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MSc Evaluation of Clinical Practice:Audit and Quality Improvement

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A Comparative Audit of Renal Dialysis in a District General Hospital

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Abstract

The question 'just *how* well are we treating our dialysis patients?' is at the core of this dissertation. This question can be answered by comparing current practice against a set of nationally agreed set of guidelines using the process of clinical audit. Until recently, clinical audit in this renal unit has always been carried out in a sporadic, fragmented and arguably in an informal way. No audit project had ever been undertaken on such a large scale using established national guidelines as a baseline for comparison.

Method

Two audit cycles, one gathering baseline data the other a re-audit to measure the impact of improvements following the first were carried out in a renal unit of a district general hospital on the south of England. Data from the results of renal peritoneal dialysis and haemodialysis were collected and analysed. This included biomedical serum data, blood pressure recordings and general patient data. A set of 17 recommendations provided by two established centres of excellence was used to compare against. Also used as a 'benchmark' were averaged figures from nine other renal units in England. Retrospective and prospective data were collected from patient records, nursing notes and dialysis forms.

Results

The results from the first audit period showed a major under-recording of biomedical data in the patients' records. Especially deficient were the recording of bicarbonate, cholesterol and Urea Reduction Ratios for Haemodialysis patients. However, raising the awareness of the need to record important biomedical data plus the familiarisation of the Renal Association Guidelines ensured an improvement which was seen in the second audit cycle. Recording of serum bicarbonate levels increased from 2.4 % to 74.0%, serum cholesterol from 15.2 % to 81.8% and Urea Reduction Ratios rose from 47.2% to 78.6%.

As a result, decisions were made involving multidisciplinary health care teams to improve the recording of data, changes to the structure of the patients' notes, development of protocols and incorporation of audit as a regular part of the renal units' activity.

Conclusion

The audit process can be viewed as an integral part of modern healthcare. This renal unit has used a set of nationally agreed guidelines as a tool for bringing audit in to the system. Continuous awareness and reporting of results is essential to improvement in practice. A second audit was initially planned simply to complete the audit cycle, but against a background of increasing departmental interest and involvement in audit it has now been added to the programme of systematic audits, to be repeated annually and updated as appropriate. Just as important is the use of information technology in a dialysis service, as in any facility, which poses the problem of the choice of the data to be stored. These will depend on how complete and reliable the stored information is, how well the management process (storage, processing and analysis) is integrated with its day to day use by the renal unit

Introduction

In a survey of renal services in England and Wales carried out in 1995 there were 23,115 patients undergoing renal replacement therapy (Renal Registry, 1998:1) at a cost (1998 figures) of £25,000 per patient per annum. At a total cost of 577 million pounds this represents 3% of the entire NHS budget. Although a low-volume service in the number of patients concerned, this is arguably a high-cost area of the National Health Service. Careful monitoring of the quality and efficiency of an expensive service is required not only for the patients' sake, but also in light of the recent explosion of evidence based practice (Renal Registry 1998), clinical practice guidelines (Walshe and Ham, 1997), and the public concern over an expensive inefficient Health Service. As the Renal Association states in its 1998 paper *'an investment in better care will often lead to savings owing to reduction in complication rates and hospital admissions.'* (Pg1). This dissertation looks at how a renal unit in an acute hospital in the South of England tackled the issues of quality by comparing its practice with two established consensus documents and, as result of its findings, changed healthcare professional's behaviour and the service they provided.

In addition to this, some of the problems encountered with the existing systems of documentation are discussed, and, gives a brief overview of other renal units' attempts to get to measure the quality of the service it provides. The renal unit at the centre of this dissertation is a large unit situated in the South of England serving several hundred thousand population for its renal services.

The following dissertation is divided in four parts. Each of the parts has its own and unique place in the structure of this dissertation. Chapter 1 is the "engine" of the dissertation: it provides the necessary background literature and develops the notions and concepts that will be of importance in this dissertation. Renal medicine and the measurement of the quality of the dialysis service provided is based mainly on the comparison of biomedical measurements against the 'norm' or a set of guidelines. Chapter 1 of this dissertation presents a background by using examples from the literature and sets the scene of the world of renal medicine and, more specifically, renal dialysis. This chapter also discusses the way in which evidence-based medicine is shaping clinical practice guidelines and the way that behaviour of clinicians is being affected. Its also presents the evidence behind the way that Quality Improvement and Quality Assurance has evolved in modern healthcare systems. Also presented here is the measurement of dialysis adequacy and how guidelines and standards for renal dialysis have developed.

In order to make the dissertation "lift off", two wings are needed. Chapter 2 is the factual wing looking at the methods involved in the audit process and details the steps involved in conducting a quality improvement process (a clinical audit project) which were undertaken by comparing the results of a selection of measurements against a set of national guidelines.

Chapter 3, the results "wing" of the dissertation, constitutes the results of the audit process comparing the results from the first and second audit periods against the Renal Association and Renal Registry guidelines.

The first three chapters together will carry Chapter 4, in which the implications of the audit project together with the supporting evidence are discussed. This final chapter of this dissertation includes a summary of the project to date, a discussion of plans for the future and the conclusions reached.

Chapter 1 – Background

'Where shall I begin, please your Majesty?' he asked.
'Begin at the beginning' the King said, gravely, 'and go on till you come to the end: then stop.'
- Lewis Carroll (1832–98) Alice's Adventures in Wonderland, Ch. 11

In order to 'begin at the beginning', it is necessary to give the various backgrounds to the fundamentals of this dissertation. Here are presented the detail of the settings and features from the frameworks of the quality of healthcare, the environment of the Renal Association Guidelines. Also included is a look at some of the work involved in improving dialysis for renal patients.

1.1. Quality of care

The main aim of all health care professionals is to provide high quality patient centered care. They are personally accountable for their practice and in the exercise of their accountability must continually ask questions and monitor the care given (Berwick. 1998) The approach and efforts must be multi-disciplinary, investigating best practice and ensuring that this is carried out (Brighton Health Care NHS Trust, 1998). One way of achieving this is through the processes of clinical audit. This is a way of measuring against best practice, allowing changes to be made and then measuring against best practice again. This cyclical application is part of a 'toolbox' of Continuous Quality Improvement (CQI).

In healthcare, there is increasing emphasis to carry out clinical audit at national level, and it is also acknowledged to reflect this need in at local level. In the renal unit of the hospital where the audit took place, dialysis (the subject of the audit) is spread over several sites so it is particularly important that there is good communication between modalities (the individual units involved in renal dialysis) and that the same appropriate procedures are followed. In those instances where different practices have evolved in different locations, patients would benefit if best practice was adopted throughout. This can only come about if a snapshot of activity is taken, and so in this audit the Renal Association Guidelines (Renal Association, 1998) have been used as a yardstick of the performance in the quality of care of patients with renal disease.

Clinical audit has a key role in both informing and changing clinical practice. It is crucial to monitoring and is a tool to maintain and develop the quality of care delivered. It informs us about the care being provided, identifies where change is necessary and helps to monitor the impact of those changes. Clinical audit can identify poor practice and point to ways to improve it and is inextricably linked to the development and use of clinical guidelines. In other words, it enables processes that lead to improved clinical practice. (Brighton Health Care NHS Trust, 1998)

1.2. A brief history of the measurement of quality in healthcare

Before describing the audit process, it is worth reflecting upon how the measurement of the quality of healthcare has evolved in the last 90 years. In the 20th century the measurement and monitoring of quality in healthcare has gradually developed in one format or another in the healthcare systems of most Western countries. Accreditation began in 1917 in the USA and evolved to become the Joint Commission of Accreditation of Hospital Organisations (JCAHO). The standards are based on an optimum level in achievement. Critics of this system suggest it is a bureaucratic and complex system to administer. It is a system of self-regulation for the health care industry, and although in theory the JCAHO is independent and participation is voluntary, in practice many hospitals are obliged to comply.

An accreditation approach was suggested by Maxwell (1983) to be beneficial to the NHS in the UK. This has so far been developed and adopted only marginally by hospital organisations.

In the UK, quality assurance and improvement in healthcare has developed more slowly and has clearly been influenced by the development of quality in industry. A number of separate initiatives, usually addressing particular issues or departments include, the Confidential Enquiry into Maternal Deaths and the more recent National Confidential Enquiry into Perioperative Deaths.

However, until recently, most care provided within the NHS was not subject to any formal quality assessment. While many clinicians examined their own practice informally, others did not. In the NHS Reforms of 1989 (Department of Health. (1989)), for the first time, the Department of Health endorsed audit and quality improvement and said that all medical staff should participate in these activities. The professional organisations, like the Royal Colleges, supported the government's initiative. Since then, the Department of Health has broadened the quality improvement programme to include all clinical professionals (not just doctors) and has invested substantial resources in helping all hospitals and healthcare services to set up their own quality programmes.

The term "quality" is dependent on the context in which it is used. In fact, Spickernell (1987) states that quality is defined as "an entity meaning different things to different people". Another term to describe quality is "consistently achieving agreed requirements" (Brighton Health Care NHS Trust, 1997). Having tried to define what quality means, quality improvement has been described by several authors. Berwick (1998) stated that quality improvement is "the continuous search for opportunities for all processes to get better". This is the definition that has been accepted by several Trusts in the UK. Although this definition has been applied to healthcare it could, by all accounts, be applied to other industries. Other attempts to define quality improvement have included "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs" (BS4778 1987); "The total composite product and service characteristics of marketing, engineering, manufacture and maintenance through which the product and service in use will meet the expectation by the customer" (Feigenbaum 1983); and, "Conformance to requirements" (Crosby 1979).

In historical terms, quality has changed from quality control to quality assurance. In industry, the system of Produce, Deliver and React (or the Shewhart Problem Solving Cycle (Shewhart 1931 cited in Demming 1986 *Plan-Do-Check-Act*) was used initially as a way of ensuring quality of goods. This can be still seen in use today in systems such as Quality Control and Quality Assurance. From the 1950's a "quality revolution" took place with Juran (1990) and Deming (1986) being seen as the "champions" of this innovation. These developments enabled the workforce (i.e. not just management) to identify causes of variation and change working practice (Joss and Kogan 1995). This in turn led to Total Quality Management (or TQM). TQM developed in response to the difficulties of using quality control in isolation. As Crosby describes it, TQM is *"a systematic way of guaranteeing that organised activities happen in the way they are planned"* (Crosby 1979).

Taking an opposing view, Øvretreit claims that although TQM is supposed to reduce costs and make service more responsive to patients, it has not delivered the benefits expected as TQM works well in a commercial setting but not so in public healthcare (1994).

Its is worth noting here (and paying homage) to the many quality frameworks that have emerged in healthcare. Morgan and Everett have defined quality assurance in health care as "A system of activities for ensuring the production of a defined service to agreed standards within given resources" (1990). In healthcare, a number of people have developed theoretical frameworks for analysing and defining the components of quality. Often these approaches work by classifying the many different attributes of care, which can be labelled as quality issues in some way or other. Three approaches which have been widely used are: -

Donabedian's *'structure-process-outcome'* model which classifies the attributes of quality according to these three dimensions (Donabedian 1966, 1969).

Maxwell's *'six dimensions of quality'*, which provide another way of categorising the different aspects of healthcare quality (Maxwell 1984).

Lang's cycle of quality assurance, which provides a framework for the activities involved in quality improvement and places initiatives like standard setting or audit in a broader context (Lang 1976). This has been adopted by the American Nurses Association as its framework for quality assurance (Dunne ,1986).

In the UK, Clinical Audit Teams or Departments predominantly facilitate the processes of measuring the quality of healthcare. Many junior doctors and nursing staff do undertake projects by themselves unaided within their own specialities or for academic use. However audit departments often have "the ears and eyes" of senior management staff, consisting of administrators and clinicians alike. In this assistance, the renal unit at the centre of this audit approached the Trusts' Clinical Audit department for such facilitation.

The process of clinical audit is often portrayed as a 'cycle' of events. This is discussed further in the next section.

1.3. The clinical audit cycle

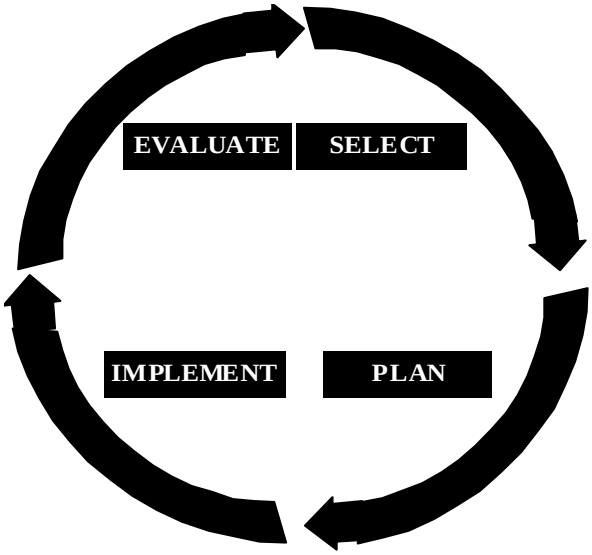
The National Health Service's (DoH 1993) standard but verbose definition of clinical audit is:

> *'… the systematic critical analysis of the quality of clinical care. This includes the procedures used for diagnosis, treatment and care of patients, the associated use of resources and effect of care on the outcome and quality of life for the patient'*

Put succinctly by the National Audit Office,

> *'Clinical audit is a process in which doctors, nurses and other health care professionals systematically review, and where necessary make changes to, the care and treatment they provide to patients. The purpose of the clinical audit initiative is to improve the quality of patient care by creating the conditions which would lead to clinical audit becoming part of routine practice for all health care professionals' (1995)*

Audit measures practice, compares it against an agreed standard, identified problems, implements any necessary changes in practice in order to achieve that standard, and then re-audits (or as we shall see, continues round the audit cycle) to see what effect this had had on practice. The clinical audit process is often represented as a spiral but more commonly as a cycle.



Adapted *from Quality Matters* (Brighton HealthCare NHS Trust, 1996)

Figure 1 - Typical Clinical Audit Cycle

This cycle has many parallels to Lang's cycle as discussed above. Both clinical audit and quality improvement pass through the stages of identifying and prioritising the problems with clear objectives, definition and analysis (including measurement) and finally implementation and evaluation. The whole process can be repeated to assess the impact of the first cycle. Its main components are: -

- **Selection**

  This involves

  - Identifying quality issues
  - Prioritising and select of the audit subject
  - Defining the objectives

- **Planning the audit**

  - The preparation of the audit including data collection, data analysis and reporting
  - Identifying the start and finish times ("the audit period") plus report deadlines
  - Assignment of duties

- **Implementation**

  - Implementing the audit plan (i.e. carry out the data collection in the specified manner)
  - Recording of critical events

- **Evaluation**

  - Assessing the project against the original objective
  - Identifying quality improvements

Unfortunately a far too common scenario that meets many excellent audits is that they gather dust whilst waiting for recommended changes to happen. Although we have become increasingly sophisticated in our execution of the audit project bringing the full forces of evidence-based practise to bear on our evaluation of current practise, when it comes to the implementation stage hope seems to replace evidence. Indeed often the approach is akin to the Italian philosophers maxim *"the pessimism of the intellect, the optimism of the will"* Gramsci (1972).

Indeed at a recent audit conference *"fear and money"* was one experts suggestion for changing health care professionals behaviour, whilst another when asked how to change difficult clinicians suggested that "*whilst there is death, there is hope"*. As a long-term solution neither of these options seem that tenable or palatable. We have therefore mustered the forces of critical appraisal to the subject of changing behaviour, and whilst their are no easy solutions we would like to think that an evidence-based approach is more appropriate than hope.

Renwick argues that the assurance of quality cannot be initiated into health care easily and that the issues involved are as complex as the issues in health care itself (1992). Many terms to describe activities such as quality assessment, quality control, quality assurance and quality evaluation are useful for describing the management of an industrial production line. Human well-being and the health care industry are more complex than production lines and involve more than a limited number processes carried out in a fixed sequence (Crombie et al 1993). However, Clinical Audit (DoH 1989, 1993) as a vehicle for quality assurance is now commonplace in NHS Trusts with over 220 million pounds in 1995 being spent since its conception according to the National Audit Office (1995). Extrapolating this would indicate a figure in excess of 300 million pounds by the year 2000. Clinical Audit is seen by many as the *de facto* quality assurance tool. Humphris and Littlejohns state that only through the effective co-operation of professional groups will change in clinical practice (and arguably quality of care) be achieved (1995). But how does "Best practice" evolve and be agreed upon? Arguably one major development of the latter half of the 1990's was the emergence and acceptance of evidence-based practice.

1.4. The search for evidence

Evidence-based practice involves a shift in the culture of healthcare provision away from basing decisions on opinions, past practice and precedents and towards making more use of science, research and evidence to guide decision making.

As the emerging new NHS of the UK had *'quality at its heart'* (DoH, 1997), it has been acknowledged that quality will only evolve through if relevant research findings and valid guideline recommendations are incorporated into practice. In doing so it is necessary for relevant research articles to form the evidence-base to support a service or practice in health. As the Renal Association have extensively carried out an exhaustive search to form their standards for audit, I have sought not to repeat the Association's search but to find supporting documentation to investigate the assessment of adequacy in renal dialysis and the way in which other units have used quality initiatives to assess their service.

By using the Renal Association Guidelines and the Renal Registry 1998 report the renal unit has assumed that the contents are watertight as to their grounding in evidence-based medicine. David Sackett *et al* (1996) describes 'evidence-based medicine' as *"the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"*.

This posed a problem: Should the evidence which formed the guidelines be accepted as *de facto* statements regarding the care (and hence adequacy) given to dialysis patients? Without doubt, the renal unit at this hospital has accepted the documents as being *the* document that should be used as the basis of a comparative audit. However, although generally accepting this as the current best evidence, I questioned how this could support the Units own findings in the search for adequacy. Therefore, formulating a focused question on the subject of adequacy was directed towards the question *'What is the evidence to support the measurement of the adequacy of renal dialysis in an acute hospital setting?'*

The initial searches of the Medline, Cochrane and Best Evidence databases were performed by both the Post Graduate Medical Centre and the author. There were a plethora of articles regarding the scientific and sometimes baffling use of complex formulae to explain the monitoring urea kinetics (Kt/V). Other articles were specific to one modality. As the audit carried out in the renal unit focused on both haemodialysis, and peritoneal dialysis, there were not many articles relating to both. As an example, the Medline search on English articles pertaining to humans for the period 1992-2000 produced the following results:

Renal Dialysis	2439	articles
And Adequacy	94	articles
And Comparative Stud*	20	articles

These resultant articles are discussed in more detail later on in this chapter.

Although the electronic search of databases failed to return articles that met the criteria for the question posed above, some of the articles identified made reference to adequacy and comparative studies. Much improved results came from a redefined search and the following subject areas were formed from the results of the search These could be broadly categorised as follows:

- Audit of adequacy in hospital dialysis
- Reports on the adequacy of dialysis
- Clinical Practice Guidelines and standards of renal dialysis
- Dialysis outcomes
- Quality Assurance and Quality Improvement for Dialysis
- Quality of Life in Dialysis
- Information Systems in Dialysis

In addition to the above, local information (unpublished material) was obtained from the South Coast renal unit. This included information and clinical database systems; patient information, and audit reports (again, unpublished) from a local and national reports district general hospitals within in the United Kingdom.

1.5. Background to the Renal Association Guidelines

The audit of the renal unit compared existing practice against 'best practice'. Best practice in this instance comes in the form of the Renal Association Guidelines and a supporting document, the Renal Registry Report.

Written by the Standards Sub-committee of the Renal Association, the Renal Association Guidelines are a consensus statement of recommended standards and good practice for the treatment of renal failure covering both minimum standards, mean value targets and rates. Its strength lies in the fact that reported

evidence and recommendations behind the standards are evaluated and graded. Special consideration and attention is given to the practical aspects of comparative audit and suggestions on what areas to audit. It recognises the fact that adequacy (a term used frequently in nephrology) is a global concept, *'involving not one single measurement but various biochemical, physical and patients' quality of life'.* (Renal Association, 1998).

In November 1997 the Renal Association published the Second Edition of 'Treatment of Adult Patients with Renal Failure – Recommended standards and audit measures' (known as the Renal Association Guidelines). This document is *'a consensus statement of recommended standards of good practice for treatment of renal failure'*. The purpose of the document is *'to provide a framework of quality standards and guidelines to determine the well being of, and outcomes in, patients with renal disease'* One of the aims is *'to protect patients from sub standard treatment and to improve the general quality of their care'*. (Renal Association, 1998 pg. 1)

The Renal Association has set 'Recommended Standards' (1998) where the available evidence is strong (A) and 'Recommendations' where the available evidence is weaker or speculative (B and C). This strength of evidence has been denoted throughout this report and grading is according to the US Department of Health and Human Services (1992) that is

A evidence is from at least one properly performed randomised controlled trial or meta-analysis of several controlled trials;
B well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive;
C evidence is obtained from expert committee reports or opinions, and/or clinical experience of respected authorities. This grading indicates an absence of directly applicable studies of good quality.

It is important to realise that these have been set as a minimum. On occasions local standards may be higher.

1.6. Background to the Renal Registry Report

In parallel to the Renal Associations Guidelines, The UK Renal Registry produced a timely report in September 1998, which was used as a resource for this audit project. The primary intention of the UK Renal Registry is 'to carefully monitor the quantity and quality of renal care in the UK, and thus to improve the quality and efficiency of this care' (Renal Registry 1998).

This showed the result of an anonymous comparative audit of nine renal units in England with just over 5,000 patients involved. It included the analysis of patients' treatment and compares this to nine other data sources including the Renal Associations Renal Standards Document. Adequacy of haemodialysis, which is one of the main strands of the renal unit audited here, was also compared as is biochemical indicators and blood pressure.

As stated above the primary intention of the UK Renal Registry is to carefully monitor the quantity and quality of renal care in the UK, and thus to improve the quality and efficiency of this care. This report is provided to facilitate that process. It will enable internal audit within renal centres, support comparative audit, and provide information to stimulate and inform the process of improving protocols of care.

The UK Renal Registry is part of the pioneering work of the Renal Association in support of clinical governance. The process was initiated by the Renal Association with the publication of the document about "recommended standards and audit measures for the treatment of adults with renal care". The audit and research work of the registry is essential for closing the audit loop and implementing those recommendations (1998)

1.7. Haemodialysis

Before delving into the recent improvement initiatives associated with the adequacy of dialysis, it is worth detailing the types of dialysis available to patients with End Stage Renal Failure.

In haemodialysis, an artificial kidney (haemodialyser) is used to remove waste products from the blood and restore the body's chemical balance. In order to get the patient's blood to the artificial kidney, it is necessary to make an access to the patient's blood vessels. This requires surgery on an arm or a leg. The surgical procedure connects an artery to a vein underneath the skin. The joining of an artery to a vein creates an enlarged vessel known as a fistula. Once healing occurs, two needles are placed, one in the artery side and one in the vein side of the fistula. Plastic tubing connects the patient to the artificial kidney.

The time required for each haemodialysis treatment is determined by the patient's amount of remaining kidney function, fluid weight gain between treatments and the build-up of harmful chemicals between treatments. On the average, each haemodialysis treatment lasts approximately 3 to 4 hours and is usually necessary three times per week.

1.8. Peritoneal Dialysis

In contrast to haemodialysis, which cleanses the blood outside the body, peritoneal dialysis works "inside the body," using the body's own peritoneal membrane as the semipermeable barrier through which the blood can be filtered.

Dialysis solution is introduced directly into the patient's peritoneal cavity through a catheter; the cavity is used as a reservoir for the dialysis solution. Toxins in the blood filter through the peritoneal membrane into the cleansing solution, which is then withdrawn from the body through the same catheter and discarded.

Peritoneal Dialysis was originally used only as an intermittent procedure, but the newer forms of peritoneal dialysis allow patients to self-administer the procedure four or five times daily on a continuing basis at home or "on the road." Patients sleep or go about their daily activities while dialysis occurs internally.

There are at least three types of peritoneal dialysis - Continuous Ambulatory Peritoneal Dialysis (CAPD); Continuous Cycling Peritoneal Dialysis (CCPD); and Intermittent Peritoneal Dialysis (IPD).

Continuous Ambulatory Peritoneal Dialysis (CAPD) is the only type of peritoneal dialysis that is done without the use of machines. Patients perform this procedure themselves, usually four or five times a day at home and at work. The patient drains a bag of dialysate into his/her peritoneal cavity by way of the catheter. The dialysate remains there for about 4 to5 hours. After an exchange is complete, the patient drains the used dialysate back into the bag. The patient then repeats the procedure using a new bag of dialysate. While the dialysate remains inside the peritoneal cavity, the patient can go about his/her daily activities.

Continuous Cycling Peritoneal Dialysis (CCPD) is usually done at home using a cycling machine. The process is identical to CAPD except the cycle (exchange) periods are usually 1½ hours and are performed several times a night, while the patient sleeps.

Intermittent Peritoneal Dialysis (IPD) is the oldest form of dialysis and is usually done in the hospital for 10 to 12 hours, three times each week. This treatment is often done in emergency situations or as a first dialysis treatment. The patient is hooked up to a machine during treatment, as in CCPD.

Peritoneal Dialysis is the treatment of choice for many patients are unable to withstand the stresses involved in haemodialysis. Other variables include poor vascular access, clotting problems and lifestyle choices (Dillon, 1995)

Further details on both these types of dialysis are to be found in the Mednets web pages of MDHome, Inc (2000) and the National Kidney Foundation(2000).

1.9. Adequacy of renal dialysis and quality improvement initiatives in dialysis

The definition of dialysis adequacy can encompass a number of broad categories, which includes urea kinetic modelling which combines solute clearance dietary protein intake. The recognised measurement of adequacy is the measurement of percent urea reduction rate (URR). This is the removal of blood urea nitrogen removed in a single dialysis treatment. Another measurement is Kt/V. This is an in-depth measurement, which takes into account the patient's residual renal function and a protein catabolic rate. The Renal Associations Guideline (1998) for adequacy in haemodialysis is a measurement of > 65% for URR and >1.2 for Kt/V and peritoneal dialysis a measurement of >1.7 For Kt/V

As a result of the literature search as described above, there were a number of articles detailing the work of various renal unit at home and abroad. The most outstanding articles of interest and pertinence were those aligned with the reports of the National Kidney Foundations work involving Continuous Quality Improvement (CQI) in the field of renal dialysis. These describe as programme not too dissimilar to that of the Renal Association and Renal Registry.

Eknoyan et al (2000) have described how clinical practice guidelines can have the potential to affect patient outcomes. This has been seen in the Dialysis Outcome Quality Initiative (DOQI) a guideline for the treatment of patients with end-stage kidney disease. There are strong parallels to the Renal Association 1998 recommended standards and audit measures in the way this initiative deals with both peritoneal and haemodialysis adequacy and in the way it further extends its guidelines to nutrition, renal bone disease and hypertension. One of the recommendations of DOQI is an extension of the guidelines to 'catch the patient early'. In other words the early detection of patients with renal disease so that adequate and appropriate dialysis can take place.

The National Kidney Foundation's DOQI is summarised by Eknoyan and others in explaining the brief history of the DOQI guidelines' evolution, the meta-analyses behind them and the key markers to measure adequacy in Haemodialysis and Peritoneal Dialysis. They recognise that nutrition plays an important role in the outcomes of dialysis patients and give a caveat to the users:

> *'users of … the guidelines recognise that there will always be a need to individualise treatment to the circumstances of each ESRD patient and hence there will always be some appropriate variation in the practices addressed by the DOQI guidelines'.*

The DOQI appears to be a document very much respected and replicated by the Renal Associations' own 1998 Standards and audit measures report.

Other articles of note debated the issue over whether the right patients received the right form of dialysis. A study of 154 renal facilities of nearly 7000 patients showed a statistical relationship between the way that patients were treated, the facilities of the renal unit and the patient existing condition which affected the adequacy of dialysis. (Fink et al, 2000)

As described later in this dissertation, modern healthcare practice has used a plethora of techniques and programmes of work to improve the quality (a term in itself of great debate) of the service given to patients. CQI seems to be the preferred format for renal units in the Unites States as a systematic method of choice.

Rutherford and Gibney (1997) have outlined how the use of Continuous Quality Improvement (CQI) has been applied to patients with end-stage renal disease (ESRD). They state that as CQI has been more effective than Quality Assurance as it requires an holistic management system rather than just relaying on technical issues of dialysis. They argue that the new breed of CQI begins with evidence-based practice as opposed to a cursory retrospective glance at previous work. Computerisation of clinical data is now allowing core data to be managed in such a way to give health care professionals a greater view of patient care. This is especially true when the treatment can be carried out a several sites (This has strong parallels and implications to the subject of the audit – namely the adequacy of dialysis. The renal unit at the centre of this audit has several satellite units). The authors argue that there maybe fewer nephrologists but more technical assistants to give '*more effective care for more people'*.

DeOreo (1994) has described description of a two-year change from a blame culture to a team education culture in a renal unit. The transitions from Quality Assurance to Quality Improvement involved gathering data regarding adequacy and in doing so teams of staff were set to identify and implement solutions. This is somewhat similar to the renal unit under scrutiny in this dissertation. By setting and

achieving goals DeOreo explains how adequacy can be achieved and consider ‘highest frequency problems received the highest priority’.

Levinsky and Mesler describe this process of Quality Improvement in terms of Donabedian’s *Structure, Process, and Outcome* (1966,1969) for their programme of managing and improving the quality of the care of patients with End-Stage Renal Disease. With Structure being the dialysis unit itself, Process, the type (modality) of dialysis given and Outcome the measurement adequacy. They describe the desirable attributes of a kidney disease program to be 1. Comprehensive and system-wide, 2. Scientific with data driving the decisions, 3. Organised data collection, 4. Research, training with practice guidelines and 5, Vision

VanValkenburgh and Snyder (1994) also call for a fully integrated health care programme in ESRD. Patient care plans have been re-written to meet necessary requirements of the guidelines and standards. There is also a call for more meaningful data, which should allow for opportunities to improve the benefit of care delivered to the renal patient.

A very important and often neglected area is the scant existence of decent comparative studies in measuring adequacy of dialysis. This has been described by Friedman and Jaber (2000) and casts doubt on the establishment in superiority over on particular dialysis dose or modality (that is haemo or peritoneal dialysis). They argue that the standards and methods of measuring adequacy maybe flawed owing to the number of factors involved in each patient. Despite the great technological advances in renal medicine Movilli (1999) states that it is other factors, dose of dialysis, nutrition, and biocompatibilty of dialysis that effect patient outcome and not to rely solely on the Urea Kinetic Modelling. Nutrition is again a hot topic for debate as stated by Bargman et al (1999). In a Dutch study, Kloppenberg et al (1999) have discussed in detail the nutritional aspects in measuring adequacy and stated that basing clinical decisions on a single dialysis adequacy measurement is ‘an unjustified practice’ as quite often an assessment of dietary intake is lacking. Another detractor from the use of current adequacy measurements is Gokal, who also questions the targets set for adequacy (1999). Again in the Netherlands, a renal unit reports on its adequacy over a five year period but states that it is just keeping its head above water but will be difficult in reaching all of the latest DOQI guidelines (Offerman and Kok 1999).

Another detractor from this school of thought is in Germany, where the ongoing challenge of peritoneal dialysis has been discussed by Lambert (1998). A personalised service to the patient has been suggested to give good adequacy measurements. This involves all involved with dialysis to ensure that adjustment in dose is made in order to prevent under-dialysis. This can only be done with the assistance of observant (and responsible) renal staff. The greatest responsibility is however given over to the patient.

Chapter 2 – Methodology

No task is a long one but the task on which one dare not start. It becomes a nightmare.
- Charles Baudelaire (1821–67) My Heart Laid Bare

2.1. Background to the audit

This Chapter details the format of the audit, describes the audit processes and the recommendations and recommended standards from the Renal Association and the Renal Registry.

A requisition from the renal unit's Research Audit Sister requested the assistance of the trust's own Department of Clinical Audit of which I was clinical audit officer. The request was to help facilitate and assist in the execution of the audit project. As the Clinical Audit Officer assigned to the project, I was asked to focus on quantifiable aspects of Haemodialysis (Hdx) and Peritoneal Dialysis (PD) in adult patients using the Renal Association Guidelines and the Renal Registry Report as the guide to best practice.

As a clinical audit officer, this meant initiating the literature reviews (and highlighting relevant articles); data input form design and administration; data analysis and, reporting the results. Feasible and applicable recommendations and decisions following the audit were the responsibility of the multidisciplinary groups involved.

Using patients' notes, dialysis forms, and nursing evaluation forms, data were collected retrospectively for a period between October 1, 1998, and December 31, 1998 in the first audit cycle and October 1 1999 and December 31, 1999 for the second and subsequent audit cycle.

The layout of the 1998 data collection forms was refined for ease of completion and sections relating to a change of dialysate over dialysis and membrane type deleted as being obsolete. The 1998 audit confirmed that bicarbonate buffer is routinely used throughout the unit, so the data collection form was amended to exclude this also. A combined data collection form can be found in Appendix A; in practice this was tailored to the individual modality (i.e. haemodialysis and peritoneal dialysis). Data on Peritoneal Dialysis adequacy itself (that is, Creatinine Clearance and/or Kt/V frequency) are available using a dedicated computer package. At the request of individual the renal unit itself the forms were updated to incorporate additional detail on transplantation as an option, phosphate advice given and iron supplementation, all being data for future analysis.

In the absence of a comprehensive IT system, data was once again collected manually. Although still very time consuming, the process was streamlined due to the additional experience of the data collectors and the fact that a third person was enlisted. The data collectors also had to cover two satellite units within a radius of 35 miles of the main renal unit.

2.2. The project audit stages

Following the project audit cycle described in Chapter 1 the audit took shape around the following stages

- **Selection**

  Initially, at the commencement of the first audit, the renal unit wanted to compare against *all* standards within the Renal Association Guidelines. However, after a small feasibility study to determine the length of time to collect such data, it was decided to only concentrate certain aspects of the Guidelines. These were felt to be of highest priority to the renal unit and easily accessible for data collection. These were pertaining to the recommended standards for haemodialysis and recommended standards for peritoneal dialysis.

Those standards excluded from the audit were those dealing with Transplantation, Acute Potentially reversible renal failure and chronic renal failure (pre-dialysis). It was also decided to "mirror" the format of the Renal Registry report in the reporting of biomedical data.

- **Planning the audit**

A 6-week data collection period was formulated to recover information from patient records, nursing notes and dialysis forms. Input into the audit database (SPSS ver 7.0 and Excel version 6) was carried out in parallel to the data collection to reduce the amount of time. Data collection was to be carried out by renal unit staff (as they the expertise and experience of reviewing medical notes) and data input by Department of Clinical Audit staff. Analysis was carried out by both to eradicate, where possible, any bias in the interpretation of the results

- **Implementation**

Two audit periods (at time of writing) were formulated. These were the final quarters of years 1998 and 1999 (1/10/98 - 31/12/98 and 1/10/99 - 31/12/99 respectively). These corresponded to the quarters utilised by the renal registry in their report of the findings of nine renal units.

- **Evaluation**

After analysis and the synthesis, the results were presented to renal staff within 6 weeks of the completion of the data collection and evaluation. Haemodialysis and Peritoneal Dialysis results were presented separately due to the volume of the data presented.

2.3. Audit Objectives

Having initialised the audit project through a series of meetings between the Trusts' Clinical Audit Department, the Renal Research Sister and a senior consultant nephrologist, a set of principle objectives of the audit were assembled. These were: -

- to measure the performance of the renal unit against the guidelines advocated by the Renal Association
- to establish a database for those dialysis indicators that require continuous input as basis to compare against the guidelines advocated by the Renal Association
- to establish data collection forms for regular use in the gathering of data to support the audit processes
- to establish regular audit meetings between medical, nursing and support staff to examine results and plan any changes in practice
- to implement changes and re audit where necessary

2.4. Comparison against the Renal Association Guidelines

A total of sixteen standards were chosen from the Renal Association Guidelines to compare against Table 6 in chapter 3 shows a summary of the results of the comparison. These standards were felt to be relevant measurable and achievable for this particular renal unit. The sixteen standards were:

1 Haemoglobin levels (Hb)

The 'Recommendation' in the Renal Association Guidelines is: -

- *For a target Hb ≥10g/dl in >85% of patients after 3 months on dialysis. (1, p25)*

Strength of Evidence ***(A)*** **-** evidence is from at least one properly performed randomised controlled trial or meta-analysis of several controlled trials

Levels of the blood constituent Haemoglobin are a useful indicator of anaemia, which is a common problem for patients with renal failure. It should be corrected firstly by optimizing nutrition and dialysis but frequently needs treatment with human recombinant EPO. Patients who were on EPO more than 12 weeks were dealt with separately as it could take this long for their Hb levels to respond to EPO and stabilise. The Renal Registry Report notes that patients in the first few months of RRT have a higher rate of anaemia and therefore that the standard may be more appropriately applied to patients who had been on Renal Replacement Therapy (i.e. dialysis) at least 6 months (2 p.66).

2 Serum Ferritin

The Renal Association Guidelines do not recommend a range for serum ferritin. The local EPO protocol (3) used in the renal unit is in accordance with the UK Renal Registry which states '*it has been recommended that for maximum response to EPO therapy in end stage renal failure (ESRF) that serum ferritin be maintained at 100umol/l'* (2, p54).

For the purposes of the audit, the last result within 9 months of the audit period has been taken (from 1st April 1999) in line with the recommendation of the UK Renal Registry.

One of the functions of the kidney is to produce the hormone erythropoietin (EPO). This hormone stimulates the bone marrow to produce red blood cells. People with kidney failure do not produce adequate amounts of EPO and therefore suffer from chronic anaemia. A human recombinant form of EPO is commonly administered to correct the anaemia (Bennett et al, 1997)

3 Mean Serum Potassium levels (mmol/l)

The 'Recommended standard' in the Renal Association Guidelines is: -

- *3.5 – 6.5 mmol/l for pre Haemodialysis (locally 4.0 – 5.5 mmol/l) (1, p27)*
- *3.5 – 5.5 mmol/l for Peritoneal Dialysis (locally 3.2 – 5.5 mmol/l) (1, p32)*

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

4 Mean Serum Bicarbonate levels (mmol/l)

The 'Recommended standard' in the Renal Association Guidelines is: -

- *For Haemodialysis patients; The target pre dialysis serum bicarbonate level should be within the local normal range in all patients after 3 months on Haemodialysis.* (1, p25)

- *For Peritoneal Dialysis patients; The serum bicarbonate level should not fall below the local normal range, or rise more than 3 mmol/l above it.* (1, p33)

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

The local normal range at this renal unit is 22 – 30 mmol/l.

5 Mean Serum Phosphate levels (mmol/l)

The 'Recommended standard' in the Renal Association Guidelines is: -

- *1.2 – 1.7mmol/l for pre Haemodialysis (locally 1.2 – 1.7 mmol/l)* (1, p27)
- *1.2– 1.6mmol/l for peritoneal dialysis(locally 1.2 – 1.7 mmol/l)* (1, p32)

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may

be extensive but essentially descriptive

As phosphate levels can vary, mean results were calculated using all results from the audit period. Data was collected for the first time this year about whether phosphate advice was documented as being given, although this doesn't necessarily imply it was acted upon. Providing phosphate advice to patients in the upper range could prove beneficial, although the Renal Registry reported that all centres had difficulty reducing high serum phosphates.

6 Serum Albumin levels (g/l)

The 'Recommendation' in the Renal Association Guidelines is: -

- *To be within the normal range quoted by the local pathology laboratory. For Haemodialysis patients this should be the target after 6 months on regular Haemodialysis* (1, 26). *For patients on Peritoneal Dialysis the serum albumin should be within local normal range for at least 70% of patients* (1, 32).

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

The local normal range for serum albumin in this renal unit is 32 – 46g/l

7 Serum iPTH level (ng/l)

The 'Recommendation' in the Renal Association Guidelines is: -

- *iPTH should be maintained at between 2 and 3 times the local normal range* (1, p27&32)

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

The target iPTH for dialysis patients in this renal unit is 100 – 200ng/l as per the Renal Bone Disease Protocol. The last iPTH within 6 months of the audit was used.

8 Serum Cholesterol level (mmol/l)

Whilst there is no recommendation in the Renal Association Guidelines regarding cholesterol, this data is collected and analysed by the Renal Registry. The main issue raised by the first audit was non-recording/non testing and this was subsequently addressed. The last result within one year of the audit period was used.

Data on statins (cholesterol- lowering drugs) was collected at re-audit for the first time; only 3 Haemodialysis patients out of 34 with cholesterol greater than 5.0 mmol/l and 12 out of 46 Peritoneal Dialysis patients were on statins.

Whether it is useful to measure and/or treat raised plasma cholesterol and triglyceride concentrations in dialysis patients have not been tested by clinical trial. Until this information is available, fasting plasma cholesterol, HDH, LDL and triglycerides should be measured at least annually to allow correlation with cardiovascular disease and outcome.

The Renal Registry uses 5.2mmol/l as its cut-off point for acceptable cholesterol; 69% Haemodialysis and 44% Peritoneal Dialysis patients were at this level or below. For this renal unit 59.7% Haemodialysis, patients and 33.8% Peritoneal Dialysis patients were at 5mmol/l or below.

9 Corrected Serum Calcium (mmol/l)

The 'Recommended standard' in the Renal Association Guidelines is: -

- *Total calcium to be within normal limits quoted by the local laboratory, corrected for serum albumin concentration. (1, p27&32*)

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

10 Calcium phosphate product

In renal failure, high phosphate and poor absorption of calcium are the leading causes of renal bone disease. There is no recommendation in the Renal Association Guidelines or the Renal Registry for calcium phosphate product, however, the local Bone Disease protocol states that the calcium phosphate product should ideally be less than 5.0 mmol/l. This was calculated using the mean phosphate and the last corrected calcium recorded within the audit period. See Appendix F for details of this protocol

11 Mean Blood Pressure

The 'Recommended Standard' in the Renal Association Guidelines is: -

- *Age<60: BP<140/90 mmHg (Korotkoff V if auscultation is used)*
- *Age>60: BP<160/90 mmHg (" " ") (1, p26)*

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

Since blood pressure can vary considerably, a mean was calculated using all results from the audit period. For most Haemodialysis patients there were approximately 40 results. The Home Haemodialysis patients were contacted by their named nurse who recorded the data over the telephone. Peritoneal Dialysis patients may have had only 3 results as generally they are seen on a monthly basis.

12 Number of dialysis sessions per week - Haemodialysis

The 'Recommendation' in the Renal Association Guidelines is: -

- *For the adoption of thrice weekly dialysis sessions as a minimum in the majority of patients. The presence of significant residual renal function (glomerular filtration rate 5-10 ml/min) must be demonstrated in each patient if twice-weekly sessions are imposed. (1, p24)*

Strength of Evidence (C) - evidence is obtained from expert committee reports or opinions, and/or clinical experience of respected authorities. This grading indicates an absence of directly applicable studies of good quality

13 Urea Reduction Ratio (URR) - Haemodialysis

The 'Recommended MINIMUM standard' in the Renal Association Guidelines is: -

- *Stable URR>65%.* (1, p23)

14 Clearance studies - Peritoneal Dialysis (CAPD)

The 'Recommendation' in the Renal Association Guidelines is: -

- *A total weekly creatinine clearance of 50l/wk/1.73m^2 for patients on CAPD.* (1, p35)

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

15 Clearance studies - Peritoneal Dialysis (APD)

The 'Recommendation' in the Renal Association Guidelines is:-

- *A total weekly creatinine clearance of >60l/wk/1.73m^2 for APD patients.* (1, p35)

Strength of Evidence (C) - evidence is obtained from expert committee reports or opinions, and/or clinical experience of respected authorities. This grading indicates an absence of directly applicable studies of good quality

The Renal Association Guidelines 'Recommendation' is for either creatinine clearance or KT/V. As the focus in the Peritoneal Dialysis department in the renal unit at the centre of this audit is on creatinine clearance, this is the data that has been used.

16 Creatinine Clearance and/or Kt/V frequency - Peritoneal Dialysis

The 'Recommendation' in the Renal Association Guidelines is: -

- *For clearance studies to be checked 6-8 weeks after beginning dialysis and repeated at least annually.*

Strength of Evidence (B) - well conducted clinical studies, but no randomised clinical trials; evidence may be extensive but essentially descriptive

17 Peritoneal Equilibration Test (PET) frequency – Peritoneal Dialysis

The 'Recommended Standard' in the Renal Association Guidelines is: -

- *For a PET to be performed after 4-8 weeks on dialysis, when clinically indicated and annually as routine. (1, p33)*

2.5. Selection of patient sample

The patient sample of the first audit consisted of all patients on dialysis between 1st October 1998 to 31st December 1998 according to the local computerised unit administration system - the Renal Administration Management System (RAMS). The second audit covered of 1st October 1999 to 31st December 1999. In arriving at the final patient sample a number of patients were excluded as shown in Table 1 below. This table shows that 60 (32%) were excluded from the haemodialysis group and 19 (21%) were excluded from the peritoneal dialysis group of patients in the first audit. Reasons for their exclusions were that they were unsuitable (see section 2.5 for details of criteria), had died or had received a transplanted kidney during this audit period. Patients whose medical records were unavailable for this audit were also excluded for the obvious fact that no data was available for comparison.

Table 2 shows the patient sample from the second audit period of 1st October 1999 to 31st December 1999. These patients again were identified from the Renal Administration Management System (RAMS) as receiving dialysis at the start of this audit period. Just over 22% of Haemodialysis patients were excluded from the sample and nearly 24% of peritoneal dialysis patients. However, from this group of excluded patients, the notes of 3 patients were unavailable for this re-audit, whereas the remaining excluded patients were excluded in accordance with the Renal Registry guidance on sampling.

The patient sample is a rolling one and this must be borne in mind when making comparisons over the two audit periods. The Haemodialysis sample of 154 patients in the second audit included 87 (56.5%) whose care had been audited in 1998. It might be expected that the Peritoneal Dialysis population would be a more stable one, as such patients tend to be younger and fitter. The fact that the Peritoneal Dialysis sample of 77 in the second audit included 49 (63.6%) from the previous year would seem to support this.

2.6. Exclusion criteria

Patients who were excluded from the audit for various clinical and functional reasons. These were:

- **Patients who had been on dialysis less than 90 days**. The UK Renal Registry excluded patients who had '*been on End Stage Renal Failure (ESRF) treatment for less than 90 days*'. The UK Renal Registry's exception which we followed was that if the patient 'transferred in' during the 3 month audit period, then they were assumed to have been on ESRF treatment earlier than this elsewhere (2, p.196).

- In line with the UK Renal Registry, **patients who had 'transferred out'** or stopped treatment without recovery of function before the end of the quarter were excluded (2, p.196)

- **Patients whose records were unavailable for the audit**. In the first audit, the notes 15.6% of Haemodialysis patients and 6.7% of peritoneal dialysis were unavailable. This was partly due to the retrospective nature of the audit. An improvement in the methodology (i.e. a more prospective approach) was applied at the second audit and Table 2 concurs a reduction in this category.

2.7. Data collection, analysis and feedback

Ethical approval was not required from the appropriate body (Medical Ethics Committee of the local NHS Trust), as the project did not cover patient surveying or research into treatment issues. As good practice in auditing involves an element of pre-testing; a pilot data collection was carried out over 10 sets of patients' notes. This included five sets of records from Haemodialysis patients and five from Peritoneal patients. In doing so, minor flaws in the design of the data collection sheets were noted. These mostly involved the order in which data was collected and subsequently the forms were re-designed in accordance with accessibility to certain information groupings held in the patients' records.

The primary sources of data were the patients' medical notes, nursing notes and other dialysis charts that are used in the Renal department for routine recording of data. Where the information was not available on record (specifically, height, smoking status and blood pressure data) it was obtained directly from patients by the appropriate nursing staff. A combined data collection form can be found in *Appendix A*; in practice this was tailored to the individual modality.

Manual collection of data proved very time consuming, approximately 16 person days in total. The data collectors also had to cover two satellite units within a radius of 35 miles of the main renal unit and were not initially familiar with the filing of records in all of these areas.

Data was entered directly by the Renal Audit team and basic analysis undertaken using Excel 97. This method was used in preference to that in the original audit (i.e. data entered manually via the Clinical Audit Department and analysed using the Statistical Package for the Social Sciences) for the following reasons:

- the Renal team now had experience of the audit
- familiarity with the data meant that inconsistencies and anomalies could be readily spotted
- easy access to the data if it was all held in the one department
- more efficient use of time and financial resources

Data was analysed according to whether the Renal Association recommended standards or recommendations were met. Since these are set as a minimum to be achieved, where local (higher) standards were in place (e.g. for haemoglobin levels) performance was also measured against these. Where available, comparative figures from the original audit in 1998 have been tabulated. A summary of comparative results can be found in table 6.

In the case of Haemodialysis patients for whom the relevant standard or target was not achieved, the data was further analysed according to the area of treatment in an attempt to highlight any inconsistencies in practice

between modalities and to take into account the differences in patient mix. The numbers of non-achievers have been expressed as a percent of the total patients per treatment centre.

The summary of comparative results (table 6) gives a useful over-view and highlights the improvements made in the year following the initial audit. However, it could be argued that the ultimate comparison is between actual performance and the very best that could be achieved for any given *individual* patient at any one time.

Chapter 3 – Results

Discovery consists of seeing what everybody has seen and thinking what nobody has thought.
- Albert Szent-Györgyi (1893–1986) The Scientist Speculates

3.1. Patient sample

The Renal Administration Management System (RAMS) identified the sample for both the first and second audit cycles. There were a number of exclusions from the audit (i.e. the inspection of medical notes) and these are detailed in the following tables.

A total of 125 patient's records from the Haemodialysis patient group were available for the first audit. This represents 67.6% of the total registered on the RAMS system. For Peritoneal Dialysis patients, 70 (78.7%) constituted the final patient sample from an original population of 89 patients

	Haemodialysis		Peritoneal Dialysis	
	Number	Percentage	Number	Percentage
Original patient sample	**185**		**89**	
Exclusions (see section 2.5)				
Unstable	19	10.3%	9	10.1%
Died or Transplanted within audit period	12	6.5%	4	4.5%
Sub total exclusions	**31**	**16.8%**	**12**	**14.6%**
Unavailable records				
Died or Transplanted after audit period	15	8.1%	2	2.2%
Unavailable records	14	7.5%	4	4.5%
Sub total unavailable records	**29**	**15.6%**	**6**	**6.7%**
Total exclusions/unavailable records	**60**	**32.4%**	**19**	**21.3%**
Final patient sample	**125**	**67.6%**	**70**	**78.7%**

Table 1 - sample size (first audit cycle 1/10/98 - 31/12/98)

The UK Renal Registry excluded patients who had '*been on End Stage Renal Failure (ESRF) treatment for less than 90 days*'. The UK Renal Registry's exception which was followed was that if the patient 'transferred in' during the 3 month audit period, then they were assumed to have been on ESRF treatment earlier than this elsewhere (2, p.196).

Patients who had 'transferred out' or stopped treatment without recovery of function before the end of the quarter were excluded (UK Renal Registry 2, p.196) from the sample and thus were excluded from the audit.

Those patients whose records were unavailable for the audit were not included. In this first audit, the notes 15.6% of Haemodialysis patients and 6.7% of peritoneal dialysis were unavailable. This was partly due to the retrospective nature of the audit. An improvement in the methodology (i.e. a more prospective approach) was applied at the second audit and Table 2 concurs a reduction in this category.

In the second audit period, a greater proportion of the notes from original patient sample were examined compared to the first audit period. In total, the notes of 154 Haemodialysis patients (77.3% of the total population) were examined. For Peritoneal Dialysis patients, a similar proportion 77 out of 101 (76.7%) were examined.

Of these eligible patients, the notes of three Haemodialysis patients were unavailable for this second audit.

	Haemodialysis		Peritoneal Dialysis	
	Number	Percentage	Number	Percentage
Original patient sample	**199**		**101**	
Exclusions (see section 2.5)				
Unstable	21	10.6%	16	15.9%
Died or Transplanted within audit period	21	10.6%	8	7.9%
Sub total exclusions	**42**	**21.2%**	**24**	**23.8%**
Unavailable records				
Died or Transplanted after audit period	2	1.0%	0	0
Unavailable records	1	0.5%	0	0
Sub total unavailable records	**3**	**1.5%**	**0**	**0**
Total exclusions/unavailable records	**45**	**22.7%**	**24**	**23.8%**
Final patient sample	**154**	**77.3%**	**77**	**76.2%**

Table 2 - sample size (second audit cycle 1/10/99 - 31/12/99)

3.2. Demographics

Tables 3 and 4 shows the demographic details of the two-sample group. In accordance with the Renal Association Guidelines the patients were divided into two distinct age ranges of 60 years and above and below 60 years. As hypertension is common in chronic renal failure and End Stage Renal Failure, the care of high blood pressure is of increasing importance in this patient group. The recommended standard in by the Renal Association states that those patients below 60 years of age should have a target blood pressure reading of less than 140/90 mmHg. In the 60 years and above group, the standard recommended target blood pressure is set as less than 160/90 mmHg.

Group	**Haemodialysis**		**Peritoneal Dialysis**	
No. of patients	125		70	
Sex (M:F)	73:52		43:27	
Age (yr.)				
	n	***%***	**n**	***%***
Below 60 years of age	65	*52.0*	32	*45.7*
60 years of age and above	60	*48.0*	38	*54.3*
Diagnosis, no. of cases (%)	**n**	***%***	**n**	***%***
Small scarred kidneys	20	*16.0*	21	*30.0*
Glomerulonephritis	17	*13.6*	11	*15.7*
Pylonephritis	15	*12.0*	3	*4.3*
Diabetes	15	*12.0*	8	*11.4*
Polycystic	7	*5.6*	10	*14.3*
Others	34	*27.2*	14	*20.0*
Not recorded	17	*13.6*	3	*4.3*

Table 3 - demographic and baseline clinical data (first audit cycle 1/10/98 - 31/12/98)

The distribution between the sexes mirrors that in the Renal Registry. There were more males in both groups, but with a greater preponderance of males in the higher age group despite the greater proportion of women in the older general population. The mean age of Haemodialysis patients was 66 years, slightly older than the Renal Registry median for England and Wales (62years). The corresponding ages for Peritoneal Dialysis were 61 years and 59 years. Patients were also split into two age groups as determined by the Renal Association guidelines (1998). These age groups were necessary in the further analysis and comparisons regarding blood pressure.

Group	**Haemodialysis**		**Peritoneal Dialysis**	
No. of patients	154		77	
Sex (M:F)	87:67		53:24	
Age (yr.)				
	n	***%***	**n**	***%***
Below 60 years of age	54	*35.1*	34	*44.2*
60 years of age and above	100	*64.9*	43	*55.8*
Diagnosis, no. of cases (%)	**n**	***%***	**n**	***%***
Small scarred kidneys	32	*20.8*	22	*28.5*
Glomerulonephritis	22	*14.3*	16	*20.8*
Pylonephritis	19	*12.4*	6	*7.8*
Diabetes	21	*13.6*	11	*14.3*
Polycystic	10	*6.5*	9	*11.7*
Others	50	*32.4*	13	*16.9*
Not recorded	0	*0*	0	*0*

Table 4 - demographic and baseline clinical data (second audit cycle 1/10/99 - 31/12/99)

In the first audit cycle, Haemodialysis patients were treated as an homogenous sample, whereas in fact the patient mix varies according to the treatment centre. As a generalisation, those patients having Haemodialysis in the main renal unit at the Hospital would have the greatest degree of dependence on nursing staff and those dialysing at home the least. Satellite Unit W is situated within an acute district hospital; it is able to cater for more unwell patients than the Satellite Unit B which is annexed to a cottage hospital. Table 5 shows the number of haemodialysis patients at the main and the various satellite units for the second audit. Data on the number of haemodialysis patients in satellite for the first audit was not available at time of writing.

Treatment Centre	**Number of patients**
Main Hdx Unit	60
Satellite Unit W	17
Satellite Unit B	29
Home Hdx	48
Total	**154**

Table 5 - distribution of Haemodialysis patients by treatment centre

Data was collected about transplant status for the second audit period. The results can be seen in Table 6.

	Haemodialysis		Peritoneal Dialysis	
	Number	Percentage	Number	Percentage
Patient sample	**154**	**100.0%**	**77**	**100.0%**
Patients not on transplant list - reasons				
Patient refusal	5	3.2%	6	7.8%
Medical refusal	28	18.2%	3	3.9%
Work up in progress	8	5.2%	11	14.3%
Unknown	79	51.3%	37	48.0%
Total patients not on transplant list	**120**	**77.9%**	**57**	**74.0%**
Patients on transplant list	**34**	**22.1%**	**20**	**26.0%**

Table 6 - Patients on transplant list - second audit

Data on reasons for patients not being on the transplant list were collected for the first time at the second audit cycle, as it had been noted from the first audit cycle that there was a relatively high proportion (84% irrespective of modality) not on the list. From subsequent discussions and investigations it was evident that in many cases the reasons were obvious and well known to staff and patient; nevertheless there was a need for these to be properly documented.

3.3. Comparison to the renal standards

The following two tables area summary of the percentage of patients achieving minimum standards or target ranges for the first audit period. Table 7a shows the results of the audit from the haemodialysis patients, whereas table 7b shows the results from those patients receiving peritoneal dialysis. The full explanation of the standards and the sources are detailed in Chapter 2 of this dissertation. More detailed results are to be found in Appendix E. The Renal Association has set either 'Recommended Standards' where the available evidence is deemed to be strong or 'Recommendations' where the available evidence is weaker or speculative. These are indicated in the column headed 'Source'. The number in the left-most column refers to the number of the standard, which is indicated in section 2.4. A comparison is made against the results from the Renal Registry Report of the findings of nine renal units in England and this is seen in the last column of the tables.

There were two standards in which the Renal Association stipulated targets. A target of 85% or more of patients were expected to reach Haemoglobin levels of ≥10g/dl in both haemodialysis (standard no. 1) and Peritoneal Dialysis groups. Similarly the Renal Association set a target of 70% or more for Albumin levels (standard no. 6).

No.	**Standard**	**Source**	**Percentage of patients achieving recommendation or recommended standard - Haemodialysis**		*Reported results from the Renal Registry (1998 activity)*
			First Audit	**Second Audit**	
1	Haemoglobin ≥10g/dl	Renal Association Guidelines Recommendation	61.6%	70.8%	*69%*
2	Ferritin 100umol/l	Renal Registry Recommendation	72.0%	78.6%	*84%*
3	Potassium *4.0 - 5.5 mmol/l*	Renal Association Guidelines Recommended standard	66.4%	72.7%	*no valid comparison*
4	Bicarbonate *22-30mmol/l*	Renal Association Guidelines Recommended standard (refers to local normal ranges)	0.8%	51.9%	*57% (Hospital Hdx)*
5	Phosphate 1.2- 1.7 mmol/l	Renal Association Guidelines Recommended standard	27.2%	37.7%	*30.0%*
6	Albumin *32-46 g/dl*	Renal Association Guidelines Recommendation (refers to local normal ranges)	82.4%	79.9%	*no valid comparison*
7	iPTH 100-200ng/l	Renal Association Guidelines Recommendation (refers to local normal ranges)	16.8%	23.4%	*no valid comparison*
8	Cholesterol *≤5.0mmol/l*	Renal Registry Recommendation	not reported	59.7%	*69%*
9	Calcium *(2.25-2.65 mmol harmonized)*	Renal Association Guidelines Recommended standard	65.6%	59.8%	*70%*

No.	Standard	Source	Percentage of patients achieving recommendation or recommended standard - Haemodialysis		*Reported results from the Renal Registry (1998 activity)*
			First Audit	**Second Audit**	
10	Calcium Phosphate product *<5.0 mmol/l*	*Local Renal Bone Disease Protocol*	55.2%	64.9%	*no valid comparison*
11	Blood Pressure	Renal Association Guidelines Recommended standard			
	Age>60:<160/90m mHg		71.0%	77.0%	*60.0%*
	Age<60:<140/90m mHg		37.5%	42.6%	*40.0%*
12	3 dialysis sessions per week	Renal Association Guidelines Recommendation	86.4%	89.0%	*no valid comparison*
13	Adequacy URR>65%	Renal Association Guidelines Recommended standard	16.8%	36.4%	*57% (Hospital Hdx)*

Table 7a - summary of results from both audits for Haemodialysis patients

No.	Standard	Source	Percentage of patients achieving recommendation or recommended standard - Peritoneal Dialysis		*Reported results from the Renal Registry (1998 activity)*
			First Audit	**Second Audit**	
1	Haemoglobin ≥10g/dl	Renal Association Guidelines Recommendation	81.4%	84.4%	*78%*
2	Ferritin 100umol/l	Renal Registry Recommendation	64.3%	76.6%	*81%*
3	Potassium *3.2 - 5.5 mmol/l*	Renal Association Guidelines Recommended standard	90.0%	90.9%	*no valid comparison*
4	Bicarbonate *22-33mmol/l*	Renal Association Guidelines Recommended standard (refers to local normal ranges)	77.1%	77.9%	*81.0%*
5	Phosphate *1.2- 1.7 mmol/l*	Renal Association Guidelines Recommended standard	54.3%	49.3%	*40.0%*
6	Albumin *32-46 g/dl*	Renal Association Guidelines Recommendation (refers to local normal ranges)	81.4%	67.5%	*no valid comparison*
7	iPTH 100-200ng/l	Renal Association Guidelines Recommendation (refers to local normal ranges)	22.9%	18.2%	*no valid comparison*
8	Cholesterol *≤5.0mmol/l*	Renal Registry recommendation	Not recorded	33.8%	*44%*
9	Calcium *(2.25-2.65 harmonized)*	Renal Association Guidelines Recommended standard	64.3%	62.3%	*74%*
10	Calcium Phosphate product *<5.0mmol/l*	*Local Renal Bone Disease Protocol*	85.7%	89.6%	
11	Blood Pressure Age>60:<160/90mmHg Age<60:<140/90mmHg	Renal Association Guidelines Recommended standard	 75.6% 37.9%	 88.4% 50.0%	 *68.0%* *49.0%*
14	Adequacy ≥ 50 litres /week	Renal Association Guidelines Recommendation	74.5%	93.3%	*no valid comparison*
15	APD: CC 60l/week	Renal Association Guidelines Recommendation	43.5%	58.8%	*no valid comparison*
16	Creatinine Clearance and/or Kt/V frequency	Renal Association Guidelines Recommendation	93%	100%	*no valid comparison*
17	Peritoneal Equilibration Test frequency	Renal Association Guidelines Recommended standard	87%	99%	*no valid comparison*

Table 7b - summary of results from both audits for peritoneal dialysis patients

3.4. Summary of differences between the two audit periods

The initial baseline data collected at the first audit suggested the under-recording of many biochemical measurements in the patients' notes, especially bicarbonate serum levels, iPTH and Ferritin. The results also show that, compared with averaged results from the Renal Registry's 1998 Report, certain blood analyses were well within targeted ranges for those patients receiving peritoneal dialysis. These were Haemoglobin and Phosphate levels together with mean Blood pressure. However, there were many areas in which performance was below that of the Renal Registry averaged results. These are highlighted in the discussion section of this dissertation as areas to concentrate on, especially those measurements where insufficient data was available to make a valid comparison.

More favourably the number of haemodialysis patients reaching adequacy in the form of Urea Reduction Ratio more than doubled from 16.8% to 36.4% over the two audit periods. Intrinsic improvements included a streamlined data collection process, in-house data input analysis, a focus on anaemia management and the introduction of inter-modality analysis.

One major finding of the audit was that data was recorded in a variety of locations and differing media, which together made a composite patient record. Information containing the results of dialysis was therefore difficult to collate as a result. This point is discussed in more detail in the following chapter.

Recording of Haemoglobin (Hb) levels improved to 100% for both Haemodialysis and Peritoneal Dialysis patients as a result of being highlighted at the first audit. Proportionately more Unit Haemodialysis patients were "underachieving" than those treated elsewhere. This was not unexpected, as they tend to be the more unwell patients, but nevertheless indicates where attention should be directed.

Haemoglobin levels improved over the audit periods in both Haemodialysis and Peritoneal Dialysis, although there was less scope for improvement in Peritoneal. Whilst still some way short of the Renal Association's recommendation, performance was better than the average according to the Renal Registry. The target range for Haemoglobin according to the Hospitals own EPO protocol is 11-12.5g/dl and this proved hard to achieve, with the target attained in only 41.6% Haemodialysis and 62.3% Peritoneal Dialysis patients.

With regards to Albumin levels, 19 out of the haemodialysis patients in the lower range were not receiving Nutrineal (an amino acid based solution used when patients have protein-calorie malnutrition). Moreover, six out of the patients is this lower range had been admitted to the Renal Ward for between 1 day and eighteen days during the audit period and 4 patients in the lower range had peritonitis during the audit period.

Since the first audit, the peritoneal department has joined the Solution Registry - a European Baxter initiative that issues annual reports (currently awaited) and this will provide a means of monitoring the efficacy of Nutrineal on Peritoneal Dialysis patients.

Data on statins (cholesterol- lowering drugs) was collected at the second audit for the first time; only 3 Haemodialysis patients out of 34 with cholesterol of greater than5.0 mmol/l and 12 out of 46 Peritoneal Dialysis patients were on statins. Whether it is useful to measure and/or treat raised plasma cholesterol and triglyceride concentrations in dialysis patients have not been tested by clinical trial. Until this information is available, fasting plasma cholesterol, high-density lipoproteins (HDL - a complex of lipids and proteins that functions as a transporter of cholesterol in the blood), low-density lipoproteins (LDL) and triglycerides should be measured at least annually to allow correlation with cardiovascular disease and outcome. (Renal Registry, 1998)

3.5 Evaluation and recommendations

Once the results were analysed and tabulated, a series of presentations were given to the members of the renal unit. The details of results from the previous sections above were presented systematically. There were several actions taken as result of the presentations and are listed below. In summary those patients who had low levels (in other words 'not achieving' or not reaching the recommendation by the Renal

Association) were identified and their details given to the appropriate member of the renal unit or the team dealing with that particular area of medical need. For example, patients with low potassium levels were referred to the renal dietician - a member of the renal team specialising in nutritional needs for renal patients. Other actions included the revising or creating a protocol where the existing one was felt to be inadequate or where there was none at all. Similarly changes to the infrastructure was called for. Hospital portering was requested to be available for 'late-in- the-day' blood results to be taken to the laboratories. There was some feedback into the audit loop. For example where it was felt that the existing recommendation from the Renal Association was inconsistent.

Appendix C and appendix D give details of the action plan and the time scales as a result of both audits. The following shows in more detail the results of the discussions following the audit presentation

Haemodialysis

- Haemoglobin

The renal unit identified those patients with a low Haemoglobin level who had been on receiving erythropoietin (EPO) therapy for more than 12 weeks. These details were given to the EPO co-ordinator within the Unit. Similar action was taken with those patients with a low Haemoglobin level who had been on not been receiving EPO therapy

- Ferritin

The renal unit identified those patients who had been receiving EPO therapy for more than 12 weeks with a low Ferritin count. Also identified were patients who had been on EPO for more than 12 weeks and had not had a Ferritin recorded within 9 months of the audit period.

- Biochemical Profiles

With regards to Phosphate, Calcium and Potassium, inconsistencies were noted in the targets set by the Renal Association Guidelines (1997), Renal Bone Disease Protocol (Appendix F) and the Dieticians / Renal Consultants protocol (1998).

A decision was made for Renal Consultants to review the Potassium levels, and to amend the local protocols. This would impact on the Renal Standards Group, to update and to make changes and to include them in the Renal Specific Policies and Procedures ("purple") folder

- Potassium

Patients with low and high Potassium levels were identified and details were given to the Renal Dietician. It was suggested that a random of pre and post dialysis Potassium levels were taken to check that the post dialysis Potassium levels are not unacceptably low

- Phosphate

Patients with a low phosphate were identified and details given to Dieticians. A suggestion to the reason for the relatively high proportion of Home Haemodialysis patients with a good Phosphate levels, were that this groups of patients were comparatively healthy and had a better diet than that of other Haemodialysis patients.

- Calcium / Phosphate product

Patients with a high calcium or phosphate product levels were identified and their details given to the renal dietician. It was decided that those patients with extremely high levels should have the intervention of a renal consultant.

- Albumin

Those patients in the lower range were identified and details given to senior nursing staff and renal dietician. It was decided that a check was made to ensure that these patients are not being systematically under-dialysed. This may include referral to the dietician or senior medical staff.

- iPTH

There was a slight improvement in the number of iPTH results recorded over the two audits but there remained a problem with getting blood samples to the laboratory .for "twilight" patients. It was suggested that such tests could perhaps be best done through outpatients' clinics. A decision was made to arrange with the hospital porters to transport samples to the laboratory during this time.

- Bicarbonate

It was agreed following the presentation to develop a simple protocol for patients with low bicarbonate levels. At time of writing this has still to be done but will be presented to the Renal Standards Group and then into the 'Purple Folder'

- Cholesterol

Patients with high cholesterol were identified and it was noted that only a low proportion were on statins. These patients were identified and referred to senior medical staff for further treatment.

- Urea Reduction Ratio (Haemodialysis)

It was suggested that patients who were not reaching the level of 65% should be discussed in the regular modality meetings. This was a practice already implemented main Unit Haemodialysis. However those receiving dialysis at home or at a satellite unit were not represented at the modality meeting.

- Creatinine Clearance (Peritoneal Dialysis)

Patients with a low creatinine clearance between 50 – 60 l/week/BSA were to be identified and their regime changed.

Chapter 4 – Discussion

'One must never lose time in vainly regretting the past nor in complaining about the changes which cause us discomfort, for change is the very essence of life.'

- Anatole France (1844–1924). Attrib.

4.1. Where things went right, where they went wrong

The project achieved its first two objectives of measuring performance against that advocated by the Renal Association and the initial audit. This is tabulated under the various criteria headings in the previous chapter and summarised in table 7, which also gives the corresponding results from the most recent Renal Registry Annual Report (December 1999, referring to activity in 1998). Direct comparisons cannot be made due to the rolling patient population and so it is difficult to show differences in measurement of biochemical data. In renal medicine, patients often transfer across modalities from haemodialysis to peritoneal dialysis, leave the system through improvement, transplantation or sadly die or move out of the area. So continuous tracking of patients can never be achieved using current systems. Nevertheless there has been an improvement over the audit period in terms of percentage achieving a given standard or target, except:

- Phosphate, where the percentage of patients achieving normal range in Peritoneal Dialysis dropped from 54.3% in 1998 to 49.3% in 1999.Control of phosphate was discussed at the multidisciplinary meeting and the local targets recommended for review. The Renal Registry reported that all centres had difficulty reducing high serum phosphates and there is some debate as to whether the current Renal Association standard is achievable or even sufficiently evidence-based.(1998)

- Albumin levels, where there was a drop of 2.5% in Haemodialysis .The 13.9% drop in patients achieving the normal range in Peritoneal Dialysis may be accounted for, in part, by ward admissions and peritonitis during the audit period, data for which was not collected during the first audit. All underachieving patients were identified to the area manager for follow-up. The Renal Registry acknowledges that measurement of serum albumin remains a complex methodological issue in renal failure and also creates interpretative difficulties with calcium measurement. As a result of activity taken by the Renal Registry, the Association of Clinical Biochemists has instigated a national audit of laboratory reference ranges to address these problems. In response to this it is proposed to review the local ranges of Albumin levels and if appropriate change local guidelines.

- Of those patients receiving peritoneal dialysis, 18.2% achieved a normal range of their iPTH levels in the second audit as opposed to 22.9% in the first. The existing arrangements for transporting iPTH samples to the laboratory for patients on "twilight" Haemodialysis (dialysis performed at the renal unit but significantly out-of-normal-hours) is also under review.

- The normal range for corrected calcium was achieved by a lower percentage of patients in both Haemodialysis and Peritoneal Dialysis; nevertheless there was an overall improvement as regards Calcium phosphate product across the modalities.

An Excel database has been maintained and extended within the renal unit as a readily accessible resource. Blood pressure data has been utilised, resulting in a publication in the American Journal of Kidney Disease. (Bandyopadhyay et al, 2000)

Actions proposed following the initial audit have been implemented as regards promoting and maintaining a high profile of standards and audit amongst the staff in the renal unit. This has contributed to the improvement in performance since the initial audit in 1998, helped by a considerable reduction in the number of staff vacancies in haemodialysis.

Specifically, the Renal Audit staff and Education/Practice Development Nurse are contributing to the induction programme for new staff, teach on the Renal Module and in the Renal Staff Education Forum. The importance and role of audit, together with the standards are emphasised and their implications for practice discussed, resulting in an increased awareness of the need to monitor performance.

4.2. Can Clinical Practice Guidelines change behaviour?

The effective practice of shifting the behaviour of clinicians will depend largely on the use of clinical benchmarks and standards to reach judgements about the quality and appropriateness of clinical activity. (Mays 1995) The development and application of such standards create a number of problems and challenges ranging from the technical to the cultural. In the former category it will be necessary to be alert staff to the pitfalls associated with "auditits" – a condition that is recognised by a tendency to equate the quality of care with the success or otherwise of a "medico-technical episode" that is often buried in a longer care experience. At the less technical end of the spectrum, there is a need to guard against the temptation to forget that while "outsiders" can bring about changes in clinical practice, only clinicians are in a position to *improve* it – a difference that is as much about attitudes as about measurement.

All these changes depend significantly on major shifts in the attitudes and behaviour of clinicians. In the absence of a comprehensive, sustained and thought-through programme of professional development, focused on the relevant clinicians, these changes in attitude and behaviour are unlikely to be forthcoming. Berwick (1998) argues that by shifting the mental boundaries of clinicians and other healthcare professionals improvements to care can be made - but it is only through good leadership that this is a real and achievable goal.

Clinical Practice Guidelines are at the heart of this dissertation: - a set of recommendations and a yardstick for measurement to assist the renal unit in delivering adequacy of dialysis. But can guidelines truly change behaviour of the clinician or the renal nurse? In this section I will look at the evidence to support (or refute) this.

In an overview of strategies and interventions to change behaviour, Mays (1995) states that changing behaviour is important as the NHS is in a constant state of rapid change. It was also assumed (wrongly at the time) that any advances in scientific thought would automatically be assimilated in day-to-day practice. From 1991, the Research and Development programme ensured that decision making should be based on best available evidence. The two major initiatives were the UK Cochrane Centre at Oxford and the NHS Centre for Review and Dissemination in York. Nick Mays identifies the four areas that promote acceptance of change are: - the general environment, the characteristics of the change and its consequences, the characteristics of the health care professional at the receiving end of the change and, the local context in which the changes takes place.

In this study, it was found that health care professionals are generally not resistant to change, and through the form of continuous feedback in the regular team meetings and briefings, a channel of reception of new ideas has been opened up. Mays (1995) insists that clinical change through guidelines is a social process in which local, personalised influences operating through networks of similar, like-minded professionals are the most potent forces.

Mays states that having a successful strategy for change, involves a combination of a number of interventions which are sensitive to the local context, has embedded prompts to aid professionals and, are sustained over time. Oxman (1995) echoes this by emphasising that there really are "no magic bullets" for improving the quality of heath care and that a number of inventions should be used appropriately.

A far more rigid system has been described by Grol (1997) who theorises that change is driven by an internal striving for professional competence and that by developing and 'marketing' an attractive product, changing practice can be made accessible if not easier. Having a set of guidelines passed down from a national body (in this case the Renal Association and the Renal Registry) may not be an attractive proposition (i.e. a book of 'rules' or standards), but professional competence is certainly at the forefront of this renal unit. Grol's important message centres on creating the necessary conditions for change. Regular team meetings, the dissemination of results, plus the raising of the awareness of the guidelines do contribute to these conditions. Finally, Grol believes that no one method is superior in changing behaviour. Evidence-based practice should be complemented by evidence-based implementation and that

‘there are many approaches to changing clinical care…’. An interesting factor noted here in this audit was that the use of team meetings was the main method of ‘getting the message across’ no other communication methods were used, for example, handouts or similar.

However, in a systematic review carried out by Davis et al (1997), serious deficiencies were revealed in the adoption of clinical practice guidelines. In their report, didactic methods were not found to be effective. Practice and community-based derivation and dissemination were a much better approach. Methods such as the Internet, practice-linked computer strategies and reminder systems were more acceptable to the clinicians and nursing staff ‘at the coal face’. At a more fundamental level, the creation of guidelines without significant attention to their adoption, ‘ is a sterile exercise’.

Clinical audit or quality improvement studies involving the adequacy of renal dialysis seem to be rarely reported in the medical press. However two outstanding studies exist, one from the United States and the other, nearer to home, from the Scottish Renal Registry (1997). The latter reports (as in the England and Wales version (Renal Registry (1998)) data collection involving over 2305 patients. The report calls for more comparative audits between institutions and endorses the routine collection of results from other renal units. An interesting question raised here is the subject of the use of information technology to assist in the audit process to make it ‘comparatively simple and inexpensive’.

The Scottish Renal Registry reported that 74% of haemodialysis patients reached a level of 65% and above in urea reduction ratio (URR). This compares with 36% achieved in the current audit. They reported that all of the units ‘bar one’ had 82% of their patients attaining the minimum standard set by the Renal Association.

The study in the United States by Bennett et al (1997) also looked at the adequacy of dialysis. They state that by introducing “algorithms” in specific renal units, improvements in the Urea Reduction Ratio were noted over a period of time. They report that patients with a URR of greater or equal to 65% increased from a mean of 50% to a mean of 81.3% as a result of introducing the improvement efforts. These improvements stemmed from a series of clinical “algorithms” and were constructed following team meetings in the renal units and, by a system of continuous feedback, the results presented to teams of healthcare professionals. A series of nine principles of Continuous Quality Improvement (CQI) were formed and these are detailed in figure 2 below.

Principle 1 Engage a physician champion who possess… "profound knowledge"

Principle 2 Physician leadership is mandatory

Principle 3 Hire a full time quality director

Principle 4 Listen to the patient

Principle 5 Maintain a computer-based patient record

Principle 6 Make CQI an integral part of your everyday life

Principle 7 CQI in health care is the application of the scientific method to the business of medicine

Principle 8 Manage change in teams

Principle 9 Develop a learning organisation

Figure 2 - Nine principles of CQI as defined by Bennett et al (1997)

According to the authors these principles are "necessary for a successful CQI program (sic)". Comparing these to the organisation and the fabric of the hospital trust in which this audit was set, there are favourable and not so favourable comparisons. Within the renal unit there is a consultant nephrologist "in charge of audit". Whilst this is good in principle there is doubt whether this is a full-time position and has the requisite authority to spend resources on the effort of quality improvement. Principle 2 above speaks for itself although it was the Research and Audit Sister who initiated this work. In can be argued that nursing staff should have equal physician status.

There is a full time quality director (Principle 3) although this senior manager also has responsibility for nursing within the Trust. With regards to principle 4 there have been several local and national studies obtaining the views of patients and carers. For an example see O'Donnell (1999).

Principle 5 is where the current system fails to compare considerably. All patients' records, with exception of the specific dialysis measurements of patients on peritoneal dialysis, are held on paper and in separate places within and without the renal unit. Implications and suggestions for improvement are discussed in the next section. There are steps being taken to make CQI integral, as this audit project will be repeated on a regular basis. Teamwork is essential in making change happen and, as can be seen in Appendix C, team decisions and delegating have been made. Which leave us with Principle 9 – develop a learning organisation. If one counts the organisation as the renal unit plus its staff then the answer in the affirmative. As far as the remainder of the hospital trust there is quite a long way to go to achieve this but with the adoption of the preceding eight principles then one day this will happen. In an internal memorandum (Brighton Health Care 2000) about the development of protocols (a component part of the learning organisation?) this seems to support this.

> *All protocols must now go through our Renal Standards Group (RSG) where there is a representative from each dept, Education Development Nurse and Renal Audit Sister, we meet on a monthly basis. The revised Bone Disease and Dieticians protocol will go through the RSG. We have a special folder in each dept now for Renal Specific Policies and Procedures (we call it the purple folder), in this folder are policies that have been passed by the Policies group and are specific to Renal.*
>
> *The Renal specific ones do not go in the normal policies group files, as it is only us who are interested in them. Also in our purple folder go guidelines and doctors policies that do not go through the policies group*

but are reviewed and passed by the RSG. we now have Terms of Reference (TOR) and all know exactly what we are about.

These terms of reference can be found in Appendix G of this dissertation.

In conclusion, these nine principles help easily identify areas for quality improvement and help gather information for the analysis of performance for a unit, department or whole hospital.

4.3. Systems for data collection

One major problem uncovered by this audit was the inherent use of a paper-based system for the recording of regular (i.e. patient records) data. This meant that collection, collation and analysis for the purposes of specific study, audit and hospital statistics proved very difficult. A large amount of time was spent in finding information recorded in patient's notes, nursing records and separate sheets. The challenges uncovered by the audit team were that data was sometimes indecipherable, recorded in the "wrong place" or simply not recorded at all. Data collection for the purposes of audit could have been a far easier exercise if a better system of recording and storing data was used. This would benefit not only the audit described in this dissertation but for day-to –day operational usage by the renal unit. The following elaborates this with examples and practical uses of such systems in this section.

Ash et al (1991) have described a system within a dialysis unit and an outpatient dialysis practice, which recorded problems, therapies, and numerics associated with renal dialysis. This electronic record allowed historical data to be kept under one place, therapies to be described, "vital signs" and the biomedical results of dialysis to be stored electronically

Similarly Viglino (1998) and others from Italy report on the theoretical use of data storage in a renal dialysis unit. They argue that storing data for the sake of storage is of no use. Complete integration with the integration of the day-to-day use of the unit paramount, as is accessibility of this data to interested parties. They state that it will be "useful in routine operations, including checking the quality of work carried out, and in study and research". Ettari and co-workers (1994) present the case for electronic patients records with the stored data not only fulfilling the use of clinical data systems but also acting as an "optimiser" of dialysis machines and to plan expenses for the unit. Formica et al (1994) from Turin describe in more detail their version of the electronic dialysis record. They suggest that in the situation where a large registry of patients (over a large region) exists, computerised medical charts would benefit these units by acting as a form of "teledialysis". This would be useful in the more remote units of dialysis (such as the ones described in this dissertation) where results of dialysis could be sent to a centre for storage, analysis and research.

Further afield in North America, the use of electronic systems for the storage and retrieval of patient data has been in use for many years. Articles by Diaz-Buxo et al (1999) describe the use of an electronic "tool" in peritoneal dialysis. They suggest that poor recording of data of the peritoneal dialysis process may lead to inadequate dialysis and poor outcomes. A "memory card" was developed to be used at each visit to the dialysis clinic in order to record accurately these processes. Although this records the parameters associated with dialysis itself (solution transit time, drain time, automated exchanges etc.) it can be easily adapted to record the biomedical information necessary to record adequacy of dialysis. The authors claim that such information can be pooled via telecommunication links via a computer modem and thus compare results among patients and satellite units. Marichal et al (1995) also echo this idea of a "memory card"

Perhaps one of the most encouraging signs of the need to adopt of a computerised system comes from Croatia where Stosovic and others report on a database of haemodialysis (1996). They describe the need for "abandoning … conventional paper work" and suggest that dialysis presents a unique case for computerised storage. Data can be recorded for patient histories and dialysis records, history and current condition, laboratory analyses and therapy. This presents an ideal situation for rapid analysis, comparison and tabular presentation.

4.4. Answering the original question

As any mathematician will tell you, there are two sides of any equation, or a philosopher may cite yin and yang, representing nature's interacting dualities, There is more than one facet to the subject of dialysis.

Although this dissertation has concentrated on the technological side of dialysis, comparisons to a set of national guidelines and the electronic tools available to treat and record the results of dialysis, the human side of renal care must not be forgotten. The prevalence of chronic problems is the dark side of stunning improvements in the treatment of ESRD that nobody would want to reverse. But chronic illness contradicts at least one dream of advanced technology. Despite all of the technology available to help renal patients, these demand large blocks of time for unautomated human care (Tenner, 1996, p 69). Even advanced dialysis equipment needs skilled operators. Most of the burden of daily care falls upon spouses, adult children, and parents. This is the hidden side of renal disease not covered by this dissertation but is a cause worthy of future study.

In addition, a dialysis machine reduces the risk of kidney failure but adds a new risk that physicians and technicians may fail to make safe connections, test the haemodialytic solution or observe other standards of good practice. These are also areas not covered by the dissertation (although be it indirectly in the case of standards) and are also worthy of further study.

4.5. Conclusions and recommendations

This dissertation highlights areas where standards are being achieved and also those requiring attention. In general comparison fared well against both the results from the first audit and those from the 1999 UK Renal Registry Report. Direct comparison of biochemical data is not possible however, as the method of analysis used by each laboratory is different, although the UK Renal Registry has attempted to overcome this difficulty by harmonising their results. However, until there is the requisite IT facilities to enable the Unit to join the UK Registry, meaningful comparative audit against other renal units are not an option.

This audit was important to the renal audit because there is an ever-increasing emphasis on the measurement of quality of care and more importantly an improvement in the quality of care given to patients. In this renal unit no audit or study of this magnitude or importance had been carried out before and here was a golden opportunity.

Prior to this audit there was no formal mechanism for judging how well (or badly) the processes of dialysis (from the point of view of the patients blood results) were being delivered. Furthermore up to this point it was difficult to compare against other units or to use this information as a learning process.

The audit has enabled the various disciplines of the renal unit to meet at regular frequencies and to discuss the results of the audit process – something not done previously. This was the major ‘conduit’ into getting changes to practice introduced

The main changes in practice that have been proposed as result of the audit process are:

- Documentation in all patients’ medical notes of the outcome of discussions regarding transplantation
- The development of a protocol for the management of ferritin in patients who are not on EPO
- Gaining a consensus regarding Phosphate, Calcium and Potassium targets and incorporating these in to the appropriate protocols / guidelines
- The development of a protocol for the management of patients with a low serum bicarbonate
- Development of a Blood Pressure protocol
- Regular review of patients who are inadequately dialysed
- Easy access by all staff to relevant targets/standards

Details of how these changes will be implemented are set out in an action plan, which can be seen in Appendix C and D.

There is a need for the implementation of an easier and more acceptable method of data storage and data collection for the purposes of future audits and research. As indicated above, this is by no means an impossible feat and it is highly recommended that the renal unit invest some time and energy into carrying out a feasibility study to seek out a technology-based solution.

The re-audit was initially planned simply to complete the audit cycle. Against a background of increasing departmental interest in audit and comparative audit, the decision was taken to add it to the programme of systematic audits and to repeat it annually and update it as appropriate. The next audit period is therefore 1st October 2000 - 31st December 2000.

This project has raised awareness in the renal unit about the Renal Association Guidelines along with audit and clinical governance in general. They are fundamentally important if we are to give our patients the best possible care. Standards and audit are now routinely recognised and promoted in this renal unit.

Despite the absence of a decent data storage system, the requirements of health care and the conformance to standards ensure that quality inspections for the good of the patient are still being and, should be, carried out. As we know, the quest for perfection continues. As Einstein once stated *"The important thing is not to stop questioning. Curiosity has its own reason for existing"*. (WGBH Educational Foundation.2000)

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Appendix A - Data Collection Form

Haemodialysis and Peritoneal Dialysis audit per Renal Association Guidelines

Patients Surname _____ Forename _____

K number_____

On transplant waiting list?

Yes ∏ No ∏

If no: Not discussed ∏ Patient Refused ∏ Medical refusal ∏

Work up in progress ∏ Unknown ∏

Height (Meters)_____Weight (Kilograms)_____

Primary Renal diagnosis code (*see reference sheet*)

A ∏ B ∏ C ∏ D ∏ E ∏ F ∏

G ∏ H ∏ I ∏ J ∏

specific diagnosis _____

Co morbidity (*see reference sheet*)

Yes ∏ No ∏

If Yes, please specify: -

A ∏ B ∏ C ∏ D ∏ E ∏ F ∏

G ∏ H ∏ I ∏ J ∏ K ∏ L ∏

M ∏ N ∏ Oa ∏ Ob ∏

Parathyroidectomy

Yes ∏ Date_____/_____/_____

No ∏

Hdx Site Unit HDX ∏

Home HDX ∏

Bexhill Satellite HDX ∏

Worthing Satellite HDX ∏

HDX Dialysate type	
884	
885	
886	
887	

Number of sessions per week 1 ∏ 2 ∏ 3 ∏ other ∏ *please specify*

Number of hours per session : 3 ∏ 3.5 ∏ 4 ∏ 4.5 ∏ other ∏ *specify*

URR recorded within previous 1 year: yes ∏ no ∏

URR_____% (most recent within 1 year)

Date of URR_____/_____/_____

LABORATORY RESULTS
- results must be within last 90 days
-obtain from patient folders/notes, not directly from computer
- mark box ND if not done

	most recent	December (last recorded in month)	November (last recorded in month)	October (last recorded in month)
Hb g/dl				
Potassium mmol/l				
Bicarbonate mmol/l				
Total Calcium mmol/l				
Phosphate mmol/l				
Albumin g/l				
iPTH ng/l - *within the last 6 months*				

CHOLESTEROL/LIPID PROFILING -o*nly record tests taken within the last one year*

-mark box ND if not done

Date of test _____/_____/_____

Last recorded cholesterol mmol/l	
Last recorded HDL mmol/	
Last recorded LDL mmol/l	
Triglycerides mmol/l	

Hb VARIABLES

Ferritin _____ug/l *(if no result within last 9 months regard as missing)*

Date of Ferritin result_____/_____/_____

Ferritin missing ? Yes ∏

Receiving EPO Yes ∏ No ∏

Date EPO started if within last 12 weeks _____/_____/_____

EPO dose per week_____units

Iron supplements within last 3 months: Oral ∏ IV ∏ Nil ∏

Phosphate advice given in last 1 year *(check for dot on pink dietetic sheet, if no dot read sheets):*

Yes ∏ No ∏

BLOOD PRESSURE AND VARIABLES - *results must be within last 90 days*

	Systolic BP	Diastolic BP
Last recorded		
Mean of all readings		
Median of all readings		

ACCESS as of 31/12/99 H'cath / Tesio ∏ Vas-cath ∏ Fistula ∏

DIURETICS:

Yes ∏ No ∏

If Yes, Please specify_____

ANTI HYPERTENSIVE MEDICATION:

Yes ∏ No ∏

Number of different antihypertensives:

1 ∏ 2 ∏ 3 ∏ 4 ∏ other ∏ please specify number

CHOLESTEROL LOWERING DRUGS

Yes ∏ No ∏

If Yes, Please specify type, dose & frequency: -_____

ANTI-COAGULANTS

Asprin Yes ∏ No ∏

If yes, indication Access ∏ Other ∏ (specify)_____

Warfarin Yes ∏ No ∏

If yes, indication Access ∏ Other

∏ (specify)_____

Alfacalcidol as at 31/12/99 Yes ∏

No ∏

(1α, 1αcalcidol)

Blood pressure records.

START	

	Finish

Appendix B - Primary Renal Diagnosis codes

A = Aetiology uncertain -small scarred kidneys

B = Glomerulonephritis - not proven

C = Glomerulonephritis - Goodpastures Syndrome, focal glomerulosclerosis, focal GN, membranous nephropathy, membranoproliferative GN, IgA nephropathy, vasculitis

D = Pyelonephritis - associated with neurogenic bladder, congenital uropathy with or without vesico-uteric reflux,vesico-uteric reflux without obstruction, acquired obstructive uropathy, urolithiasis (*N.B.analgesic nephropathy, gouty/uric acid nephropathy, drug-induced nephropathy, lead-induced nephropathy, nephrocalcinosis and hypercalcaemic nephropathy,interstitial nephritis (not pyelonephritis)due to other cause or unspecified, should all come under "J*")

E= NIDDM

F = IDDM

G= Renal Vascular Disease -ischaemic renal disease

H = Hypertension:accelerated /malignant,other

I = Polycystic Kidney

J = Other

.

Co-Morbidity codes

A = Angina
B = Previous MI within last 3 months
C = Previous MI > 3 months ago
D = Previous CABG or coronary angioplasty
E = Cerebrovascular disease
F = Diabetes (not causing ESRF),includes diet-controlled diabetes
G = Chronic Obstructive Pulmonary Disease
H = Liver Disease
I = Malignancy (any history,even if curative)
J = Claudication
K = Ischaemic / Neuropathic ulcers
L = Angioplasty (non coronary)
M = Amputation for Peripheral vascular disease
Oa = Current smoker or stopped within 1 year
Ob = Smoking now stopped for >1 year
Oc = Non smoker
P = None

APPENDIX C - Action Plan following 1st Audit

Proposal for Quality Improvement	Action	Completion Date	Person Responsible
Raise the awareness of the Renal Association Guidelines amongst existing staff	Each Modality Manager (MM) and F grade will ensure all their existing staff are made aware of the Renal Association Guidelines; this is of paramount importance as the renal unit operates a 'named nurse' system and the care for renal patients is nurse led.	June 1999	All MM's All F Grades
Ensure all new members of staff are aware of the Renal Association Guidelines.	Each new member of staff will meet with the Education / Practice development nurse and the Research and Audit Sister who introduce different aspects of the Renal Association Guidelines.	June 1999 July 1999	Education/Dev Nurse Research and Audit Sister
	Each new member of staff completes a 'Self Test' within two months of being in post. This is then discussed with the Education / Practice development nurse at their first clinical supervision session. One of the questions will be 'Where do you find out what are the current national standards for Renal Care?'	June 1999	Education/Dev Nurse
	Each new member of the medical team will receive a Staff Handbook, to include information on the Renal Association Guidelines.	Early 2000	Consultant Nephrologist

Proposal for Quality Improvement	Action	Completion Date	Person Responsible
Raise the awareness of the Renal Association Guidelines to all members of staff	In each edition of the Renal Update (a monthly/bi-monthly non-academic newsletter) there will be a 'did you know' section highlighting one standard in each edition.	June 1999	Research and Audit Sister
	In each edition of the Renal News (academic letter going out every 3–4 months), there will be a section on audit results or standards / recommendations.	June 1999	Research and Audit Sister

APPENDIX D - Action Plan following 2nd Audit

Proposal for Quality Improvement	Action	Completion Date	Responsibility
Improve, where possible, patient specific indicators for those who fell short of agreed targets	Patients to be identified to the relevant head of department / specialist and action to be taken as appropriate	April 2000 (achieved)	All Area Managers All F Grades
Address lack of documentation in medical notes concerning patients not on the transplant waiting list	Ensure all new patients are referred and assessed for consideration of renal transplantation. Design and distribute proforma to record transplant status, date discussed and any reason for refusal.	July 2000 (achieved)	Consultant Nephrologist
Extend iron management protocol to reflect proactive approach as regards ferritin levels	Develop a protocol for the management of patients not on EPO who have low ferritins but as yet normal Hb levels.	Oct 2000	Consultant Nephrologist
Review current biochemical targets to reflect local evidence based practice	Gain a consensus regarding Phosphate, Calcium and Potassium targets and incorporate these in to the appropriate protocols / guidelines	Oct 2000 (achieved)	Consultant Nephrologists
Address pre-dialysis acidosis which may affect adequacy	Develop a protocol for the management of patients with a low serum bicarbonate level	Oct 2000	Consultant Nephrologists
Development of a Blood Pressure protocol	Set local targets according to age, modality and diabetic status .	Oct 2000	Consultant Nephrologists

Proposal for Quality Improvement	Action	Completion Date	Responsibility
Optimise treatment of patients inadequately dialysed according to URR or Creatinine Clearance	Discuss such patients in regular modality meetings. Any patient who still has difficulty achieving the target must be brought to the atttention of a Renal Consultant to ensure that all avenues have been explored. If a suboptimal result is deemed acceptable by the Consultant, this must be documented in the medical notes.	Ongoing with immediate effect	Area Managers
Ensure all nursing and medical staff are aware of the relevant current renal standards/targets	In conjunction with the "named nurse" project, develop a pocket guide of relevant agreed targets for distribution amongst medical and nursing staff and produce a corresponding wall chart for display in the modalities	Oct 2000	Renal Standards Group

Appendix E - Detailed results from both audit cycles

Hb g/dl	n	% 2nd audit
≥11	64	41.6%
<11	*90	58.4%
not recorded	0	0.0%
Total	154	100.0%

Table 8 - Haemoglobin levels achieved against local standard (Hdx)

Hb g/dl	Time on EPO					
	>12weeks		<12weeks		Not on EPO	
	n	%	n	%	n	%
>10	94	69.6%	5	83.3%	10	76.9%
<10	*41	30.4%	1	16.7%	**3	23.1%
not recorded	0	0.0%	0	0.0%	0	0.0%
Total	135	100.0%	6	100.0%	13	100.0%

Table 9 - Hb levels and time spent on EPO (Hdx)

Hb g/dl	n	% 2nd audit	% 1st audit
≥10	65	84.4%	81.4%
<10	12	15.6%	17.2%
not recorded	0	0	1.4%
Total	77	100%	100.0%

Table 10 - Haemoglobin levels achieved (PD)

Hb g/dl	n	% 2nd audit
≥11	48	62.3%
<11	29	37.7%
Total	77	100%

Table 11 - Haemoglobin levels achieved against local standards (PD)

Hb g/dl	Time on EPO					
	> 12 weeks		< 12 weeks		Not on EPO	
	Count	%	Count	%	Count	%
≥10	33	84.6%	1	100%	31	83.8%
<10	6	15.4%	0	0	6	16.2%
Total	39	100.0%	1	100%	37	100.0%

Table 12 - Haemoglobin levels and time on EPO (PD)

Ferritin umol/l	n	% 2nd audit	% 1st Audit
≥100	121	78.6%	72.0%
<100	26	16.9%	22.4%
not recorded	7	4.5%	5.6%
Total	154	100.0%	100.0%

Table 13 - Serum Ferritin (Hdx)

Ferritin Group umol/l	Time on EPO					
	> 12 weeks		< 12 weeks		Not on EPO	
	n	%	n	%	n	%
>200	77	57.0%	5	83.3%	5	38.4%
100 – 200	30	22.2%	1	16.7%	3	23.1%
51 – 99	*14	10.4%	0	0.0%	3	23.1%
≤50	*7	5.2%	0	0.0%	2	15.4%
Not recorded	*7	5.2%	0	0.0%	0	0.0%
Total	135	100.0%	6	100.0%	13	100.0%

Table 14 - Serum Ferritin and time on EPO (Hdx)

Ferritin umol/l	n	% 2nd audit	% 1st Audit
≥100	59	76.6%	64.3%
<100	16	20.8%	34.3%
not recorded	2	2.6%	1.4%
Total	77	100.0%	100.0%

Table 15 - Serum Ferritin (PD)

Ferritin Group umol/l	Time on EPO					
	> 12 weeks		< 12 weeks		Not on EPO	
	n	%	n	%	n	%
>200	25	64.1%	1	100.0%	16	43.3%
100 – 200	7	17.9%	0	0	10	27.0%
51 – 99	6	15.4%	0	0	3	8.1%
≤50	1	2.6%	0	0	6	16.2%
Not recorded	0	0.0%	0	0	2	5.4%
Total	39	100.0%	1	100.0%	37	100.0%

Table 16 - Serum Ferritin and time on EPO (PD)

Potassium mmol/l	n	% 2nd audit	% 1st Audit
Normal range 4.0 – 5.5	112	72.7%	66.4%
Lower range <4.0	*8	5.2%	4.0%
Upper range >5.5	**33	21.4%	22.4%
Not recorded within last 90 days	**1	0.7%	7.2%
Total	154	100.0%	100.0%

Table 17 - Mean serum Potassium achieved (Hdx)

Potassium mmol/l	n	% 2nd audit	% 1st Audit
5.51 – 6.0	22	66.7%	78.6%
6.01 – 6.5	8	24.2%	21.4%
6.51 – 6.7	3	9.1%	0.0%
Total	33	100.0%	100.0%

Table 18 - Upper range of mean Potassium (Hdx)

Potassium mmol/l	n	% 2nd audit	% 1st Audit
Normal range 3.2 – 5.5	70	90.9%	90.0%
Lower range <3.2	7	9.1%	5.7%
Not recorded within last 90 days	0	0.0%	4.3%
Total	77	100.0%	100.0%

Table 19 - Mean serum Potassium achieved (PD)

Bicarbonate mmol/l	n	% 2nd audit	% 1st Audit
Normal range 22 – 30	80	51.9%	0.8%
Lower range 0 – 21.9	*32	20.8%	1.6%
Upper range ≥31	**2	1.3%	0.0%
Not recorded within last 90 days	***40	26.0%	97.6%
Total	154	100.0%	100.0%

Table 20 - Bicarbonate levels achieved (Hdx)

Bicarbonate mmol/l	n	% 2nd audit	% 1st Audit
Normal range 22 – 30	60	77.9%	77.1%
Lower range 0 – 21.9	4	5.2%	4.3%
Upper range ≥31	3	3.9%	8.6%
Not recorded within last 90 days	10	13.0%	10.0%
Total	77	100.0%	100.0%

Table 21 - Bicarbonate levels achieved (PD)

Phosphate mmol/l	PO4 advice 1999 (n)	n	% 2nd audit	% 1st Audit
Normal range 1.20 – 1.70	46	58	37.7%	27.2%
Lower range 0 – 1.19	9	*11	7.1%	4.8%
Upper range ≥1.71	66	**84	54.5%	60.8%
Not recorded within last 90 days	1	***1	0.7%	7.2%
Total	122	154	100.0%	100.0%

Table 22 - Mean serum phosphate (Hdx)

Phosphate mmol/l	PO4 advice 1999 (n)	n	% 2nd audit	% 1st Audit
1.71 – 2.00	29	39	46.4%	30.3%
2.01 – 2.20	18	21	25.0%	26.3%
≥2.21	19	24	28.6%	43.4%
Total	66	84	100.0%	100.0%

Table 23 - Upper range of mean phosphate (Hdx)

Phosphate mmol/l	PO4 advice 1999 (n)	n	% 2nd audit	% 1st Audit
Normal range 1.20– 1.70	28	38	49.3%	54.3%
Lower range 0 – 1.19	5	12	15.6%	14.3%
Upper range ≥1.71	18	27	35.1%	28.6%
Not recorded within last 90 days	0	0	0.0%	2.8%
Total	51	77	100.0%	100.0%

Table 24 - Mean serum phosphate (PD)

Phosphate groups	PO4 advice 1999 (n)	n	% 2nd audit	% 1st Audit
1.71 – 2.00	11	19	70.4%	70.0%
2.01 – 2.20	4	4	14.8%	15.0%
≥2.21	3	4	14.8%	15.0%
Total	18	27	100.0%	100.0%

Table 25 - Upper range mean phosphate (PD)

Albumin g/l	n	% 2nd audit	% 1st Audit
Normal range 32 – 46	123	79.9%	82.4%
Lower range 0 – 31	30	19.5%	12.8%
Not recorded within last 90 days	1	0.6%	4.8%
Total	154	100.0%	100.0%

Table 26 - Albumin levels (Hdx)

Albumin g/l	n	% 2nd audit	% 1st Audit
Normal range 32 – 46	52	67.5%	81.4%
Lower range 0 – 31	25	32.5%	15.7%
Not recorded within last 90 days	0	0	2.9%
Total	77	100.0%	100.0%

Table 27 - Albumin levels (PD)

iPTH ng/l	On Alfacalcidol	n	% 2nd audit	% 1st Audit
Normal range 100 – 200	25	36	23.4%	16.8%
Lower range 0 – 99	10	29	18.8%	27.2%
Upper range ≥201	49	*61	39.6%	36.8%
Not recorded within last 6 months	17	**28	18.2%	19.2%
Total	101	154	100.0%	100.0%

Table 28 - iPTH levels (Hdx)

iPTH ng/l	On Alfacalcidol	n	% 2nd audit	% 1st Audit
Normal range 100 – 200	13	14	18.2%	22.9%
Lower range 0 – 99	4	29	37.7%	44.2%
Upper range ≥201	15	22	28.6%	22.9%
Not recorded within last 6 months	4	12	15.5%	10.0%
Total	36	77	100.0%	100.0%

Table 29 - iPTH levels (PD)

Cholesterol mmol/l	No. of patients on Statins	Total n	% 2nd audit	% 1st Audit
1 – 1.9	0	1	0.6%	0.0%
2 – 2.9	1	4	2.6%	0.0%
3 – 3.9	3	28	18.2%	2.4%
4 – 4.9	7	59	38.3%	6.4%
5 – 5.9	2	22	14.3%	3.2%
6 – 6.9	1	9	5.9%	3.2%
7 – 7.9	0	2	1.3%	0.0%
8 – 8.9	0	1	0.6%	0.0%
Not recorded within last 12 months	1	28	18.2%	84.8%
Total	15	154	100.0%	100.0%

Table 30 - Cholesterol (Hdx)

Cholesterol mmol/l	No. of patients on Statins	Total n	% 2nd audit	% 1st Audit
2 - 2.9	0	0	0.0%	1.4%
3 – 3.9	2	7	9.1%	1.4%
4 – 4.9	7	19	24.7%	8.6%
5 – 5.9	6	22	28.5%	20.0%
6 – 6.9	1	15	19.5%	18.6%
7 - 7.9	4	7	9.1%	10.0%
≥8	1	2	2.6%	1.4%
Not recorded within last 12 months	1	5	6.5%	38.6%
Total	22	77	100.0%	100.0%

Table 31 - Cholesterol (PD)

Corrected Calcium ranges	n	% 2nd audit	% 1st Audit
Normal range 2.10 – 2.55	92	59.8%	65.6%
Lower range 0 – 2.09	*9	5.8%	3.2%
Upper range ≥2.56	**49	31.8%	24.0%
Not recorded within last 90 days	***4	2.6%	7.2%
Total	154	100.0%	100.0%

Table 32 - Corrected Calcium (Hdx)

Corrected total calcium from the laboratory using the following formula: -

[(40 - patients albumin) x 0.02] + total calcium.

Corrected Calcium ranges	n	% 2nd audit	% 1st Audit
Normal range 2.10 – 2.55	48	62.3%	64.3%
Upper range ≥2.56	29	37.7%	30.0%
Not recorded within last 90 days	0	0.0%	5.7%
Total	77	100.0%	100.0%

Table 33 - Corrected Calcium (PD)

Calcium phosphate product levels	n	% 2nd audit	% 1st Audit
<5.0	100	64.9%	55.2%
5.0 – 5.5	*25	16.2%	13.6%
5.6 – 6.0	**10	6.5%	10.4%
6.1 – 8.9	***15	9.8%	13.6%
Not recorded	4	2.6%	7.2%
Total	154	100.0%	100.0%

Table 34 - Calcium Phosphate product (Hdx)

Calcium phosphate product levels	n	% 2nd audit	% 1st Audit
<5.0	69	89.6%	85.7%
5.0 – 5.5	6	7.8%	4.3%
5.6 – 6.0	1	1.3%	1.4%
≥6.1	1	1.3%	2.9%
Not recorded	0	0.0%	5.7%
Total	77	100.0%	100.0%

Table 35 - Calcium Phosphate product (PD)

2nd Audit	Age group			
	59 and below		60 and above	
	n	%	n	%
Within normal range	23	42.6%	77	77%
Above normal range	*29	53.7%	**23	23%
Not recorded	2	3.7%	0	0.0%
Total	54	100.0%	100	100.0%
1st Audit	Age group			
	59 and below		60 and above	
	n	%	n	%
Within normal range	21	37.5%	49	71.0%
Above normal range	26	46.4%	17	24.6%
Not recorded	9	16.1%	3	4.4%
Total	56	100.0%	69	100.0%

Table 36 - Mean blood pressure (Hdx)

2nd Audit	Age group			
	59 and below		60 and above	
	n	%	n	%
Within normal range	17	50.0%	38	88.4%
Above normal range	17	50.0%	5	11.6%
Total	34	100.0%	43	100.0%
1st Audit	Age group			
	59 and below		60 and above	
	n	%	n	%
Within normal range	11	37.9%	31	75.6%
Above normal range	16	55.2%	7	17.1%
Not recorded	2	6.9%	3	7.3%
Total	29	100.0%	41	100.0%

Table 37 - Mean blood pressure (PD)

Sessions per week	n	% 2nd audit	% 1st Audit
2	*17	11.0%	12.8%
3	137	89.0%	86.4%
Not recorded	0	0	0.8%
Total	154	100.0%	100.0%

Table 38 - number of dialysis sessions per week (Hdx)

URR	n	% 2nd audit	% 1st Audit
> 65%	56	36.4%	16.8%
≤ 65%	65	*42.2%	30.4%
Not recorded	33	**21.4%	52.8%
Total	154	100.0%	100.0%

Table 39 - Urea Reduction Ration (URR) (Hdx)

Creatinine clearance l/wk/1.73m^2	n	% 2nd audit	% 1st Audit
≥ 50 litres	56	93.3%	74.5%
< 50 litres	4	6.7%	19.0%
Not recorded	0	0	6.5%
Total	60	100.0%	100.0%

Table 40 - Creatinine clearance (CAPD)

Appendix F - Renal Bone Disease Protocol

RENAL BONE DISEASE PROTOCOL FOR UNIT/HOME HAEMODIALYSIS and CAPD

Most patients should be assumed to need vitamin D analogues. All should have been receiving these prior to the start of dialysis, except if PTH values not elevated or where acute renal failure caused dialysis dependancy.

BASIC DOSE

0.25 MCG 1-ALPHACALCIDOL PER DAY (but titrate to PTH)

Titralac Calcichew Alucaps PBM to reduce phosphate

Target these at main meals / chew with just before meal

Alter dialvsis Calcium concentration (885 PD4 to lower ca1cium.

884 Normal PD fluid to raise/ maintain calcium

Routine Monitoring	Ca. PO4.Mg bony Alk Phos	Monthly
	PTH	Every 4 monthly
	AL	Every 4 months if on AL

Targets	Ca	2.4 2.5 corrected to albumin 40) PTH 100-200	
	Mg	0.8-1.4	AP < 130
	P04	1.2-1.8	AL <20ug ml

Ca x P <5.0 ideally (must avoid> 6)

Regular therapy

If PTH < 100 NO THERAPY (unless no parathyriod glands)

If PTHI 101-200 0.25 MICROGRAMS X 3 PER WEEK

If PTH 200-400 0.25 MICROGRAM PER DAY

Hand. clavic1e and pelvis Xrays each year

Reduce dose if plasma calcium (corrected) is >2.6 mmol/l

Pulsed therapy	IF PTH 401 - 700	4 MIICROGRAMS ONCE PER WEEK
	IF PTH 701 - 1200	8 MIICROGRAMS ONCE PER WEEK
	IF PTH 1201 - 2000	12 MIICROGRAMS ONCE PER WEEK
	IF PTH > 2000	OPT FOR PARATHYROID SURGERY

<u>Once started using pulsed 1alphacalcidol therapy</u>

(1) hand. clavicle and pelvis Xrays every 6/12

(2) When PTH <400 again go back to oral daily dose

(3) need to measure PTK monthly - AND watch for HYPERCALCAEMIA.. If calcium (corrected) 2.40 mmol/l at start of pulsed therapy, use 885 lower-calcium haemodialysate/PD4 CAPD fluid.

(4) If excess ALUMINIUM then calcium may rise rapidly. Do DFO tests and consider stopping all

aluminium salts before starting pulsed therapy.

(5) PTH should fall to BY 50% STARTING VALUE within 6/12 of starting pulsed therapy -if not. and if calcium is high-normal. re-consider parathyroid surgery.

Appendix G – Terms of Reference of Renal Standards Group

RENAL STANDARDS GROUP

Terms of Reference

1. Purpose

The primary purpose of the Renal Standards group is to provide a forum to ensure the care of renal patients, is based upon the best available evidence and can be shown, through audit to be of a consistently high standard.

2. Objectives

2.1 To collate all renal specific documents that support and guide nursing practice.

2.2 Maintain an up-to-date file of these on computer, plus a paper (hard) copy to be placed in each clinical area.

2.3 Plan a programme to critically appraise each document, validate with the best evidence and allocate set review dates.

2.4 Act as a central co-ordinating body to ensure that duplication in the development of renal specific documents is avoided.

2.5 Liase with the PAPER group to ensure that all the renal specific documents meet BHC NHS Trust's set format and avoid duplication with other care centres.

2.6 Lead on regular audits of selected standards. Ensure that required changes are implemented and evaluated.

2.7 Produce a brief annual report, identifying objectives and setting out future plans.

2.8 Assist in obtaining patient views on the renal services provided.

2.9 Protocol Led Drug Administration (PLDA) - To cover existing good practice and investigate future extended roles, where patient need is highlighted.

3. Membership

The meeting will be chaired by a standard group member on a permanent basis. For personal and professional development there is an opportunity to appoint an associate chairperson, when a member so wishes, for a period of six months. The action points will be recorded in rotation by a standard group member. The minutes will be recorded and distributed by the chairperson. The remaining membership will consist of:

One representative from each modality
Education/development facilitator
Research and Audit Sister
Associate members:
Care Centre Manager
Renal Pharmacist
Consultant Nephrologist

4. Quorum

A minimum of four is required for the meeting to go ahead.

5. Attendance at meeting
The chairperson or member of the standards group may invite non-members to attend to contribute to the work of the group. If a member can not attend, apologies are to be sent to the Chairperson, and where possible a deputy from that area should be considered.

6. Frequency of Meeting
This group will meet on a monthly basis. The dates will be set one year in advance.

7. Authority
The group is accountable to the Renal Care Centre Manager. All new and revised documents
will be sent for approval to - Modality Managers, the Renal Care Centre Manager, Consultant Nephrologist and other appropriate Policy development teams e.g. PAPER group, Drugs and Therapeutic Committee, Health Records Committee.