you felt you needed to do that fine. I personally feel you don't need to do it. And if I was on dialysis I wouldn't have any objection to anybody using my data for audit. All it is audit.

Q.8 What barriers do you perceive to be in place preventing the setting up of the National Renal Registry?

A. A lot of units don't have proper IT infrastructure to allow it, to be quite honest. I would personally, whatever system every unit goes for, it should be interchangeable to hook up for eg with Dr Stack in Sligo/ Letterkenny and allow him also to access my data. Whatever IT platform the Registry takes, it has got to be able to take all the data from every unit seamlessly. The system too should be paperless. Whatever system we use ,we shouldn't have anybody filling out any form whatsoever. It should all be done on the computer. Once you start filling out forms, you nearly have to give someone a job to do it and a title. Half or whole time equivalent. Whereas if the Registry was set up, so that it could just interrogate the data, on everybody's system say at the end of the year, eg 31./12/08 even quarterly or whatever.

Interview with Nephrologist 4 Beaumont Hospital
Re: MSc on Health Informatics
3.30pm 22nd August 2008

Q.1 Dr *** have you ever utilised any Renal Registry?**

A. Yes I did in the U.S.A and found it very helpful

Q.2 Do you feel there is a requirement for a Renal Registry in Ireland?

A. Yes

Q.3 Why do you feel there is a requirement?

A. Firstly its becoming standard practice in many countries such as the U.S.A, Canada and the U.K, So clearly there is an international precedent for such a Registry. Secondly a Registry would give us very useful information about the demographics of kidney disease in Ireland, which would be important for planning of resources, staff etc. Thirdly the Registry can be analysed to improve patient outcomes and fourthly it can be used for research purposes, which again would benefit Irish patients with kidney disease.

Q.4 Who should have governance over the Renal Registry?

A. I suggest some committee that would change every 3-5 years composed of a Consultant Nephrologist, perhaps a patient representative, it might be worth looking at the U.K model of governance and adopting what's good from that, to us.

Q.5 On that same note and related to it; do you feel that all potential participants should be consented to be part of the Renal Registry?

A. No. Provided data on individual patients is completely confidential, which should be the case with any renal registry. I believe the precedent internally is that you don't need consent, that would make the whole process unnecessarily cumbersome.

Q.6 In your opinion where should the main funding for the Registry come from?

A. I would suggest the HSE. Perhaps some funding from the Pharmaceutical industry but that would need to be treated with care and obviously would need to be shown not to influence data collection or research studies etc, that are being done.

Q.7 And would you feel that if the funding came from the government coffers, that the data would be protected better and be free of individual interference?

A. I would not be concerned about the government funding the Registry. In fact its better to have it more government funded than commercially funded.

Q.8 Why do you feel there is not a Registry already in existence in Ireland at the moment?

A. Probably a lack of resources in part

Q.9 Do you see any other barriers to the creation of a Renal Registry in Ireland. Do you think there is enough will there from all concerned?

A. No barriers, but skilled staff would be needed to input the data and analyse it. People would be required to actually start the Registry and then of course there would be the need for efficient data collection, which would have to be sent in from all the centres.

Interview with Nephrologist 5 Beaumont Hospital

Re: MSc on Health Informatics

Friday 22nd August 2008

Q.1 Have you ever utilised a Renal Registry?

A. Yes I'm familiar with the U.S Registry having worked in the United States for 15years. I also was exposed to the Transplant Registry there. I found it extremely useful. Also about 10years I contributed to the European Renal Registry.

Q.2 Do you feel there is a requirement for a National Renal Registry in Ireland?

A.Yes For the optimal delivery of care, there should be a Registry in the country.

Q.3 Who should have governance over the Registry?

A. The Nephrologists should have governance over it, in the form of the Irish Nephrologists Society and the HSE should also play a role.

Q.4 So where do you think the funding should come from?

A. The HSE being the paymaster should fund the Registry.

Q.5 Do you think all potential participants should be consented?

A. No I do not think so, as I feel this would be a waste of time, as I do not foresee any ethical issues arising.

Q.6 Do you see any barriers arising from the creation of the National Renal Registry?

A. Appropriate funding could potential be a barrier. Also a lack of will on behalf of those concerned.

Interview concluded

Interview with Nephrologist 6 Mater Hospital Dublin
Re: MSc on Health Informatics.
25th August 2008 at 3pm

Q.1 Have you ever utilised the Renal Registry?

A. Yes When I worked in North America, they had the U.S.R for all end stage renal disease patients and so I was indirectly involved in using the data but I would also be very au fait with the information system per say.

Q.2 Do you see a requirement for an Irish Renal Registry?

A. Absolutely, because I think it helps firstly from a practical point of view, it helps identify the prevalence of disease. Secondly it allows for the standardisation of care across the population. Thirdly it provides very important outcomes data about our patients, relevant to other populations.

Also it would help provide a huge amount of research data which could be very important, and perhaps highlight issues which are specific to Ireland, more so than other countries. At the moment, most of our data we extrapolate from other populations. It would be nice to have our own!

Q.3 What barriers do you feel are there to setting up a National Renal Registry?

A. I suppose the practicalities especially the money would be the main issue, in providing the infrastructure and data managers and putting in the proper programmes. I would not see a political barrier. I would imagine there would be absolute forthcoming across all the hospitals in the nation to do it. So I think everyone would see the merits. So the barriers would be more practical e.g trying to get the computer software and trying to make sure that each dialysis unit's data, I mean most dialysis units now keep an electronic record of what's going on, so its just a matter of getting all the units connected. So the concept would not be a barrier

Q.4 So who do you think should have governance of the National Registry?

A. Well I imagine that those people who are the primary carers, and that would be the Nephrologists who would have governance.

Q.5 Where would you see the funding coming from?

A. It would have to come from the HSE, on an ongoing basis. There would have to be a commitment for the management of the data of patients in the same waypatients, and increasingly as they build up a network model, it is more important, that the HSE support the funding of the National Renal Registry.

Q.6 Do you feel there is a need to consent all the patients?

A. I don't have particularly strong feelings. I feel there are merits to it and not to it. I think you have to get 100% capture to be conclusive so ' therefore consenting would leave you short a lot of data' It would also be very labour intensive. If the HSE or running it and funding it, and providing all the patients treatment, I don't see the need for consent'.

Interview with Nephrologist 7 – Limerick Regional Hospital
Re: MSc on Health Informatics
29th August 2008

Q.1 Have you ever utilised a Renal Registry?

A. Yes directly and indirectly I suppose. The biggest Registry I would have used was in the United States, where we would automatically fill in data on any patients that were being dialysed. That was collected from many different units, you paid on line and went in I would have been involved in analysing data in the States as well, when I was there but here in Ireland – NO.

Q.2 Do you feel there is a requirement for a Renal Registry in Ireland?

A. Absolutely, there is a requirement. I mean we are providing one of the most expensive medical treatments in the modern era and to provide a service for each individual patient, it is invaluable in our understanding of how the money is being spent, and also from the data on patient outcomes, in predicting how the service needs to be delivered and improved, and the only way this can absolutely be done is by using the Renal Registry so that you can account for all the patients and their modalities and so forth and assess the standards being provided in that service.

Q.3 What barriers would you see to setting up a National Renal Registry?

A. Well firstly buying the IT Systems and secondly 'manning it'. Manning would be a big issue. Obviously there are two ways. You could do it like the States where data is sent in every time somebody starts dialysis, somebody else enters the data on a central computer system, or you could have it automatically dragged up from an IT system locally in each of the units. Here in Ireland it's a smaller country, there is a very limited number of dialysis units around the country and putting the IT system in those hospitals shouldn't be a major cost, but both manning it and maintaining the system locally would be more an issue, cause if the system is down for 6 months, we lose a lot of data. It's the cost of maintaining that IT system, it's expensive to have a dedicated IT system, and then manning the Registry, I would see as being an issue.

Q.4 Who do you think should have governance over the Registry?

A. Whoever pays for it obviously would but I think it should be shared between the Government and the Nephrologists, and the government if they provide the bulk of the money should have responsibility for how the money is being spent and what it is being spent on. From the Nephrologists point of view, we would use it for trying to improve the care of our patients by improving standards. I don't think the Pharmaceutical companies shouldn't have anything to do with it. – 100%

Q.5 Do you feel that all potential participants should be consented to be part of a National Renal Registry?

A. A registry doesn't need people to consent. It is possibly an easy thing for those entering the data to have it completely anonymous. This can be all set up with the ethics committees beforehand, before the Registry is set up and as long as data is anonymised in it, I don't see any reason why patients should have to be consented.

Q.6 Do you feel there is a risk?

A. The explosion in dialysis services has only taken place in the last 5-8 years and that is the real pressures, that wasn't around in the earlier years. I suspect that the real crisis is coming on the dialysis services now, either from money and what services can be provided. ... come to terms with how big the whole dialysis issue is in Ireland. And when you come to predict what services are going to be needed in the next couple of years, the only way you can do that accurately, is with a Renal Registry. To be able to predict what's going to happen in the next couple of years, is dependent on this Renal Registry; how much man power, laboratory support, services, everything that you need for the next years, is going to be dependent on this.

Interview with Nephrologist 8, St James Hospital
Re: MSc Health Informatics
Friday 29th August 2008

Q1. Have you ever utilised a Renal Registry?

A. Well I actually set up one in 1998. What we did was, we got everybody to write in with the names and addresses of all the patients in the units. Just to give us a snapshot of points presence of dialysis. We got Northern Ireland involved. We found that there was certain discrepancies, certain differences between, I remember in particular the Western & Midland Health boards had the lowest point of dialysis, not transplants, just dialysis and that Northern Ireland and the Eastern Health Board had the highest and there was a sort of north / south divide where Northern Ireland had a much higher point prevalence than southern Ireland, and north Eastern was probably the highest at the time, even than Dublin. There was a 'square' difference between the two. Dublin was relatively low but it was above average, but the points presence was lower than the Midlands. Ironically the Midlands was quite high even though at the time, they had no Nephrologist. There were certain discrepancies, in the points presence, even though it was very crude, it didn't look into diagnosis. We didn't at the time deal with diagnosis and that was about it. The results were published in Abstract form.

Q.2 Is there a requirement for a Renal Registry in Ireland and if so why.

A. Well I think the model in the U.K and particularly the model in Northern Ireland has shown that only with knowledge can we plan the future. The issues are we have no idea where the growth is, where the patients are going to come from, what number of patients, what the age profile might be and If you are setting up a Renal Registry, you have to be able to look up not only those who are on dialysis, but also those who are approaching dialysis. In an ideal world, I would like to see everybody with Stage IV CKD, to be flagged, at least then you can plan and look and see, The studies are there that allow you actually see what are the anticipated requirements in 2 years time. If we look at the ? evidence and compare Northern Ireland with Southern Ireland, there is a huge deficit in dialysis prolific? I mean there is going to have to be

Q.3 What barriers do you see in setting up a National Renal Registry?

A. Firstly funding. It cost a lot of money and effort . Secondly there has got to be a certain amount of paperless transactions. If you are relying on somebody to fill in the data,... You should try and collect as much information as possible, eg patients labs, Xray reports everything, you need to be able to link it in to patients electronic records. How would you look at trends of changing dialysis? But it has been done. You know the U.S Renal Registry do but the U.K don't do it. But I think there is an element of 'should we buy into the U.K Renal Registry and just use their software and report in to them. In theory that's the U.K's registry. I think its better to have our own. In Northern Ireland they have centralised the data and that has been published. There are issues.

Q.4 Who do you think should have governance?

A. Governance and access I think are 2 separate things. What I would mean by governance is who would be responsible for the integrity of the data base. I think that definitely somebody has got to be in charge, somebody has got to have the ability to come in and check that everything is kosher. I think the HSE has the responsibility to see that patients records are correct. Here in Dublin county, one of the issues we discovered for instance, was that some units were counting, saying they had 135patients on dialysis eg, what they meant was they had 135 but 5 of their patients were on dialysis in a different satellite unit.

And that Satellite was also counting the same patients. So there is a responsibility in making sure that the data is accurate. Then there is the questing of Access. I think it should be open access. Anyone who is qualified should have Access to the whole renal database.

Q.5 Where do you think the funding for the National Renal Registry should Come from?

The HSE – its in their own interest. Otherwise what's going to happen is that they are going to have the proliferation of ?

Q.6 Do you think that potential participants in the Renal Registry should be consented?

A. I think it should be part of your consent when you start to go on dialysis, there should be a general consent form, ' I agree the following', I agree that my blood can be taken, I agree my information can be held in a specific database. It should be part of the consent when going on dialysis.

Q.7 Anything you would like to add?

A. You know if using your MSc, what you are trying to do is what are the figures, I think we need to look at other countries have done. We are an IT country, we should be looking at it a lot more pro-actively. We should be looking at dialysis data, integrate it with HIPE data, integrate it with GP primary care, because only if 40% of patients that are at risk and that need to be followed are actually being recorded. Probably even less in this country because there are a lot less Nephrologists here.