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The development and evaluation of a self-management package for people with diabetes at risk of chronic kidney disease

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THE FOLLOWING PARTS OF THIS THESIS HAVE BEEN REDACTED FOR COPYRIGHT REASONS:

Appendix 11: Publications directly related to thesis findings

Thomas, N (2009) Chronic Kidney Disease – promoting self-management. British Journal of Primary Care Nursing. Special issue, CKD. 34-35.

Thomas, N, Bryar, R and Makanjuola, D (2008) Development of a self-management package for people with diabetes at risk of chronic kidney disease Journal of Renal Care, 34, 3, 151-5. **DOI:** 10.1111/j.1755-6686.2008.00032.x

Appendix 13: Publication: Journal of Diabetes Nursing

Thomas, N (2009) Diabetes and Chronic Kidney Disease: what does the new NICE guidance say? Journal of Diabetes Nursing, 13, 4, 126-136.

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ACKNOWLEDGEMENTS

DECLARATION

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ABSTRACT

Progression of chronic kidney disease (CKD) in diabetes can be slowed by strict blood pressure and blood sugar control, prescription of medicines that modify the renin-angiotensin system and lifestyle changes, such as smoking cessation. Because of the large numbers of people with diabetes whose condition progresses (and eventually require dialysis or transplantation), it is possible that the management of their diabetes remains sub-optimal. The overall purpose of this thesis is to develop, test and evaluate an educational package to help people self-manage their risk of CKD progression. This thesis contains a case study, a critical review of literature, the main research study and an artefact (the self-management package).

The case study developed from a three-month observation period in six general practitioner (GP) practices. The literature review evaluates the effect of patient education and self-management on diabetes control and outcomes. The research project develops and evaluates the self-management package. Development of the package was informed by the findings of the case study and literature review, and also through interviews with 15 people at high risk of CKD progression. The resulting self-management package comprises written information; a 20-minute DVD filmed with patients; a fridge magnet (with key messages); a monitoring diary; and a blood pressure machine if required.

Testing of the package was undertaken in the same six practices mentioned above, with one additional control practice. Patients with Type 1 or Type 2 diabetes at risk of kidney disease were included. Data on renal function (serum creatinine, eGFR and proteinuria), systolic and diastolic blood pressure (BP), glycated haemoglobin (HbA1c), body mass index (BMI) and smoking status were collected at six time points, before, during and after the intervention. Outcomes in patients in the participating surgeries who did receive a pack (n=116) were compared with patients in the control group (n=61).

At time point 4 mean systolic BP in the intervention group was 129.2 ± 19.2 mmHg vs. 134.6 ± 15.0 mmHg in the control group (p=0.057). At time point 5 there was mild significance (p=0.053) in mean diastolic BP. At the end of the study (time point 6) the intervention group had a mean systolic BP of 132.1 ± 14.2 mmHg vs. 136.2 ± 16.4 mmHg and mean diastolic BP of 74.9 ± 8.5 mmHg vs. 77.6 ± 9.1 mmHg in the control group (p=ns). There were no significant differences in HbA1c and BMI at any time period.

The results of the research project have shown the importance of self-management techniques to control blood pressure, which in turn can slow the rate of CKD progression and reduce cardio-vascular risk. Following evaluation by patients, the self-management package has been amended and strategies for local and national dissemination of the package have been put in place.

ABBREVIATIONS AND GLOSSARY

NAME	ABBREVIATION	EXPLANATION
Albumin-creatinine ratio	ACR	A test to quantify microalbuminuria (see below). An abnormal result for a man with diabetes is >2.5 mg/mmol and an abnormal result for a woman with diabetes is >3.5 mg/mmol
Angiotensin-converting enzyme inhibitor	ACEi	A drug that inhibits ACE (angiotensin-converting enzyme), which is important for the formation of angiotensin II. ACE inhibitors are used for blood pressure control and can reduce microalbuminuria in people with diabetes
Angiotensin receptor blocker	ARB	A drug that blocks the actions of angiotensin II. ARBs are used for blood pressure control and can reduce microalbuminuria in people with diabetes
Blood pressure	BP	For people with diabetes and chronic kidney disease, a systolic blood pressure of below 130mmHg (target range 120-129 mmHg) and a diastolic blood pressure below 80 mmHg is recommended (NICE, 2008)
Body Mass Index	BMI	The body mass index compares a person's weight and height using the formula: BMI = weight (kg) / (height (m) x height (m)). The result can be used to assess how much an individual's body weight departs from what is normal or desirable for a person of his or her height
Chronic kidney disease	CKD	CKD is staged according to international classification. CKD is defined as either kidney damage (proteinuria, haematuria or anatomical abnormality) or GFR <60 ml/min/1.73m^2 present on at least 2 occasions for ≥3 months.
Estimated glomerular filtration rate	eGFR	A formula to estimate kidney function usually based on serum creatinine, age, gender and

		ethnicity. Normal GFR is approximately 100mls/min/1.73m^2
Glycated haemoglobin	HbA1c	The test shows how well diabetes has been controlled over the past 6-8 weeks. HbA1c is reported as a percentage of the total amount of haemoglobin in the blood. A target of less than 6.5% is recommended. HbA1c results are currently given as a percentage, however the way in which HbA1c results are reported in the UK is changing. From 1 June 2009 HbA1c results will be also be given in millimoles per mol (mmol/mol). For the purposes of this thesis, HbA1c results will be given as a percentage (%).
Microalbuminuria	MA	Albuminuria of a magnitude below the limits of detection by the urine dipstick. Characterised by an ACR 2.5–30 mg/mmol in men and 3.5–30 mg/mmol in women.
p values	p	The probability that an observed difference could have occurred by chance. A p value of less than 0.05 is conventionally considered to be 'statistically significant', and not due to chance.
Serum creatinine	SCr	An endogenous marker used to estimate kidney function. Creatinine is derived from the muscles of the body and is normally removed from blood by the kidneys. As kidney disease progresses, the level of creatinine in the blood increases.
Standard deviation	SD Shown as ± in this thesis	A measure of the variability or dispersion of a population, a data set, or a probability distribution. A low standard deviation indicates that the data points tend to be very close to the same value (the mean), while high standard deviation indicates that the data are spread out over a large range of values.

1. INTRODUCTION

1.1.   Background to the thesis

Chronic kidney disease (CKD) is now recognised as a major world-wide health problem (Davis et al. 2008). Mild to moderate CKD is very common in unselected populations, with some surveys suggesting that as many as 16% of the adult population have some marker of kidney disease (Chadban et al. 2003). It is estimated that the prevalence of chronic kidney disease in the UK is currently around 8% (Stevens et al. 2007), although only around 0.4% of the whole population may eventually require dialysis or a renal transplant.

Diabetes mellitus has become the most common cause of CKD, not only within the developed world, but also increasingly within the emerging world, mainly due to the rise in the incidence of Type 2 diabetes (Atkins 2005).

There has recently been a change in focus in managing CKD, from one of treating established kidney disease, to one of earlier identification and prevention. As a result, there have been a number of important national initiatives concerning the care of people with early CKD in recent years, namely:

- the publication of the National Service Framework (NSF) for Renal Services Part Two (Department of Health 2005b)
- the recommendation that all hospital laboratories should report estimated glomerular filtration rate (eGFR) as a measure of kidney function from April 2006 (Department of Health 2005b)
- publication of local and national guidance in 2005/6 for managing CKD in primary care (Joint Specialty Committee on Renal Medicine of the Royal College of Physicians and the Renal Association and the Royal College of General Practitioners 2006)
- the General Medical Services (GMS) contract (NHS Confederation and the General Practitioners Committee (GPC) of the British Medical Association (BMA) 2006) included a new Quality and Outcomes Framework (QOF) domain for CKD in 2006, with amendments to the domain in 2008 and 2009
- National Institute for Health and Clinical Excellence (NICE) guidance on CKD (National Institute for Health and Clinical Excellence 2008a)

Collectively these initiatives have had an enormous impact on the way in which people at risk of CKD are managed in both primary and secondary care. The staging of CKD is now

recognised internationally and is based on the Kidney Disease Outcome Quality Initiative (KDOQI) study (Levey et al. 2006), although the staging of CKD has been amended in the recent NICE guidance (National Institute for Health and Clinical Excellence 2008a) with the inclusion of two categories for stage 3 CKD, namely stages 3a and 3b. The amended staging as recommended by NICE (2008) is shown in Figure 1.1.

Figure 1.1: Staging of CKD following NICE (2008) guidance

Stage CKD	eGFR $mls/min/1.73m^2$	Description
1	>90	Normal or increased eGFR with other evidence of kidney damage
2	60-89	Slight decrease in GFR with other evidence of kidney damage
3a	45-59	Mild decrease in GFR with or without other evidence of kidney damage
3b	30-44	Moderate decrease in GFR with or without other evidence of kidney damage
4	15-29	Severe decrease in GFR with or without other evidence of kidney damage
5	<15	Established renal failure - dialysis or transplantation may be required

It is particularly important to recognise that people with severe kidney damage (stage 5), who are managed in secondary care, make up a very small minority (0.4%) of those with the condition (de Lusignan et al. 2009). It is health care professionals working in primary care who deal with large numbers of people with CKD, and who have the possibility to prevent and delay the progression of the disease.

1.2. Personal interest

I have worked as a renal nurse for over twenty-five years in nephrology wards, haemodialysis and peritoneal dialysis units, mostly in London teaching hospitals. During this time I developed a keen interest in diabetes management and the ways in which people with long-term conditions can self-care. Theses for both Bachelors and Masters degrees developed this interest. In recent years I have taught renal care to diploma and undergraduate nursing students and I have taught and managed specialist renal and diabetes courses.

When I commenced this Doctorate, I was working on a secondment as the Lead Research Nurse in a tertiary renal centre in South-West London. This role involved supporting staff and

developing evidence and research-based renal practice. At the time I was involved in local projects concerning early kidney disease, including audit of the local pre-dialysis patient education programme, implementation of a local 'Expert Patient Programme' (Department of Health 2001a) for people with CKD and, most importantly, worked with a nephrologist in educating primary care professionals about managing chronic kidney disease (CKD) in the community. My previous clinical experience and then more recent practice development in the areas of CKD and diabetes led to the ideas for this Doctorate.

1.3.   Rationale for the work undertaken

In the early part of this decade when ideas for the thesis were being developed, diabetes mellitus affected at least 3% of adults in the UK with numbers of those with Type 2 diabetes increasing because of the ageing population and levels of obesity (Audit Commission 2000). At the same time there was concern that that the rate of established renal failure (ERF) due to diabetes would be increased in the years ahead and, as cited by Roderick et al (2002), in the 2002 Renal Registry report,

> *'the key question is whether the transition to ERF can be prevented or reduced by more effective management and, by implication, whether the rate of diabetic ERF can be reduced.' (UK Renal Registry 2002)(p. 81)*

Although efforts were starting to be made nationally and locally to improve the management of patients with diabetic renal disease, a large number of patients still progressed to established renal failure and were often referred late for commencement of dialysis therapy. In 2004, 30% of people requiring renal replacement were referred to a renal unit within 3 months of requiring dialysis or a transplant (UK Renal Registry 2005), when the recommended time for dialysis preparation is one year (Department of Health 2005b). It was questioned whether primary care professionals were making prevention of deterioration of kidney function one of the priorities of care or, perhaps, that patient education initiatives were inappropriate and/or under-researched.

As over 2% of the total NHS budget is spent on renal replacement therapy (dialysis and transplantation) for those with established renal failure, strategies aimed at earlier identification and (where possible) prevention of progression to established renal failure are therefore clearly needed (National Institute for Health and Clinical Excellence 2008a).

1.4.   Prevention of kidney disease

Although several factors have been associated with an increased risk of developing diabetic kidney disease, no single factor has yet been shown to be predictive. Those at risk are those with proteinuria, uncontrolled blood pressure, poorly controlled blood sugar, those who smoke and those with a family history and/or specific ethnicity (Koppiker et al. 1998).

Many studies have shown that the course of diabetic kidney disease can be slowed by identifying those at risk and subsequently managing blood pressure to target, improving glycaemic control and giving advice and support on lifestyle changes, such as exercise, weight loss and smoking cessation (Bilous 2008, DCCT Research Group 1995, Gerstein 2002, Mancia 2007). However at the start of this Doctorate there was evidence that implementation of these guidelines was less than optimal, with screening rates for microalbuminuria (MA) ranging from 10-48% (Sikka et al. 1999) and systolic blood pressure targets reached in only 35% of those with a positive MA (Craig et al. 2003). By the end of the Doctoral work, there was still evidence that risk factors for CKD and its progression remained sub-optimally managed (New et al. 2007).

Figure 1.2 provides an overview of the NICE 2002 recommendations for the care and management of patients with diabetic kidney disease (National Institute for Health and Clinical Excellence 2002).

Figure 1.2: Care and management of patients with diabetes and renal impairment

- Annual review for all those with Type 1 and Type 2 diabetes
- Send annual urine sample for albumin-creatinine ratio (ACR) and treat microalbuminuria (MA) if abnormal
- Maintain blood pressure below 135/75 mm Hg (Type 2)
- Treat MA/hypertension with angiotensin converting enzyme inhibitors (ACEis) or angiotensin receptor blockers (ARBs)
- Optimise glycaemic control (HbA1c below 6.5-7.5%, according to individual's target)
- Measure, assess and manage cardiovascular risk factors aggressively and educate about smoking cessation
- Refer for nephrology opinion if serum creatinine greater than 150umol/L

Adapted from NICE guidelines (2002)

1.5.   Diabetes and self-care

The best way to effectively manage diabetes is to empower patients with knowledge of their condition and likely outcomes. Most people with diabetes spend only a few hours in contact with health care professionals each year. The rest of the time they manage their diabetes themselves. Supporting people to manage their own diabetes is therefore at the heart of empowering people with diabetes, improving their experiences of services and improving their health outcomes (Department of Health 2001b).

Just before the start of the Doctorate, the National Institute for Health and Clinical Excellence (NICE) (National Institute for Health and Clinical Excellence 2003) produced an appraisal of structured education in diabetes. It was found that education was often offered on an 'ad hoc' basis and was not ongoing. The report suggested that patient education, if provided, does not tend to be based on proven educational or behavioural principles, nor is it usually evaluated properly to ascertain its effects in improving outcomes. Many healthcare professionals also have little or no formal training in the adult education or psychosocial skills required to educate patients effectively (Bradshaw 1999). Although empowering people to manage their diabetes is encouraged through education, further work needs to be carried out in the areas of implementation, evaluation and training needs of health-care professionals.

Finally, despite the evidence that slowing-down of kidney disease progression can be achieved in those at risk, there have been no evidence-based educational resources developed to help health-care professionals and patients achieve that aim. Even the NICE (2003) guidelines mentioned in the above paragraph did not specifically mention kidney disease as a complication of diabetes in the recommended list of topics for discussion with patients.

It is therefore possible that a patient-centred educational resource, delivered in primary care, may have benefits in terms of reduction of progression of renal disease. The aim of this thesis is to develop and evaluate such a resource.

1.6.   Thesis outline

This thesis is submitted as a PhD (Professional Practice), formally known as the Doctorate in Health. The University guidelines for submission of this type of Doctorate state that the emphasis is on developing a thesis that contains one or more reflective accounts of case

study work, a critical review of literature, a main research area and a dissemination artefact and plan.

1.7.   Aims of thesis

The overall aim of the thesis is to develop, test and evaluate a self-management package for people with diabetes who are at risk of kidney disease. Secondary aims are to carry out a case study in six general practice (GP) surgeries, to perform a literature review on diabetes and self-care, to undertake a research project that develops and tests the self-management package, and to evaluate the package prior to further dissemination.

1.7.1.   <u>Linkage between elements of thesis</u>

Chapter 1: Introduction

The introductory chapter outlines the rationale for the work, the context within which the thesis is set, the aims and the content of the thesis.

Chapter 2: Case study

In order to develop a patient-centred educational resource, it was important to understand the context within which the patients with diabetic kidney disease were being cared for and managed. The case study was undertaken from February-May 2004 through a period of participant observation. The main aim was to observe care and education delivered by GPs and practice nurses to people with diabetes at risk of CKD.

Chapter 3: Literature review

The main aim of the review is to evaluate the literature pertaining to diabetes and self-care/management, thereby comparing the best ways in which a patient-centred self-care/management programme can be developed. The findings of the review contributed to informing the development of the educational package to be evaluated in the subsequent research project.

Chapter 4: Research project

The main aims of the research project are:

- to develop a self-management education package which educates people with diabetes about the risks of kidney disease, and encourages them to self-manage their condition.
- to test the package in six GP surgeries and compare results with a control group.
- to evaluate the package following feedback from patients and health-care professionals.

Ethical approval for the research project was granted by the Local Research Ethics Committee in November 2003 (see Appendix 1).

The research design and method are discussed in Chapter 5, the findings are presented in Chapter 6 and discussed in Chapter 7.

Chapter 8: Dissemination artefact and plan

The artefact is the self-management package and this chapter of the thesis will describe how the package has been evaluated, the subsequent changes made, and the ways in which the package can be disseminated to a wider audience.

Chapter 9: Conclusions and recommendations

The last chapter will present the final conclusions and recommendations from the entire thesis.

1.8. Chapter summary

This chapter had explained the background to the thesis and the rationale for undertaking the work. The main aims of the thesis have been described and the linkage between the different elements of the thesis has been discussed. The following chapter describes the rationale, the aims, the design and findings of the case study.

2. THE CASE STUDY

2.1. Introduction

This case study was written during August 2004 to March 2005, following a period of participant observation in six participating GP surgeries. This case study acts as an introduction to the literature review, research project and resulting artefact, all of which are requirements for the PhD (Professional Practice).

2.2. The Case Study Approach

A case study can be defined as

> '...an empirical enquiry that investigates a contemporary phenomenon within its real life context.' (Yin 1994)(p.8)

Case studies can be used when 'how' or 'why' questions are being posed and where the investigator has little control over events. Case studies can be utilised for an in-depth investigation, where a variety of methods are used to investigate the phenomena in question (Hamill 1999). The 'case' can be an individual or a 'group case' such as a hospital or community centre.

For the purposes of this thesis, the 'case' will comprise six General Practitioner (GP) surgeries in South-West London. The overall aim of the case study is to analyse and evaluate the diabetes care and management provided in these surgeries following a period of participant observation. The case study will set the context for the main research project that is described later in the thesis.

The case study will be written in the first person. Although it has been noted and discussed by Hamill (1999), that first-person writing may be viewed by some as being less academic and does not necessarily require integration of evidence from published literature, this is not necessarily the case. Hamill (1999) observed that the ability of the student to write in a style appropriate to the demands of the exercise and to integrate relevant and up-to-date literature is the hallmark of a truly reflective practitioner. The case study demanded that I become involved and engaged with health professionals, patients and their families; in other words I have given of myself in the critique and writing of the study, and to write about this

in a distant and objective way (third person) would be incongruent. So this case study has been written in the first person because of the compatibility with the approach.

One main data collection strategy was used in this case study: qualitative hand-written field notes taken when I was observing consultations between practice nurses/GPs and patients. These notes were often supplemented by notes taken during direct questioning of practice nurses concerning clinical management issues.

2.3. Rationale for the case study

It was important to me that this case study laid a solid foundation for the rest of the thesis and provided a rationale and cohesive argument for why the research project was justified. As discussed in the previous chapter, diabetes mellitus affected at least 3% of adults in the UK in the early part of the decade, with numbers of those with Type 2 diabetes increasing because of the ageing population and levels of obesity (Ryan and Ryan 2009). As diabetes is one of the leading causes of kidney disease, there will be a resulting increase in people with kidney disease if the global epidemic of increased prevalence of diabetes continues (Wild et al. 2004).

At the start of the Doctorate, national initiatives such as the NSF for Renal Services (Department of Health 2005b) were urging improvements in the management of patients with diabetic renal disease, particularly as a large number of patients with diabetes still progressed to established renal failure and required dialysis. It was hypothesised that patient education initiatives were not being implemented, were inappropriate and/or under-researched. A case study could provide some of the answers to these questions.

2.4. Aims of case study

In order to develop a patient-centred educational resource, it was important to understand the context within which the patients with diabetic kidney disease were being cared for and managed. I was unfamiliar with working practices in GP surgeries, such as the scope of the extended role of the practice nurse and the working relationships between practice nurses and GPs. I had brief experience of working in South-East London in the community (1985-1987) with patients on home dialysis, but generally my knowledge of primary care was poor. I also needed to update my knowledge on managing people who were *newly diagnosed* with diabetes, as this had been outside my past clinical experience.

Case study data were collected from February-May 2004 through a period of participant observation. The main aim was to observe and reflect on the ways in which practice nurses and GPs delivered care and education to people with diabetes at risk of CKD.

As the case study progressed it became clear that some additional aims were emerging. These were to provide educational input about kidney disease to practice nurses, GPs and patients, and to investigate and recommend practical guidelines on chronic kidney disease (CKD) management. These secondary aims will be discussed in more detail later.

The main aim of the case study was:

- To observe care and education delivered by GPs and practice nurses to people with diabetes at risk of CKD

Secondary aims were:

- To analyse data collected during the period of participant observation using a theoretical framework
- To identify themes within these data to subsequently inform the development of a self-management package for people with diabetes at risk of CKD
- To provide educational input about kidney disease to practice nurses, GPs and patients

2.5. Gaining access

In December 2003 I was invited by one of the clinical nurse specialists in the local diabetes centre to present two seminars on diabetic kidney disease to a group of practice nurses. The seminars were part of an ongoing programme that was provided monthly for community nurses interested in diabetes care.

The main aim of the seminar was to educate primary care nurses on the importance of screening for diabetic kidney disease. A secondary aim was to inform the participants about the forthcoming research study and to request their participation in the project, which had been granted ethical approval in December 2003 (see Appendix 1). At the end of the seminars twelve practice nurses had registered their interest in the project. A letter was sent to all the interested surgeries in January 2004, and of these, six volunteered to be actively involved in the project. I then visited all six surgeries to discuss their involvement. At this

meeting, I met with either the Practice Nurse (PN) (four surgeries) or the Practice Nurse and General Practitioner (two surgeries) who were responsible for diabetes care.

It is recognised that the surgeries were self-selecting and therefore it is likely that the diabetes care and management provided in each surgery was likely to be of a good standard. However, I discussed this possible methodological limitation with the clinical nurse specialist in the diabetes centre, and she felt that involvement of other, perhaps less-motivated practice nurses would perhaps be difficult at this stage. She suggested that once the first phase of the project was complete, and my intervention viewed as perhaps less threatening, she would help me make contact with other local surgeries that did not have such a keen interest in improving diabetes care. However this suggestion did not prove viable after the first stage of the study because I had already recruited six practices as per the study protocol. See section 8.5 for discussion on the dissemination plan for the self-management package throughout the Primary Care Trust (PCT).

2.6. Comparison of surgeries

Figure 2.1 compares the demographics and structure of diabetes care in each surgery.

Figure 2.1: Demographics and outline of diabetes care in each GP surgery in March 2004

Surgery	Total number of patients	Total number of patients with diabetes	Dedicated diabetes clinic?	Person responsible for diabetes clinic	Times of diabetes clinics
1	10 060	299	N	-	-
2	7650	194	Y	PN	Wednesday pm
3	14 000	396	Y	PN / GP	Friday am
4	9 000	340	Y	PN	Wednesday am
5	9 500	250	Y	PN	Wednesday pm
6	10 850	431	Y	PN	Varied

All surgeries are within a five-mile radius of the tertiary renal centre, and are located within the same primary care trust (PCT). The overall management structure of patients with

diabetes did not appear to vary much between surgeries. In five surgeries, one or two practice nurses ran nurse-led diabetes clinics at specified times each week. Surgery 1 did not run a dedicated clinic for diabetes at that time, but rather saw patients on unspecified days, at a time convenient to the patient.

2.7. Situational analysis

2.7.1. Introduction

Observation of diabetes care took place from February–May 2004. All six surgeries were visited on two occasions during a normal diabetes clinic. As Surgery 1 did not hold routine diabetes clinics, the practice nurse (PN) organised for me to visit one afternoon when a small number of patients with diabetes had a booked consultation.

On each occasion I recorded hand-written field notes. The notes were taken when I was sitting in on patient consultations with practice nurses and GPs and when I was talking with practice nurses about how patients were managed. I often wrote personal reflections about the surgery visits once I had returned home. The notes covered all aspects of communication between nurse and patient/family member; details concerning care and management of diabetic kidney disease, such as patient education strategies and use of nursing protocols; the interaction between the practice nurses and other members of the professional team; and the use of the computer database. The questions that I wanted to answer were:

- How many patients have diabetes and how is diabetes care organised?
- Is the care and management of diabetic kidney disease based on evidence/best-practice?
- What educational strategies are used to empower patients about their diabetes?
- How do practice nurses interact with colleagues?

From June 2004 onwards I also started to identify all patients in each surgery who had chronic kidney disease (CKD) and diabetes. This activity was carried out with the help of the practice manager/information technology (IT) assistant in each surgery. I needed to identify all patients at risk of CKD (defined by an albumin:creatinine ratio recording >3)[1] so I could map their care throughout the whole research project and ultimately see if the education programme had made any difference to the parameters (blood pressure, blood sugar, body mass index and smoking status) that affect progression of their renal disease.

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[1] *In 2004 local PCT/laboratory guidance regarding the threshold for abnormal ACR results was >3 for both men and women, despite NICE (2002) guidance recommending >2.5 in men and >3.5 in women.*

2.7.2.   Framework used for analysis of case study data

I was unclear how to analyse and evaluate the hand-written field notes into identified themes that could then be used as a basis for development of the subsequent literature review required for the thesis submission. My first supervisor suggested that I should enrol on a day course in social research methodology at the University of Surrey. This was an update for me, as I had used this type of approach in an earlier Master's degree thesis.

I attended a day course on 'Introduction to Qualitative Analysis' at Surrey University in October 2004. The course enabled participants to understand the complexities of managing qualitative data and during practical exercises demonstrated how hand-written field notes could be managed and analysed. Subsequently I decided that a framework of *content analysis* used for the practical exercise during the day course (Miles and Huberman 1994) would be utilised for the analysis of this case study. An outline of this framework is shown in Figure 2.2.

Figure 2.2: Content Analysis Framework (Miles and Huberman, 1994)

Data Reduction — *Summarise; code; divide into themes, clusters, categories*

Data Display — *Diagrams, pictures, visual forms*

Conclusions and Verification — *Interpret displayed data, look for comparisons and contrasts, note and explore themes*

Miles and Huberman (1994) (2nd ed.) Qualitative Data Analysis: An expanded sourcebook. Sage Publications
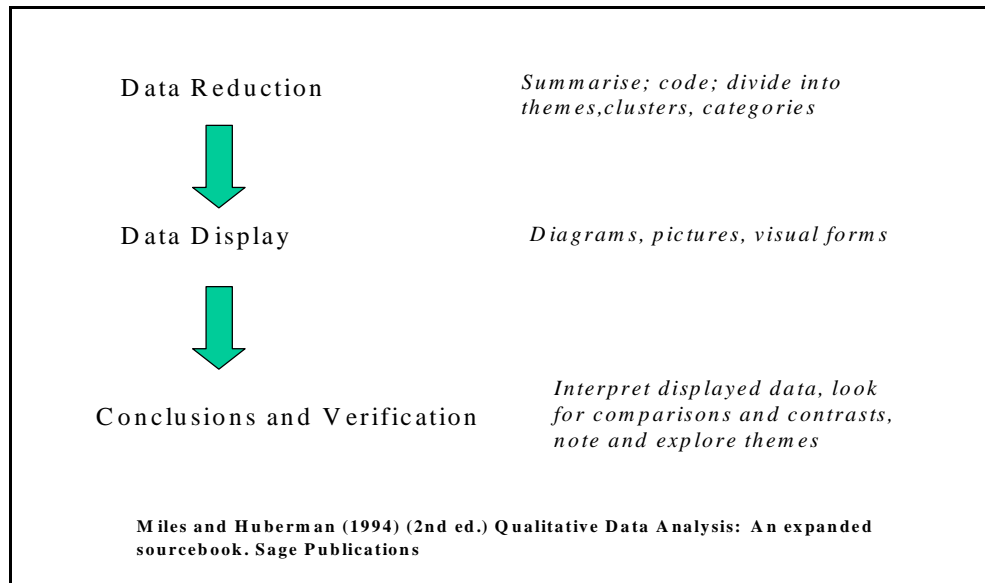
Miles and Huberman (1994) describe content analysis as a process that facilitates the production of core constructs from textual data through a systematic method of reduction and analysis. Text is coded into established themes to support the generation of ideas. The number of times a similar piece of text or idea is attributed to a particular theme is counted and the importance of that theme can therefore be deduced.

2.8.   The theoretical framework

A number of theoretical frameworks were considered for use in the case study and for the rest of the thesis. I had used the locus of control framework (Rotter 1966) in a previous Master's thesis (Master of Arts Education), and also considered the use of a change theory (Kotter 1995) as a framework. Although both these frameworks would be useful in explaining an individual's attitude and behaviour change to health education, they would not necessarily be useful in engaging the wider variables, such as the importance of societal beliefs or organisational constraints, on an individual's care and management.

I have therefore utilised Silverman's action approach to organisations (Silverman 1971) as the theoretical framework, which suggests that change is dependent on the interrelationship of a number of factors, including the knowledge, attitudes and beliefs held by the wider society, by the organisational structure, as well as by individuals. This model was adopted by Bryar in a project which aimed to introduce more individualised care for women into midwifery practice (Bryar 1995). Figure 2.3 shows an adaptation of the Silverman (1970) model which will be used as the theoretical framework for the case study.

Figure 2.3: Silverman's (1970) action approach to organisations
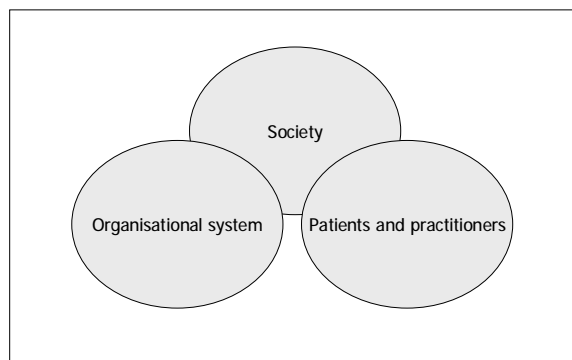
2.8.1. The rapidly changing health care environment

It is important to place this case study within the rapidly changing renal care environment. During the time that the case study took place two significant events took place. The first was the introduction of the General Medical Services Contract (GMS) contract for GPs, which was introduced in April 2004. For the first time General Practitioners were to be financially rewarded for achieving a number of quality standards in the areas of coronary heart disease (CHD), stroke or transient ischaemic attacks, hypertension, diabetes, chronic obstructive pulmonary disease (COPD), epilepsy, cancer, mental health and asthma.

There are targets for diabetes, and targets relevant to this study are shown in Figure 2.4.

Figure 2.4: Relevant QOF targets for diabetes mellitus (2004)

DM 13. The percentage of patients with diabetes who have a record of micro-albuminuria testing in the previous 15 months (exception reporting for patients with proteinuria). Target 90% (3 points)

DM 14. The percentage of patients with diabetes who have a record of serum creatinine testing in the previous 15 months. Target 90% (3 points)

DM 15. The percentage of patients with diabetes with proteinuria or micro-albuminuria who are treated with ACE inhibitors (or ARBs). Target 70% (3 points)

It was possible that this contract could improve the rates of MA testing, serum creatinine testing and prescribing of medication for those with renal disease. Almost concurrently the Renal Association (RA) of the UK published a draft document outlining the care and management of patients with CKD that emphasised primary care management. Although the final draft did not appear on the RA website until January 2005, many nephrologists were becoming interested in collaborating with primary care physicians particularly as it was well-known that the second part of the National Service Framework for Renal Services was due to give further recommendations on CKD management.

Although I was not aware of any nephrologist colleagues having direct involvement with local GP surgeries at that time, there was much publicity around CKD. I was involved in running a national symposium in June 2004 which debated the issues of renal disease prevention, and this possibly also had an effect on CKD management in primary care.

As a consequence of all these initiatives, the practice nurses and GPs in the study were most interested in MA screening and during the course of the participant observation, they began to involve me more in the care of patients. For example, I was asked direct questions about the practicalities of providing urine samples for MA testing such as 'was it crucial to have the first sample of the day and could the sample be kept in the fridge overnight?' I was also asked to give advice to patients about the need to reduce blood pressure and give up smoking. I therefore moved from non-participant to participant researcher as the observation period progressed. I was aware that my objectivity was becoming curtailed but realised that ethically I had to impart my specialist knowledge when asked. Further discussion and analysis on practitioner research is included at the end of this chapter.

2.9. Method

2.9.1. Data collection

The analytical process began during data collection, as once exposed to the case study environment I immediately began to start thinking about what was being heard and seen. As the data collection progressed I was able to go back and refine questions and pursue emerging avenues of inquiry which I had not thought about before. Continuous analysis was inevitable because I was "in the field" collecting data on a number of consecutive weeks. I was also able to reflect on examples of situations or events that ran counter to emerging themes, and I was able to use these situations to further refine the case study's questions.

2.9.2. Data reduction

Once I had completed the observation, I made photocopies of the field-notes and cut the photocopied sheets to sort the data into large categories defined by the case study's questions. I then sorted into smaller discreet sections informed by the analytical and theoretical ideas developed during the observation. In other words, I selected sections of data on like or related themes and put them together. Themes were derived inductively, that is, they were obtained gradually from the data as the observation progressed. By the end of this process I was very familiar with the data, and realised that there were some gaps in my knowledge. In October 2004 I went back to each surgery to check the accuracy of some information and to fill in some knowledge deficits.

2.9.3. Data display

Figure 2.5 shows how the large categories of data were reduced into smaller themes within the theoretical framework.

Figure 2.5: Data reduction and identification of themes
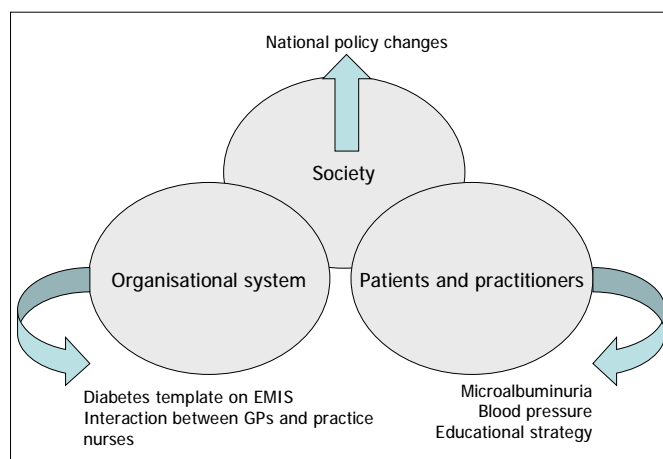
2.10. Emerging themes

The hand-written field notes taken during the observation were summarised, displayed and then divided into themes. In the following section, each theme will be described and evaluated alongside pertinent evidence and literature. The conclusions from the thematic analysis of the case study will form the basis of the literature review and resulting methodology for the main research project.

A theme is an abstract entity that brings meaning and identity to a recurrent experience and its variant manifestations. As such, a theme captures and unifies the nature or basis of the experience into a meaningful whole (DeSantis and Ugarriza 2000)p. 362).

Six main themes emerged from the data. Two related to clinical care (microalbuminuria and blood pressure measurement and management), one related to the educational strategies used by the practice nurses, one related to the use of the computer during patient

consultation, another theme was concerned with the doctor-nurse relationship. A theme around the effect of national policy change also emerged. Although each theme is important in its own right, together they can provide information about the impact and outcome of diabetes management in the primary care setting.

2.10.1.   Measurement and monitoring of microalbuminuria

The most important theme which was identified following the analysis of the field-notes was measurement and monitoring of microalbuminuria (MA). In every surgery on my first visit, the monitoring, measuring and interpretation of MA was raised as an issue. The challenges of understanding the importance and relevance of MA appeared to be partly historical ("I have never really understood the kidneys"), but also there was increased interest in MA testing because of the recent introduction of the General Medical Services (GMS) contract for GPs. Diabetes was included as one of the ten clinical indicators within the Contract's framework, with testing of MA recommended for 90% of patients with diabetes within a fifteen-month period.

Practice nurses seemed aware of the importance of MA testing but spoke of the difficulties of what information to tell patients, the challenges of obtaining samples, how to receive and interpret results and how to act on abnormal values. On three occasions I was asked to give information directly to patients (why the test was necessary; what the results meant; why a patient may need to be referred to the renal unit).

The main theme of MA will be broken down into the following sub-topics:

- Measurement of MA
- Patient education and MA testing
- Interpretation of results of abnormal MA values
- Quality and Outcomes Framework (QOF) and MA testing

2.10.1.1.   Measurement of MA

Microalbuminuria (MA) is the earliest indicator of kidney disease attributable to diabetes. Values of MA are between 30-300 mg of albumin in the urine. MA is predictive of total mortality, cardiovascular mortality and cardiovascular morbidity for patients with diabetic kidney disease and can be measured in three ways (Miedema 2003):

- Timed test (by 24 hour urine)

- Albumin:creatinine ratio (ACR) (by early morning urine (EMU))
- Point of care testing (by dipstick eg. Micral test strips)

Since current clinical guidelines (NICE, 2002) recommended the use of albumin:creatinine ratio to measure MA because of convenience and consistency, five out of six surgeries in this case study screened for MA using the ACR test. However there were reported difficulties in two surgeries with patients not being able to return EMUs to the surgery in time for the early morning courier to the hospital where the ACR is measured. Patients also reported difficulties in taking the sample directly to the hospital laboratory because of the distance involved (up to five miles for Surgery 3). There were also reported problems with the hospital laboratory allegedly not reporting all results back to the surgery.

Surgery 2 had been using Micral (ImmunoDip®) test strips for some time, as it was decided that point-of-care testing would overcome some of the challenges of low testing rates. At the time of observation of diabetes care and management at the surgery (May 2004), I found difficulty in identifying any evidence that gave comparisons of Micral tests with ACR tests on specificity and accuracy of measurement. Discussion with a nephrologist in North Wales (oral communication) suggested that Micral strips accounted for 30% false negative readings. I also had email discussion with the author of a paper who had systematically reviewed the evidence to establish whether a dipstick method of detecting MA was as effective as a laboratory method (Berry 2003). The conclusion was that Micral testing has a high sensitivity but not very high specificity with low positive predictive value; that is, it is adequate as a screening tool but not as a diagnostic tool.

Interestingly there have been a number of recently published studies on the performance characteristics of Micral test strips for MA, since the debate with surgery 2 was raised. One study (Parikh et al. 2004) found that the performance characteristics of the Micral test strips for detecting microalbuminuria (30-300 mg albumin/24 h) were adequate but not optimal. In this prospective study, a total of 444 urine samples of patients with Type 2 diabetes were obtained. Urinary albumin concentrations were determined using Micral test strips and compared with results measuring albumin by the immunoturbidimetry method of timed collections. They concluded that while the use of Micral test strips provides a rapid approach to detecting microalbuminuria in diabetes, this method has limitations because the positive predictive value was 69%, and negative predictive value found to be 92%. However as this study did not compare point-of-care testing with EMU testing (which is random and therefore less accurate than a timed collection), it was necessary to keep searching the literature for newly published studies.

A study published in July 2004 compared the advantages and disadvantages of using the 'gold standard' method of 24 hour timed collection compared with a random sample such as an EMU. A systematic review and meta-analysis (Ewald and Attia 2004) was carried out on studies comparing albumin to creatinine ratio (ACR) on a random specimen with albumin excretion rate from an overnight or 24 hour timed sample. Studies were identified using Medline and EMBASE to June 2003 and ten studies covering 1470 patients were included. The authors suggested there was a marginal benefit of using a timed urine collection over a spot ACR to detect microalbuminuria in the screening of diabetic patients, but not worth the cost and inconvenience of collecting a timed sample.

In July 2004 I discussed the practical issues of using Micral strips with surgery 2, and provided them with the above evidence that suggested that EMU testing was preferable. After meeting with the practice nurse and practice manager, the protocol in the surgery was changed. All patients now have annual ACR testing with an EMU which is sent to the hospital laboratory. In July 2004 it was not possible to evaluate whether the practical problems of getting the samples to the hospital would be resolved, so further audit to measure the percentage of patients who had been tested was suggested to the practices affected.

2.10.1.2. Patient education and ACR testing

There was variation in the information given to patients. The following is a summary of the advice given to patients when I first visited each surgery:

- Surgery 1 told patients to use the first sample of the morning (EMU)
- Surgery 2 used point of care testing (Micral test strips)
- Surgery 3 told patients to use the first or second sample of the morning (EMU)
- Surgery 4 was very strict in the guidance given to patients, telling patients that the sample had to taken immediately upon rising from bed in the morning. The practice nurse had questions for me about whether an EMU sample could be taken if the patient had passed urine in the night
- Surgery 5 told patients to use the first sample of the morning (EMU)
- Surgery 6 told patients to use the first sample of the morning (EMU)

It appeared that practice nurses needed more guidance on the testing of MA, particularly as ongoing monitoring of MA has shown to be an important issue in diabetes management.

2.10.1.3.   Interpretation of results of abnormal MA values

There was variation in how the results of the ACR were interpreted. All surgeries were aware of the likelihood of false positive readings if the patient had a urinary infection, but there did not appear to be consistency in how this was put into practice. Two surgeries required two positive readings (ACR>3) in order to make the diagnosis of MA, whilst two surgeries reported that infection needed to be ruled out (by sending off a mid-stream specimen of urine) once a positive MA was found. More specific guidance was needed to clarify when a positive diagnosis of MA could be made.

NICE guidance on MA testing (NICE, 2002) recommended that an ACR > 2.5 mg/mmol (in men) or >3.5 mg/mmol (in women) classified patients at high risk of kidney disease. However in all six surgeries, an ACR of greater than 3, regardless of whether they were men or women appeared to define a patient as being high risk. It was not clear why the local laboratory/PCT used the threshold of > 3 for all patients, although the thresholds were changed during 2005.

2.10.1.4.   Quality and Outcomes Framework (QOF) targets and MA testing

As described earlier, in April 2004 the new GMS contract commenced. Figure 2.6 shows the relevant QOF targets for diabetes achieved for each surgery in May 2004.

Figure 2.6: Diabetes QOF targets May 2004

SURGERY	MA % testing in past 15 months	Serum creatinine % testing in past 15 months
1	59	80
2	86 (using Micral strips)	95
3	64	86
4	38	91
5	62	87
6	47	91

There was an improvement on May 2004 testing rates for MA as the year progressed. Rates for December 2004 are shown in Figure 2.7. Possible reasons for increased testing rates could have been the effect of QOF incentivisation (although financial remuneration was not

high for MA testing), increased awareness due to my visits to the surgeries, or ease of taking a random urine sample compared with an EMU (see section below for explanation).

Figure 2.7: Diabetes QOF targets December 2004

SURGERY	MA % testing in past 15 months	Serum creatinine % testing in past 15 months
A	72	83
B	93	95
C	66	91
D	66	92
E	73	90
F	58	93

2.10.1.5. Summary

During 2004 practice nurses needed more guidance on the testing of MA. I searched for evidence-based guidance on MA testing and the following recommendations were communicated to the practice nurses.

- An ordinary urine specimen (preferably taken in the morning) is acceptable for measurement of ACR.
- It is preferable to have a morning sample as the urine needs to be reasonably concentrated for the laboratory test to be carried out.
- It is possible for samples to be taken from the patient in the afternoon and kept refrigerated overnight (this is beneficial to surgeries as often the courier to the hospital laboratory leaves in the early morning).

2.10.2. Measurement and monitoring of blood pressure

Control of blood pressure is one of the most important variables in delaying progression of renal disease in diabetes (Perry et al. 2003). During the observation of diabetes care and management in the six selected GP surgeries, the challenges of measuring and managing blood pressure was the second most significant theme to be identified. This was partly because most practice nurses wanted to discuss the ongoing challenge of controlling BP in diabetes, and more specifically wanted advice on which BP target they should be aiming for.

The following topics will now be discussed within the context of the case study:

- Ways in which blood pressure was measured
- Ways in which blood pressure was controlled
- Use of clinical guidelines in identifying blood pressure targets

2.10.2.1. Measurement of blood pressure

In all surgeries, BP was routinely measured in every patient at each visit. In all surgeries the BP was measured at the start of the consultation, usually because this was prompted by the diabetes template on the computer (see section 2.10.4). Surgery 6 employed a health care assistant to take BP and test urine samples prior to the consultation with the PN, whereas in all other surgeries the PN took the BP recording.

BP readings were mostly taken using electronic Omron upper arm monitors (all surgeries except surgery 2). Some practices used both manual (mercury) and electronic sphygmomanometers. Only one surgery (Surgery 6) offered BP machines to patients to take home, but this appeared to be a rare event. Two PNs did raise the pertinent issue of 'white coat hypertension'. The white coat effect on BP was first described in 1983 (Mancia 1983) and since then various alternative definitions of white coat effect and white coat hypertension have appeared in the literature. One definition of white coat hypertension describes it as a condition in which a person's BP rises above the normal range when measured in the clinic but falls within the normal range when measured outside the clinic (Tsai 2002). It was this definition to which the PNs referred, but neither offered any solution to the problem.

Patients were advised not to talk when their BP was being measured (four surgeries), but on no occasion did I observe other actions being taken to yield more accurate recordings of BP, such as cuff size tailored to the size of patient (Mansoor 2003), or taking the mean value of two-three readings as recommended by the European Society of Hypertension (O'Brien et al. 2003).

Consistent underestimation of blood pressure values can have an impact on the numbers of patients treated with medication. It has been suggested that constant underestimation of diastolic pressure by 5 mm Hg would reduce by 62% the number of patients perceived as hypertensive (Campbell and McKay 1999). Although it is likely that the variables described here (white coat hypertension; talking; small cuff size) would be most likely to overestimate blood pressure in this group of patients, the large clinical trials on which treatment

recommendations are based use standardised blood pressure measuring techniques and patient preparation.

It is likely that home blood pressure monitoring would yield less overestimation of blood pressure. To determine the effect of home blood pressure monitoring on blood pressure levels, a meta-analysis of 18 randomised controlled trials was carried out (Cappuccio et al. 2004). They concluded that blood pressure in people with hypertension is more likely to be controlled to target when home blood pressure monitoring is used, compared with standard blood pressure monitoring in a clinic. Clearly there are implications for practice. As BP is likely to be overestimated when measured in a clinic setting, the importance of measures to facilitate accurate readings for this high-risk patient group is crucial.

2.10.2.2. <u>Ways in which blood pressure was controlled</u>

There is generally accepted evidence that BP can be reduced through weight loss and exercise (Costa 2002, Kastarinen et al. 2002) and reduction of salt in the diet (Siani et al. 2000). During the observation of diabetes care, there was never any occasion when I observed a PN or a GP giving advice to patients in this way. Control of blood pressure was always managed through prescription of medications, although there did not appear to be a clear evidence-base as to why one medication was prescribed over another. In surgery 6 15/71 (21%) patients were prescribed bendrofluazide (a thiazide diuretic) to control their BP, often instead of the recommended angiotensin-converting enzyme inhibitor (ACEi) or angiotensin-receptor blocker (ARB) (National Institute for Health and Clinical Excellence 2002).

2.10.2.3. <u>Use of clinical guidelines in identifying blood pressure targets</u>

In 2004 there were a number of recent evidence-based guidelines that had been published on care and management of those with diabetic renal disease. The National Institute for Health and Clinical Excellence (NICE) produced guidelines for Type 1 (National Institute for Health and Clinical Excellence 2004) and Type 2 diabetes (National Institute for Health and Clinical Excellence 2002); the Scottish Intercollegiate Guidelines Group published guidelines for diabetic nephropathy (Scottish Intercollegiate Guidelines Network 2001); the local diabetes centre also had standardised guidelines for diabetes care. In each surgery I asked the practice nurses if their care was based on evidence and all answered that this was the case. In two surgeries I asked if I could see the guidelines on which care was based, but neither could produce anything on paper. However when I asked specifically about

management of patients with renal disease, all the practice nurses could describe the management which generally followed the evidence-base, that is:

- aim for annual MA testing

- prescribe ACEi or ARB when MA was present or when the patient is hypertensive

- refer to a nephrologist when serum creatinine reaches 150umol/L.

In practice of course these guidelines are difficult to follow. The most difficult aspect of care is control of blood pressure, especially in African-Caribbeans (Oparil and Wright 2005) and many patients were having multiple therapy. Blood pressure was always controlled through medication, and I never observed any other advice or therapy being offered such as lifestyle modification or weight loss.

2.10.3.   Educational strategies

It is recommended that structured patient education is made available to all people with diabetes at the time of initial diagnosis and then as required on an ongoing basis, based on a formal, regular assessment of need (National Institute for Health and Clinical Excellence 2003). However, NICE in the 2003 report, concluded that there was insufficient evidence currently available to recommend a specific type of education or provide guidance on the setting for, or frequency of, sessions.

However, some principles of good practice were recommended, and these included:

- educational interventions should reflect established principles of adult learning

- educational programmes should use a variety of techniques to promote active learning (engaging individuals in the process of learning and relating the content of programmes to personal experience)

- programmes should be adapted wherever possible to meet the different needs, personal choices and learning styles of people with diabetes, and should be integrated into routine diabetes care over the longer term

Throughout the entire three months of observation in the diabetes clinics, I never observed one occasion when a patient or family member was offered any written advice on any aspect of diabetes care. Neither did I see any patient being offered information through a relevant website or other resource/interactive medium.

The reasons for this are unclear. It may be that practice nurses believe that education is best delivered on a one-to-one basis using personal experience and individualised examples. This was said to me by two of the practice nurses when I asked them whether they thought written patient information might be useful. Other reasons were not suggested by the practice nurses, but it may be that they do not know that suitable materials are available. This may have been the case in 2004 for diabetic *kidney* disease, but not the case for general aspects of diabetes. Diabetes UK www.diabetes.org.uk offers numerous patient information leaflets on-line and also in hard copy, on all aspects of the condition. It could also be possible that practice nurses believe that education should be provided by the local diabetes centre. To some extent this might be true, as the local diabetes centre at the time did offer all new patients a structured education programme, backed-up with written materials and information. However it is important to recognise that education has the most effective outcome when key messages are reinforced on a regular basis (Renders et al. 2001).

As discussed already, NICE (2003) guidance on patient education initiatives is not encouraging, yet there is a plethora of other pertinent research literature on the benefits of good diabetes education. A Cochrane Systematic Review (Renders et al. 2001) suggested that the addition of patient-oriented interventions in primary care can lead to improved patient health outcomes in diabetes. The review concluded that practice nurses can play an important role in patient-oriented interventions, through patient education and facilitating adherence to treatment.

For me, another crucial issue which emerged is how far the patients felt empowered by their practice nurses or GPs. I rarely saw a consultation were patients were asked:

- how they felt they were managing their diabetes
- how far they were able to control their diabetes
- what was realistic and acceptable in terms of goal setting
- what was preventing them changing their attitude or behaviour to diabetes

This is despite Standard Three of the Diabetes National Service Framework (Department of Health 2001b) which focuses on patient empowerment, which stated that:

> *"All children, young people and adults with diabetes will receive a service which encourages partnership in decision-making, supports them in managing their diabetes and helps them to adopt and maintain a healthy lifestyle. This will be reflected in an agreed and shared care plan in an appropriate format and language.*

Where appropriate, parents and carers should be fully engaged in this process."
(Department of Health 2001b)(p.5)

Clearly the way in which patient education and empowerment is facilitated in primary care requires further analysis and evaluation. There may well be a good rationale why care is delivered in this way, and of course it is easy for me to question the educational methods when I am not the nurse responsible for implementing them. However renal nurses are very familiar with the empowerment philosophy and traditionally have promoted the concept of self-care. It seems that the way in which consultations are carried out has to be challenged. If the focus continues to be on data input to the computer and questioning being led by the diabetes template, there is little chance for a patient-centred approach.

2.10.4.   Use of diabetes template on computer

Each surgery utilises the Egton Medical Information Systems (EMIS) LV system for patient record management, and it is one of the leading text-based clinical systems in the primary care market. Approximately 5,000 GP practices currently use EMIS LV. The system offers consultation mode, medical record, search and reports, prescribing and appointment modes.

EMIS LV enables GPs to easily meet the requirements of the GMS contract. The 'Population Manager' contains a set of approximately 160 searches that extract the information required for the new Contract. All surgeries in this case study use the Population Manager facility.

All surgeries reported that they had access to the newly developed (end of 2003) PCT template for diabetes care, and surgery 3 described how they were involved in the steering group that developed the template. However only four surgeries appeared to use this template in practice and two surgeries seemed to be using both the new template and the original template, which made extraction of data complicated. Each surgery had then made local adjustments to the template, so for example patient ethnicity was recorded on the diabetes template in two surgeries, and amount of exercise undertaken by patients was only recorded on the templates in three surgeries.

During the period of observation it was interesting to note how the interaction between PN and patient was directed by the diabetes template on the computer. In five surgeries (Surgery 5 excepted) all the questions asked during the consultation were initiated by use of the template, and the PN inputted the data (weight, BP measurement, blood glucose level) as the consultation progressed.

In Surgery 5, the consultation was led by the PN and there was a greater likelihood that the consultation would be directed by the patient or family member. In this surgery the PNs inputted data at the end of the clinic. To the uninitiated researcher at my first visit, it appeared that the PNs in this surgery wanted to encourage a more patient-centred approach to the consultation. On my second visit, I asked one of the PNs the reason for this arrangement and was told of the simple pragmatic reason why the data entry did not happen concurrently during the consultation: the electrical lead to the computer did not stretch to the chair/couch where the consultation took place!

In all surgeries it was rare that patients were asked about how well they were coping with their diabetes. Although it is recognised that many of the patients had been diagnosed with diabetes many years ago and therefore were well known to the PN and GP, it was notable that they were rarely asked about how far they felt able to control their illness.

When computers started to become a part of nurse/GP consultation in the primary care setting in the early 1990s, there were many papers exploring the impact of computers on interaction with patients (Mitchell and Sullivan 2001). A review (Brown 1998) described the position and use of computers during the consultation, the behaviour associated with the computer, and also the patient and doctor perspective. At that time, the review concluded that computers had potentially had a deleterious effect on patient interaction with the health-care professional, although this does not appear to have affected the rise in computer use in general practice consultations. At a later date (Hsu et al. 2005) a study into the effect of computer on patient-centred consultations appeared to show that the computer had positive effects on physician-patient interactions without significant negative effects on other areas such as time available for patient concerns.

2.10.5.   Interaction between practice nurses and GP

It was interesting to note the different ways in which GPs and practice nurses work together. In surgeries 3, 4 and 6, the PN appeared to direct care, making suggestions to the GP about MA testing, prescribing of medication and referral to the renal unit. In other surgeries the PNs took a less pro-active role, and in some cases made suggestions which were not taken up. Examples of this were recommendations to control blood pressure which clearly were above accepted evidence-based standards, but were ignored by GPs as unnecessary.

An historical perspective to the role of the PN makes interesting comparison. An historical review (Atkin and Lunt 1996) describes how the origins of practice nursing are closely associated with the development of general practice. It was back in 1966 that amendments

to the general practitioner (GP) contract established the potential for employing nurses, and GPs slowly took advantage of this by employing nursing staff to undertake 'treatment room' tasks. In 1990, further amendments to the GPs' system of payments and associated incentives created an expanded role for nurses in general practice and family doctors were attracted to the idea of directly employing a nurse (Robinson et al. 1993) . At that time, although many GPs created a new nursing post or expanded the role of existing nurses to meet contractual requirements, their views varied considerably in the tasks that practice nurses should undertake.

There is an important question as to who makes the decisions concerning diabetes care and management in the primary care team. In some practices, the nurses with specialist knowledge are directing and managing care, whilst in other surgeries the doctors are leading. Some surgeries have strong links with the local diabetes centre (surgery 5 for example did not manage any patients with Type 1 diabetes), whilst others do not. For the purposes of this case study and resulting research project, the importance of who the key players are in diabetes care and management cannot be underestimated. In a truly patient-centred environment of course, it is the person with diabetes who should be empowered to be in charge of their care, in partnership with health-care professionals.

2.10.6. National policy

As already discussed, the period of time from April 2004 to early 2005 saw many changes to renal health care practice, culminating in the publication of the National Service Framework (NSF) for Renal Services (Part Two) (Department of Health 2005b). Two of the quality indicators described in this NSF made recommendations for the management of CKD in the community.

As a result of my findings regarding inconsistency in managing diabetic kidney disease in the local PCT, I developed some evidence-based local guidelines for diabetic kidney disease in collaboration with a local nephrologist, at the end of 2004. The aim was to ensure that all practices in the forthcoming research project were providing consistent care. To complement this guidance, draft guidelines for general CKD management (not specific to diabetes care) in primary care were published on the Renal Association website www.renal.org in January 2005. In February 2005 local clinical guidelines on CKD management were developed by the local renal unit and in April 2005 an educational programme for GPs and practice nurses in management of CKD was implemented.

Later in 2005, a number of local GP practices had improved knowledge of CKD management, either through the published local/national guidance, or from attendance at local seminars on the subject. Chapter 5 will explain the timelines of the national agenda on CKD in relation to the research project which was carried out after the case study.

2.11. Limitations of a case study approach

2.11.1. Validity of case-notes

Following a period of reflection once the case study observation period was completed, I realised that many questions were still unanswered and many issues were still being raised. This may have been because the questions which I had identified at the start of the observation period were not specific enough, or it may have been that the case notes that I wrote during the observation period were too superficial.

On reflection, the notes which I had made during each visit at the start of the observation period were scanty in parts. At times it seemed to be inappropriate to write notes during sensitive patient consultations, so sometimes I would write notes after returning home. However it was not until I was coming to the end of the case study observation period that I realised that I had not always written enough detail on two topic areas, such as the interaction between nurse and patient and also the educational strategies which were used to explain diabetic kidney disease to the patient and family. Once I had realised this I tried to 'fill in the gaps' as best I could by direct questioning of the practice nurses. Examples of the questions I asked were 'do you have written materials for handing out to patient regarding early kidney disease?' and 'do you like the PCT diabetes template for managing diabetes/early kidney disease?'

2.11.2. Influencing practice

The other main challenge which I encountered when observing care and subsequently writing the case study was the extent to which I wanted to influence practice during the observation period. As the main aim of the research project, which is described later in the thesis, is to develop and test a patient-centred education programme, it was preferable that I did not change care/management too much prior to the start of the main study. However the observation period and subsequent identification of patients with early kidney disease showed that some patients were receiving sub-optimal care with respect to prescription of ACE inhibitors, and a very small minority of patients did indeed require referral to the renal unit.

As described in the previous section, draft clinical guidelines for care of patients with diabetes and CKD were developed following the observation period so it could be assumed that patient management would change prior to the educational intervention which is to follow. Although the challenges of 'practitioner research' have been identified to some extent in the literature (Meyer et al. 2003), the tension for me between being a researcher and being a practitioner was very challenging. The main ethical dilemma which I encountered was trying to do the best for the patient yet at the same time avoiding change in practice which could subsequently affect results. This was never really completely resolved for me, although I did attend a student seminar on 'action research' (Bridges et al. 2001) in March 2005 which went some way in justifying the changes that I had made to practice.

2.12. Summary

In summary, a number of important issues have been raised as a result of this case study. The main aim was to observe care and education delivered by GPs and practice nurses to people with diabetes at risk of CKD. This was achieved and as a result I gained valuable insight into the ways in which CKD was managed in primary care. The secondary aims were to analyse collected using a theoretical framework and to identify themes within these data to subsequently inform the development of the self-management package. These themes and a summary of the case study findings are shown in Figure 2.8

Figure 2.8: Case study themes and findings
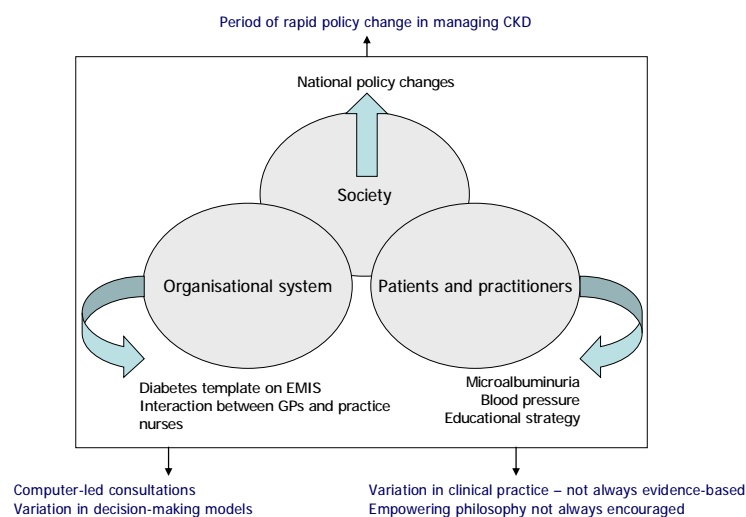
These aims were also achieved as a number of uncertainties regarding specialist clinical practice were identified, namely problems with undertaking MA testing and understanding blood pressure targets. These uncertainties experienced by the staff would have a resulting effect on patient care and education.

I had also intended that the case study would be an opportunity for me to provide educational input about kidney disease to practice nurses, GPs and patients. This was also achieved, as I gave clinical support especially in the areas of MA testing, blood pressure control and controlling CKD progression.

2.13. Chapter summary

The case study was undertaken five years ago, and it is recognised that clinical practice in the care of diabetes in primary care is likely to have changed and developed since then. The introduction of the QOF targets for both diabetes (2004) and CKD (2006) has certainly made practitioners aware of how they might improve the care of people at risk of CKD.

However, at the time of the case study, the conclusions that were drawn provided a very useful framework upon which to base the literature review and resulting research project. The next chapter will discuss the relevant underpinning literature that supports the evidence base for diabetes self-management.

3. CRITICAL REVIEW OF THE LITERATURE

3.1. Introduction

This review is directly linked to the findings of the case study and aims to identify and understand the best ways in which patients with diabetes can positively influence the evolution of their disease and its potential complications by self-care and self-management. The review utilises the theoretical framework developed in the case study. The findings of the review will shape the next stage of the Doctorate, that is, the development of a patient-centred education programme for patients with early diabetic kidney disease who are being managed in primary care.

The review is divided into sections: aims, method, findings and discussion. The review will conclude with concrete recommendations for development of the educational programme, which will subsequently be implemented and evaluated as part of the research project.

The overall aim is to carry out a comprehensive review of the literature that evaluates the effectiveness of educational interventions aimed at improving outcomes for patients with diabetes.

3.2. The review question

The review question is 'how far can self-care and self-management make a difference to improving outcomes for patients with diabetes?'

3.3. Aims of the literature review

- To carry out a review of the literature pertaining to diabetes and self-care/management
- To analyse the societal, organisational and inter-personal variables within the theoretical framework which impact on diabetes self-care/management
- To evaluate the different ways in which a patient-centred self-care/management programme can be developed
- For the findings of the review to inform the development of the educational model to be evaluated in the subsequent research project

The review was first developed at the start of the Doctorate in 2004, and written up in the following year. It is recognised that over the following three years, as the Doctorate progressed, further pertinent papers were published. As the thesis was being written up in 2008/9, the review was revisited and additional, important studies were added.

3.4.   Methods

Whilst preparing to commence the review, many questions concerning structure, method, writing style and scope were raised. The accepted method for undertaking a 'systematic' review is well-documented (Woolf 1992). However it was not clear how far the requirement to undertake 'a critical review of the literature' (as defined in the City University guidelines to undertake the Doctorate) meant that the review had to be systematic in its truest sense. A discussion now follows.

3.4.1.   <u>Definition</u>

The Centre for Reviews and Dissemination (CRD) University of York (2009) explain that the aim of a 'systematic review' is

"to identify, evaluate and summarise the findings of all relevant individual studies, thereby making the available evidence more accessible to decision makers. When appropriate, combining the results of several studies gives a more reliable and precise estimate of an intervention's effectiveness than one study alone." (Centre for Reviews and Dissemination 2009)(p.1)

The question is how far this review, which is essentially evaluating research papers with no hard endpoints, can be defined as systematic. If the CRD definition is broken down, it is possible to conclude whether a 'systematic review' is realistic within the time and word limits of this thesis.

There is certainly a clearly formulated question, that is, how far can self-care/management improve the outcome for patients with diabetes? It is possible that explicit methods of data collection can be developed in order to identify and select relevant primary research. But it is how far these papers can be critically appraised that is the tension here. Critical appraisal of literature with a qualitative methodology is possible (Boulton and Fitzpatrick 1997), but it is likely that many of the reports, unpublished studies, internal documents and articles in non-indexed journals (narrative literature) which are valuable to this review, cannot be appraised in a systematic way.

Other authors have been confronted with the same challenges. A strategy designed to overcome the barriers associated with integrating narrative literature into a systematic review of student interdisciplinary learning was carried out (Cooper et al. 2001) by one study group. This group developed a hierarchy (Kirkpatrick 1967) to judge the size of the effect of the intervention based on reported outcomes. They discovered that narrative reports, rather than quantitative outcomes, were the common mode of describing the effects of student learning. To evaluate these reports and papers, they used this hierarchy to monitor both the educational process and its effects. As shown in Figure 3.1, each stage 'reflects a hierarchy of levels of evaluation, with the complexity of behavioural change increasing as the evaluation of the intervention ascends the hierarchy' (Cooper et al. 2001).

Figure 3.1: Hierarchical levels of evaluation of inter-professional educational interventions developed from Kirkpatrick (1967)

RESULTS
Effect on learning environments

BEHAVIOUR
Transfer of learning into behaviour

LEARNING
Effects on knowledge, attitudes and beliefs

REACTION
Evaluation of the learning experience
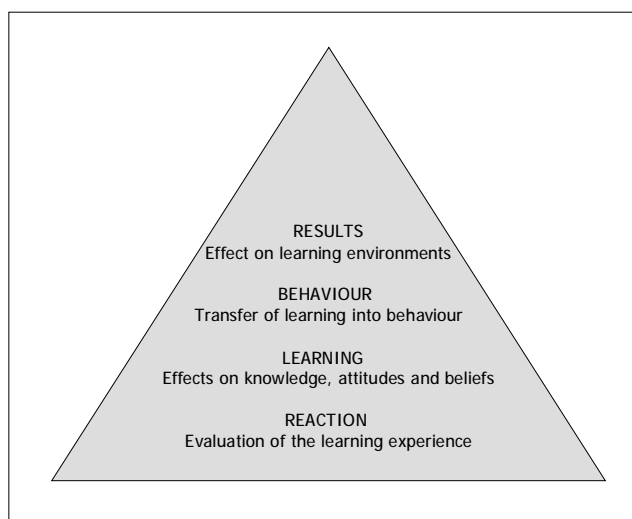
As this review faces similar challenges in evaluating the literature on patient-centred education, it was considered that this instrument of evaluation would also be helpful here. Figure 3.2 shows how the effects of the educational intervention identified within the Kirkpatrick model could be used to rate the outcomes of research studies evaluated in this review.

Figure 3.2: Effects of educational interventions

Effect	Relevance to this review
Effect on learning environment	Whether participants were asked to evaluate/modify the learning resources
Transfer of learning into behaviour	Whether participants had a change in behaviour measured (eg. controlling blood pressure and blood sugar, reducing weight, stopping smoking)
Change in knowledge, attitudes and beliefs	Whether participants had their knowledge or attitudes/beliefs assessed
Change in the learning experience	Whether participants evaluated the teaching and learning experience

The literature review undertaken here could therefore be defined as a 'narrative review undertaken in a systematic way'. In other words, I have undertaken a literature review within an identified framework which collates relevant studies and draws conclusions from them. However I have not been able to make explicit the review methods or decision-making rules that are possible to undertake with studies that have hard end-points such as randomised controlled trials (Smith 1996).

Rating the literature can only be successfully carried out if as much of the relevant research base as possible has been considered. The following sections explain how the CRD framework, first developed in 2001, then modified in 2009 (Centre for Reviews and Dissemination 2009) was used to collect and appraise all relevant information sources.

In summary, the data collection methods recommended by the CRD were used in this review, and the literature will be appraised using the Kirkpatrick (1967) model. Literature will be organised within the theoretical framework identified within the case study, which was based on the work of Silverman (1970).

3.4.2. Existing or commissioned reviews

The CRD (2009) makes recommendations for first identifying whether a good quality review already exists.

The original search question was 'how far can self-care and self-management make a difference to improving outcomes for patients with diabetes?' At the commencement of this Doctorate in February 2004, few specific reviews on this topic could be found.

One technology appraisal (NICE, 2003) had examined the clinical and cost-effectiveness of patient education models for adults with Type 1 or Type 2 diabetes. The review found that educational programmes for those with Type 1 diabetes could result in significant and long-lasting improvements in metabolic control and reduction in complications, however a diversity of educational programmes in Type 2 diabetes did not yield consistent results. The review concluded that:

> ".....the paucity of high quality trials that have tested education *per se* in diabetes reveals a need for more research." (National Institute for Health and Clinical Excellence 2003)(p.xi)

However, the NICE (2003) committee was convinced of the importance of patient education in improving glycaemic control and quality of life, while reducing the rate of complications associated with diabetes.

In June 2005, a joint report from the Department of Health and Diabetes UK, reported gaps in education provision, and recommended that local services ensure that all people with diabetes have access to high-quality education to support self-management.

Since this literature review was written at the beginning of the Doctorate in 2004/5, there has been an increasing interest in the evaluation of self-care/management programmes, not just for people with diabetes but also for all those with long-term conditions. As a consequence a number of pertinent reviews have been published (Boren et al. 2007, Loveman et al. 2008a). If these reviews had been published prior to the start of the research project, the findings would have contributed to the development of the self-management package. As they were published after this date, their findings will be discussed later in this thesis in Chapter 7.

3.4.3. Conducting the review

Collection of pertinent literature was commenced immediately after the registration for the Doctorate had been confirmed. The initial collection of material was not structured in any way, but rather was noted and/or filed as pertinent papers were found. During the time period February 2004-April 2005 relevant papers and publications were filed in categorised folders until the formal review commenced in May 2005.

Reading around the method of developing and writing the review started in mid 2005, and initially an experienced hospital librarian was involved in the search process. He made good suggestions for additional information sources (e.g. the TRIP database) which had been not been originally identified.

As discussed above, guidance from the Information Service Centre for Reviews and Dissemination, University of York (December 2004) was used to provide a framework for the review process.

3.4.4. Selection of studies and other information sources

Figure 3.3 describes the search criteria used in this review.

Figure 3.3: Search criteria

Keywords	diabetes mellitus, diabetes, education, health education, patient education, self-care, self-management, learning, teaching, learning strategies, program(me) evaluation, effectiveness, outcome, evaluation
Date of publication	1996 – present
Language	English

Figure 3.4 summarises the key sources and ongoing reviews which were searched during the period May-August 2005, and is structured on guidance from the Centre for Reviews and Dissemination (CRD), York (2009). In addition, the reference lists of all retrieved papers were examined for pertinent studies useful to the review.

Figure 3.4: Key literature sources (adapted from CRD, 2009)

The Cochrane Library

Three databases of published and ongoing systematic reviews:

- The Cochrane Database of Systematic Reviews (CDSR)

- Database of Abstracts of Reviews of Effectiveness (DARE)

- Critical appraisals of systematic reviews not published in the CDSR.

Health Technology Assessment (HTA) Database

Abstracts of completed technology assessments and ongoing projects being conducted by members of the International Network of Agencies for Health Technology Assessment (INAHTA) and other healthcare technology agencies.

Selected Internet sites and indexes (focusing on clinical effectiveness)

- TRIP - http://www.tripdatabase.com

- Health services/technology assessment text (HSTAT) - http://text.nlm.nih.gov/

- National Coordinating Centre for Health Technology Assessment
  http://www.hta.nhsweb.nhs.uk/

- ARIF appraisals – http://www.arif.bham.ac.uk/critical-apraisal-index.shtml

- NICE appraisals – http://nice.org.uk/

- SIGN guidelines - http://www.sign.ac.uk

General databases

MEDLINE, EMBASE, CINAHL, PsycINFO

Researchers

Personal contact with experts in the field

Research in progress

National Research Register (NRR) – https://portal.nihr.ac.uk/Pages/NRRArchive.aspx
(site has now changed to https://portal.nihr.ac.uk/Pages/NIHRResearchInfoStatement.aspx)

Figure 3.5 shows the number of studies and relevant papers that were found during the search. Abstracts to all papers were retrieved, and if thought to be relevant and pertinent to

the review, the full paper was found either on-line or by visiting local hospital and university libraries. Few requests for inter-library journals or book loans were needed.

Figure 3.5: Number of relevant information sources used in the review (in 2005)

Source		Number of papers found	Number of papers used in the review
COCHRANE	CDSR	6	4
	DARE	22	2
	HTA	2	1
INTERNET SITES	TRIP	0	0
	ARIF	0	0
	NICE	6	4
	DEPARTMENT OF HEALTH	7	6
	SIGN	2	2
GENERAL DATABASES	MEDLINE	147	27
	EMBASE	9	1
	CINAHL	23	15 (some duplication with MEDLINE)
	PsycINFO	10	8
	BIDS	6	1
	Blackwell Synergy	26	10
PERSONAL CONTACT		1	Personal communication
RESEARCH IN PROGRESS	National Research Register	3	2
HAND SEARCH	Journals in local library (eg. Diabetes Educator)	26	14

3.5.   The theoretical framework

The framework used for the review is the same as that utilised in the case study, and is shown in Figure 3.6. This framework will be used to structure the review within the themes of society, organisational system and patients/practitioners.

Figure 3.6: Theoretical framework for literature review
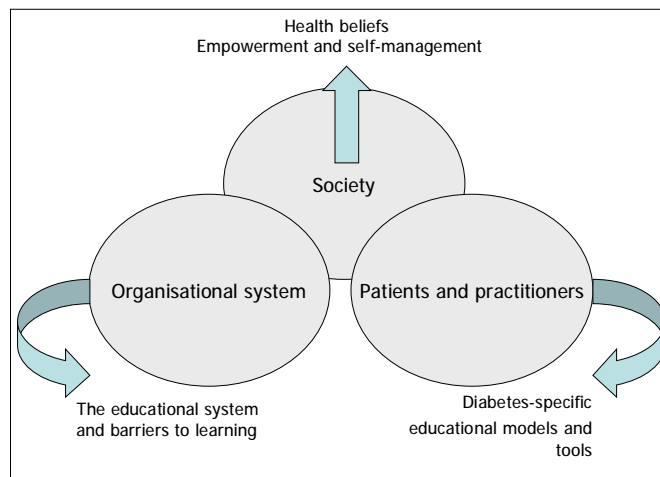
3.6.   Introduction to the literature review

Each of the three sections identified in the theoretical framework (society, organisational system, patients/practitioners) will be analysed, discussed and evaluated in this review. The first section explores how health behaviours can be influenced on a societal level. First, it is important to describe and evaluate how far the theory underpinning health beliefs can explain the health behaviours of those with diabetes.

3.7.   Society

3.7.1.   Societal beliefs about health

There are a number of significant theories and models that underpin the practice of health education and many of these can be attributed to beliefs about health. The most utilised theories which underpin research into education of patients with diabetes appear to be the health belief model (Rosenstock et al. 1988) and the locus of control model (Rotter 1966). A detailed explanation of these seminal theories and models can be readily found in textbooks (Connor and Norman 2005). For the purposes of this analysis, the relevance and validity of these models to diabetes care will be explored.

3.7.1.1.   Health belief model

The Health Belief Model (HBM) (Rosenstock 1966) which was modified at a later date (Janz and Becker 1984) attempts to explore why individuals with a chronic illness behave as they do. Rosenstock (1966) postulated that in order for a person to take action about his/her health they must believe that they are susceptible to the illness, have beliefs about the severity of the illness, and believe that the advantages of taking action outweigh the disadvantages.

In diabetes there have been a number of studies which have evaluated the use of the Rosenstock model to explain health-related behaviour (Cosby and Houlden 1996). A Chinese study (Tan 2004) concluded that poor preventive behaviour was associated with lack of perceived seriousness of diabetes and lack of perceived susceptibility to complications of diabetes. Cosby and Houlden (1996) reported health behaviours of those with diabetes in a Canadian aboriginal population. All the interviewees expressed the belief that the increased prevalence of diabetes was related to the loss of traditional lifestyle and therefore this made them susceptible. However they also described the importance of the role of family caregiver – this was believed to strongly influence adherence to dietary advice.

So it is not just an individual's belief about the disease which must be taken into account but also the attitudes of the people around them. The importance of assessing beliefs about health prior to commencing educational intervention is clear, although the evolution of health behaviours cannot be wholly understood through the application of the HBM.

This assertion is supported by other authors (Coates and Boore 1998) who concluded that:

> *'it is apparent that there are methodological weaknesses which need to be addressed in attempting to examine the relationship of the variables described in this (HBM) model and behaviours related to management of the condition (diabetes)'. (p. 532)*

3.7.1.2.   Locus of control

Rotter's theory of locus of control (LOC), written in 1966, is based on social learning theory. He described LOC as

> *'the amount of personal control over the environment individuals believe that they possess'.* (Rotter 1966)(p. 2)

The construct describes three variables: internal control, external control, and the influence of powerful others. People differ in the degree to which they believe that the events which occur to them are due to their own behaviour (internal LOC) or are due to circumstances outside their control (external LOC).

It could be expected that those with an internal LOC could take more responsibility for their condition, and this would manifest in better outcomes. However, findings from studies which explore this relationship are conflicting. Although patients with internal LOC are more likely to achieve greater levels of self-care and management of their illness, (Chin et al. 2000) there are studies (Lowery and Ducette 1976) which have not found this correlation. In Lowery and Ducette's study, the hypothesis that 'internals' know more about their illness and therefore have better outcomes, was unfounded. As predicted, those with internal control did have more information about their diabetes, although this superiority over 'externals' diminished as the length of the disease increased. What was surprising was that those with internal control seemed to incur more problems with disease as the disease progressed.

It could be argued that it is the way in which *health professionals* respond to those who want information (more control) about their condition which affects the long-term outcome. Firstly, information has to be valid, up-to-date and consistent for internally controlled people to use it effectively. Dietary advice given to patients with diabetes for example can often be outdated, and conflicting. There is also evidence to suggest that internally controlled patients (often termed 'expert patients') are not necessarily being well accepted by the health professionals they interact with. As Liam Donaldson, Chief Medical Officer, Department of Health, commenting on the Department of Health's Expert Patient Programme, said

> *"A true partnership will be achieved only with a significant change in the attitude of both patients and healthcare professionals and the way in which they interact with one another".* (Donaldson 2003)(p. 1279)

Using the LOC theory, it may be possible to understand what it is like to live with diabetes, in terms of how patients make behaviour changes to achieve self-management goals. However it may not be possible to find the positive correlation between internal control and health outcome as long as health professionals' behaviour is at odds with the underlying concept of empowerment.

According to the findings of a study by Coates and Boore (1998), neither health beliefs nor perceptions of control have a demonstrable influence upon the outcomes of diabetic

management. They suggested that despite the large amount of research that uses these models as a theoretical framework to explain participants' behaviour, their value in practice remains unclear.

3.7.1.3. Changing behaviour

A number of studies have attempted to utilise a theoretical model of change to understand the stages that individuals may go through when contemplating a change in behaviour. One study (Wells 1998) describes how the trans-theoretical model (Prochaska and DiClemente 1982) can explain why diabetes self-care can sometimes result in behaviour change, yet sometimes does not. The author supports the assertion underpinning Prochaska and DiClemente's model, that patients must have reached a specific point in the stage of change continuum (at least contemplation stage) before change is likely. An overview of the model is shown in Figure 3.7.

Figure 3.7: The Trans-theoretical Stages of Change Model

Pre-contemplation
 Has no intention to take action within the next 6 months

Contemplation
 Intends to take action within the next 6 months

Preparation
 Intends to take action within the next 30 days and has taken some
 behavioural steps in this direction.

Action
 Has changed overt behaviour for less than 6 months

Maintenance
 Has changed overt behaviour for more than 6 months

Termination
 Overt behaviour will never return, and there is complete confidence that one
 can cope without fear of relapse

Adapted from Prochaska and DiClemente, 1982

One study (Jones et al. 2003) compared usual diabetes management with a new 'Pathways To Change' model - an intervention developed from the Trans-theoretical Model, to determine whether this new intervention would result in greater readiness to change, greater increases in self-care, and improved diabetes control (n=1029 patients). Individuals who were in one

of three pre-action stages, either self-monitoring of blood glucose, healthy eating or smoking, were recruited.

43.4% of those having access to the new model moved to an action stage. In those who moved to an action stage for the blood glucose and healthy eating interventions, blood glucose levels (HbA1c) were significantly reduced (p < 0.001). This adds support to the hypothesis that individuals can only change when they are well prepared to do so.

However another study (Gaede et al. 2001) contradicted this hypothesis. Patients, aged 45-65 years, were randomly assigned either to an intensive group focusing on change of behaviour (n = 80) or to a control group receiving conventional treatment (n = 80). Despite the 'many resources invested in behaviour modification' in their study, only modest changes were obtained in dietary intake, measured by decreases in total and saturated fat in the diet. Changes in exercise and smoking habits did not differ between groups. The authors suggested that further studies are required to determine the best ways to induce long-lasting changes in behaviour in patients with diabetes.

So can these theoretical models translate into real changes in behaviour? The answer should not necessarily be framed in terms of *changing* behaviour, but rather in terms of facilitation and support. Recently in the UK there has been increased interest in exploring ways in which patients themselves can achieve health-related goals in partnership with health care professionals. The patient empowerment model is based on the pioneering work of Dr. Bob Anderson and Martha Funnell at the University of Michigan. At the heart of the patient empowerment model is the concept that health care providers listen to, and collaborate with, patients. As Funnell wrote,

> *"Within this model, our role is not to change our patients' behaviours, but to inspire, inform, support, and facilitate their efforts to identify and attain their own goals . . ."*
> (Funnell 2004)(p.202)

The Department of Health in the UK has supported this concept of empowerment on a number of different levels: national service frameworks, national policy and support for local initiatives which empower people to take responsibility for their health.

3.7.2. National Service Frameworks

The National Service Frameworks (NSFs) of relevance to this review are the NSF for Diabetes (2001) and the NSF for Long-Term Conditions (Department of Health 2005a).

Interestingly, the concept of empowerment is not overtly recognised or discussed in either of these documents, despite the Department's assertion that 'patient empowerment is at the heart of the government's plan to modernise the National Health Service' (Department of Health 2000). In spite of this, recognisable support for this underlying philosophy is promoted in the NSF for Long-Term Conditions (2005) as Quality Requirement One is termed: A Person-Centred Service. However there is no evidence in this document of practical ways in which patients can be empowered to take control of their condition.

The NSF for Diabetes (Department of Health 2001b) is a little more explicit and explains that

> "*The aims will be to empower people with diabetes through skills, knowledge and access to services to manage their own diabetes and fulfil their potential to live long lives free of the complications that can accompany diabetes*" (Department of Health 2001b)(p.14)

3.7.3. Other national policy documents

Other national policy documents are more encouraging. In 2004, the White Paper 'Choosing Health' was published (Department of Health 2004). This publication set out the key principles for supporting the public to make more healthy and informed choices with regards to their health. Information and practical support to get people motivated and improve emotional wellbeing and access to services were included. Interestingly there were few references to self-care or self-management within the 207 page document. Two pages highlight the success of self-care approaches in managing long-term conditions but confusingly appear to use the terms 'self-care' and 'expert patient' interchangeably.

> "*In recent years there has been growing evidence of the success of the 'self-care' or 'expert patient' approaches to people when they are ill. This approach helps people to learn more about their own illness, and how to manage it effectively without always depending on professionals for support. It helps to put patients in control of their plans for how they manage their own disease.*" (Department of Health, 2004) (p.111)

The term 'expert patient' is clearly a misnomer and this inappropriate label was discussed on a radio programme entitled 'The Expert Patient'. Joanne Shaw, Director of the Medicines Partnership, spoke for many by saying that

> *"the 'expert patient' is a difficult term and it certainly is one that's caused some barriers within the NHS and with doctors. Our view is that the term 'involved patient' is possibly a better one".* (Joanne Shaw, Director of the Medicines Partnership talking on BBC Radio 4 broadcast, 11 August 2005)

Whether the term 'expert patient' or 'involved patient' is used, the Department of Health has discussed the need to extend this approach into prevention of ill-health, enabling people to take greater control of their condition and enabling them to plan for their health on their own terms.

An interesting initiative based on this philosophy is the development of a personal health guide called *HealthSpace.* This is a secure personal health organiser on the internet (www.healthspace.nhs.uk). People can record personal information and preferences in *HealthSpace* and make decisions on sharing information with the professionals who organise their care. Figure 3.8 shows the type of information which can be accessed and inputted.

Figure 3.8: Information in an HealthSpace account

- access to NHS information services;
- graphical presentation of variable personal data (weight, height, dietary intake, smoking, alcohol intake, blood sugar levels, peak flow readings; immunisation log and reminder service;
- location maps for NHS services;
- access to 'Choose and Book' service

It was launched in 2003, although data on the number of users are not available. However a spokesperson for NHS Connecting for Health said, in March 2009, that it was hoping to sign up 4 million patients by 2014. It was hoped that the new communicator tool on *Healthspace* would enable patients to carry out e-mail consultations with GPs and other clinicians. Although the scheme had originally been given the go-ahead for launch in 2009 (costing £80m) patients have recently been invited to give their views on the future development. An online survey in July 2009 www.healthspace.nhs.uk asked patients to give their views on what functionality they would find useful and how often they would be likely to use such features.

The long term aim for the portal is to provide patients with a secure way of accessing their transactions with the NHS from anywhere in the world. Patients will be able to view their 'Summary Care Record', see the results of tests and letters sent about them, make GP appointments and order repeat prescriptions. The future of this scheme now seems uncertain.

As part of the implementation of the NSF for Long-Term Conditions, an NHS and Social Care Model to support local innovation was published (Department of Health 2005c). This report said:

> *"Health and social care providers will need to develop appropriate and accessible information, skills training and tools and equipment in order to empower patients and their carers to maximise their role as providers of care." (Department of Health 2005c)* (p.31)

> *"By increasing the amount of information available to patients, health and social care providers can empower them to take better care of themselves and their own conditions."* (Department of Health 2005c) (p.32)

This report contains practical details about how to empower patients with knowledge of their condition and recommends local initiatives such as the Expert Patient Programme (EPP) to develop generic self-care skills. Disease-specific programmes such as Dose Adjustment for Normal Eating (DAFNE) and Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) for diabetes are also recommended. The EPP, DAFNE and DESMOND education programmes will be discussed later in this review.

In January 2006, the Health Secretary announced the publication of a White Paper (WP) "Our health, our care, our say: a new direction for community services" (Department of Health 2006).

The National Diabetes Support Team (NDST) which helps support the implementation of the Diabetes NSF by working with local services to improve diabetes care, commented that the principles at the heart of the WP go right back to the NHS Plan and are aimed to accelerate the move into a new era where 'the service is designed around the patient rather than the needs of the patient being forced to fit around the service already provided' (Department of Health 2006)(p.1).

The whole focus of this WP is to put patients at centre-stage in designing health services and place them as equal partners in the provision of care through promotion of the self-management philosophy. The emphasis is on supporting self-care, promoting well-being and community engagement, as well as prevention and early intervention. The WP recommended a number of areas for consideration: the topic of most significance to this review is 'Support for people with longer-term needs'.

3.7.4. <u>Supporting self-care</u>

"People will be supported to take better control of their care and condition through a wide range of initiatives. These include a major new focus on self-care and self-management." (Department of Health 2006)(p.112)

The WP stated that a comprehensive framework with guidelines on developing local strategies to support self-care for people with long-term conditions will be published by the Department of Health in due course. Examples of changes to current provision include an increase in capacity to deliver the EPP from 12,000 course places a year to over 100,000 by 2012. There was also emphasis on engaging general practice in self-care. It was proposed that the Government would seek to ensure that practices use the information in their QOF (Quality and Outcomes Framework) registers to effectively commission services that support self-care for patients with long-term conditions.

There is the possibility that people with diabetes will benefit from these initiatives, perhaps most importantly where the General Services Contract (GMS) contract will increasingly contain requirements to support people in self-care. Practitioners will offer patients real involvement in planning their own care, whilst increasing access to the EPP has the potential to reap enormous benefits.

Overall the use of self-management programmes in chronic disease is developing, and some of these programmes are beginning to show success (Chodosh et al. 2005). Unfortunately there is "a lack of empirical evidence about the essential elements of such a program" (Chodosh et al. 2005)(p. 436). In a systematic review, (Boren et al. 2007) found evidence of the benefits of educational self-management interventions for reducing risks for diabetes. Boden et al (2007) stated that "future research should include intervention studies on diabetes risk reduction where evidence is lacking, such as diabetic nephropathy." (p.1075)

3.7.5. The Expert Patient Programme

The Expert Patient Programme (EPP) is a NHS-based training programme that provides opportunities to people who live with long-term chronic conditions to develop new skills to manage their condition better on a day-to-day basis. Set up in April 2002, it is based on research from the US and UK over the last two decades which shows that people living with chronic illnesses are often in the best position to know what they need in managing their own condition (www.expertpatients.nhs.uk). The EPP is one among a range of new policies and initiatives to modernise the NHS to emphasise the importance of the patient in the design and delivery of services.

Examination of the evidence shows that this type of self-management can potentially be beneficial for those with diabetes. Evaluation is ongoing in many centres but evaluation data from approximately 1000 EPP participants who completed the course between January 2003 and January 2005 in the UK (Department of Health 2005) indicated that the programme was achieving its aims in:

a. Providing significant numbers of people with long term conditions with the confidence and skills to better manage their condition on a daily basis:

Patient self-reported data were showing

- 45% more confident that they would not let common symptoms

(pain, tiredness, depression and breathlessness) interfere with their lives.

- 38% felt that such symptoms were less severe 4 – 6 months after completing

the course.

- 33% felt better prepared for consultations with health professionals

b. Providing significant reductions in service usage by people with long-term conditions completing the EPP course:

Patient self-reported data were showing

- 7% reductions in GP consultations
- 10% reductions in outpatient visits
- 16% reductions in A&E attendances
- 9% reductions in physiotherapy use

A local EPP for those with kidney problems was developed by me, my colleagues and patients in the renal unit. Courses for 10-12 participants ran in April 2005, March and June 2006.

Evaluation was only anecdotal, but the words of one participant suggest the potential impact of these programmes:

"I feel 100% better in my attitude and outlook and am proud of what I have achieved"

Since the time when this literature review was first undertaken, there have been developments in the Expert Patient Programme. The Health Foundation are now funding a new initiative called 'Co-creating Health', whereby self-management programmes, including those for people with diabetes, are being evaluated by the University of Coventry (Health Foundation 2008). Results are awaited.

A two arm, patient level, randomised controlled trial (RCT) and economic analysis has been carried out by the National Primary Care Research and Development Centres at Manchester and York Universities in partnership with Bristol University. The RCT involved 629 participants in England with self-defined long-term conditions, who were randomised to either the EPP course or to a waiting list for the course. Patient outcomes were measured at six months. Results showed that the EPP increased patients' self-efficacy by a moderate amount, and had a relatively smaller impact on the amount of energy people reported (chosen as the health status outcome most relevant to people with a range of long-term conditions)(Kennedy et al. 2007).

There was no change in health services utilisation (sum of GP consultations, practice nurse appointments, A&E attendances and outpatient visits) although overnight hospital stays and use of day-case facilities were reduced in the EPP group. There were small gains in secondary outcomes including psychological wellbeing and partnerships with doctors. There was high satisfaction with the course and particularly the experience of being in a group. The authors concluded that the EPP is likely to be a useful addition to current chronic disease management provision (Kennedy et al. 2007).

A systematic review (Foster et al. 2007) into lay-led self-management education programmes found that they could lead to small, short-term improvements in participants' self-efficacy, self-rated health, cognitive symptom management and frequency of aerobic exercise. However the review found that there was no evidence to suggest that such programmes improve psychological health, symptoms or health-related quality of life. The authors of this review suggested that further research was needed into clinical and longer term outcomes arising from such programmes.

3.7.6.   Health-care professionals and empowerment

Although a self-management approach has shown some benefits in chronic disease management, there is evidence that health professionals are not necessarily promoting an empowering ideology. In 1999, a survey of 200 doctors was undertaken by the Association of the British Pharmaceutical Industry (ABPI 1999). The survey found that only 21 per cent of doctors were in favour of the idea of 'Expert Patients'. 58 per cent thought it would increase workload and 42 per cent thought it would increase NHS costs. Only 24 per cent thought the EPP would lead to better health outcomes and 37 per cent thought it would lead to deterioration in the doctor-patient relationship.

It could be argued that the results of this survey are now outdated and many health care professionals are beginning to support the concept of self-management. The British Medical Association (BMA) conducted a review into the EPP, because it believes that self-management of long-term conditions is a crucially important issue for the NHS and the medical profession (British Medical Association 2005).

At the same time, diabetes educators are being encouraged to develop behaviourally based, effective education programmes (Funnell and Anderson 2004). However it could be argued that although clinical specialists are well-placed to provide the content of these programmes they do not have the necessary skills to deliver this approach. It appears that minimal research concerning the actual process of providing such programmes to patients has been carried out (Arnold et al. 1995).

One important topic for patients with diabetes and health care professionals alike is how far patients are enabled to take control of insulin requirements on a daily basis. Many hospital-based services do not allow patients to vary their insulin dose. However one study (Howorka et al. 2000) investigated short- and long-term effects of structured outpatient education on perceived control over diabetes and related health beliefs. A four-week study with 32 participants, and a 3 year uncontrolled pilot study with 68 participants, were performed. The programme focused on an individual's choice of insulin dosage. In the three-year study, participants were increasingly freed from the feeling of being under the control of physician and treatment-related restrictions which together, with higher perceived self-efficacy, contributed to the feeling of empowerment. Other outcome measures were not included in the study.

The conflict in roles for physicians and nurses implementing empowerment group education (EGE) in diabetes was investigated (Adolfsson et al. 2004). After implementing the 'empowerment approach', in two groups of patients with Type 2 diabetes, they were asked after three to nine months to evaluate the EGE. The authors asserted that the physicians and nurses were comfortable in their traditional role but not with the empowering approach. They needed to grow into this role as it had changed from being an expert to being a facilitator, and asserted that as experts they felt secure; as facilitators they needed support in their educational process.

This assertion was supported by another study group (Cooper et al. 2003) who found that whilst patients can be educated toward greater autonomy, not all health professionals are ready to work in partnership with them. It highlighted the importance of clinical staff not only gaining a better understanding of diabetes management, but also of the theoretical principles underlying patient empowerment.

Some practitioners might argue that empowerment is defined in different ways and therefore they find it difficult to practise in a consistent way. However, there seems to be commonly-accepted constituents of 'empowerment', namely that people are encouraged to participate as equal partners in decisions about the health care they receive and health care professionals respect patients' abilities to make decisions, value their input in such decisions, and are able to relinquish control when a patient rejects their advice (Chapman 1994).

So it cannot be that health professionals do not simply understand what the concept is. It could be that committing to its principles and philosophy is rather more difficult. It is possible that some health care professionals are not able to 'let go' and are unable to facilitate rather than 'control' (Cooper et al. 2003). These authors concluded that whilst education can empower patients to take on greater responsibility for the management of their disease, they cannot achieve long-term success without the co-operation of health professionals who can support and facilitate achievement of patients' goals.

3.7.7. Summary

This section on societal beliefs about health has described the significant theories and models that underpin the practice of health education with respect to diabetes mellitus. Despite a plethora of literature that attempts to evaluate the use of the models in explaining health behaviour in diabetes, there appears to be little consensus on whether these models are of value in practice.

The notion of empowerment however is becoming increasingly accepted as a positive way to change behaviour through patient involvement and support. National policy appears to consistently support this view, although there is little convincing data that shows improved patient outcome as a result of empowering interventions. It is possible that there is a mismatch between what is written about empowering patients and what is actually practised by health care professionals. Clearly any new intervention which is based on an empowering philosophy requires careful and consistent investment in staff education and training.

3.8.   Organisational system

3.8.1.   Introduction

A central question in the debate about patient education is how far the health care system can influence patient outcomes. The educational system in healthcare is diverse and sometimes 'ad hoc'. It ranges from individual consultations and interactions with a variety of health care professionals, through group education sessions to self-help groups and charitable advisory services. Of course much information 'learnt' by patients with a long-term condition is serendipitous – casual learning whilst waiting in out-patient clinics or as an in-patient. Learning also takes place through a variety of media, such as television, radio, or the internet.

This section will explore the effect of formal education provided by the health care system on patient outcomes, focussing on patients with diabetes. Literature pertaining to the educational systems for diabetes such as the environment, the effect of the social context and the effect of the condition itself will be discussed here.

3.8.2.   Environment

Only one review that evaluated the environmental impact on educational intervention and outcome was identified (Norris et al. 2002b). The authors reported the results of a systematic review into the effectiveness and economic efficiency of self-management education in a

variety of settings. The review concluded that education is more effective in community-gathering places for adults with Type 2 diabetes, yet can be effective in the home for adolescents with Type 1 diabetes.

Evidence was insufficient to assess whether self-management programmes at work or at summer camps were more effective for either people with Type 1 or Type 2 diabetes or in the home for people with Type 2 diabetes. The question is whether it is the positive effect of having other people with the same condition sharing the experiences which promote learning, or whether it is the environment alone.

3.8.3. Social Context

3.8.3.1. Social support

A systematic review of literature which assessed how far family interventions are effective in improving outcomes in people with diabetes and family members (blood or non-blood relatives) residing in their homes was carried out (Armour et al. 2005). The search identified 19 randomised controlled trials. Positive effects of family interventions on knowledge were demonstrated in five studies and on glucose control (HbA1c) in eight studies. The conclusion was that family support and advice for people with diabetes may be effective in improving diabetes-related knowledge and glycaemic control.

The positive effect of social variables on learning has been identified by a number of studies (Gleeson-Kreig et al. 2002). However, it is well-recognised that social support is not a simple variable which can be easily quantified, but rather a multi-dimensional concept, which has been described primarily according to three characteristics:

(a) the structural aspects of the support (who)
(b) the functional types of assistance (how)
(c) the nature of the support (what, where) (Vrabec 1997)

So when studying the effect of good/poor social support on diabetes education, the different aspects of social support must be taken into account. One Japanese study (Fukunishi et al. 1998) examined the influence of social support (measured by perception and utilisation) on 178 patients with diabetes mellitus. They concluded that although diabetes education is effective for decreasing HbA1c, a combination of two social supports (perceived and utilised)

decreases the HbA1c value, independent of diabetic education. This makes comparison between studies difficult.

Socio-economic status can also play its part. It is well accepted, and supported by one study (Kumari et al. 2004), that an inverse relationship exists between social position and incidence of diabetes, that can only be partly explained by health behaviours and other risk factors. But the question under review here is not just concerning the effect of socio-economic status on incidence, but rather how far *self-management* can be affected by social standing.

A review of the development of diabetes self-management programmes in under-served and minority populations has been carried out (Eakin et al. 2002). The review identified five formative evaluations and ten controlled intervention trials focusing on under-served (low-income, minority or aged) populations. The authors evaluated the methodological quality of the articles and found them to be generally good. Although they found that short-term reporting of behavioural outcomes was encouraging, data on implementation of the programmes were almost never reported. They concluded that 'the promising formative evaluation work that has been conducted needs to be extended for more systematic study of the process of intervention, implementation and adaptation.' (Eakin et al. 2002)(p. 26)

3.8.3.2. <u>Culture</u>

Much is written about how cultural issues need to be taken into consideration when implementing diabetes education programmes. One study (Chowdhury et al. 2000) emphasised the importance of considering culture when designing health education messages. They suggest that dietary advice should reflect religious restrictions, ethnic customs and the different cultural meaning of particular foods.

Cultural beliefs in the West Indian community have been explored (Scott 2001), but no evidence that cultural beliefs or practices conflicted with medical advice was found. However, the West Indian interviewees stated that the dietary advice provided did not take into account their traditional foods or cooking methods. More importantly, the subjects expressed a general distrust of doctors, the majority having developed a range of strategies which they used to negotiate consultations with doctors and the heath service. It is this aspect of belief which is strangely absent in the literature. Despite rigorous searching there was little strong evidence to suggest that cultural belief had a deleterious effect on outcome in diabetes.

The question of how far culture-specific education programmes make a difference to outcome is not well evaluated in the literature. For example, one study from the Netherlands (Uitewaal et al. 2004) described a specific programme for Turkish people with diabetes, and reported a

41% drop-out from the course of 54 patients. The only explanation was that most of the participants did not finish the course because they were travelling back to their country of birth.

Another programme specifically for Bangladeshi people in East London (Griffiths et al. 2005) was implemented and evaluated by comparing with a control group. The study aimed to determine the effectiveness of this culturally-adapted lay-led self-management programme for Bangladeshi adults with chronic disease. The findings showed that a culturally-adapted self-management programme could improve self-efficacy and self-care behaviour in this group, although the effects on health status were marginal. Benefits were limited by moderate uptake and attendance (34% out of 1363 invited agreed to take part). The challenge of improving uptake of self-management programmes, especially in so called 'hard-to-reach' groups, remains difficult to overcome.

Kidney Research UK started a project in 2004 whereby 'peer educators', who are active members of their community and representative of the diverse religious and cultural sub groups, were trained in health promotion matters and received extra training in renal health. Through the ABLE (A Better Life through Empowerment) programme, peer educators, with supervision and guidance from the project team, delivered imperative messages in a culturally sensitive manner, with a good knowledge of the needs, attitudes and experiences of their audience. This programme is still being evaluated in terms of outcome, although initial findings have shown positive feedback from participants, increased knowledge and evidence of positive lifestyle change (Jain et al. 2008).

A systematic review (Hawthorne et al. 2008) into 'culturally-appropriate' diabetes health education concluded that education specifically for people from a variety of different ethnic groups appears to have short term effects (3-6 months) on glycaemic control and knowledge of diabetes and healthy lifestyles. The definition of 'culturally appropriate' however does further discussion. In the Hawthorne review it was taken to mean any programme which was developed specifically for people from an ethnic minority, rather than a programme which was underpinned by a specific culture's health beliefs and values.

It was disappointing that few research projects which evaluated the effect of cultural beliefs about diabetes could be found. In my clinical experience and as found in the patient interviews (see section 4.16), it is often fatalistic beliefs ('only God can decide what happens to me') or beliefs about body size (being overweight is a sign of affluence) which have a strong impact on behaviour. These variables need to be researched in more depth in relation to changing behaviours in care of people with diabetes.

3.8.3.3.   <u>Literacy</u>

Few studies were found which rigorously examined the interventions that could improve outcomes for patients with low literacy. The impact of low literacy skills on the effectiveness of a comprehensive disease management programme for patients with diabetes have been investigated by (Rothman et al. 2004).   217 patients with Type 2 diabetes and poor glycaemic control (HbA1c ≥8.0%) were included in their study. Each of these patients with low literacy were either given intensive disease management from a multidisciplinary team or offered an initial management session and continued with usual care (control group).

The intensive management group received education from three clinical pharmacist practitioners (two were certified diabetes educators). The intervention included (1) one-to-one educational sessions (2) application of evidence-based treatment algorithms (3) help with practical aspects such telephone reminders, transportation, and insurance. Patients were contacted by telephone or in person every 2 to 4 weeks (more frequently if indicated). Communication to patients was individualised - verbal education with concrete, simplified explanations, "teach-back" to assess patient comprehension and picture-based materials. Outcome measures were HbA1c levels and systolic blood pressure at 12-months. Although patients receiving the intervention were more likely than patients in the control group to achieve HbA1c levels of <7.0%, (p=0.02), patients with higher literacy had similar odds of achieving goal HbA1c levels regardless of intervention status.

Unfortunately there are few other studies which have tested an intervention for patients with low literacy. These findings are from a small cohort with perhaps expected results. Yet the intervention requires extensive input with regard to expertise, time and of course, motivation from the participants. The debate is whether health care professionals can eradicate the inequality in outcome between those who are literate and those who are not.

3.8.3.4.   <u>Age</u>

Only two reviews which evaluated the effect of age on ability to self-manage diabetes were found. One review (Asimakopoulou and Hampson 2002) concluded that cognitive impairment is not associated with clinically significant impairment on self-management tasks. They cautiously suggested that older people with diabetes can be reassured that 'even if diabetes

is associated with some modest cognitive decline, this decline in itself is unlikely to endanger their ability to self-manage their illness.' (Asimakopoulou and Hampson 2002)(p. 116)

Adolescents' views on the acceptability and design of a diabetes education programme have been studied (Waller et al. 2005). The authors found, through a focus group analysis, that young people preferred to use electronic reference materials, and more importantly that education should always be enjoyable. The focus group participants (n=24) recommended fun and practical educational sessions and that education should sometimes be held away from the hospital or clinic setting.

3.8.3.5. Gender

Hawthorne and colleagues studied over one hundred British Pakistani women within a larger randomised controlled trial of two hundred patients with diabetes of Pakistani origin (Hawthorne 2001). The trial used one-to-one structured diabetes health education, delivered by a link worker with pictorial flashcards as a visual aid. Earlier published results from this study have shown that the women in the study knew less about diabetes and had poorer glycaemic control than men, which is why this assessment was performed to see what happened to them when they received appropriate health education. All patients were assessed before, and six months after intervention by HbA1c blood tests to measure their overall blood sugar control. Nearly everyone improved their knowledge scores after 6 months in the intervention group, with women showing a significant catch-up improvement such that they equalled men in HbA1c outcomes.

What is not clear however, is how far literacy or language had an impact. Was it the pictorial flashcards which made a difference (women may learn best with visual images) or was it that prior education had been given by written or verbal education only (these women did not have English as their first language)? What could be concluded is that women may learn in different ways from men, and this has to be considered when developing education programmes.

3.8.4. Diabetes mellitus and cognitive function

Although the impact of the illness on learning could not necessarily be described as an organisational variable, issues concerning the possible barriers to learning brought about by the disease process are highly pertinent to the debate. It was decided to include the section on the disease process here, rather than in the following section on patients and

practitioners. This is because the condition of diabetes itself (altered cognitive function for example) can impact on learning, and therefore should subsequently shape the organisation of the educational intervention.

Both chronic hyperglycemia (Ryan and Williams 1993), recurrent episodes of severe hypoglycemia (Deary, 1993) and the subsequent occurrence of the complications of diabetes (Ferguson et al. 2003) are thought to be associated with cognitive dysfunction in patients with diabetes. In a meta-analysis (Brands et al. 2005) of 33 studies on the effects of cognitive function in Type 1 diabetes, the authors concluded that cognitive dysfunction in this group is characterised by a slowing of mental speed and a diminished mental agility. They hypothesise that learning and memory are not necessarily affected, but go on to suggest that even mild forms of cognitive dysfunction might hamper everyday activities.

It appears that from the outset of any learning process, patients with diabetes may have challenges with regard to the mental agility that is required for processing information. Clearly this has implications for the teaching method and media – it is possible that 'bite-size' chunks of information delivered in an uncomplicated way would be most beneficial.

3.8.5. Summary

This section has reviewed the organisational issues that can affect educational interventions in diabetes care. Interestingly this is one area that appears to have a deficit in terms of evaluative research. Questions relating to whether individual or group education has a better outcome; and who can get the most effective message across when teaching about diabetes; remain unanswered. What has been seen is that any educational intervention has to take into account the possible barriers to learning, such as poor family support, and that any educational programme should ensure that learning and teaching materials are appropriate in terms of culture, age and gender.

3.9. Patients and practitioners

3.9.1. Context

The NSF for Diabetes (2001) recognised that the provision of information, education, and psychological support that facilitates self-management is the cornerstone of diabetes care. The NSF set primary care trusts (PCTs) the task of providing 'empowering education' by March 2006. But it is likely that PCTs were already well-behind with the identified timeframe,

with the Department of Health report (2005) on structured patient education in diabetes citing three national programmes that meet the key criteria for diabetes education. Of these, DESMOND was only ready to start implementation of courses at the end of 2005.

A review of the three national programmes for diabetes education now follows.

3.9.2.   DAFNE

The Dose Adjustment for Normal Eating (DAFNE) study was originally carried out as a randomised controlled trial in three centres (DAFNE study group 2002). Outcomes were measured by glycated haemoglobin (HbA1c) and quality of life. DAFNE has since been successfully rolled out to centres in the United Kingdom. It is a skills-based structured education programme in intensive insulin therapy (IIT) delivered by specially trained diabetes specialist nurses and dietitians. The course is taught in groups of 6-8 over a consecutive 5-day period on an outpatient basis.

The main principles of the DAFNE course are:

- Skills based training to teach flexible insulin adjustment to match carbohydrate in a free diet on a meal-by-meal basis.
- Emphasis on self-management and independence from the diabetes care team.
- Use of adult education principles to facilitate new learning in a group setting.

The course consists of three main topic areas: nutrition; insulin dose adjustment at mealtimes and special circumstances (exercise, illness); other topics such as hypoglycaemia and complications of diabetes. An evaluative economic study by the York Health Economics Consortium showed that reduced complications meant that DAFNE pays for itself within 5 years (DAFNE study group 2002).

The course was evaluated with a randomised design with participants either attending training immediately (the immediate DAFNE group) or acting as controls (the delayed DAFNE group) and attending training 6 months later (DAFNE study group 2002). 169 adults with Type 1 diabetes and moderate or poor glycaemic control took part. Outcome was measured by glycated haemoglobin (HbA1c), and at 6 months, HbA1c was significantly better in immediate DAFNE patients (mean 8.4%) than in delayed DAFNE patients (9.4%) ($p < 0.0001$). The authors concluded that skills training that promotes dietary freedom improves the quality of life and glycaemic control in people with Type 1 diabetes without worsening severe hypoglycaemia or cardiovascular risk (DAFNE study group 2002).

3.9.3. DESMOND

The Diabetes National Service Framework (NSF) (Department of Health 2001b) and the NICE technology appraisal of patient-education models for diabetes (National Institute for Health and Clinical Excellence 2003) make it clear that patients with Type 2 diabetes need to be able to access structured education programmes as well as those with Type 1 diabetes. The Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme is for people with Type 2 diabetes. The programme was piloted in 15 Primary Care Trusts in England in 2004, and was subject to reflection and revision following feedback from all those participating in the pilot process. The second version of the programme has been the subject of a randomised control trial of 1000 patients taking place in selected PCT sites in England and Scotland (Davies et al 2008a).

The programme has the following characteristics:

- It provides 6 hours of structured group education according to a formal curriculum
- Groups consist of 6-10 people newly diagnosed with Type 2 diabetes
- Each person attending a group can choose to be accompanied by a partner, family member or friend
- Each person attending a group is provided with patient material especially developed to accompany the programme and intended as a reference guide subsequent to attending the course

The programme is delivered by two healthcare professionals who:

- Have attended a two-day initial formal training programme to graduate as DESMOND Educators
- Will submit to a quality assurance programme in the first year of 'graduating', and subsequently every three years
- Will use defined resources to deliver the programme
- Will deliver 5 courses annually to maintain competency as a DESMOND Educator

When this literature review was first written, results from the programme evaluation were not available. However a large cluster randomised controlled trial, to measure the effect and duration of the intervention, involving 170 subjects had commenced. The primary outcome was HbA1c at 12 months, whilst secondary outcomes included: BP; lipids; BMI; and waist

circumference at 4, 8 and 12 months. Patient well-being questionnaires were also being used at the same time intervals and a health economic questionnaire was also to be implemented at 12 months.

Results were subsequently published in 2008 (Davies et al. 2008). It was found that the DESMOND programme resulted in improvements in weight loss and smoking cessation and positive improvements in beliefs about illness but no significant difference in HbA1c levels up to 12 months after diagnosis. These results were disappointing but may be due in part to the limitations of HbA1c as an outcome measure as reported by the research team (Davies 2008). It is possible for example that people newly-diagnosed with diabetes have lower baseline levels of HbA1c than those who have had diabetes for some time, therefore reductions in HbA1c as a result of the DESMOND programme might not be significant.

3.9.4.   X-PERT

The diabetes X-PERT Programme was designed in conjunction with patients and a local branch of Diabetes UK. It is a six-week group education programme based on the theories of patient empowerment and patient activation. The programme has been evaluated by means of a randomised controlled trial involving 314 participants (Deakin et al. 2006).

The control group received routine treatment, individual appointments from the GP, practice nurse and dietitian. Each X-PERT session used visual aids to explore health issues related to diabetes and each participant received a copy of their own health results with an explanation. The X-PERT Programme aimed to increase knowledge, skills and confidence so that individuals were able to make informed decisions regarding their diabetes self-management. Participants were then encouraged to set goals based on a five step empowerment model developed by Anderson and Funnell at the Michigan Diabetes and Training Centre, USA (Anderson et al. 2000).

Highly significant statistical differences were found in favour of the X-PERT Programme for biomedical, lifestyle and psychosocial outcomes. The participants assigned to the X-PERT programme had significantly improved diabetes control, a reduced requirement for diabetes medication, clinically important reductions to blood pressure and a three centimetre reduction in waist circumference. They had improved diabetes self-management skills, increased physical activity levels and were enjoying a healthier diet. Quality of life had improved through freedom to eat and drink and enjoyment of food. Self-empowerment scores had significantly improved (Deakin et al. 2006).

As discussed, there are a number of nationally recognised educational interventions for those with diabetes in the UK, although evaluation in some studies has only identified increased satisfaction and not always a benefit in controlling glycaemia.

Each of these programmes uses an educational method whereby patients come together in groups to learn from each other. It is recognised however that other variables in learning and teaching method can impact on the outcomes. It is possible that patient-preparedness when visiting for traditional consultations, interactive learning through DVD or CD-ROM, or by consultation over the internet (telemedicine) could also be beneficial.

3.9.5. Patient-preparedness

Another consideration is how far patients need to be prepared for visiting a doctor or nurse in a traditional consultation. A systematic review (van Dam et al. 2003) was undertaken to test the effects of modification of provider-patient interaction and provider consulting style on patient diabetes self-care and diabetes outcomes. The authors came to a tentative conclusion that focusing on patient behaviour (such as enhancing patient participation in a consultation) is more effective than focusing on health professionals to change their consulting style into a more patient-centred one. The authors concluded that trying to change health professionals' behaviour is often hard to sustain and is not very effective in improving patient self-care and health outcomes when executed alone.

It could be argued that outcome can only be improved when a true partnership between health professional and patient is initiated – even if patients know how to ask the right questions, they can surely only benefit if the health professionals have an open mind to true patient-centred care and empowerment

A Multidisciplinary Intensive Education Program (MIEP) (Keers et al. 2004), based on the empowerment approach, was developed to help patients obtain good glycaemic control and quality of life. The aim was to identify the effects of MIEP and it's mechanisms of influence. MIEP consisted of 12 days of group-sessions and individual counselling. HbA1c measures and knowledge improved significantly, whilst patients rated themselves healthier. Although this was just a pilot study it appeared that MIEP benefited patients who had prolonged self-management difficulties, and this form of care seemed to complement regular care. Although this type of approach may not be feasible or realistic for everyone, the importance of understanding *why* people may not find it easy to self-manage cannot be underestimated.

3.9.6. Learning and teaching media

3.9.6.1.   Telemedicine

Telemedicine can be defined as the use of telecommunications technology for medical diagnosis and patient care when the provider and client are separated by distance (Currell et al. 2001). Increasingly this technique is being used in managing the care of people with diabetes.

A Cochrane review (Currell et al. 2000) evaluated telemedicine versus face-to-face patient care, and also the effects on professional practice and health care outcomes. Seven trials involving more than 800 people were included in the review, with five of the studies concerned with the provision of home care or patient self-monitoring of chronic disease. The authors concluded that although none of the studies showed any detrimental effects from the interventions, neither did they show unequivocal benefits and the findings did not constitute evidence of the safety of telemedicine. In other words, establishing systems for patient care using telecommunications technologies is feasible, but there is little evidence of clinical benefits.

Only two of the studies in the Cochrane review were concerned with diabetes management, and one of these evaluated paediatric care. Before dismissing telemedicine as a technology which does not necessarily have beneficial outcomes for patients with diabetes, it is important to review other papers. Two are of note.

One paper (Farmer et al. 2005) determined whether a system of telemedicine support could improve glycaemic control in Type 1 diabetes. They utilised a 9-month randomised trial and compared traditional glucose self-monitoring in a control group with an intervention group. The intervention group used phone-based feedback together with nurse-initiated support using a web-based graphical analysis of glucose self-monitoring. In total, the intervention and control groups transmitted 29,765 and 21,400 results, respectively.

Findings showed a reduction in blood glucose levels between the two groups ($p < 0.0001$), although the reduction in HbA1c in the intervention group after 9 months was not statistically significant. The authors concluded that telemedicine transmission and feedback of information about blood glucose results with nurse support is feasible and acceptable to patients. However to significantly improve glycaemic control, access to *real-time* decision support for medication dosing and changes in diet and exercise may be required.

In a similar study (Izquierdo et al. 2003) the researchers determined whether diabetes education could be provided as effectively through telemedicine technology as through in-

person encounters with diabetes nurse and nutrition educators. A total of 56 adults with diabetes were randomised to receive diabetes education in person (control group) or via telemedicine and were followed prospectively. Similar changes in HbA1c were observed in both groups. Although these data suggest that telemedicine can be successfully used to provide diabetes education to patients, the authors asserted that there was no clear benefit in using a telemedicine approach. However using HbA1c as the sole hard end-point to evaluate the success of this initiative is perhaps misleading as patients only received three educational visits in both the control and the telemedicine group. As HbA1c measures longer-term glycaemic control the effect may have been missed as only *one* HbA1c reading was taken 3 months after the intervention.

3.9.7. <u>Other interactive technologies</u>

The internet and read-only memory compact disks (CD-ROMs) as supplements to, and extensions of, diabetes self-management education have been compared in an evaluative study (Glasgow and Bull 2001). A RE-AIM framework was used to consider how different interactive technologies have been used to enhance the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) of interventions.

One of the review authors' own studies (Glasgow and Toobert 2000) compared a computer-assisted, dietary goal-setting intervention with normal practice, and found it to be moderately successful in producing dietary improvements but less so in producing HbA1c or quality-of-life outcomes. Another study (King et al. 2004) described the benefits and drawbacks of read-only memory compact disks (CD-ROMs) to facilitate diabetes self-management, using the experience from two efficacy trials with CD-ROMs as the primary modality for intervention. The CD-ROMs were designed to promote health behaviour change and prevent complications by increasing attention to diabetes care guidelines and providing tailored self-management plans to patients with Type 2 diabetes.

A meta-analysis (Ellis et al. 2004) of randomised controlled trials of diabetes patient education published between 1990 and December 2000 summarises very well the discussion in this review. They identified which variables within an education intervention best explained variance in glycaemic control. Twenty-eight educational interventions (n=2439) were included in the analysis and meta-regression revealed that current patient education interventions only *modestly* improve glycaemic control in adults with diabetes. The interventions most likely to improve glycaemic control included face-to-face delivery, 'cognitive reframing' teaching methods, and programmes with an exercise content.

3.10. Discussion

The main aim of this chapter has been to examine the evidence to see to what extent patient education, specifically self-care or self-management programmes, can make a difference to patients with diabetes. The main flaw in drawing a finite conclusion has been the difficulty in comparing results that have been found from varying methodologies.

Difficulties in finding firm conclusions have also arisen because of differences in outcome measures. As suggested in the early part of this chapter, it is challenging to judge the size of the effect of the intervention, when results are based on very different reported outcomes. Some outcomes are measured by how well the participants evaluated the learning experience (were the facilitators friendly, were the learning resources easy to read), some are measured by change in knowledge (can participants explain what might happen with a low blood sugar), whilst some studies measure the transfer of learning into behaviour. With studies into diabetes, the most common measurable outcome utilised by researchers, is the effect on HbA1c, although this too can have shortcomings.

It is likely that different types of educational model and/or styles of teaching may suit different people in different ways. Learning styles are often cited as being the most important attribute to assess before any learning plan or implementation of learning can take place. The four following learning styles have been suggested (Honey and Mumford 1982). See Figure 3.9.

Figure 3.9: Learning styles (adapted from Honey and Mumford, 1982)

Activists	Like to be involved in new experiences. They learn best when involved in new experiences, problems and opportunities, and being thrown in the deep end with a difficult task. They learn less well when listening to lectures or long explanations, or reading, writing or thinking on their own.
Reflectors	They like to stand back and look at a situation from different perspectives. Reflectors learn best when observing individuals or groups at work but learn less when acting as leader or role-playing in front of others, and doing things with no time to prepare.
Theorists	They like to adapt and integrate observations into complex and logically sound theories. Theorists learn best when they are put in complex situations where they have to use their skills and knowledge, but they learn less well when they have to participate in situations which emphasise emotion and feelings.
Pragmatists	They like to try things out. They learn best when they have the chance to try out techniques with feedback. They learn less well when there is no obvious or immediate benefit that they can recognise, or there is no practice or guidance on how to do it.

By thinking about a person's preferred style, it is possible that teaching and subsequent learning becomes much easier and quicker.

3.11. **Chapter summary**

This review identified some important conclusions about diabetes education, which in turn will inform the development of the education package.

It appears that better outcomes can be achieved by face-to-face delivery of education. Group education has also shown some success although not consistently. There is some evidence that educational interventions work best when tailored to individual circumstances (gender, age, ethnic group) although evidence for this assertion is patchy.

The best medium by which the content is delivered is also inconclusive. Good results have been achieved with telemedicine, although long-term effects are not enduring. Similarly other findings suggest that the benefit of CD-ROMS in self-management programmes is not always apparent.

Since this review was first written there has been a systematic review of diabetes education models undertaken (Vermeire et al. 2009). Twenty-one studies assessing interventions aimed at improving adherence to treatment recommendations, in people with Type 2 diabetes in primary care, outpatient settings, community and hospital settings, were included. Disappointingly the authors concluded that efforts to improve or to facilitate adherence of people with Type 2 diabetes to treatment recommendations do not show significant effects, although some interventions such as diabetes education, and adaptation of dosing and frequency of medication taking showed a small effect on a variety of outcomes, including HbA1c. In other words, the question of whether any particular type of education or intervention is more effective than another remains unanswered.

Vermeire et al (2009) go on to state that their conclusions are concordant with those of another systematic review (Loveman et al. 2008a), which found that although educational interventions can produce improvement in diabetic control in people with Type 1 diabetes, there are mixed results for people with Type 2 diabetes. In other words it is difficult to identify what specific features of education may be beneficial.

Finally the review had identified that health-care professionals may need training and support in facilitating a true patient-centred empowering approach. These findings might be of particular significance when the practical aspects of rolling-out a self-management package are considered.

3.12. Conclusion

Whilst the case study identified some potential content for the education programme, the literature review in contrast identified the need for further research particularly as studies with differing methods are difficult to compare.

The following chapter will explain how the development of the self-management pack was informed by the findings of the case study, also from the findings of some pertinent studies from the literature review and also from the results of the interviews with patients.

4. RESEARCH REPORT: DEVELOPMENT OF THE SELF-MANAGEMENT PACK

4.1. Introduction

This report details the research study carried out between February 2003 and June 2008 in a Renal and Transplantation Unit/Research Institute in Greater London and six GP surgeries in one local Primary Care Trust (PCT). The research study evolved from the work undertaken for the case study (Chapter 2) and the literature review (Chapter 3).

This chapter is divided into three main sections: the background to the study; the aims of the study and the way in which the self-management package was developed. The implementation and testing of the self-management package will follow in Chapter 5. The results and discussion are incorporated in Chapters 6 and 7.

4.2. Background to the study

4.2.1. <u>Diabetes and kidney disease</u>

Diabetes mellitus affects at least 4% of adults in the UK (Evans 2007) with numbers of those with Type 2 diabetes increasing because of the ageing population and levels of obesity (Sorensen 2000). Consequently, it is likely that the rate of established renal failure (ERF) due to diabetes will be increased in the years ahead. At present, diabetic nephropathy is the leading cause of ERF in new patients each year who require renal replacement therapy (dialysis or a transplant) (UK Renal Registry 2007). In 2006 approximately 22% of the UK dialysis population had diabetes as the primary renal diagnosis, although there is a large variation due to ethnicity. In Bradford and East London for example, more than 35% of the dialysis population had diabetes as the underlying disease (UK Renal Registry 2007). The percentage of new patients with diabetes on dialysis in the UK has risen 2% since 2005 (UK Renal Registry 2007) and this increase in the rate of diabetic kidney disease is a cause for concern.

As stated in the introductory chapter, many studies have shown that the course of diabetic kidney disease can be slowed by identifying those at risk and subsequently managing blood pressure to target, improving glycaemic control and giving advice and support on lifestyle changes, such as exercise, weight loss and smoking cessation (Bilous 2008, DCCT Research Group 1995, Gerstein 2002, Mancia 2007).

4.2.2.   Preventing deterioration of kidney function

Many recent initiatives have identified the need to prevent the deterioration of renal disease in diabetes. The National Institute for Health and Clinical Excellence (NICE) published guidelines in 2002 for the management of renal disease in Type 2 diabetes (National Institute for Health and Clinical Excellence 2002). The General Medical Services (GMS) contract for GPs introduced targets for diabetes such as blood pressure control, prescription of angiotensin-converting enzyme (ACE) inhibitors, and microalbuminuria and creatinine testing (NHS Confederation and the General Practitioners Committee (GPC) of the British Medical Association (BMA), 2004). The National Service Framework (NSF) for Renal Services (Department of Health 2005) called for:

> 'people at increased risk of developing or having undiagnosed chronic kidney disease (CKD), especially people with diabetes or hypertension, to be identified, assessed and their condition managed to preserve their kidney function' (Department of Health 2005)(p.vii).

In April 2006 the GMS contract (NHS Confederation and the GPC of the BMA 2006) included for the first time, targets for CKD. These Quality and Outcome (QOF) targets are shown in Figure 4.1.

Figure 4.1: QOF Targets for CKD 2006

Indicator	Points	Payment Stages
CKD 1: The practice can produce a register of patients aged 18 years and over with CKD. (US National Kidney Foundation: Stage 3-5 CKD)	6	
CKD 2: The percentage of patients on the CKD register whose notes have a record of blood pressure in the previous 15 months	6	40-90%
CKD 3: The percentage of patients on the CKD register in whom the last blood pressure reading, measured in the previous 15 months, is 140/85 or less	11	40-70%
CKD 4: The percentage of patients on the CKD register who are treated with an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) (Unless a contraindication or side effects are recorded)	4	40-80%

In addition, the QOF indicator CKD 4 as shown in Figure 4.1, was changed in April 2008 to indicator CKD 5. This new indicator included proteinuria measurement, as follows, with changes in italics.

CKD 5: The percentage of patients on the CKD register *with hypertension and proteinuria* who are treated with an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) (Unless a contraindication or side effects are recorded).

In April 2009, another additional QOF indicator was added:

CKD 6: The percentage of patients on the CKD register whose notes have a record of an albumin: creatinine ratio (or protein: creatinine ratio) value in the previous 15 months.

As the existence of proteinuria is known to be associated with accelerated decline in renal function (Iseki et al. 2003) this amendment to the QOF indicator may mean further improvements in the management and outcome of people with CKD.

In September 2008 NICE published guidance on the management of CKD in primary care (National Institute for Health and Clinical Excellence 2008). This new guidance will influence the way in which people with CKD are managed in primary care, and provides guidance on:

- identifying people who have or are at risk of developing CKD
- identifying who needs intervention to minimise cardiovascular risk and what that intervention should be
- identifying who will develop progressive kidney disease and/or complications of kidney disease and how they can be managed
- identifying who needs referral for specialist kidney care

Since this research study has been running, national initiatives have aimed to improve the management of patients with diabetic kidney disease. These initiatives are welcomed, although they will of course take time to have an effect on patient outcomes. In 2008, large numbers of patients with diabetes still progress to established renal disease, and will eventually require dialysis or a kidney transplant, equating to around 22% of the total dialysis population, with huge regional variation due to ethnicity (UK Renal Registry 2007).

Another challenge is that around 24% patients (range 10-38%) commencing renal replacement therapy are referred late to renal units, that is, within three months of needing dialysis (UK Renal Registry 2007), yet the NSF for Renal Services (Department of Health 2005) has recommended that patients should be referred at least one year ahead. Although there has been a sustained and significant reduction in late referral over the past five years (Renal Registry 2007), 16% of all those who are late-referred have diabetes as their primary renal diagnosis. What is concerning is that this cohort should be in a system, the Quality and Outcomes Framework, that recalls individuals for an annual review in primary care. Referral in good time to renal units, enabling a planned start to dialysis, should therefore be a top priority for primary care teams when caring for this vulnerable group. The greater the emphasis on early detection of CKD, the more likely it is that those at risk will be managed better and referred to secondary care in good time.

4.2.3.   Self-management of early kidney disease

Much is being done to improve primary and secondary care collaboration, which in turn might influence better understanding of CKD, and, as a consequence, improved management and timely referral. However it could be argued that care from health care professionals can only be optimised if people themselves are given information about their condition, and empowered to take control of the disease progression.

Most people with diabetes spend only a few hours in contact with health care professionals each year, and the rest of the time they manage their diabetes themselves. Supporting people to manage their own diabetes is therefore at the heart of empowering people with diabetes, improving their experiences of services and improving their health outcomes (Department of Health 2001).

In 2003 NICE produced an appraisal of structured education in diabetes (National Institute for Health and Clinical Excellence 2003) . It was found that education is often offered on an 'ad hoc' basis and is not ongoing. Large studies have shown that patient education, if provided, does not tend to be based on proven educational or behavioural principles, nor is it usually evaluated properly to ascertain its effects in improving outcomes. Of concern is that these NICE guidelines do not specifically mention kidney disease as a complication of diabetes in the recommended list of topics for discussion with patients.

In June 2005 a joint publication between the Department of Health and Diabetes UK also reviewed structured patient education programmes for diabetes (Department of Health and Diabetes UK 2005). The report outlines quality standards and key criteria for education programmes and aims to be a useful reference point for those involved in the provision of care for people with diabetes. The report also highlights gaps in education provision, such as involving people with poor language and literacy skills, and carers. This present study aims to develop and implement a programme for those with kidney disease in line with the recommended quality educational standards.

A final question is whether there is enough evidence to demonstrate that self-management is effective. A British Medical Association (BMA) (2007) report evaluated how far self-management could make a difference to long-term health outcomes. The BMA cites the Picker Institute review (Coulter and Ellins 2006) which reported that although a great deal of research had been undertaken into self care, the majority of trials tended to measure only short term outcomes, typically 6 months or less. The review concluded that even though there was currently little known about the effectiveness of self care over the long term, self management education did lead to short term improvements in health behaviour.

As a consequence, the BMA has made recommendations which include the following:

- Every person diagnosed with a long-term condition should know how to gain information on their condition and how to develop their self-management skills through education available from the NHS and voluntary and community sector organisations. Every patient should also know who, as well as their GP, may be able to give advice and support.
- Resources and information need to be given to GPs to help them encourage self-care, including information on commissioning services, in order to assist patients who wish to improve their ability to self care through attending self-management education programmes.
- PCTs should encourage self-care through self-management education programmes at a local level as part of a wider strategy for long-term conditions. Costs involved for commissioners should be seen as a good investment to gain a long-term benefit.
- Further research over a longer period should be undertaken in order to ascertain the effectiveness of self-management education to both patients and the health service.

Self-management education programmes have resulted in small to moderate effects for selected chronic diseases (Warsi et al. 2004). A variety of reviews have concluded that, at

least in the short to medium term, diabetes self-management support is effective (Glasgow et al. 2007). A systematic review of self-management programmes for diabetes (Warsi et al. 2004) found small but significant reductions in glycated hemoglobin levels (HbA1c) and improvements in systolic blood pressure.

However the evidence for effective self-management programmes for those with early CKD appears to be lacking.

4.2.4. <u>Summary</u>

Around 4% of the population have diabetes and, of those, around one quarter is at risk of kidney damage. Although management of this group is improving because of recent national initiatives, there is scope to improve this group's health outcomes through self-management. Self-management has been shown to be of benefit in the short-term for those with chronic conditions, but has not been shown to be of benefit in the longer-term. Following review of current literature (see Chapter 3) no self-management programmes or packages for those with diabetic kidney disease could be located. This study will therefore develop a self-management package for people with diabetes and early kidney disease, with patients' experiences informing package content and design. The second part of the study will then test the developed self-management programme in a selected population, by comparing with a control group. The aim of the self-management package is to control the factors that can contribute to kidney disease progression.

4.3. Main aims of the study

The aims of this research project have been formulated from the findings of the case study and literature review. It is known that progressive kidney disease can be slowed down through better blood pressure and blood sugar control and lifestyle modification, but not whether these variables can be controlled even better if patients with evidence of early kidney disease are well-informed and supported in their responsibility to manage the condition themselves.

The main aims of the study are:

- To develop a self-management education package which informs patients with diabetes about the risks of kidney disease
- To test the self-management package by comparing with a control group

- To evaluate the self-management package and consider ways to disseminate the package to a wider audience

4.4.   Research question

The study aims to investigate whether the parameters that can lead to deterioration of kidney function in diabetes can be better controlled through patient education and self-management.

The research question is

"Can an innovative self-management package control the parameters that contribute to the progression of kidney disease caused by diabetes?"

This is a mixed-method study that entails two main separate stages:

1. Development of the self-management package
2. Testing of the self-management package

There now follows a description and analysis of the first main stage of the study, outlining how the design of the study evolved.

4.5.   Initial ideas that developed the research question

The research question was first contemplated in 2003. As a renal nurse, I have had an ongoing interest in diabetes, and also patient education. My dissertations for both Bachelor and Master's Degrees had focused on quality of life issues and self-care activities of patients with diabetes and kidney disease. However these studies had focused on patients who were either undergoing or about to start dialysis.

In 2005, with the publication of the NSF for Renal Services (DH, 2005) the national agenda for renal care turned its focus towards the management of those with early kidney disease in primary care. Collaboration between primary and secondary care was improving, and I began to see the gap in the evidence for how best to self-manage the complications of kidney disease in people who had diabetes.

The idea for the study was debated with hospital, community and academic colleagues and a draft project outline was submitted to the Research Degrees Committee in Autumn 2003. Two research supervisors were identified concurrently; a Professor of Community and Primary

Care Nursing, School of Community and Health Sciences, City University London and a Consultant Nephrologist, Surrey.

It was important to submit concurrent grant applications to fund this study and the submission date for the first grant application (National Kidney Research Fund/British Renal Society Fellowship February 2004) ensured that initial ideas for the project design had to be realistic and well defined by early 2004. Successful grant applications are shown in Appendix 2.

4.5.1. <u>Timescale</u>

I registered for the PhD in February 2004. This overall timeline was proposed at the start of the study.

2004	2005	2006	2007	2008

Case study   Literature review   Data collection   Interviews   Development of package   Implementation   Evaluation
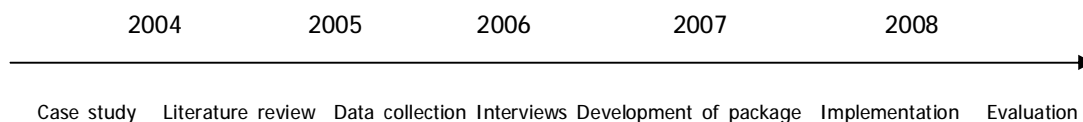
The research component commenced with baseline data collection in late 2005. Patient interviews took place during late 2005, with development of the self-management package being undertaken during 2006. Roll-out of the package was carried out in 2006-7, with final data collection and analysis of data in 2008.

It was hoped that the Doctorate could be completed within five years, particularly as I was undertaking the study as part of my seconded role to the renal unit/research institute. The research institute was keen to promote a multi-professional focus to its portfolio, as previously it had only been concerned with laboratory-based renal research, particularly inflammation, fibrosis and signalling. As a consequence, it was possible for me to devote two days per week to the Doctorate at the outset, and this comprised one day per week funded from the research institute and one day per week funded from the Kidney Research UK/British Renal Society Fellowship.

Later in the study, from October 2006, it was only possible to devote one day per week to the research, as the secondment to the renal unit had been terminated, and a return to 3 days/week employment at City University was commenced. However it was possible to use the School's lecturers' study leave allowance and this was utilised during 2007-2009.

4.6.   Development of the self-management package

4.6.1.   Ethical approval

Ethical approval was required for both parts of the study: the development and also the testing of the self-management package. Approval for both parts was requested concurrently. Initial ethical approval was granted by the local NHS local research ethics committee (LREC) in December 2003. See Appendix 1. At this time, changes to the national process for submission of ethics applications had not been made, so the application was submitted in hard copy to this LREC. The application was not submitted on-line to the National Research Ethics Service (NRES) as this service was not launched until 1 April 2004. Similarly Primary Care Trust Research and Development Approval was not required at the time, as procedures for research governance in PCTs had not been put in place.

I was not invited to the LREC meeting but subsequently received a letter asking for clarification on a few issues. These questions were duly answered and a letter of approval was received in December 2003.

An information sheet for participants was also devised for the ethics committee and this was approved (see Appendix 3) at the same time.

Two amendments to the protocol were submitted over the course of the study period, namely:

Amendment (not considered substantial by ethics committee): March 2005. Addition of a named research nurse to the research protocol. A staff nurse in the renal unit was funded to collect data from GP practice databases to assist the main researcher. This role will be discussed later in the chapter.

Amendment 1: March 2006. A 'control group' was added to the research protocol.

These amendments will be discussed in more detail in section 5.3. The research protocol was also registered with the Trust's Research and Development Department. The University Research Ethics Committee also gave approval for me to carry out the study in March 2004.

A number of ethical considerations developed during the study, and these will be discussed later in Chapter 7.

4.6.2. Recruitment of practices

This stage has been described in some extent in the case study (see section 2.5), but is summarised again here to explain the context within which the overall study has been set.

I was requested to facilitate a number of continuing education sessions on kidney disease for practice nurses in the local Diabetes Centre in early 2004. During these sessions an overview of my upcoming research project was presented and practice nurses (PNs) who were willing to take part were asked to leave their contact details so they could be sent further information. Thirteen PNs left their names/contact details and all were sent further information asking them to discuss the project with their GP and practice manager colleagues. Eventually six GP surgeries in one PCT agreed to take part in the project. The practices observed in the case study thus became the intervention practices. In all six surgeries the main points of contact during the study have been the practice nurses and/or nurse practitioners who are responsible for running diabetes clinics.

There are issues around recruitment of participant GP practices that now need to be discussed in more detail.

4.6.3. Representative sampling

It is possible that the practices that volunteered to take part were not representative of other practices in the same PCT, as individual practice nurses *volunteered* to take part at the education event. For many nurses, attendance at an education programme was difficult because of time and financial constraints. Wide-scale recognition of the hiatus between research and practice exists (Hicks 1996) and it is possible that only those with up-to-date knowledge, or those with an enquiring mind would have volunteered to take part. However it is quite often advantageous to enlist participants who have volunteered, as quality improvement programmes often have more success when enlisting the help of those who are *innovative adopters* rather than *laggards* or *late adopters* (Rogers 2005).

Originally the study was to be of a time-series design, that is, the self-management package would be tested by comparing individual patients' data over time, before and after the package (the intervention) had been implemented (Weiss and Heckbert 1988). However the method had to amended at a later date (see section 5.3.1) because of changes to national policy in the management of CKD during the period of the study, so a control group was

subsequently introduced. Further details on the rationale for the method and the statistical analysis will be discussed in more detail in Chapter 5.

4.7. Demographics and representation of local PCT

The demographics of the surgeries taking part in the study are shown in Figure 4.2.

Figure 4.2: Demographic data from each participating surgery (from 2004/2005 QOF data)

SURGERY	TOTAL NUMBER OF REGISTERED PATIENTS	TOTAL NUMBER OF PATIENTS WITH DIABETES	PREVALENCE OF DIABETES MELLITUS
1	10536	315	3.0%
2	7858	219	2.8%
3	14241	393	2.8%
4	9405	336	3.6%
5	9041	247	2.7%
6	10810	436	4.0%
Mean	*10315*	*324*	*3.15%*

There was 3.2% mean prevalence of diabetes across the entire PCT in 2004/2005 (QOF database 2005) whilst the mean prevalence of diabetes in the participating practices was 3.15%. Mean diabetes prevalence in each practice did not vary much from the mean prevalence across the whole PCT, apart from a higher prevalence recording in Surgery 6. This is possibly because surgery 6 has a nurse practitioner who runs a nurse-led clinic for diabetes, and it is possible that people with diabetes attend that practice because of the good reputation of that clinic. There was some anecdotal evidence to support this, with participants in the study telling me that this is the case.

4.8. Participant observation

I subsequently attended and observed diabetes clinics (led by both GPs and practice nurses) in each surgery over a three-month period. The aim was to understand the challenges of managing diabetes in primary care and to understand how far the patients were empowered to take control of their disease. A detailed analysis of this participant observation phase is detailed in Chapter 2, the case study.

4.9. Findings from participant observation and effect on method

In summary, five main themes were identified during the participant observation period. These were:

1. Confusion over microalbuminuria testing
2. Discrepancies over blood pressure measurement and management
3. Use of the computer during consultations
4. How far patients were empowered to take control of their condition - differing learning and teaching strategies amongst practitioners.
5. The doctor-nurse relationship.

The three most important issues that were considered to have the most impact on development of the educational package were themes 1, 2 and 4. Each of these themes was subsequently taken into account when developing the educational intervention. These themes will be discussed again later in this chapter.

4.9.1. Identification of patients with early kidney disease

Patients with early kidney disease needed to be identified for both developing and testing the education package.

- Developing the package: a small cohort needed to be identified as possible interviewees.

- Testing the package: the entire population with diabetes and early kidney damage needed to be identified as possible participants to receive the package.

The overall aim was therefore to identify all patients with early kidney disease in each surgery and then map these patients for the duration of the study, recording a variety of data from practice databases every six months. The starting point was to identify all patients in each surgery who had Type 1 or Type 2 diabetes and then to identify those who had the early stages of kidney disease.

Microalbuminuria (MA) is the earliest indicator of renal disease attributable to diabetes mellitus and MA is predictive of total mortality, cardiovascular mortality and cardiovascular morbidity for patients with diabetic kidney disease (Klausen et al. 2007). Microalbuminuria is defined as 30-300 mg of albumin in the urine, measured by an albumin:creatinine ratio (ACR)

in an early morning urine (EMU) sample. An ACR >2.5 mg/mmol in a male or >3.5 mg/mmol in a female is consistent with MA (National Institute for Health and Clinical Excellence 2002)[2]. A meta-analysis (Wang et al. 1996) found that the death-rate among people with MA was more than double the rate in people with normal urinary albumin levels.

4.10.   Case-finding

The initial case-finding strategy used Egton Medical Information Systems (EMIS) LV. EMIS LV is a text-based clinical software system used by all surgeries in this study and this software allows users to search for clinical conditions that have been assigned a 'Read Code'. Each clinical term has a unique Read Code, allowing recorded material to be stored as data which can be retrieved and analysed to provide information for activity statistics and audit in addition to clinical applications. When called up on screen, the information is presented not as a code sequence, but translated back into the original clinical language (Department of Health 1996).

EMIS LV databases were searched by identifying all patients currently registered with the surgery; who had Type 1 or Type 2 diabetes; and who also had microalbuminuria (ACR>3) on at least three occasions. Patients with established renal disease (who were already under the care of the renal team) were not included. Read codes for diabetes (C10) and microalbuminuria (C10EL and C10 FM) were initially used for the search. These codes were those recommended by the Department of Health (Department of Health 1996) and this activity was anticipated to be able to identify all patients with diabetes who also had known renal impairment. However, when numbers of patients identified in the initial search were checked with known prevalence data on microalbuminuria and also with practice nurses working in each surgery, it became apparent that not all patients with microalbuminuria had been identified.

In the initial search using Read Codes, only 9% of patients with diabetes were identified as having MA. This compares with a known prevalence of around 20-30% (Mather et al. 1998) in the UK and 58.6% in Asia (Wu et al. 2005). Subsequently, personnel responsible for information services in three practices were asked to assist with the search. It appeared that other Read Codes were also in use for MA (46TC, 46 TD, 46W, R1103) so the search was repeated. After identifying a new set of patients with MA, (n= 224) I checked with practice nurses once more but still could not be confident that all patients with MA had been

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[2] *In 2004 local PCT/laboratory guidance regarding the threshold for abnormal ACR results was >3 for both men and women, despite NICE (2002) guidance recommending >2.5 in men and >3.5 in women.*

identified. It appeared Read Codes had not necessarily been assigned for all patients with MA. A manual search for ACR measurements >3 was then conducted through the computerised records of all patients coded as having diabetes. A total number of 370 patients were identified in the six surgeries and these patients formed the initial cohort to be studied throughout the project. An additional number of possible participants joined the study at a later date because of increased MA screening rates.

Each of these patients has had audit data extracted from the practice database six-monthly for the duration of the study. As these data have been used to test the effect of the intervention, the dataset will be discussed separately in section 5.4.

4.11. Interviews

The aim of the study is to find out how far a patient-centred education programme can influence the progression of kidney damage. This thesis has hypothesised that increasing patient knowledge about kidney disease could subsequently affect patient behaviour. In order to develop a patient-centred programme it was important to seek the views of those who already had early kidney damage.

A semi-structured interview was identified as being the best way to elicit the experiences of those with early kidney disease. Structured interviews can force respondents to choose from answers already provided and there is little opportunity for free expression (Newell 1994). Semi-structured interviews can allow the interviewer to focus on issues that are of particular importance to the research question, to probe and clarify comments made by the informant and to use prior knowledge to help him or her in this process (Dearnley 2005).

There are limitations to the use of semi-structured interviews, namely the effects that interviewers can have on respondents and the effects that interviewers may have on the validity and reliability of the data (Fielding 1994). These limitations will be discussed later in the chapter in section 4.12.

The aim of the interviews was to find out how much patients knew about their renal disease, how much they understood about the consequences of renal impairment and to find out what they perceived to be the best ways of managing and controlling the renal complications. Findings would inform the development of the educational package. Questions were developed during the observation period in diabetes clinics, from the literature review and during informal conversation with patients at the surgeries. Questions were collated together

around three key concepts identified from the observation period and review: impact of diabetes, barriers to control of diabetes and the concept of self-management.

A pilot interview schedule was developed and discussed with two patients in the dialysis unit to see if the questions were easily understood. This informal discussion did not radically change the interview schedule but rather highlighted the importance of the interviewer 'setting the scene' for interviewees before the interview commenced. For example it was possible that not all patients would be aware that they were at risk of kidney damage, so it was important to check with the practice nurse before potential interviewees were contacted that they had been told that they were at risk.

A pilot interview was carried out in November 2005 at Surgery 1 and although questions were not amended following the pilot interview, the ordering of questions was changed to improve the flow of conversation between interviewer and interviewee.

The semi-structured interview schedule is shown in Figure 4.3.

Figure 4.3: Semi-structured interview schedule

General questions about diabetes (key concept = impact of diabetes)

- For how long have you had diabetes?

- How did you feel when you were first told?

- How well do you think that you manage your diabetes?

- What are the most difficult aspects of having diabetes – what is it like for you?

More specific questions about diabetes and renal disease (key concept = barriers to control)

- Can diabetes cause kidney damage?

- Have you ever been told that you are at risk of having kidney damage?

- What do you think can slow down kidney damage?

- How well do you think you control your blood sugar levels?

- Are you taking blood pressure tablets?

- Do you have any side effects from these tablets?

- Do you smoke?

- How difficult is it for you to take health care advice about your diabetes?

- What can make it difficult?

Questions about health education (key concept = self-management)

- How much information have you had about kidney damage from diabetes?

- When did you realise that it was one of the major complications of diabetes?

- Do you try to take control of your diabetes? How?

- How best do you take in information about your health? (examples – one-to-one discussion, reading, videos, internet etc.)

- If you were going to try to educate people with diabetes about the risk of kidney damage, what do you think would be the best way of doing it?

- Do you use organisations such as Diabetes UK for advice? (website, magazine etc.)

4.11.1.   Interviewees

4.11.1.1.   Selection of interviewees

All the patients who had been identified as having diabetes and MA in each surgery were potential interviewees. After discussion with the practice nurses it was thought most likely that patients with deteriorating kidney function (now called the 'high-risk' group) were most

likely to have been informed about their potential risk, so were most likely to be able to answer questions about kidney disease.

Those at high risk were identified as being those with ACR>30 and BP ≥140/80 mm Hg at their last clinic visit (Adler et al. 2003). These patients were then identified and discussed with the relevant practice nurse (PN), and a shortlist of suitable interviewees was drawn up. Patients thought to be unsuitable by the PN included those who were acutely unwell, and those could not communicate easily in English without an interpreter.

A list of 48 patients was compiled (see Appendix 4) and I accessed the GP databases to see when the patients were next due to attend the practice for a consultation. Each month I telephoned each surgery to check if any of the identified patients were due at the practice in the following month and, if so, the patient was sent a letter informing them about the project (see Appendix 3). I asked them to return a form to me if they were interested in taking part. Once I had received the names of interested participants, I contacted them by telephone and a suitable time to be interviewed was agreed, usually before or after a clinic appointment. A small number of patients (n=3) preferred to be interviewed at home.

Patients were asked if they had further questions prior to being interviewed and if they were still willing to take part. If so, they were asked to complete a consent form (Appendix 5) and three copies were made – one for the patient, one for the practice record and one for me to keep on file.

I planned to interview 15 patients. Sample sizes are

> *"not determined by hard and fast rules, but by other factors, such as the depth and duration required for each interview and how much it is feasible for a single interviewer to undertake."* (Pope and Mays 2006)(p. 19)

There were a number of reasons behind the rationale for picking 15 interviews. The main reason was saturation of themes – that is, the importance of ensuring that no new themes were likely to emerge with a greater number of interviews (Creswell 1998). A preliminary review of themes was carried out after 12 interviews had been completed to evaluate how far interviewees were making similar responses to the questions. The responses to crucial questions such as how far the interviewees understood whether they were at risk of kidney disease and what techniques they could use to slow down progression were analysed. At this point it appeared that, in general terms, people understood that they were at risk, but had little idea that they themselves could do anything to self-manage. There were a wider range

of responses concerning the ways in which self-management could be facilitated (through face-to-face consultations, by talking to other patients, by watching a video etc), but given the inconclusive findings of the literature review, this was to be expected.

Secondly there was only one interviewer and a short timeframe. The interviews had to be completed before the end of 2005 in order to keep within the specified timeline and prior to the development of the learning materials. In December 2005 a decision was made to undertake 15 interviews as planned, and the final interview was undertaken in January 2006.

4.11.1.2. Demographics of interviewees

A summary of the demographics of the patients who were interviewed is shown in Figure 4.4. Male gender and older age is to be expected, and is representative of people with diabetes and microalbuminuria (Klein et al. 1993).

The PCT in which the participating practices are located has a population that lives within two local London boroughs. In one borough the 2001 census (Office for National Statistics 2001) showed 84% of the population was white whilst in the other borough 64% of the population was white (average of two boroughs 74%). In this cohort of interviewees 11/15 (73%) are white.

Figure 4.4: Demographics of interviewees

Gender	Male:11	Female: 4	
Age range	45-78 years		
Ethnicity	White: 11	Asian: 2	Mixed race: 1

4.11.2. Practicalities of interviewing

I had experience of interviewing patients for my Master's dissertation, so the experience of interviewing patients was not new. Eleven interviews were carried out in the GP practices, usually a clinic room that was vacant because a GP was on leave or away for the day. There were few problems with this arrangement. The most difficult problem was noise from traffic outside, although no tapes were spoiled because of this.

The interviews were taped on a standard tape recorder that was placed near to the interviewer and interviewee. The quality of the recording was checked at the start of the interview, to ensure that the microphone had been placed near enough to the interviewer and the interviewee. Unfortunately on one occasion the recorder did not work properly

(interview 10), and despite the test at the start of the interview, the tape was blank once it was replayed at the end. Fortunately I was able to make notes of the interview once the mistake had been discovered, and key topics were written down and reviewed. Although this was not an ideal situation, I telephoned the patient at home and asked whether she could verify the notes that had been made, and whether she wanted to add anything to them. She was happy with my notes and her contribution was subsequently used, although direct quotes were obviously not able to be included below.

Interviews lasted between 20 and 45 minutes.

4.11.3.   Questioning techniques

Semi-structured interviews allow interviewees to be asked similar questions within a flexible framework. All the patients were asked questions from the same framework, but the ordering of the questions varied according to how the interviewee responded to the questioning. After the pilot and first two interviews had been carried out, I realised that answers to some of my questions were not as detailed as I had hoped. For example, when I asked people whether they tried to control their condition themselves (see questions about health education in Figure 4.3), some people were not that forthcoming in their answers. Subsequently I had to reflect on how far the difficulty in extracting responses was due to my questioning technique, how far it was due to the nature of the questions or how far it was due to the interviewee not having really thought about these questions before. Latterly I ensured that my questions did not contain any medical jargon, I emphasised to the interviewees that there was no right or wrong answers and that all responses were interesting and very much valued.

It was important to 'reflect on action' after each interview, by asking myself whether any new concepts emerged, whether I probed an issue sufficiently and whether I had asked any leading questions (Dearnley 2005).

4.12. Reflection on interviewing techniques

Although there are benefits in using a semi-structured approach such as eliciting certain types of information from all respondents, and allowing flexibility in phrasing and ordering of questions (Kvale 1996), the 'credibility' of data from semi-structured interviews needs to be reflected upon.

It is possible that the interview questions became shaped by my past experiences of working with people who had diabetes and CKD. It is possible that occasionally some questions arose

because of my interest in one aspect of an interviewee's response, or that my concern for the interviewee's well-being distracted me from the interview itself. For example, one interviewee stated that she was confused with the contradictory messages she was being given by nurses in primary and secondary care, so I responded by offering care:

> NT: I'm sorry you have had somebody saying one thing and then somebody saying something else.

> *Interviewee: They confuse you, they really confuse you. I am with Hospital X and Hospital Y and it really does confuse me because I get so much from one and then the other and I don't know where I am. I would like one hospital to take over everything like it was before, because Hospital X is nearer, it is easier for me to go there.*

> NT: What we could do, when we have finished here, I could come with you and look at your blood results and make some decisions on your diet because M (practice nurse) and I are used to dealing with people with early kidney problems and we've got an idea about what advice to give. I know it is confusing.

On reflection it was not necessary for me to respond in this way in the middle of the interview, as potentially it could have deflected the interviewee's attention away from the focus of the interview. Nurses are socialised to care and to educate, and it is likely that I assumed my nursing role to the detriment of my researcher role during the early interviews.

However some authors (Murray 2003, Parnis et al. 2005) have identified the potential therapeutic value of research interviews, and it is possible that this interviewee did gain some useful clinical support after I intervened in this way.

It is also the case that when interviewees were not very responsive to my questions, I became more talkative, with the result being that the transcript revealed that I engaged in more narrative than the interviewee.

I think that I recognised these shortcomings in early interviews, and learnt to become more flexible in my questioning. Flexibility is an important attribute for an interviewer to have, especially when it is important to listen attentively and to respond to cues by formulating additional relevant questions (Hutchinson and Wilson 1992). It is also possible that I needed some formal preparation in interview technique and I will keep this in mind when supervising students who also have little or moderate experience in interviewing techniques.

4.13. Transcribing of interviews

I evaluated whether it would be beneficial for an outside agency to be employed to transcribe the taped interviews. With transcribing potentially taking up to 70 hours for every 15 interviews (Aveyard and Schofield 2002), such help was thought to be welcome because of my time constraints. A number of colleagues advised me that I could not become 'fully immersed' in the data unless the transcribing was carried out myself and some authors also support this (Duffy et al. 2004). However this could be overcome to some extent by spending time in listening to the tapes before reading the returned transcripts.

However there were some additional issues to be considered in making this decision. These were not just practical issues such as accuracy and reliability, but also less tangible concerns such as maintaining patient confidentiality and ensuring that the transcriber was not upset by the content of the interviews. These issues were all taken into account, and the decision was made to employ a transcriber, mostly because it was crucial to keep to the intended timelines.

A number of freelance typist/transcribers were scrutinised, such as those who had either been identified through personal recommendation or via the internet. Once costs and timeframes had been discussed, the most suitable freelance typist was 'interviewed' by me on the telephone. Issues discussed were those identified in the previous paragraph, including confidentiality. The freelancer confirmed that she had recently worked for another health care researcher in another university on a similar project and was happy for her previous employer to be contacted for a reference. She seemed to understand all the issues and was even familiar with the topic area.

Once the terms had been agreed, all tapes were sent by recorded delivery to the typist who later sent the transcriptions back by email. Confidentiality was assured as each interview was only identified by a number and places/names of institutions were not used in the interview process. The transcriber was not local to the research area so it was unlikely that she would be able to identify the location of the hospital/PCT.

There are questions as to whether interviewees should verify the transcripts once they had been typed up, but there are potential problems with returning transcripts (Kvale 1996). Kvale (1996) warns that some participants may experience shock when reading their own interview that is transcribed verbatim. He also warns that if oral language, when transcribed, appears as incoherent or confused speech, participants may feel they are being portrayed as

having a lower level of intellectual functioning. The decision was made not to return transcripts to the interviewees after they had been transcribed, mostly because of the time-lag between the interview and the returned transcript (up to six weeks), and also because of the logistics of making a new appointment for re-visiting. This decision was taken at the start of the study when ethical approval was sought. However all transcripts were checked against the taped interviews for accuracy.

All interviews had been completed by early 2006.

4.14. Data analysis

A manual system of thematic data analysis was used to collate and cross-compare the participants' responses. Thematic data analysis involves the creation and application of 'codes' to data. Codes are applied to different sets of data that have the same themes. The coding process enables retrieval and collection of all the patient responses that have the same thematic idea, so that they can be examined together and then utilised in developing the self-management package.

4.14.1. Thematic data analysis

There are a number of different approaches that can be used to analyse and interpret data. The main approaches are grounded theory analysis, content analysis and narrative analysis (Priest et al. 2002). All approaches were considered, and content analysis was chosen as the most appropriate approach. This is because the interviews are being conducted as part of an exploratory study into peoples' views about self-management of CKD, and the main analytic categories for this study were already known. If the main categories for questions are already known, then content analysis is recommended (Priest et al. 2002). For example, key concepts in the interview questions formed the master codes, i.e. 'impact of diabetes', 'barriers to control' and 'self-management of kidney disease'.

4.14.2. Content analysis

Content analysis is a widely used method of eliciting meaning from text through the development of emergent themes (Elo and Kyngas 2008). All of the text is reviewed and master codes (M1, M2, M3...), followed by first (F1, F2, F3...) and secondary codes (S1, S2, S3...) are applied, whereby more detailed indexing is undertaken. Repetition of coding produces the significance of particular themes (Burns and Grove 2005), as the number of times a similar piece of text is attributed to a particular code can be counted. There are

different types of content: *manifest* content, whereby respondents' actual words form concepts, or *latent* content, whereby concepts are derived from the interpretation and judgement of participants' responses (Woods et al. 2002).

Although computerised analysis (for example QSR NVivo™) can be used to rapidly code large sections of text, I did not ultimately utilise a software package to do this.

However QSR NVivo™ 7 (software developed by QSR International) was evaluated before rejecting its usage for this thesis. A half-day course on NVivo application and usage was attended in March 2006 and subsequently a copy of the QSR software was downloaded under the City University licence. The transcribed interviews were easily inserted into the software programme and it was easy to find similar words (manifest content) within the text in order to identify codes. The difficulty arose when latent content needed to be coded, and at this point it was decided that interviewee responses could be coded more accurately and quickly if the data were coded manually. Although the software could facilitate further development of the data, such as 'visual index trees' (concept formation comprising sub-categories), this additional application was not thought to be worth the time and effort required to learn the package in more detail.

Although it is recognised that computerised analysis packages provide 'perfect coder reliability' (Robson 1994), it was decided that coder reliability could be checked in different ways. In one way, reliability of coding decisions can be confirmed by revisiting previously coded data periodically to check the stability over time; also two different coders could be used to enhance reliability. In summary, a manual coding process was utilised as the main limitations of using software, which is an 'overemphasis on standardisation' (Burton 2000), could detract from contextual meaning.

4.14.3.   Content analysis: practical application

An example of how first and second level codes were identified is now shown. The process undertaken was based on recommendations by Woods (Woods et al. 2002). Through line-by-line analysis, the master level codes were applied, followed by first and second level coding. The master codes (impact of diabetes, barriers to control and self-management) had already been identified, as these were the three main categories that directed the semi-structured interview schedule. Text of differing size (one word, one sentence or even a paragraph) was highlighted and assigned to particular analytic categories. In addition, an analytic category or 'free node' was established for data that did not readily fit into existing codes.

If several pieces of text, either from within one text or several texts pertained to the same concept they would be copied and pasted under the appropriate sub-code. It is then necessary to undertake thematic interpretation of meaning. In other words, if different interviewees use similar wording then it is possible to apply *manifest* content analysis. *Latent* analysis is where the researcher can also interpret the interviewee's meaning and apply a code.

Figure 4.5 shows a piece of transcribed text from the pilot interview, with the applied master (M), first (F) and second (S) level codes highlighted. A list of the identified codes can be found in Appendix 6.

Figure 4.5: Applied first (F) and second (S) level coding

Code	Text
F4 S12 S13 S11 F4	What happens, it is just like in this country, we see a lot of food in the shops and a lot of food has a lot of sugar, a lot of fat, a lot of calories, lots of different things. So we are used to it and also eat a lot - that was the order of the day! So what happens when we become middle aged and old, it all comes on, so that's what happens to Mauritian people or Indian people, they don't think oh well – I mean when we are young we take chances, we smoke a lot, drink a lot, go to bed late and all sorts of things and when you are middle aged it all comes on. When you are a teenager, young and that, you have a set pattern and what happens... we accept a lot of bad things today. When you are young in [country name] or anywhere, 16 or 17, you look for a girl and then 19 or 20 you get married and then you join the men's club and you have to drink the strong stuff and a lot of it and then you have a family whether you can afford it or not. You might finish off with half a dozen! So we are in that thing. As you know there are many people of 30 or 40 who seem to be very old, I don't know so much in this country but back home I can see 50 is very old.

In this extract, the interviewee talked about the way of life in his home country which had an effect on the population's health (F4: health beliefs). This first-level code can be broken down to secondary codes (S11, S12 and S13), namely cultural beliefs, beliefs about ideal weight and fatalism respectively.

4.15. Data presentation: background

4.15.1. Aim of interviews

As discussed in chapter 3, in order to facilitate self-management in people with long-term conditions, a patient-empowering approach is warranted. This approach recognises the nature of the actual experience of having diabetes and views the health-care professional as a resource person or consultant. In order to effect behavioural change, the empowering approach must focus on patient goals and needs and acknowledge the individual's experience of living with diabetes (Funnell and Anderson 2004). The main aim of the interviews was to identify how much knowledge individuals had about the risk of kidney disease and to assess how far individuals felt they could control their condition. It was possible that interviewees would also talk about their experiences of living with diabetes, and it was possible that these insights might contribute to understanding why some people were able to self-manage their condition and others did not.

In order to acknowledge the actual experience of having diabetes, interview questions were centred around living with the condition; finding out how much patients knew about kidney damage, and most importantly discovering what was perceived to be the best ways of managing and controlling kidney disease progression.

It must be emphasised that the (small number of) respondents' views were obtained with the purpose that they would be used only as a basis for the development of the self-management package, rather than to make generalisable claims about the overall experiences of people with diabetes.

4.15.2.   Interviewees

Eleven men and four women were interviewed. The age range was 45-78 years (mean 60.8 years). Twelve were white, two were Asian and one interviewee was of mixed race. The demographics of the interviewees were representative of the local PCT, as discussed in section 4.7. See Figure 4.6 for an overview of the interviewees (data from October 2005).

Figure 4.6: Demographics of individual interviewees

Interview	Name (pseudonym)	Age	Gender	Ethnicity
1	Azam	65	M	Asian
2	Edward	55	M	White
3	David	65	M	White
4	John	61	M	White
5	Paul	58	M	White
6	Raju	45	M	Asian
7	Richard	48	M	White
8	Stelios	78	M	Mixed race
9	Anne	62	F	White
10	Elaine	64	F	White
11	Catherine	45	F	White
12	Fred	70	M	White
13	Brian	66	M	White
14	Tom	73	M	White
15	Judy	60	F	White

Interviews were recorded and following transcription, thematic data analysis was carried out. Master and secondary codes (themes) were identified.

4.16. Data presentation: themes

4.16.1. Impact of diabetes

I started the interview by asking the interviewee if they could recall when they were first told that they had diabetes. Some people responded immediately with stories about the day they were diagnosed accompanied by explicit explanations of how diabetes affects a number of aspects of their life quality:

> "Oh I wish I never had it, it ruins everything....it ruins your sex life for a start, you can't do the things you like, I couldn't play golf no more, I just didn't have the energy and then I got the angina which made it worse and then the eyesight goes and

everything goes and it's all down to the diabetes really, I was a very active man at one time but now......." (Fred)

"I suppose the lack of energy, that seems to be one of my problems, it's an effort to get out of the house, out of the bed." (Edward)

Edward also said:

"All in all it's not been the be all and end all of my life, but I think the two things combined, the not having a job and the diabetes......"

Other people discussed specific activities concerned with controlling the condition. David described the difficulties with injecting and monitoring:

"Since I started taking insulin I have noticed that it is a lot harder than taking the tablets, injecting all the time now and checking three times a day." (David)

whilst others found difficulties with dietary recommendations,

"The having to eat and having to lose weight at the same time, they're kind of mutually exclusive activities and to try and keep fat down and not eat too many sugars, and watch the carbohydrates and must eat three times a day. I have a very busy life so trying to then fit those meals in around lifestyle and it does get very difficult especially because I work away from home, I'm eating canteen food and restaurant food at least one meal a day."(Catherine)

"I've put on so much weight, ten years ago I was only half this weight and it's piled on now." (Edward)

"Having to pack up eating foods that I like." (David)

and also with alcohol:

"I used to like a drink but I don't bother now. I'd sooner have a Diet Coke or a Pepsi Max, so that suits me fine and I've packed up smoking." (David)

The complications of diabetes were also identified as being challenging to cope with, and manage. Richard described sexual problems:

> "Sex, there isn't none, that is the worst thing, even at my age, and I don't class myself being old. "I mean I still feel I can do it and all that, but I need help sort of thing, Viagra injections and all that, ever since I got circumcised through the diabetes it's just hasn't, you know, hasn't worked properly and it is, that is the biggest....I mean I say to doctors and all that, it doesn't bother me, but it does bother me, bothers me big time. I mean don't get me wrong, I'm not no oil painting but you know I do, I miss it, at the end of the day, been all over the world, you know what I mean, so..... that is the biggest downfall of diabetes, it's from that." (Richard)

and one person identified eye problems:

> "I have noticed in the last two years and I talk to the optician about this, I find reading more of a strain now even though I've had my glasses upgraded. I saw him in December and I'm seeing him again, I've got a bit of diabetes in this eye." (Tom)

In contrast some respondents described how were able to cope with the condition by not necessarily taking on health-care advice, sometimes called non-compliance or non-adherence (Martin 2008):

> "....but it's not always easy and sometimes you think, oh to hell with it, I want to live life, I don't want to be, don't do this, don't do that, don't eat this and don't eat that, every now and again I say, oh sod it I'm going to have a piece of fried bread you know." (Fred)

> "I must confess you cheat sometimes......diabetics cheat all over the place...." (Tom)

Stelios and Azam suggested that they did not always keep to dietary recommendations, but doing that was acceptable:

> "As far as I'm concerned, I more or less, what I say..... cheese and butter and all that, animal fat, keep off it, a little bit I can have, and as much as I like, but I do watch it and I more or less lead normal life, no problem at all." (Stelios)

"reading the diabetic things (information sheets), you can spoil yourself now and again but if you do bad food regularly, fatty or sugary, that is not good." (Azam)

The main messages from this theme appear to be that the impact of having diabetes is often intense, with many people reporting that the condition has daily and long-term effects. For some people this means that activities of daily living are severely restricted, whereas others try hard to integrate the condition into their day-to-day lives. These experiences reflect the findings from other, larger studies (Phillips and Phillips 2007, Stodberg et al. 2007) .

For the purposes of this study, these short extracts illustrate the importance of not underestimating the impact that diabetes can have on everyday activities and life quality. As a consequence, guidance on self-care for kidney damage must be realistic, that is, not based on unattainable goals, and must show appreciation of how hard it can be to take on health-care advice.

4.16.2. Barriers to control

When questioned about how far they were able to manage their condition (diabetes), a number of barriers to enablement of controlling the condition emerged. These included some physiological barriers such as poor sight or memory:

"I have a terrible memory and it has got to the stage where I have got a system for taking my medications but that doesn't always help." (Edward)

Catherine cited difficulties at work which did not enable her to take the recommended dietary choices:

"with canteen people and pointing out to them that the foods they're providing are not very diabetic friendly and ask for more choices other than pieces of fresh fruit in a basket, there are no other fruit options and just at lunch it's like a sandwich and a bag of crisps - and the crisps are full of fat so you can't have the crisps, and there's all the puddings on the side - and I'm not supposed to eat the puddings, and if I have a whole meal - then I can't eat with my family in the evening." (Catherine)

Another generally accepted barrier to adherence, is differing cultural beliefs and health beliefs (Naeem 2003).

Raju spoke about some prejudices that he had against western medicine:

> "I'm not totally convinced that being on Western medication is the right way forward, there are alternatives, my wife is a nurse and she doesn't believe in a lot of medicines, it has side effects. So there must be an alternative, so, she just went home yesterday, her mum suffers for example, from blood pressure, all her mum does is go in the garden, pull up a lot of weeds, but they're just growing there, mixes it all up and you drink it, and that's it, so that sounds like a positive way forward, but what about the kidneys?" (Raju)

whilst Azam thought that eating well was a cultural issue – not just that food was widely available but also perhaps that being overweight was accepted and a sign of wealth (Powell and Kahn 1995).

> "What happens (in [country name]), it is just like in this country, we see a lot of food in the shops and a lot of food has a lot of sugar, a lot of fat, a lot of calories, lots of different things. So we are used to it, and also eat a lot, that was the order of the day!" (Azam)

Some people thought that not taking diabetes seriously enough could lead to people not taking on health care advice:

> "But I was a bit blasé about it when I was initially diagnosed with it........but no, I think if I had taken it seriously in those days and learnt what I know now, I would be a completely different person." (Edward)

David also spoke about not taking advice seriously enough, but when he was asked about kidney damage he said:

> "and your kidneys, how that comes into it, and I think, that was a shock, that bit." (David)

The importance of getting good consistent advice was also highlighted. It could be argued that people are not able to self-manage if the advice is contradictory or unachievable.

One example of inconsistency of message was particularly noticeable when Anne and her husband were discussing nutrition:

"I go to the doctor and she told me not to have vegetables, or just boil the vegetables, throw away the water, boil it again and then you can eat it. They confuse me so much. Then I go to the diabetic nurse and told her what she said and she said oh no, you mustn't do that, you must have this and that." (Anne)

This inconsistency was summed up by David:

"Sometimes you think you can't win." (David)

Another cited issue was difficulty in putting the health-care advice into practice:

"so I was looking at that (blood sugar reading) and calling them up and saying it is so and so and so and so today and I could never find out, and they couldn't explain it either, why I can go a whole week with no problems and no highs or anything, nothing has changed and all of a sudden I get a massive great blip and I don't know why that happens...." (Edward)

"You are so disappointed when you stick to what you are supposed to be eating and not supposed to eat, you follow it right through and you take a reading later on and it is about 15 and it's ridiculous." (David)

David went on to say:

"It is disheartening, yes. I found when I went on holiday, I went to Greece about three years ago and I more or less had what I wanted, because you don't get the food you have over here obviously, but I just had anything and I found my numbers was low all the time. That's what annoys me." (David)

Anne agreed with David:

"I go through so many times with the nurses, the diabetic nurses and if you look at what I eat, it is nothing out of the normal, you know. But they still don't understand why that diabetes goes up and down, up and down. Sometimes it goes up to 28, 27, 25......." (Anne)

In summary this master theme has highlighted three barriers to taking and acting on the advice. These are physiological barriers, health beliefs and inability to take-on health-care advice. These barriers can be sub-divided into secondary themes (codes) including cultural beliefs, fatalism and the belief that diabetes is not a serious condition.

For the purposes of this study these themes must be considered when developing the self-management package. For example advice must be practical and it must recognise the different ways in which people have accepted and coped with the disease. Most importantly, the information must be agreed on by all the health-care team (to avoid inconsistency of message), and must give advice that enables people to take control of their condition.

4.16.3.   Self-management

4.16.3.1.   Risk of kidney disease

The interviewees were asked in detail about how far they thought they were at risk of kidney damage. Some respondents were aware of the risk of kidney damage in diabetes. Fred said:

"Well yes, I mean when they first told me they said to me something like, you're likely to have kidney damage by the time you're 85 and I just thought, to hell with being 85....... I'll probably never make 85 anyway."

NT: How old are you now?

"72, so I thought I'll never make 85 anyway but I was only, I don't know how old I was then, 70's or 65, so I didn't worry too much as I'll probably have so many things wrong with me by then that would be the least of my worries but when you start to think about it, I mean I've got enough problems I don't want another problem, it frightened me in a way because my father had kidney damage, he died of TB, he was only 46 years old. I'm the oldest surviving man in my family thanks to you lot,

nobody has ever lived as long as me in our family, none of my brothers lived over 60, no uncles who lived over 50." (Fred)

Catherine commented:

"Its only been in the last year or two that someone happened to mention that the three were related and that by having my blood pressure under control it would help to stop kidney damage and so on." (Catherine)

When Edward was asked about the risk of kidney damage, he replied:

"That was never said, never. I've never been told that." (Edward)

whilst Tom said:

"they said that that I could be vulnerable but they haven't said to me in terms of the data that they have that I have a kidney problem. I go to Doctor B every six months." (Tom) (Note: Dr B is a nephrologist).

Catherine reinforced the point by saying:

"I would say that I'm much less well-informed about the link between diabetes, heart disease and kidney disease (compared with other complications)*." (Catherine)*

4.16.3.2. Opportunities for self-management

When the interviewees were questioned further about how far they thought they could control kidney disease progression, with the question, "do you know of any things that you yourself can do to try and delay the kidney disease getting worse?", this answer typified many responses:

"Not at all." (Raju)

Although later, when pushed, Raju was able to identify some strategies that could help. Only a few people were able to offer any suggestions:

"It could be the blood pressure." (Azam)

However only Azam thought it may be blood pressure. One person mentioned blood sugar control; diet was mentioned by one person; taking tablets as prescribed and watching for proteinuria was mentioned by one person:

"check the protein levels in the urine, the medication I'm on, obviously the beta blockers, etc etc, got to watch the kidneys and protein in the urine is not high." (Raju)

No-one mentioned lifestyle modification such as smoking cessation although two respondents thought that alcohol was a key factor:

"I don't know hardly anything about what causes it; I always thought too much alcohol caused a lot of trouble with the kidneys." (Brian)

"Kidneys? I think it was drink, oh no that's liver isn't it? Oh the bad thing that's made.... no I don't know, is the answer." (Paul)

Generally these quotes typify the responses:

"Well they didn't really enlighten me, nobody has said you have got this because you indulge in A or B." (David)

"It is just decay of the kidneys presumably and that's irreversible isn't it?" (Edward)

Only one patient understood why they were providing a urine sample for microalbuminuiria. Most believed the sample was being taken to check there was no infection in the urine.

4.16.3.3. Blood pressure

Concerning blood pressure control, interviewees were asked about the link between kidney damage and blood pressure:

> *"Well, I've had more blood pressure taken than anyone in England! I'm always having my blood pressure taken. The doctor's always keeping an eye on my blood pressure. I don't know what it has to do with kidneys." (Brian)*

If the interviewees did not realise there was a link between kidney damage and blood pressure control, they were then questioned further about their own blood pressure:

> *"I think part of it is a bit high but there are the two parts of course, one is good and one is bad but which one, I don't know which way round it is." (Azam)*

> *"I think I've always been the type of person who's had high blood pressure, I'm sure of it, the environment I've worked in, I've been pressurised and I react appropriately, blood pressure's down, I feel like I'm asleep, so I'm not sure how that relates but I'm still of the opinion that levels the doctors want it to be down to, are not realistic for me as an individual, but not having any medical background, I cannot comment." (Raju)*

Stelios was confused about the blood pressure readings:

NT: And what about your blood pressure, is that high?

> *"Blood pressure, when I had a slipped disc, it was very high, so it does affect, the illness does affect it. It was up 112, 116 and on my operation day, you know they were talking about it's very risky for my slipped disc."*

NT: Do you know what the top number was?

> *"Top number about 100, around, anything around 120, I was in the hospital....."*

NT: Ah, would it be.... the top number would have been higher than that, it's probably the bottom number.

"Oh I see. Anyway they say it's very high to have operation." (Stelios)

Further questions were asked more specifically about medication (ACEIs and ARBs) and their role in kidney disease progression:

NT: It is called an ACE inhibitor, lisinopril, which is the one you take.

"Oh I thought that was for blood pressure." (Edward)

They were also asked about side-effects:

"Yeah, I was terrible, I had terrible headaches, I was itching, cough, terrible cough yeah." (Fred)

"I did at first (have side-effects) yes. When I first took it I was very heavy, heavy headed and things like that." (David)

NT: Did you just carry on or did you stop taking them?

"I did stop taking them at first but then I saw Dr Y and he said you've got to take it morning and evening, I had one in the morning and one in the evening. I think since I've retired from work that's helped because you don't get the side effects like I did before, getting up at three in the morning, unhealthy hours." (David)

"All the pills I'm taking and there is the side effects, say may make you drowsy, so no wonder I keep falling asleep, I take all these pills and they just knock me out and then they say I don't get exercise, well I can't I'm asleep all the time. You know ones fighting against the other, that's what I find personally." (Raju)

4.16.3.4.   <u>Smoking</u>

A small number of people who were interviewed used to smoke, and generally there was recognition that smoking contributed to bad health, and might be potentially dangerous to continue:

"No, I don't smoke. I used to but I don't now. I gave up three years ago now. That was my own choice, one day I had a wheezing and I'd never wheezed before and I thought this is stupid so I just gave it up and it wasn't a problem to me after that." *(Edward)*

"I had a heart bypass and that frightened the life out of me and I thought that's it, now's the time. I don't regret it neither although I used to like smoking to tell you the truth." (David)

Two people however were still smoking, and did recognise that it was potentially harmful to their health:

"Okay, doctors, nurses, hospital have all advised and saying, you know I'm the only smoker in the family, started smoking to stay awake.....the work I was doing in sales.... I was out of the house by eight in the morning, or earlier, and which I did until one and two in the morning, sometimes way out of town, needed something to keep me awake, so I started smoking those huge cigars and moved on to cigarettes, went from the lite to something a bit stronger, 20 years later I'm hooked, well and truly hooked, I accept fully the benefits of coming off it, especially being a diabetic, mind's willing but my body doesn't want to know." (Raju)

"I know it's the smoking, I don't need telling, I know smoking does my blood pressure. And I know it's silly what I'm doing but it's very hard, very hard." (John)

NT: You said you have tried hypnosis, have you tried anything else?

I've tried patches. Without lying, I've had a patch on, been chewing the chewing gum and smoking at the same time. You don't have to tell me I have to be backward to do it, but I can't stop. I can't help it.

NT: Is there anything that would make you stop?

"Yes, if I died." (John)

4.16.3.5. <u>Exercise</u>

Only Raju mentioned taking exercise when asked about managing kidney disease, and his response was:

"As far as I'm concerned, it's all well and good saying to me exercise and everyone says that, doctors, nurses, hospitals, whatever, where the hell are you supposed to walk?" (Raju)

4.16.3.6. <u>How to get key messages across</u>

One question concerned the different ways in which people can get information about diabetes care and management:

"It is good to have things on the television and the radio - that is good to put over a message." (Azam)

A few people mentioned the positive use of internet to find out information:

"*Yes, I have done that (*searched the internet*) a few times, yes." (Edward)*

Oh yes, oh yes. I mean it's there (the internet) *and it's free. I don't remember everything I read about it but there are things that go at you, punch at you and I think, right and it gets left there whereas a lot of the stuff you read, you don't remember it." (David)*

but David later added:

"It can cause all sorts of problems, when you read what's on the computer – and there were a couple of reports from the Lancet on there and things like that – what!" (David)

Others described why they did not use the internet at all:

"....and in general that's what I find with the internet, there's so much information and separating the wheat from that chaff, and it can be scary of course as well." (Catherine)

"No, I can't get into that, too complicated" (Judy)

"but us people who it's all new to, over 50s or over 55s anyway, they're not going to bother too much are they?" (Paul)

A number of people mentioned books or other written information that informed them about diabetes and its management:

"And I've got a book about diabetes, which I've had for many a year now. It tells you what you should eat and what you shouldn't eat and all that." (Brian)

"I've had some stuff from them (Diabetes UK) and it's quite good.......but if I tend to read too much into I find I can't have this and I can't have that." (David)

Stelios was asked:

NT: So if you have any questions about your diabetes where do you normally go? Do you ask D (practice nurse) or ....?

"Well no, not really, in the hospital, the nurse, before I left the hospital, they come, the diabetes, she showed me how to, come down and all that and the booklet they told me that's the best thing, you know about low and high and the blood pressure and sugar level and. ...."

NT: So do you have any other questions?

"No not really. Keep it simple." (Stelios)

Two people thought that DVDs might be a good way to get the information across:

"I would use DVDs. If there was a DVD which gave me direct relevant information about that sort of thing, I would use that either on the PC or on the television, that could be quite useful. I think in the DVD you need some visual aids so that it actually describes what you might call the physiology and the anatomy of the kidney as to how it is approached." (Tom)

"I think a picture will tell a thousand words.....if you can get people to watch a video or DVD....."(Paul)

The implication is that generally people like to basic information which is presented in a visual and understandable way, and is not too complicated.

4.16.3.7.   Individual versus group sessions

When asked about the best way to get information, many people spoke of individual consultations, and sometimes 'group sessions':

"Of all the various sessions that I've had through the course of my diabetes the one that worked the best was a classroom session, it was myself and a number of other diabetics, this was in [country name] by the way, we came to the local hospital, it was a one day session and it wasn't any one particular facet of diabetes but whole diabetes, very intensive, classroom time as a group, individual time, it was particularly helpful, sort of realising, I'm not the only person trying to deal with this and hearing about some of the problems others were having." (Catherine)

"I don't know, sometimes large groups work, because a lot of people ask the questions and then other people do, but I think a one to one's a lot better, personally, maybe like a group therapy afterwards but a one to one is better." (Richard)

Only two people mentioned 'group sessions' as a place to get information, and although the question was not asked explicitly, it appears that very few have had access to formalised education programmes such as DESMOND, or those offered by the local diabetes centre.

Two people did talk about information giving on a one-to-one basis:

"I think people like yourself, nurse J and the doctor, them saying things, then I take notice of it." (David)

"My preference is one to one, big difference, for example both of you make eye contact, a lot of people don't, once you've got the attention, you open up, speak your mind, say what you need to say, ask what you need to ask......" (Judy)

A number of interviewees talked about learning from other people, not just those with the condition, but from family and friends:

"they show you a video all about diabetes and I happened to be sitting to another chap and afterwards he said to me, well whatever you do listen to what they tell you, he said, I've been diagnosed 10 years ago, I've already lost my foot and I'm here because I'm trying to save this one, and obviously I was very interested in what you had to do." (Fred)

".....he was on insulin and he used to eat anything, cream cakes and things like that but to me that is ridiculous because you are just going from one extreme to the other. He ended up having a heart attack." (David)

"I think it is a lot to do with the family, the family should just keep pointing out to them, look it's bad, it's bad." (Azam)

4.16.3.8. Location

Fred said that the location of the information-giving was important, and thought that kidney problems should be dealt with in a separate clinic:

"I think it would be better to separate it from the diabetes clinic in a way, if it was done at like the renal centre I think because you know that it is the kidney and it is a

different thing and if you got a leaflet or a letter from them, I think you'd be more likely to take notice, I mean I get things from the diabetes society all the time and you just don't read them, it's like junk mail you know but if it was something more serious like the kidney I'd be more inclined to take notice from say someone like you and dealing with it separately from the diabetes." (Fred)

4.16.3.9. Timing

Other people mentioned timing of education sessions. Catherine thought that too much information at the start might be detrimental to learning:

"I guess it depends, if I was planning a training programme, right up front I would make sure people were aware there was a link but I probably wouldn't try and front load because when you're first diagnosed you're so busy with, again Type 2 specifically, what you're eating, watching your sugar, all the other things, there's just not enough time left but your mind is so busy with those things that to take in some of the other things, it's just too much." (Catherine)

whereas Richard thought that the risk of kidney disease should explained at the outset:

"I think, yes, I think straight from scratch, straight from the start, because obviously, people should be informed as well, you know it's going to change big time, so I think they should be you know, you're going to get a shock, if you've got somebody with diabetes, second biggest disease in the country and also, going to have a problem, you should tell them right from the start, not wait." (Richard)

Edward suggested that he was not told early enough about the risk of kidney disease:

"As I say, after five years of just taking pills and being blasé about things, I got the first lectures and there were little alarm bells ringing then but if I had known then what I know now I'm sure I would have been a lot better now in a lot of respects, including my kidneys. It is just education isn't it? Which is what you are all about." (Edward)

The optimum delivery point for education concerning the risk of kidney disease appears to be contentious amongst this group. This warrants further consideration when making recommendations for timing of distribution of the self-management package.

Comments concerning educational content were made by Edward:

"I think explaining to them in layman's terms exactly what the problem is and I can guarantee that about 50% of the people I know don't even know what the kidney function is. So you have got to start with what the actual kidney does, why it is not working properly and the reasons why it is not working properly." (Edward)

whilst Azam thought that follow-up was important:

"I think also if someone doesn't attend the surgery someone should say why is Johnny not coming to the surgery, they need to check up to see if he is all right and get in contact with him and say there may be a problem maybe with your blood pressure or your blood sugar." (Azam)

4.16.4. Learning and teaching leading to a change in behaviour

Although people were asked about how best to deliver education and promote self-care, interviewees were also asked about what might make them change their behaviour.

NT: So when she (the practice nurse) explains to you about the complications, what makes you change the way you are, in terms of maybe what you eat or, or.....?

Paul responded:

"Well I suppose you don't...... I don't know the answer to that, I know it's just stupidity I suppose, if someone's telling you if you keep hitting your finger with that hammer, and you know you're going to lose it, eventually you will stop doing it, I suppose that's, so that's what it is......... well for me I don't mind people saying well he's fat, but I wouldn't like them to say he's stupid." (Paul)

Paul also identified the importance of not just informing patients about how kidney damage might progress, but also of shocking people into changing their behaviour:

".....I mean it's all right telling people, yes I suppose you've got to encourage, but I mean it's the other one as well, about the shock one..... I didn't do it and this is what happened to me, off come the legs, I'm now walking with a stick you know." (Paul)

Paul also added:

"They perhaps don't frighten people enough."

Brian could clearly recollect one practice team member who tried to change his behaviour:

"...so some doctor there used to hammer me, slaughter me, there..... 'You're not helping yourself ...' and they were giving me hell because I was putting on weight and my blood pressure wasn't good." (Brian)

Some people thought that kidney damage should be made to sound serious:

"I think with the kidney thing it's different because it's a vital organ, it's like having heart problems, you've got to take that very seriously." (Judy)

"I'd tell it straight, that's what you've got to do." (Paul)

"They should tell us the downfalls of diabetes, not to brush it off ....". (Richard)

"I mean kidney damage is a bit more serious I think and if there's a way of slowing it down then yeah all well and good, I mean if you can find a way of slowing down losing your eyesight every month then I'd be interested." (Fred)

A number of people were concerned that they were not being told the truth about what could happen if kidney damage progressed:

"I think a picture will tell a thousand words.....if you can get people to watch a video or DVD showing how it is and what <u>will</u> happen, not <u>may</u>.....that would, oh crikey, that would make me think......" (Paul)

"I think specific instruction from people who know is actually very helpful and also to be told the truth. I don't want anyone to tell me anything other than the truth about myself." (Tom)

Raju showed his mistrust of medical staff, which could also result in not taking health-care advice:

"my parents are of a generation where they believe doctors are Gods and we now know that's not the case." (Raju)

The question that was partly answered in these interviews by a small number of respondents was how far good education might have changed behaviour:

"Would it have changed me? I don't know, I wouldn't have thought so. The first five years of me knowing about it, it was just an inconvenience but if I had been, how should I say, a bit more regimental in the system I probably wouldn't be in quite such a bad condition as I am now but that was probably from misinformation or lack of information probably but when they put me under the specialist diabetes people at St M's, they gave me some proper lectures and I realised just how serious it was. Before I thought it was just one of those things because 6% of the population are diabetic." (Edward)

Azam suggests though that even if a person received good education, it would make no difference:

"Today's generation have all the information available but ...they drink a lot and smoke all day long."

and he later added:

"...that's what happens to Mauritian people or Indian people, they don't think oh well – I mean when we are young we take chances." (Azam)

presumably meaning that people often don't think that ill-health will happen to them.

However when the interviewees were asked about how far it was an individual's responsibility to look after one-self, a number of people were very clear about their role:

"I listen to the advice and deal with it accordingly, put it that way!"(Edward)

"Honestly if people want to, they can help themselves. You can help so much, but people have to help themselves" (Azam)

"No, if there's anything I think will help me, then I'll do it." (David)

"So, if they say something, you've got to try and do something about it yourself. It's the only way you'll do it, isn't it?"(Brian)

4.17. Summary of interview findings

In this small group of patients it appeared that few people had good understanding of the possible risk of kidney disease, and the majority had little idea of exactly how they could control the condition themselves. With regards getting key messages across a few interviewees thought that that visual media (TV, film, internet) might be helpful whilst others preferred an individualised approach with a health-care professional. Most spoke of the seriousness of kidney disease and how people would take notice if there was a clear message, underpinned by 'truthfulness' (clarity) about what could potentially happen. One potential barrier to taking on healthcare advice in this small group of patients was inconsistency of message from health care professionals.

 Each of these themes was taken into consideration when developing the self-management materials, and will be discussed in the following section.

These extracts have highlighted the main issues that affect people with diabetes in this small sample. The main barriers to controlling the condition have been identified, alongside the different ways in which health care professionals can provide information and education to facilitate self-care.

4.18. Development of the self-management package

4.18.1. <u>Educational package: contents</u>

Findings from the participant observation, a systematic review of the literature and the interviews informed the development of the patient-centred education package. Findings from the participant observation were presented in detail in Chapter 2; findings from the literature review were discussed and analysed in Chapter 3. A summary of both is reviewed here.

4.18.2. <u>Findings from the 3-month participant observation in 2004</u>

In summary the findings relevant to the self-management package were staff and patient confusion over microalbuminuria testing and discrepancies over blood pressure measurement and management, possibly indicating an underlying lack of knowledge amongst primary care staff.

4.18.3. <u>Findings from the literature review</u>

In summary the overall finding was that the use of self-management programmes in chronic disease is developing, and some of these programmes are beginning to show success (Chodosh et al. 2005). What is not clear is exactly how these programmes should be executed (face-to-face versus group education), what the method of facilitating behavioural change should be, or what the content should include. It is difficult to compare findings across different studies because of differing methods and outcome measures. Health policy however is clear, with Department of Health reports consistently outlining the importance of implementing patient-centred self-management programmes (Department of Health 2008b).

4.18.4. <u>Findings from the interviews</u>

It must be emphasised again that the small number of respondents' views were used only as a basis for the package development, rather than to make generalisable claims about the overall experiences of people with diabetes.

One main finding was the importance of realistic guidance for self-management: guidance must be not based on unattainable goals with lack of empathy about how hard it can be to take on health-care advice.

A number of people were concerned that they were not being told the truth about what could happen if kidney damage progressed. The key issue appears to be that patients at risk of kidney disease were not necessarily told (or perhaps did not hear) what might happen if they did not take on health care advice.

Few respondents were aware of the risk of kidney damage in diabetes. Not one patient understood why they were providing a urine sample for microalbuminuiria. Most believed the sample was being taken to check there was no infection in the urine.

When questioned directly about whether they themselves could do anything to prevent the kidney disease progression, only a few respondents were able to offer any suggestions: blood pressure control (1 patient); blood sugar control (1 patient): diet (1 patient); taking tablets as prescribed (1 patient). No-one mentioned lifestyle modification such as smoking cessation although two respondents thought that alcohol was a key factor. Few understood the link between kidney disease and high blood pressure.

The interviews confirmed my original anecdotal evidence that led to this study, that although most people had some understanding of the possible risk of kidney disease, they had little idea of exactly how they could control the condition themselves.

4.19. Curriculum

Although the aim of this thesis is to develop and test an educational *package*, rather than an education *programme*, an outline 'curriculum' needed to be developed to make explicit the aims of the package, the philosophy underpinning the package, the content and the ways in which the package can be used by health care professionals (Diabetes Education Network 2009).

The aims of the package are:

- To inform people with diabetes of the risk factors for developing kidney damage
- To provide key points for managing the ways in which kidney damage can be slowed down in people with diabetes who are at risk
- To give more detailed information on how they can self-manage their condition
- To provide practical ways for increasing self-management

The educational philosophy that underpins the package emerged from the thematic analysis of the interviews. It was important to utilise a patient-centred approach, that is, one that was based on what the interviewees had said, and not one based on an educational theory that was rooted in academia.

The three concepts that were identified from the literature review and patient interviews were:

(1) Patient-centred - with patients themselves telling the story (learning from each other)
(2) Empowering - with an emphasis on what can be done to control the condition
(3) Truthful - what can happen if kidney disease progresses.

Overall the package was based on the concept of self-management – a concept that was encouraged by GPs and practice nurses in the diabetes clinics at the six participating surgeries, and reinforced by national policy (National Institute for Health and Clinical Excellence (NICE) 2003).

The content of the package was based on the findings of the case study, literature review and interviews, that is, topic areas that interviewees wanted to know more about or did not understand. A summary of these topics is shown in Figure 4.7.

Figure 4.7: A summary of the findings that informed the development of the education package
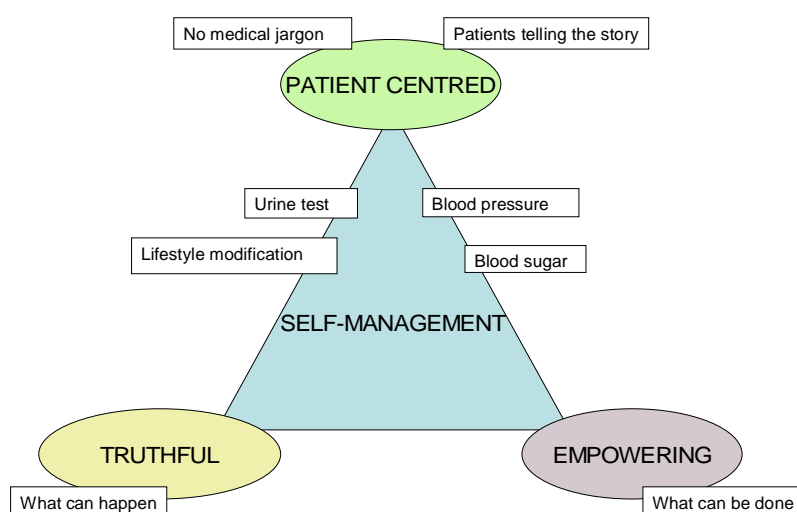
As the study progressed it became clear that there were a number of challenges in developing a true 'patient-centred' package. As much of the literature suggests, there are constraints on time, pressure to achieve targets and also the realisation that empowering people to control their condition may not necessarily mean that care is 'patient-centred'. For some patients, there is a tension between the emphasis on self-management and doing what the individual wants. Some people may prefer to rely on professionals or family members to control their condition (a so-called external locus of control). An empowering education package may not necessarily be a patient-centred one, or indeed may not appear to be patient-centred to the patient (Funnell et al. 2005).

4.20.   Overall design of the package

A number of criteria were considered important when developing the package.

A range of different types of educational media had to be developed as people learn and take in health information in different ways (Honey and Mumford 1982). The package had to be able to stand-alone without the necessity of a health-care professional being present to explain the content. However there had to be a facility whereby patients could consolidate their learned knowledge and also had the opportunity to ask questions. The educational content had to be presented in a language that was patient-friendly and also contained no hospital jargon. There was local Trust guidance and national guidance (Patient Information Forum (PiF) 2005) available on how to write clear and understandable patient information materials, and this guidance was used to both help plan and write the materials.

Figure 4.8 outlines the main issues to be considered and included when developing health information materials. The self-management package was developed using these recommendations

Figure 4.8: Main issues to be considered when developing learning materials for patients

- Details of who produced the information and when

- Written in easy to understand language

- Clearly arranged with helpful and appropriate illustrations

- Contains contact details for the organisation, department and any support organisations

- Based on current research information and evidence

- Answers patients' questions

- Clear about any risks, side effects and benefits of a procedure

- Explains about the impact the condition or procedure will have on the patient's everyday life

(adapted from Patient Information Forum www.pifonline.org.uk*)*

It was also crucial that a range of materials were developed that accounted for differing information needs and different leaning styles. Figure 4.9 demonstrates the range of materials that provide differing levels of information, which in turn can facilitate different levels of self-management. For example some people may want simple messages about managing CKD, and headline messages for this purpose are shown on the fridge magnet. Other people may want to understand why they are providing an annual urine sample (as explained on the DVD), and then engage in discussion with their GP or practice nurse about taking ACEi/ARBs. This discussion could then be recorded in the monitoring diary.

The contents of the package are shown in Figure 4.9 and a photograph of the package is shown in Figure 4.10. Further discussion about the development, implementation and evaluation of the package is provided in Chapter 8. Both versions of the package (before and after evaluation) can be found in Appendices A (before evaluation) and B (after evaluation).

Figure 4.9: Contents of the self-management pack

Kidney Disease: Reducing the Risk   ***Self-help for people with Diabetes***
A fridge magnet (with key messages)
Written information
A 20-minute DVD filmed with patients. Eight sections including screening for MA, BP and blood sugar management, lifestyle modification, and a section on what can happen if kidney damage becomes worse. The emphasis is on what can be done to control the condition.
A monitoring diary to record results and questions to be asked at clinic visits
A blood pressure machine if required

Depth of information and opportunities for self-management

Figure 4.10: Photograph of the contents of the self-management pack

The costs, rationale for inclusion, a description and explanation of each of the materials now follows.

4.21. Costs

The project has been partially funded by a variety of different organisations and charities, and these are itemised in Appendix 2. I developed a budget for the project prior to submitting applications for funding. Once the funding had been secured, the total amount of money available to fund the development of the package was approximately £12,500. It was envisaged that the majority of costs would be taken with the planning and filming of the DVD (see Appendix 7). Although the start-up costs were high, subsequent production costs will be approximately £1.00 per pack.

4.22. Packaging

It was important that all the materials could be kept together in a small box. This would enable the materials to be kept clean and easy to store. The size of the box was determined by the minimum size (length and breadth) that could hold a DVD, and also a depth that could easily keep all the other materials together. It would also be beneficial for the box to be of a size that could easily be accommodated on a book shelf.

The next consideration was price and the internet was searched to source the cheapest and most appropriately-sized box. A specialist company 'The Bag N Box Man' was able to provide boxes at approximately 15 pence each, although these boxes were delivered in a flat-pack and had to be assembled by hand.

4.23. Logo and 'house style'

National guidance on developing patient information materials had highlighted the importance of using a 'house style.' This meant that the use of logos, fonts and formatting had to be consistent throughout all the materials. It was not necessary to include a hospital or primary care trust logo, but rather to show that the project had been funded and endorsed by a number of organisations and charities.

The type font that was used throughout was 'Acoustic Bass'. An example is shown in Figure 4.11.

Figure 4.11: Acoustic Bass font

What This Font Looks Like
Acoustic Bass
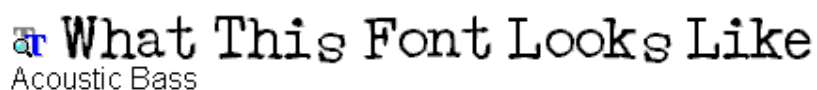
This font that had been found by the film production team (see section on film below) and was thought by the team to be contemporary and eye-catching. I was unsure about the font, especially as it might possibly be difficult to read by an individual who had eye problems, which is common in diabetes.

In order to verify whether the font might be suitable, I asked a small number of people with kidney disease and diabetes whether the font was clear to read. In addition the Royal National Institute for the Blind (RNIB) website was searched to see if there were any recommendations for font type for those with impaired vision. The site suggested that as long as the colour was black on white, or white on black, and of a font size of ≥14, it was likely that it would be readable.

4.24. Pack contents

4.24.1. Written information

The written information was developed as an additional resource, either as a stand-alone learning tool, or to be read in conjunction with the film. The written information was presented in the same format as the film, with sections on screening for MA, BP and blood sugar management, lifestyle modification, and a section on what can happen if kidney damage becomes worse. Each section was written in an easy to read style without medical jargon. The information was reviewed by the second supervisor, a specialist renal nurse and a practice nurse. A patient in the renal unit was asked to check the document for clarity and understanding.

An A5 leaflet was developed and costed by the Medical Illustration Department in the local hospital. 200 copies could be printed for under £50 if the leaflet was printed in black and white, and one colour (red) to be used in the heading.

4.24.2. Film

I had been involved in giving a presentation at a national conference on chronic kidney disease, and the event had been organised by a pharmaceutical company. The pharmaceutical company had used an advertising/marketing company to organise and promote the day, and the contact at this company was able to provide names of two film production companies.

Both companies were contacted and given a brief. The brief was to develop, film, edit and produce a 15-minute film that would be produced within a three-month timeframe (end April 2006). One was selected as the director of the chosen company appeared to understand the remit and also because he used freelance cameramen and directors, so the price was considerably less. Once the price for filming had been negotiated, it was checked by a friend employed in a marketing company to confirm that the price was reasonable. A breakdown of the costs is shown in Appendix 7.

I met the director of the film company on two occasions to discuss the content of the film. After the second meeting a draft script was written (see Appendix 8). I then met with the film director one week prior to filming to discuss practicalities of filming in a patient's home, in a GP surgery and also in the hospital.

4.24.2.1. Filming in a patient's home

A number of patients had been identified for a possible film case study during the interviewing process. It was important to find a 'typical patient', one who would relate to other people in the same situation and one who was able to articulate on film the concerns and day-to-day experiences of having diabetes. It was important to find people who had a positive attitude to their condition, and therefore gave the message that diabetes is a condition that can be controlled. It was vital to show that it is not always possible to take every bit of health-care advice on board and to be realistic about living with the condition. For these reasons the gentleman who was chosen was a retired man of 73 years, who lived at home with his wife. He is a man who manages his condition well, but at the same time was able to talk eloquently about how he loved food and how he sometimes struggled to keep to the advice offered.

The day of filming went well. We arrived at the gentleman's house at around 8:30 and surprisingly the film crew took up the offer of a cooked breakfast from the gentleman's wife so the start time was delayed. There were some anxious moments for me. When filming the gentleman taking his blood sugar using a not-quite perfect technique, there was the dilemma about whether I should ask him to repeat the technique and next time make sure that his

finger does not touch the test strip. There was also a worrying time during filming when the gentleman was riding his bike with the film crew following in their 4x4 vehicle. I was concerned that he might fall from his bike as he was being filmed or whether he might return to the house very breathless after undertaking a number of circuits of the local roads.

4.24.2.2. Filming in a GP surgery

The second patient who was requested to take part was a 68 year-old lady who lived with her husband, and had been diagnosed with Type 2 diabetes around ten years ago. I understood from her GP that she had difficulty in coming to terms with needing insulin to keep her blood sugars under control, but nevertheless she worked hard to take exercise and heed dietary advice. She was delighted when I asked her to take part, and enjoyed the experience of filming with the staff in her local surgery.

In the surgery it took some time to set up the equipment, as we needed to film in three locations: the waiting room, the nurses' consulting room and also the GPs office. Permission was taken from staff members (receptionist, nurse and GP) and also from a couple of patients who were waiting for an appointment in the waiting area.

Overall it took half a day to complete. The GP and practice nurse had been given an outline script before the filming took place. The scripts were based on the content of what some of the interviewees had been unsure about (such as target blood pressure for people with diabetes).

4.24.2.3. Filming in the hospital

The Press Office at the Trust was contacted before filming commenced. They instructed me and film team to take informed consent from all the patients who were to appear in the film. It was also necessary to inform the security team about the film crew and the Head of Security was advised that the Press Office were aware of the project.

Filming in the renal unit was more problematical as many patients needed to be consented before filming took place. There were some ethical dilemmas for me at this point in the study, namely the difficulty in using people who by their own admission, had not managed their diabetes very well. The dilemma was how far to approach people who had not looked after themselves, such as non-attendance at diabetes clinics, not taking blood pressure medications or continuing to smoke. I considered that it would be acceptable to request

people to take part if they had insight into how far their poor management had affected their kidney function.

The brief to staff was therefore to identify patients who had diabetes, who were on dialysis and had *verbalised* their insight into how poor management of their diabetes in previous years had to some extent caused their kidney damage. There was one lady in particular who appeared to fit these criteria, and she was chosen to be the main interviewee on the film. I visited this lady on two occasions explaining the project, to make sure that she knew the aim of the film and why she had been chosen. Other patients who were dialysing on the same day as this lady, were also asked if they would mind being filmed/interviewed. These patients were told that a film about prevention of kidney disease was being made and it would be very helpful if they could explain their experiences of being on dialysis.

The aim of filming in the hospital was to show 'what can happen' if diabetic kidney disease progresses. It was important however not to show a very negative side to the message, but rather to balance the difficulties of a life with dialysis with the possibility that people can help themselves to delay progression of the disease.

Once all the filming was complete the film company then took approximately two weeks to develop the first draft of the film (the "rushes"). At this stage I was keen to get feedback from the patients, the health care professionals who appeared in the film and also a selected 'lay' audience. Over a two-week period I visited both patients at home, and also sent the film to the first and second supervisor, the GP and practice nurse who had appeared in the film. Two non-clinical members of staff at the Trust were also shown the film, and were requested to make comments.

A few minor amendments were made at this point. The original version included a scene where a computer screen was showing the Diabetes UK website. One patient and his wife were concerned that important information was being shown on the screen that they could not read. Although it was not the intention that the information should be visible, this part of the film was edited out to save confusion. One other scene filmed in the dialysis unit was also removed as the non-clinical reviewers both considered that it was disturbing and might potentially upset patients. I made a note to ask a specific question about whether the film was upsetting to participants at a later date.

4.24.3.   Key Messages: 'Fridge Magnet'

A number of interviewees had spoken about the importance of having the main messages reinforced when taking on health-care advice. This is supported by health education literature that suggests that reinforcing key messages can change behaviour (Ko et al. 2004). I was interested in evaluating how far the package could be relied on to 'get the message across'. I undertook a web-based review on different ways of 'getting the message across' and found a number of sites that promoted 'fridge magnets' as doing just that. Refrigerator (fridge) magnets are small magnetic strips, usually made of rubber or plastic and are often used to advertise products or services. Although there appears to be no evidence base to support the assertion that fridge magnets with key health messages can affect health outcomes, I decided that this could be another novel way to try to improve people's knowledge of kidney disease. The key messages incorporated on the magnet are shown in Figure 4.12.

I evaluated the plethora of websites that produce fridge magnets upon upload of a picture file, and selected the site that gave the best price for 200 magnets. The magnet had to be small enough to fit in the box but large enough for key messages to be visible (10x15 cms portrait). The magnet was manufactured in Israel and produced within three working days for a cost of approximately 50 pence per magnet.

Figure 4.12: Key messages on the fridge magnet

Give a yearly urine sample

Aim for blood pressure below 135 (top) and 75 (bottom)*

Take blood pressure tablets as prescribed

Keep blood sugar under control

Try not to smoke
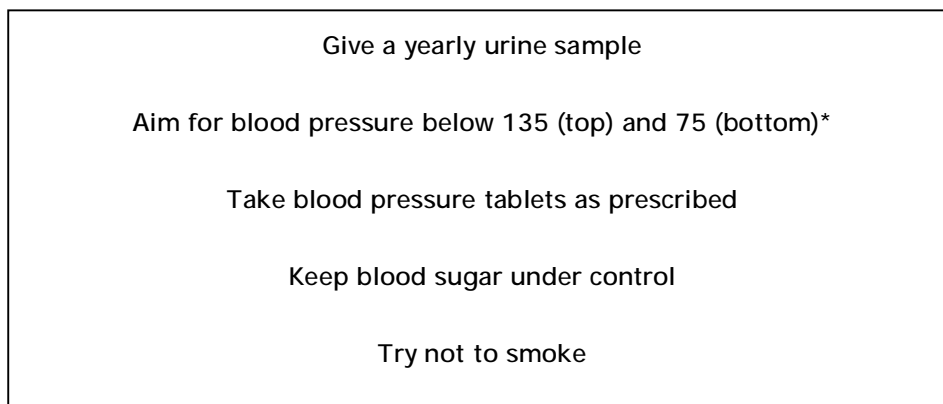
* BP target needed amendment during evaluation phase as a result of national guidance

4.24.4. Monitoring diary

People with Type 1 diabetes and those with Type 2 diabetes on insulin/medication are advised to undertake blood glucose monitoring in line with national guidance (Diabetes UK 2006). All the patients in the six participating GP surgeries who monitored their own blood glucose were routinely given 'monitoring diaries' by their practice nurses. These diaries are

printed and distributed by pharmaceutical companies. These diaries are of pocket size, and are printed with boxed type that allow patients to fill-in their blood glucose readings, blood pressure readings and any other relevant information such as clinic appointments.

In an early phase of the study I considered printing an alternative 'monitoring diary', which would be developed specifically for the study. However after discussion with three practice nurses in the participating surgeries, each thought that the patients would feel more comfortable in using the diaries that they were familiar with. It was agreed that the diaries already used by the practices would be included in the pack, and additional information about their usage would be included in the pack's written information.

4.24.5.   Blood pressure machine

There has been much debate about how far patients are able to manage their own blood pressure, especially if they have access to a blood pressure machine at home. Since the literature review was completed in 2007, an additional recommendation from the American Heart Association has been published. A joint scientific statement, recommends that people should routinely monitor their blood pressure at home (Pickering et al. 2008).

For the purposes of this study, it was decided that a small sample of patients would have access to a blood pressure machine to use at home. Although it would not be possible to purchase large numbers of BP machines, and therefore include the effects of home monitoring in the data analysis, it would be useful to understand the possible (qualitative) benefits or problems of home monitoring. The main difficulty was funding the equipment and the first step was to compare reliability and costs of different machines.

The British Hypertension Society assesses and recommends different meters, so their website http://www.bhsoc.org/blood_pressure_list.stm was consulted for a current list of machines that met their strict criteria. There were a small number of different machines for home-use that appeared cost-effective, valid and reliable.

Figure 4.13 shows the two different models that were considered for ease-of-use, ease-of-purchase and price, plus validity. Both the Boots Upper Arm (Coleman et al. 2005) and the Microlife devices (Cuckson et al. 2002) had been validated in accordance with the European Society of Hypertension International Protocol. Both the Microlife 'as easy as 123' model and Boots 'Upper Arm Omron' devices were investigated further.

Figure 4.13: A comparison of two different models of BP machine suitable for self-monitoring

Manufacturer	Cost (rrp incl VAT)	Features	Cuff sizes (cm)	Weight (g)	Dimensions (l x w x h) (mm)
Boots Upper Arm Model: Upper Arm (Omron HEM-742-E)	£49.95	4 x AA Battery	Small adult (17-22) Standard adult (22-32) Large adult (32-42)	830	177 x 135 x 112
Microlife Model: 'As easy as 123'	£44.98	Single button operation Last reading memory Mains adaptor available	Standard adult (22-32, included) Large adult (32-42, available from Microlife)	335	115 x 155 x 60

The distributor for Microlife models in the UK was contacted by letter in the first instance. He was chosen to be contacted because the distributor's website showed a photograph of the Managing Director of Microlife donating a number of devices for clinical research to the British Heart Foundation. It was hoped that perhaps he would do the same for this study.

After two weeks he had not responded, so I telephoned him. He told me that as he was the only distributor in the UK he was not able to donate the machines for free but rather would be able to sell them at cost price. The retail price was around £45, and the cost price was £23. Twelve machines were purchased at cost price for the study, two for each practice.

4.25. Chapter summary

The self-management package was developed for and with patients. The pack contained a variety of educational learning materials, the aim of which was to cater for different people with a variety of learning styles. The pack was to be distributed to all people in the six participating GP surgeries who had diabetes and confirmed microalbuminuria.

5. RESEARCH REPORT: TESTING OF THE SELF-MANAGEMENT PACK

5.1. Introduction

Once the pack had been developed, the aim was to test the pack by collecting patient data before, during and after pack distribution.

5.2. Rationale for research design

Possible study designs were discussed at the start of the study with my supervisors, after books and journal articles on research methods had been scrutinised. I received feedback on the design from the grant reviewing committee of the British Renal Society/Kidney Research UK Fellowship. I also consulted academics and clinicians in other institutions, who were experts in renal disease, diabetes or family practice.

It was important to evaluate the longitudinal effect of the intervention, and the *interrupted time series design* (ITSD) has been cited as being the strongest quasi-experimental approach for evaluating longitudinal effects (Green 2006). This design involves collecting data at multiple time points before and after an intervention.

The time series design can therefore be sensitive to trends in performance. The aim is to determine whether or not the intervention had an effect over and above any trend present in the data. For example, it is possible that data collected prior to the educational package being implemented could have been affected by my presence. When I visited the practices, I was often asked general questions about managing patients with kidney disease, and as such, education could have resulted in changes in management, such as initiation of ACEis for microalbuminuria. This pharmacological intervention could have then resulted in reduction in blood pressure in the subjects in the study.

The design was originally planned to be the most basic of the ITSDs: the simple interrupted time series. In this design there is only one experimental group. This design can be depicted as follows, using the classical notation system (Campbell and Stanley 1963)

O - O - O - X - O - O - O

where O represents an observation or measurement and X represents an exposure of a group to an experimental variable or event, the effects of which are to be measured.

5.3. Study design

A summary of the design of the study is shown in Figure 5.1.

Figure 5.1: Summary of study design

Participants – inclusion criteria	• A diagnosis of Type 1 or Type 2 diabetes mellitus (Read code C10) • Microalbuminuria, defined by two abnormal albumin-creatinine ratio (ACR) results >2.5 mg/mmol (men) >3.5 mg/mmol (women)
Intervention	The self-management package Delivered September 2006-September 2007
Objectives	To measure the effectiveness of a self-management package for people with diabetes at risk of kidney disease.
Outcome measures	Blood pressure (systolic and diastolic) mmHg HbA1c % Body Mass Index Smoking status
Data collection time points	Three data collections before intervention - March 2005; October 2005; March 2006 Two data collections during intervention - November 2006 and June 2007 One data collection after intervention - January 2008

Patient data from participating practices were originally planned to be collected on 6 occasions, every 6 months during the study, that is: in March and October 2005; March and October 2006; and in March and October 2007. The educational pack was originally planned to be distributed after the third data collection in mid 2006. Unfortunately changes to this

timeframe and to the study design had to be made because of national policy changes in managing CKD.

5.3.1.   Changes to study design

CKD has been a high-profile, quick-changing issue, especially during the period 2004-2008, the timeframe for this study. There has been the introduction of the NSF for Renal Services in 2004/2005, followed by the introduction of the Quality and Outcomes Framework (QOF) for CKD in 2006. As a consequence, many primary care physicians and practice nurses changed their clinical practice because of national guidance and incentivised targets, and the evidence for this will now be presented.

During 2006 it became clear that the clinical care of people with CKD was improving, particularly in the area of microalbuminuria (MA) testing. Improved MA testing would result in more people with MA being identified, and in turn may mean more people being prescribed an ACEi or ARB, which could lead to reduced blood pressure. The improvements were reflected in the QOF scores (see Figure 5.2) but were also reflected in the way in which practitioners were engaging with, and questioning me about CKD. It became apparent that because of all the changes in kidney care it might not be possible to differentiate between changes that could occur as a result of the education package, and changes that have occurred as a result of the national initiatives and targets.

Figure 5.2: QOF results (2004-2006) for % people with diabetes having microalbuminuria testing in participating practices

Surgery	2004/2005 (%)	2005/2006 (%)
1	76.6	84.4
2	100	100
3	72.1	100
4	100	100
5	91	100
6	67.5	79.6

As it would be difficult to demonstrate that possible changes in the patients' bio-physical data had come about as a result of the intervention rather than the effect of the national

initiatives, it was necessary to include a control group in the study to identify the impact of national policy on physiological outcomes. I submitted an amendment to the local research ethics committee (LREC), and my request to include a control group was granted by the LREC in March 2006.

In summary, the greatest threat to the internal validity of this study design is 'history' (changes to national policy), although other threats such as instrumentation and selection can occur (Green 2006). Adding a non-equivalent control group to the simple interrupted time series has the potential to improve on some of the limitations mentioned. This design, called an interrupted time series with a non-equivalent control group (Campbell and Stanley 1963) is depicted as follows.

O - O - O - X - O - O – O
O - O - O - - - O - O - O

As shown, a series of observations are collected both prior to and following the administration of the treatment for the experimental group; during this same time period, a series of observations are also collected for a comparison group, although in this study data in the control group were collected retrospectively (see section 5.3.2). This design allows the researcher to control for history effects, as an historical event would most likely affect both treatment and control groups equally.

5.3.2.   Control group

The original aim was to recruit six practices in the same PCT as control practices. I searched QOF data to find six practices of the same list size, and QOF results (MA screening and BP control) as the participating practices (matched pairs). I identified six control practices within the same PCT that fulfilled these criteria, and approached the lead clinician in each practice by letter. The letter explained the aim of the study, their possible involvement, and offered them a fee of £150 for their time and inconvenience. The letter was followed up with a phone call two weeks later. Unfortunately only one practice agreed to participate. Following discussion with my supervisors and the statistician, it was agreed that one set of control group data would be better than having no control data, so I went ahead and made arrangements to collect data from the control practice.

5.3.2.1. Data from control practice

I had a challenge in overcoming the practical difficulties of obtaining retrospective data from the control surgery. I needed to obtain data on the same patient group as the participating surgery group, that is, people with diabetes and microalbuminuria. The data needed to be found for the time period March 2005 onwards.

During 2007 I started to work with a Biomedical Informatics team at a different University, on a national study that is exploring the best ways to improve the management of CKD in primary care. This study is using Morbidity Information QUery and Export SynTax (MIQUEST) software to extract data from GP practices. This is a Department of Health sponsored data extraction tool, and the principal investigator suggested to me that I use MIQUEST software to extract the data from the control practice, rather than searching by hand which could take a great amount of time. The lead GP in the practice agreed that I could collect data in this way.

I worked with the data team in the Biomedical Informatics department to create a dataset for this control practice, by simplifying another dataset for CKD already in use by that team. A programme was written to extract anonymised data (no date of birth or postcode) from the control practice, on all patients registered on the date of data extraction. The dataset included age, gender, ethnicity, Read codes for diabetes, blood pressure, HbA1c, body mass index, exercise and smoking status.

A member of the data team accompanied me to the practice and helped me extract the data. The process took one half-day to complete, and once retrieved, the data were contained within a MS Excel spreadsheet. Data collection in the control practice took place in December 2007, at the end of the data collection period. The control practice data were collected retrospectively from the date of extraction back to December 2004.

5.3.3. Statistical tests

At the study's inception, and during the writing of the original protocol, statistical advice was sought from another University. A statistician from this University had been recommended by the Local Research Ethics Committee (LREC), as statistical clearance had to be given by the LREC before ethical approval was granted. At this point the statistician gave very basic advice to me, and advised that patients could act as their own controls, as they were going to be mapped throughout the study, before, during and after the intervention.

At a later date a statistician from City University advised and directed the statistical analysis. She advised on powering the study and discussed the possible ways in which the data could be compared. Unfortunately during Spring 2008 this statistician left the University, but was eventually replaced in September 2008. This third statistician advised on using SPSS and which statistical tests to use.

5.3.4.   Powering the study

The original City University statistician understood the design and requested that I identify the numbers of people in each practice at the start of the study who met the inclusion criteria and had a blood pressure at the recommended target of 135/75 mmHg. Figure 5.3 shows the BP readings of patients who met the study's inclusion criteria in the participating surgeries in March 2005.

Figure 5.3: Number of patients with diabetes and MA achieving BP target of <135/75 mmHg in the participating surgeries in March 2005

Surgery	Total number of patients who met study's inclusion criteria in March 2005	Total number of patients achieving BP target of <135/75 mmHg
1	56	34
2	48	20
3	62	23
4	41	24
5	65	15
6	59	38

These figures equated to 46.5% of the total number of patients having BP values below the recommended targets. I wanted this to increase to 100% following the intervention.

I asked the statistician to make a power calculation based on these data, and she undertook a standard sample size calculation. She calculated that 13 patients in each surgery needed to be given the intervention, for 5% level of significance with 90% power. However it was necessary to increase this sample size to take account of the clustering of the practices.

5.3.5.   Cluster design

Cluster design trials are those in which groups of patients rather than individuals are being investigated. The main consequence of adopting a cluster design is that the outcome for each patient can no longer be assumed to be independent of that for any other patient (Campbell and Grimshaw 1998) and patients within any one cluster are more likely to have similar outcomes. In this study, all the patients in one surgery are allocated to the same intervention, so each GP practice forms a cluster. This needs to be taken into account in the analysis, and preferably the design, of the study.

Methods which ignore clustering may mislead, because they assume that all subjects are independent observations. This is not the case in a cluster design, because observations within the same cluster are correlated. If simple statistical methods are applied to such data, without taking the clustering into account, this may lead to confidence intervals which are too narrow and p values which are too small (Bland 2004).

The University statistician advised me on how to adjust the sample size to take account of the cluster design. The calculation required to adjust the sample size to take account of the clustering was adapted from Bland (2004).

It was necessary to adjust the sample size by Y, where Y=1+a (n-1), where a is the median intra-cluster correlation co-efficient, the correlation between pairs of subjects chosen at random from the same cluster, and n is the size of the cluster.

For GP practices, 'a' is usually taken to be 0.04. This was the median intra-cluster correlation coefficient reported in a systematic review of trials in primary care (Eldridge et al. 2004). The average cluster size is 55, the average number of patients across 6 practices at the time of the first data collection. The calculation then becomes

Y = 1+0.04(55-1) = 3.16

Therefore the sample size needed to be adjusted by 3.16. This gives a sample size per practice of 13 (original power calculation without clustering) x 3.16=41.08. So a sample size of 42 per practice (rounded up) would be able to detect a difference with 90% power at 5% level of significance. In total 252 packs needed to be distributed for the study to be powered. Figure 5.4 summarises the sample size and statistical methods used in the study.

Figure 5.4: Sample size and statistical methods

Sample size	Intervention practices: 436 patients identified as possible participants
	Control practice: 61 participants
Primary outcome measure	Systolic blood pressure
Power calculation (with clustering taken into account)	42 patients per practice needed to detect a difference with 90% power at 5% level of significance.
Statistical methods	Repeated measures analysis of variance
	Comparison between 2 groups:
	Group 1: patients from participating practices who did receive the pack
	Group 2: patients in the control group
	Note: there was an additional group: patients from participating practices who did not receive the pack. The makeup of this group will be discussed in Chapter 7.

An overview of the study timeframe is shown in Figure 5.5.

Figure 5.5: Timeframe of study

Data collection	1	2	3	4	5	6
Date	March 2005	October 2005	March 2006	November 2006	June 2007	January 2008
Intervention Sept 06 – Sept 07			←		→	

Although the packs were distributed between September 2006 and September 2007, 15% of packs had been distributed by November 2006, with the majority of packs (>80%) being distributed by June 2007, time point 5. It was important to collect data at least four months after the last self-management pack was given out. This additional time period allowed time for the latest-distributed pack to have an effect, and also for the practices to settle to 'usual practice' without the effect of the researcher visits.

In summary there was

- a pre-intervention period of 18 months;
- an intervention phase of one year;
- a post-intervention phase of six months when there was only minimal contact between the researcher and the practices/participant.

5.3.6. <u>Time to complete data collections</u>

Each round of data collections took approximately four weeks to complete. The process involved contacting the practice manager (PM) or information technology (IT) manager in each of the practices to book a four-hour slot at a convenient time. Each practice had a different process for accessing the data, but for the majority, a login and password were created for me and the research nurse at the start of the study. All patient data at each of the time points were collected manually from practice computer databases.

In late 2004 I first had access to the participating practice computer databases. Extraction of data from the primary care computer systems was a learning experience for me. At first I had to familiarise myself with the computer system used by each practice (EMIS LV), and to find out exactly where relevant data were stored. I had little training by the PM or IT manager in each surgery, although the main menu/screens were explained. In the following six months I spent a great deal of time liaising with the practice team, trying to identify exactly which patients might be eligible to participate. Time was also spent exploring the EMIS system, and understanding how good/poor the data entry was in each of the categories. For example, ethnicity recording in early 2005 in the study practices was poor (around 10% recording) although this appeared to be a national trend (Kumarapeli et al. 2006)

5.4. Dataset

The aim of this data collection was to evaluate how far the proposed education package could make a difference to influencing the control of the parameters that affect the condition. There were no additional investigations carried out over and above routine care.

5.4.1. Dataset pro-forma

A pro-forma was developed to provide a framework for data extracted from individual patients' records. The pro-forma was developed incorporating the risk-factors for diabetic kidney disease outlined in NICE guidelines (National Institute for Health and Cinical Excellence 2002) and these include

- annual urine testing for microalbuminuria (MA)
- prescription of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) if MA is present
- blood pressure to be controlled below 135/75 mm Hg
- HbA1c to be maintained between 6.5-7.5% according to the individual's target
- patients to be given advice about smoking cessation, weight control and exercise

See Appendix 9 for the developed data collection pro-forma.

Baseline data were collected over a three month period (March-May 2005) and entailed:

- type of diabetes (Type 1 / Type 2)
- latest microalbuminuria test result (ACR)
- latest serum creatinine result (to assess renal function) (mmol/L)
- estimated glomerular filtration rate (eGFR) was calculated from serum creatinine using the 4-variable Modification of Diet in Renal Disease (MDRD) formula, obtained from the Renal Association website. Although estimation of GFRs were available from patient records from Feb 2006, when it was introduced by hospital laboratories, it was possible that the calculation undertaken by the laboratory may have differed from that calculated by me using the on-line calculator. For consistency, I decided to continue with the on-line formula to allow greater consistency and enable comparison, so did not therefore use the laboratory calculation.
- latest blood pressure recording (mm Hg) as recorded by the GP/practice nurse
- latest HbA1c (glycated haemoglobin) result (%)
- most recent body mass index (BMI)
- amount of exercise as recorded by the practice nurse at the last visit
- smoking pattern (number of cigarettes or ounces of tobacco per day)
- medicines for blood pressure control
- medicines for diabetes control

5.4.2. Rationale for dataset

The variables that were originally identified were based on the known risk factors for kidney disease, as cited by NICE guidance (National Institute for Health and Cinical Excellence 2002). Previous studies were also taken into account, and the variables were also discussed with the second supervisor, a consultant nephrologist.

Each of these variables will now be presented and the rationale for their inclusion in the dataset will be discussed.

5.4.3. Risk factors associated with progression of CKD

There is extensive clinical evidence that diabetes, hypertension, and the presence of proteinuria are well-recognised risk factors for the progression of CKD (National Institute for Health and Clinical Excellence 2008a). Data on each of these risk factors were collected as follows.

5.4.3.1. Diabetes mellitus

Patients with diabetes mellitus were identified using the Read Code C10. Each practice was asked to confirm at the start of the study whether this was the code in use for patients with diabetes (Type 1 or Type 2). Further down the coding hierarchy, it appeared that there was greater variability for using Read codes (such as coding for type of diabetes, or complication such as kidney damage). A study of 17 practices in south-west London (Gray, Orr et al. 2003) found only one Read code (C10, diabetes mellitus) and its sub-codes was being used in all practices, although the use of other key Read codes for monitoring the care of patients with diabetes varied widely between practices. Less than half of patients with diabetes had their type of diabetes coded and < 20% of practices used the code for the location of care.

As it was likely that the C10 codes were being applied to those with diabetes, this code was used to identify the research participants. However I could not be sure that diabetes sub-codes (C108 and C109) to identify type of diabetes were always being applied appropriately.

5.4.3.2. Hypertension

There is strong evidence that lowering blood pressure reduces cardiovascular risk and progression of CKD (Coresh et al. 2003, Hallan et al. 2006, Haroun et al. 2003). Although it

would be simple to extract blood pressure recordings from GP databases, it was important to discuss the possible methods that practices have for recording patients' blood pressure readings. Following discussion with participating practices, it became apparent that some practitioners took two readings in the surgery (before and after consultation) and then recorded the lowest value; other practitioners took the reading that the patient had carried out at home; others recorded a blood pressure reading taken by another practitioner (for example health care assistant) before the consultation. Although these issues are important to be integrated in the discussion, it was decided that the only practical way to record blood pressure readings for this study was to extract the latest blood pressure measurement (systolic and diastolic)(mm Hg) from the GP database, before recording this value in the dataset.

5.4.3.3. Proteinuria and microalbuminuria

Proteinuria is a risk factor for progression of CKD. In the most common types of CKD (i.e. those due to diabetes, hypertension and glomerular disease) albumin is both the most abundant protein in urine and a sensitive marker of disease (Iseki et al. 2003).

Microalbuminuria is a term for the excretion of albumin in the urine in amounts that are abnormal but below the limit of detection of conventional urine dipsticks. The recognition of microalbuminuria in people with diabetes mellitus allows identification of diabetic kidney disease, and institution of treatment to reduce the risk of progressive kidney damage, at an *earlier* stage than would be possible with conventional protein dipstick testing. There is clear evidence that the detection of early diabetic nephropathy, manifested by microalbuminuria, is responsive to antihypertensive therapy, in particular the use of ACEis or ARBs (National Institute for Health and Clinical Excellence 2002).

Figure 5.6 shows national guidance (published by the Royal College of Physicians and the Renal Association, and the Royal College of General Practitioners) for microalbuminuria testing (Joint Specialty Committee on Renal Medicine of the Royal College of Physicians and the Renal Association 2006).

Figure 5.6: Recommendations for microalbuminuria testing

Recommendation number	Recommendation
R28	Urine albumin should be measured using a laboratory method in an early morning (preferred) or random mid-stream urine sample and expressed as an albumin: creatinine ratio.
R29	An albumin: creatinine ratio > 2.5 mg/mmol in a male or > 3.5 mg/mmol in a female is consistent with microalbuminuria. Patients demonstrating albumin: creatinine ratios above or equal to, this cut-off should have urine samples sent to the laboratory on two further occasions (ideally within one to three months) for albumin estimation. Patients demonstrating persistently elevated albumin: creatinine ratios in one or both of these further samples have microalbuminuria.
R 30	The diagnosis of microalbuminuria cannot be made in the presence of an acute metabolic crisis. As far as is practicable, the best possible metabolic control of diabetes should be achieved before investigating patients for microalbuminuria. Patients should not be screened during inter-current illness.
R 33	Patients with diabetes mellitus who have persistent proteinuria (as defined above) do not require testing for microalbuminuria
R 34	All other patients with diabetes mellitus should undergo, as a minimum, annual testing for microalbuminuria.

In summary, the presence of microalbuminuria, defined by an albumin: creatinine ratio >2.5 mg/mmol in a male or >3.5 mg/mmol in a female on two or more occasions, enables those at risk of kidney damage to be identified. Once MA had been identified, patients were included in the study. Once in the study, the latest microalbuminuria test result (ACR) was collected from the GP database on each participant at each time point.

5.4.3.4. Ethnicity

Another risk factor for CKD is ethnicity, with South Asians and African-Caribbeans most at risk (Xue et al 2007). This risk applies to development of kidney disease, progression of kidney disease and also numbers requiring dialysis and transplantation.

In a US study of over 40000 people, people of African-Caribbean descent with diabetes were 2.4 times more likely to develop established renal failure (ERF) compared with Caucasians

with diabetes (Xue et al. 2007). In the same study, African-Caribbeans with baseline hypertension (n=51016) were 2.5 times more likely to develop ERF than Caucasians with baseline hypertension (n=426300). Compared with Caucasians with neither baseline hypertension nor diabetes, African-Caribbeans with neither hypertension nor diabetes at baseline were 3.5 times more likely to develop established renal failure (Xue et al. 2007).

With regard to Type 2 diabetes, 100% of Indo-Asians experienced a doubling of serum creatinine compared with 45% of African Caribbeans and 50% of Caucasians (p=0.025) during follow-up (Xue et al. 2007).

Asians and African-Caribbeans have significantly higher rates of dialysis or renal transplantation, compared with Caucasians (Roderick et al. 1996). Although ethnicity of participants is a risk factor in progression of diabetic kidney disease, it is well-known that ethnicity recording in primary care is variable (Jones 2007). However a number of practices emphasised to me that recording of ethnicity data was being improved as a result of the Quality and Outcomes Framework (2006).

5.4.3.5. Latest HbA1c (glycated haemoglobin) result (%)

Haemoglobin A1c (HbA1c) has become established as the monitoring test of choice to assess medium term diabetic control and as a key parameter on which to base changes in management of patients (Reynolds et al. 2006). One of the mainstays of therapy for slowing the progression of kidney disease in diabetes remains attaining optimum glycaemic control (Cooper 1998), although the prime importance of blood pressure control has received recent interest (Adler et al. 2003). Two landmark clinical trials, the UK Prospective Diabetes Study (UKPDS) (Adler et al. 2003) and the Diabetes Control and Complications Trial (DCCT) (DCCT Research Group 1995), found a reduction in the microvascular complications of diabetes when HbA1c was intensively controlled. More recently it has been shown that a decrease in HbA1c by 1% increased the probability for remission of kidney damage (Gaede et al. 2004).

5.4.3.6. Body Mass Index

There has been some controversy regarding the effect of obesity on renal disease progression. Although one clinical trial showed that there were no significant changes in renal function after 5 months of a low calorie diet, renal function significantly decreased in the usual diet group (Morales et al. 2003). Two studies found that BMI was not associated with

risk of renal disease progression (Evans et al. 2005, Saiki et al. 2005)

Although NICE guidance (National Institute for Health and Clinical Excellence 2008a) stated that it was not necessary to screen those with BMI ≥30 for CKD, several reviewed studies (Eknoyan and Eknoyan 2007) have found that observational, cross-sectional, and longitudinal studies have documented obesity as an independent risk factor for the onset, aggravated course, and poor outcomes of chronic kidney disease. Although it is debateable whether obesity may not be an independent risk factor for CKD, obesity can lead to CKD through diabetes mellitus and hypertension. Weight reduction is also one variable that can be controlled by people themselves, and therefore it was important to monitor BMI within this study.

5.4.3.7. Exercise

Only one study was found that suggested that people with low physical activity have a significantly increased risk of established renal failure (ERF) or a CKD-related death compared with people who have high physical activity (Stengel et al. 2003). Although there appears to be little research to support the assertion that increasing the amount of exercise correlates with slowing down of kidney disease progression, it was important to monitor the amount of exercise undertaken by the subjects. If behaviour is going to change as a result of the intervention, then amount of exercise undertaken might be one way to measure whether changes have been made.

5.4.3.8. Smoking status and pattern

Three studies showed that smokers had a significantly increased risk for CKD compared with non-smokers (Haroun et al. 2003, Orth et al. 2005, Retnakaran et al. 2006). In a study of adults with diabetic nephropathy, smokers had significantly increased odds of a 20% decline in GFR compared with non-smokers (Orth et al. 2005). As smoking is a risk factor for CKD, data on smoking patterns were collected from the subjects' records.

5.4.3.9. Medicines

National policy guidance (National Institute for Health and Clinical Excellence 2002, National Institute for Health and Clinical Excellence 2008a) recommends tight control of blood pressure, particularly with two classes of drugs namely angiotensin converting enzyme inhibitors (ACEis) and angiotensin II receptor blockers (ARBs), for people with diabetes and

microalbuminuria. Data on these medicines prescribed to the study population were collected throughout the study. At baseline it was important to ascertain which patients were being prescribed this medication, as patients not prescribed were more likely to have progression of kidney damage, and this needed to be taken into account when comparing the effect of the intervention.

5.4.3.10. Measurement of kidney function

The study participants have diabetes and albuminuria, both risk factors for CKD progression. Data on other known risk factors, hypertension, poor glycaemic control and smoking were also collected. Data on *possible* risk factors (obesity and lack of exercise) are also part of the dataset. In order to identify whether the intervention has any effect on patient behaviour, and subsequent control of the risk factors, monitoring of kidney function also needed to be carried out.

5.4.3.11. Latest serum creatinine result (mmol/L)

NICE (National Institute for Health and Clinical Excellence 2002) guidance recommended annual measurement of serum creatinine concentration, irrespective of the presence of microalbuminuria or clinical proteinuria. Annual measurement of serum creatinine concentration in patients with diabetes mellitus is also a quality indicator in the NHS General Medical Services Contract. The SIGN guidelines (Scottish Intercollegiate Guidelines Network 2001) on management of diabetes mellitus also recommended that patients with diabetes mellitus should have their serum creatinine measured at diagnosis and at regular intervals, usually annually.

In 2005, the Royal College of Physicians, the Renal Association and the Royal College of General Practitioners drafted guidance, later published in 2006 (Joint Specialty Committee on Renal Medicine of the Royal College of Physicians and the Renal Association 2006) which gave a recommendation for measurement of serum creatinine concentration. Recommendation R12 stated that serum creatinine concentration should be measured at initial assessment and then *at least annually* in all adult patients with conditions known to be associated with a high risk of silent development of CKD, including hypertension and diabetes mellitus.

<u>Estimated glomerular filtration rate (eGFR)</u>

Serum creatinine concentration is determined not only by the rate of renal excretion of creatinine but also by the rate of production, which is dependent on muscle mass. Thus serum creatinine may be above the upper limit of normal in patients with normal kidney function but higher than average muscle mass (for example young males), but may remain within the reference range despite marked renal impairment in patients with low muscle mass (such as older females). In other words, some patients may have a normal serum creatinine but may have moderately reduced kidney function.

Because of this, the National Service Framework for Renal Services (Part Two) (Department of Health 2005) recommended the use of the four-variable Modification of Diet in Renal Disease (MDRD) formula to estimate glomerular filtration rate (GFR). The formula requires the gender, age, serum creatinine and ethnicity (black/non-black) of the patient. This is known as the 4-variable MDRD equation. Assumption of Caucasian ethnicity should be made if ethnicity is unknown. However the local hospital laboratory did not start reporting eGFR until February 2006, so a calculation of eGFR was performed using an electronic calculator on all the patients in this study for the duration of the study. The electronic calculator used may be found on the Renal Association website http://www.renal.org/eGFRcalc/GFR.pl.

5.5.   Data collection

All data were collected at approximate six-seven monthly intervals following baseline data collection. Baseline data were collected in March 2005, followed by subsequent collections in October 2005, March 2006, November 2006, June 2007 and January 2008.

On each occasion I telephoned the practice manager to arrange a suitable time for accessing these data. In three surgeries the practice manager was the main point of contact, but in another three surgeries there was an identified information services manager who organised the appointment. It was necessary for me to have access to the EMIS LV system, so in all cases a username and password were set up for the duration of the study.

For two sets of data collection there was research money available to pay for a research assistant to help with data collection. An internal advertisement was distributed to the nursing staff of the local Renal Unit, and one ward nurse contacted me and asked if she could help. Her motivation was to 'do something a bit different' as her family were now grown-up, and it seemed she had a real interest in prevention of chronic kidney disease. After an

informal interview, arrangements were made regarding days to be worked and mechanisms for payment.

After contacting the Research and Development Department at the NHS Trust, clearance was given for the assistant to retrieve research data from the surgeries, and research practices were also asked if they were happy with the arrangement. Training was given to the assistant on a one-to-one basis. Training was initially given in the hospital, when the purpose and layout of the spreadsheets was explained. At a later date, experiential training was carried out in three surgeries, with the assistant eventually becoming confident and competent in retrieving data on her own. The assistant then retrieved half of the required data (three surgeries) during the data collection periods. This arrangement continued for one year before research funds were used up. The contribution from this very experienced renal nurse was invaluable, not only in terms of time but also it was someone who I could bounce ideas off regarding the best ways in which to deliver the education programme.

5.5.1.   Management of quantitative data

Patients who were included in the study had anonymised data collected at six time points. There was no collection of patient identifiers such as date of birth or postcode, and participants' data were identified by the practice patient number only. Data were transferred from the practice computer screen onto a paper version of the Excel spreadsheet and later transferred onto an electronic version of the spreadsheet. See Appendix 9 for Excel spreadsheet. Finally the data were transferred to SPSS for Windows v12 for descriptive analysis. Each set of data collected took a visit of between two-three hours per practice, so each six-monthly data collection took around four full days including travel time. Transfer of manually collected data from the paper version to the electronic version of the spreadsheet took approximately 40 hours in total.

Once on the electronic version of the spreadsheet, data were cleaned for errors before being transferred to SPSS. Once in SPSS the data were cleaned again by checking categorical and continuous errors, such as examining maximum and minimum values, and mean scores.

5.6.   Evaluation of education package

The aim was to distribute the education package to patients in the six participating GP surgeries and compare clinical outcomes of people who had received the pack with the

control group. It was also important to evaluate the pack itself (content, ease of understanding, usefulness) and this was evaluated in two ways:

1. Ongoing feedback: Each pack contained a feedback form that gave my contact number and address. I requested that if anyone had questions or comments they were to contact me directly.

2. Post-study feedback: Through a short questionnaire sent by post to 15 people who had received the pack.

The findings of the evaluation are discussed in Chapter 8.

5.7.   Chapter summary

This chapter has described the way in which the self-management pack was tested and evaluated. A rationale for the time series design was given and a rationale for the required change in study design to include a control group was presented. Data were collected at six time points and data on risk factors associated with progression of CKD (microalbuminuria, blood pressure, eGFR, HbA1c, body mass index, exercise and smoking patterns) were collected.

6. RESEARCH REPORT: RESULTS

6.1. Introduction

The results chapter will explore the quantitative data collected from the six participating practices and the control practice, and will draw conclusions about how far the educational package has enabled control of the parameters that can delay progression of kidney disease.

Demographic statistics (age, gender, ethnicity) on all participants from all practices will be described. Clinical characteristics such as mean blood pressure, glycated haemoglobin (HbA1c) and Body Mass Index (BMI), will be compared across all practices at the start and end of the study. Other parameters such as smoking status and exercise levels will also be analysed.

Section 6.2 will compare the data from two groups:

- Group 1 – patients from participating practices who did receive the self-management pack (the intervention group)
- Group 2 – patients in the control group

There was a third group, which included patients from participating practices who did not receive the self-management pack. This group warrants analysis and will be discussed in section 7.2.4. A discussion about the powering of the study will be included in this chapter, alongside data that describes the reasons for non-distribution of the education pack. All the results are presented as mean and (SD) as all data are normally distributed.

6.2. Data from participating and control practices

6.2.1. Identification of the participants

In March 2005, across six practices in one London PCT with a combined list size of 61 800, there were 1946 people (3.14%) with diabetes. Of these, 370 people (19%) were identified as having microalbuminuria, and were therefore included in the study. In early 2005 the screening rate for MA across the six practices was 71%. Later in the year, possibly because of QOF incentives, average screening rates for microalbuminuria had risen to 86% across the six practices. An additional search for people who reached the inclusion criteria was then

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repeated, and subsequently 450 people (23%) were identified as having microalbuminuria. Following checks for possible errors and data cleansing, 436 people in the participating surgeries were included in the study and 61 people in the control group, making a total of 497 patients. See Figure 6.1.

Baseline data in the six participating practices were collected in March 2005, followed by subsequent data collections in October 2005, March 2006, November 2006, June 2007 and January 2008, that is, six time periods. Data collection in the control practice took place in December 2007, at the end of the data collection period. The control practice data were collected retrospectively for the time period stated above, from December 2007 retrospectively to late 2004. Data collection was carried out using Morbidity Information QUery and Export SynTax (MIQUEST) software.

The results for the participating practices were inputted into Microsoft™Office Excel 2003, and from there were imported into the Statistical Package for the Social Sciences (SPSS) for Windows® version 16. The results shown below have been analysed using both Excel and SPSS programmes. The participating practices are named as Surgery 1-6. The control practice is named Surgery 7.

6.2.2. <u>Demographic data</u>

6.2.2.1. <u>Age</u>

The mean age and age range of participants in each practice are shown in Figure 6.1. The age is the age of the participant in March 2005, the first data collection period.

Figure 6.1: Mean age and age range of participants in March 2005

Age of participants (years)				
Surgery	N	Mean	Std. Deviation	Age Range (years)
1	83	68.43	12.994	33-88
2	65	67.46	13.337	32-90
3	82	66.72	13.187	34-100
4	77	68.74	13.752	32-91
5	56	64.70	15.633	22-90
6	73	70.92	13.022	43-95
7	61	61.34	11.162	38-87
Total	497	67.14	13.515	22-78

Figure 6.2 shows the ages of participants in each surgery divided into 20 year bands (20-39 years; 40-59 years; 60-79 years; over 80 years). This figure shows that the control surgery with a lower mean age of 61.34 years has a younger population with more participants in the age range 40-60 years, but fewer participants in the 60-80 year and 80-100 year range. The reasons for this are unclear but possibly it is because this practice is located within the main town centre (population size 180 000) within the PCT, and may be more convenient for families with children (schools, other amenities for children/teenagers) and also for commuting into London. The train station into London is within ½ mile of the surgery with a commuting time of approximately 40 minutes. The other surgeries in the study, although within the same PCT, are not within the same town centre.

Figure 6.2: Ages of participants in each surgery divided into 20 year bands
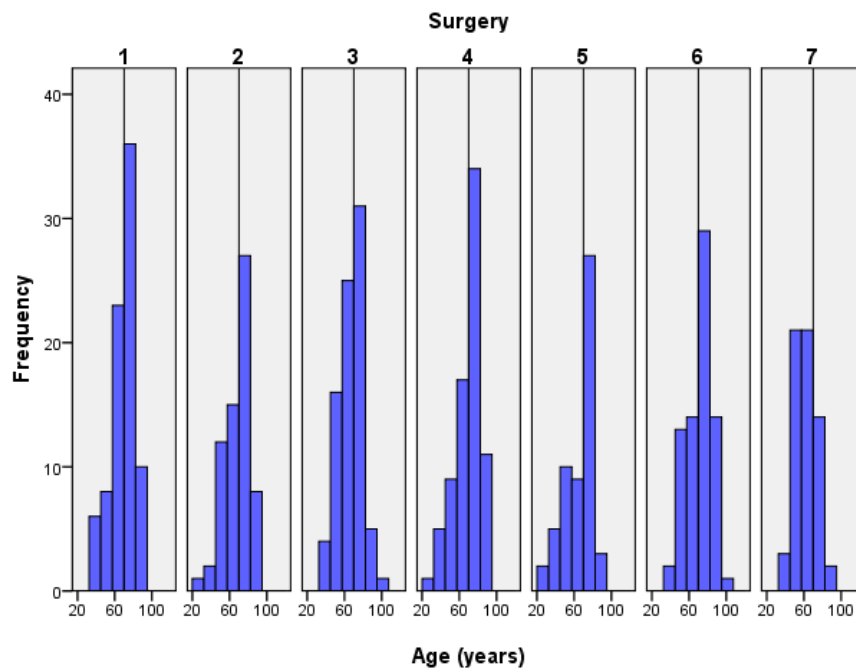
Another possibility is that this control surgery has a higher ethnicity compared with other practices, with >30% of the subjects in the control surgery recorded as being of Asian descent. See Figure 6.5 below. Being of South Asian descent is a risk factor for not only developing diabetes, but also developing diabetic nephropathy (Davis 2008), so it is possible that the control group with higher ethnicity has developed microalbuminuria at a younger age than white participants. These suggestions must be considered with caution though, as ethnicity recording was variable across practices.

6.2.2.2.   Gender

The gender of the participants in the practices is shown in Figure 6.3.

Figure 6.3: Gender of participants

Gender							
Surgery	Male		Female		Total		
1	46	55.4%	37	44.6%	83	100%	
2	33	50.8%	32	49.2%	65	100%	
3	59	71.9%	23	28.1%	82	100%	
4	47	61.0%	30	39.0%	77	100%	
5	28	50.0%	28	50.0%	56	100%	
6	38	52.1%	35	47.9%	73	100%	
7	43	70.5%	18	29.5%	61	100%	
Total	294	59.3%	202	40.7%	496	100%	

Participants in this study (having diabetes and microalbuminuria) are more likely to be men, with all surgeries having the same or greater percentage of men than women. However as CKD is increasingly prevalent with increased age, the female gender is predominant in older age groups with CKD. Some suggest that this is largely a function of ageing and an epiphenomenon of the use of the Modification of Diet in Renal Disease (MDRD) equation to estimate GFR (Levey et al. 2006), whereas others maintain that this is a true effect (NICE, 2008).

Results from this study appear to suggest that for this cohort of people with diabetes and early kidney damage, there is also a skewed distribution of women in the older age groups, over 70 years. See Figure 6.4. Further discussion of age and effect on kidney damage and cardio-vascular risk will continue in section 7.2.

<u>Figure 6.4: Gender and age of participants</u>
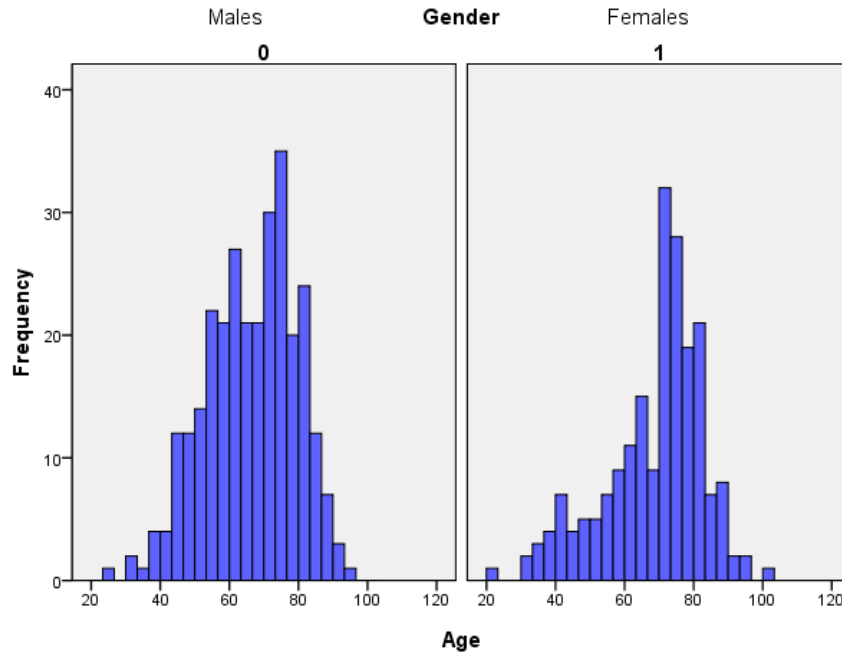
6.2.2.3.   <u>Ethnicity</u>

Ethnicity recording in general practice is known to be variable, although improvements have been made (Bramley and Latimer 2007). The following figures for ethnicity and diabetes diagnosis recording show a column for missing data (numbers and percentage). There was quite a high percentage of missing ethnicity data in this study, especially in surgery 2 (57% missing).

In these cases the missing data has arisen because there were no data available on these participants at any time during the study. I did repeat the search for ethnicity data at the penultimate collection period (November 2006) and some additional ethnicity data were found at this time. Figure 6.5 shows the ethnicity of participants by practice.

Figure 6.5: Ethnicity of participants recorded in November 2006

Ethnicity									
Surgery	White		African-Caribbean		Asian		Mixed race		Collected data	% missing
1	35	74.5%	1	2.1%	10	21.3%	1	2.1%	47/83	43.3%
2	23	82.0%	2	7.1%	3	10.7%	0	0%	28/65	56.9%
3	38	82.6%	1	2.2%	7	15.2%	0	0%	46/82	43.9%
4	55	88.7%	0	0%	6	9.7%	1	1.6%	62/77	19.5%
5	23	67.6%	1	2.9%	9	26.5%	1	2.9%	34/56	39.3%
6	32	80.0%	1	2.5%	7	17.5%	0	0%	40/73	45.2%
7	36	60.0%	2	3.3%	20	33.3%	2	3.3%	60/61	1.6%
Total	242	76.3%	8	2.5%	62	19.5%	5	1.6%	317/497	36.2%

Ethnicity data for this PCT from the 2001 census showed 90% white; 2.5% black; 4.7% Asian and 2% mixed race (Office for National Statistics, 2001). The ethnicity of participants in all the practices (even with significant under-recording) shows a very different ethnicity spread from the census returns of 2001, indicating a possible significant change in the composition of the population since 2001. These increased percentages of ethnic groups could also have had an effect of diabetes prevalence in this PCT, especially in those of south Asian origin (Davis 2008).

Since the final collection of ethnicity data in November 2007, ethnicity data collected in 2008 for the participating practices and the whole PCT were published in June 2009 by the London Health Observatory (LHO)(London Health Observatory 2009). The LHO provides information for policy makers and practitioners to enable them to improve health and health care. The LHO works in partnership with the NHS, local authorities, the Greater London Authority, researchers and national agencies. Recently published data contain the breakdown of individual practice list populations, which includes geographical spread, age, gender and ethnicity.

Figure 6.6 shows the ethnicity of the practice populations in the participating and control practices, adapted from 2008 LHO data

Practice	White	African-Caribbean	Asian	Mixed race
1	82.0%	3.4%	7.3%	3.1%
2	83.8%	4.5%	4.1%	3.1%
3	79.3%	2.4%	10.3%	3.5%
4	84.2%	3.0%	6.2%	2.8%
5	83.6%	3.9%	6.6%	2.7%
6	83.0%	4.0%	7.2%	2.7%
7	80.0%	3.6%	6.1%	3.1%

This shows a different picture from the data collected from the surgeries by me, with much less high rates of Asian ethnicity in all surgeries. This is possibly because surgeries were identifying people of Asian ethnicity by name alone (there is specific software available to do this) thus leading to a skewed distribution of people from Asian descent. There may also have been other reasons for the discrepancy but these were difficult to identify after the data collection period had passed. In general terms there is a lower ethnic diversity in this PCT compared with London PCTs overall where in 2001 71% were white; 12.0% were Asian and 10.9% were African Caribbean (Office for National Statistics 2001).

6.2.3. Diabetes

Figure 6.7 shows the participants' diagnoses (type of diabetes).

Figure 6.7: Diabetes type of participants

Diabetes					
Surgery	Type 1		Type 2		Collected data	% missing
1	6	7.2%	77	92.8%	83/83	0%
2	0	0%	10	100%	10/65	76.9%
3	1	1.2%	81	98.8%	82/82	0%
4	13	16.9%	64	83.1%	77/77	0%
5	2	3.6%	54	96.4%	56/56	0%
6	4	5.5%	69	94.5%	73/73	0%
7	2	3.7%	52	96.3%	54/61	11.5%
Total	28	6.4%	407	93.6%	435/497	12.5%

The World Health Organisation (WHO) classifies diabetes into Type 1, Type 2 and other types of diabetes (Alberti and Zimmet 1998). The general Read Code for diabetes is C10, whilst the codes for Type 1 and Type 2 are C10E and C10F respectively. In this study, diabetes diagnosis data were missing on 62 participants, mostly in Surgery 2 where data were missing on 77% of patients. Although these patients were coded with the Diabetes Read code C10, there was no distinction made between Type 1 and Type 2 diabetes. In other surgeries the codes for Type 1 diabetes (C10E) and Type 2 diabetes (C10F) had been used to differentiate between the two types. It is possible that surgery 4 had miscoded some of the patients as having Type 1 diabetes instead of Type 2, because of the high percentage of people with Type 1 diabetes (16.8%).

It is difficult to compare these data with the general population as recent national data have been collected by the diagnosis of diabetes that are accounted for by diet controlled, oral hypoglycaemic-treated and insulin treated diabetes, rather than type of diabetes (Majeed and Moser 2005). It is likely that in the general population, prevalence of Type 1 diabetes compared with Type 2 is around 5-10% of those with diabetes (The Information Centre National Clinical Audit Support Programme 2006). For the purposes of this study however, it is not essential to have the definite types, as there is no evidence that type of diabetes is a risk factor for microalbuminuria (Young et al. 2005). The diabetes codes were collected at the start of the study and were not re-visited or checked at a later date.

6.2.4. Clinical characteristics

Clinical characteristics (mean and SD) at start and end of the study are shown in Figures 6.9-6.13. Clinical measurements of mean systolic and diastolic blood pressure, HbA1c, body mass index have been compared across practices. There is also a commentary on smoking status in this section.

The results table for each clinical characteristic has a column which shows the number of collected data items in each practice over the total number of participants in the practice. An adjacent column shows the % of missing data. In these tables the high % of missing data should not be attributed to data not being measured or inputted. In these cases it is due to the number of patients who had not joined the study in March 2005 or the number who had either moved away, had died or who had commenced dialysis at the end.

In total 497 people were included in the study. The numbers in each practice at the last data collection period in January 2008 are shown in Figure 6.8. Each practice had a number of participants who were not included in the study for the entire time period. The reasons for non-inclusion are shown.

Figure 6.8: Status of participants in each surgery at January 2008

Status at end of study										
Surgery	In study		Moved away		Died		On dialysis		Total	
1	71	85%	6	7.2%	6	7.2%	0	0%	83	100%
2	48	74%	10	15.4%	6	9.2%	1	1.5%	65	100%
3	67	82%	6	7.3%	9	11.0%	0	0%	82	100%
4	60	78%	10	13.0%	7	9.1%	0	0%	77	100%
5	47	84%	4	7.1%	4	7.1%	1	1.8%	56	100%
6	48	66%	6	8.2%	17	23.3%	2	2.7%	73	100%
7	61	100%*	0*	0%	0*	0%	0*	0%	61	100%
Total	400	80.5%	42	8.5%	49	9.9%	4	0.8%	497	100%

*There were no people moving away or deaths in the control group as these data were collected retrospectively at the last data collection period

6.2.4.1.   Blood pressure

Figures 6.9 and 6.10 show the mean systolic and diastolic blood pressures at the start and end of the study. These results have to be considered against changes to policy during the study. At the start and end of the study the blood pressure target for people with Type 1 diabetes and microalbuminuria was 130/80 mmHg (National Institute for Health and Clinical Excellence 2004). For Type 2 diabetes the target at the start of the study was 135/75 mmHg (National Institute for Health and Clinical Excellence 2002) although NICE guidance had been amended by the end of the study (National Institute for Health and Clinical Excellence 2008a) to a target of 130/80mmHg for people with Type 1 and Type 2 diabetes.

Figure 6.9: Mean systolic blood pressure (mm Hg) at March 2005 and January 2008

Surgery	Mean BP systolic start	SD	Collected data start	Mean BP systolic end	SD	Collected data end
1	144.72	16.687	64/83	137.30	16.532	71/83
2	138.92	14.862	49/65	131.58	18.729	48/65
3	137.89	20.270	55/82	134.49	15.863	67/82
4	137.54	15.712	63/77	131.75	8.453	60/77
5	138.15	21.283	40/56	134.72	20.276	47/56
6	145.40	17.302	67/73	134.10	16.598	48/73
7	134.41	14.372	61/61	136.15	16.392	61/61
Total	139.81	17.476	399/497	134.46	16.260	402/497

Figure 6.10: Mean diastolic blood pressure (mmHg) at March 2005 and January 2008

Surgery	Mean BP diastolic start	SD	Collected data start	Mean BP diastolic end	SD	Collected data end
1	78.12	9.361	64/83	74.79	11.254	71/83
2	76.67	9.342	49/65	78.50	9.794	48/65
3	75.85	8.623	55/82	74.24	7.758	67/82
4	76.95	10.825	63/77	75.10	8.435	60/77
5	76.82	13.015	40/56	73.02	12.458	47/56
6	78.64	9.728	67/73	75.92	10.204	48/73
7	78.08	10.688	61/61	77.57	9.065	61/61
Total	77.4	10.155	399/497	75.54	9.944	402/497

6.2.4.2. Glycated haemoglobin (HbA1c)

It is recommended that people with Type 1 diabetes should have HbA1c tested every 2-6 months (NICE, 2004) and those with Type 2 diabetes should be tested at least every six months (NICE, 2008). Targets for people with Type 1 diabetes are HbA1c < 7.5 %, with a target of <6.5 % for people with high arterial risk (microalbuminuria and BP >130/80 mmHg). For people with Type 2 diabetes, the HbA1c should be in a range of 6.5-7.5%. Figure 6.11 shows the mean HbA1c of the participants at the start and end of the study.

Figure 6.11: Mean HbA1c (%) at March 2005 and January 2008

Surgery	Mean HbA1c start	SD	Collected data start	Mean HbA1c end	SD	Collected data end
1	8.190	1.7559	62/83	7.720	1.3745	71/83
2	8.006	2.1697	49/65	7.304	1.5121	48/65
3	7.626	1.5364	53/82	7.640	1.9982	67/82
4	7.755	1.6602	60/77	7.227	1.5975	60/77
5	7.081	1.2202	37/56	6.932	1.7980	47/56
6	7.343	1.6448	61/73	7.763	1.8046	46/73
7	8.120	1.8377	61/61	7.990	1.7430	59/61
Total	7.767	1.7493	383/497	7.534	1.7155	398/497

6.2.4.3.   Body Mass Index (BMI)

Although there have been concerns raised about the accuracy of BMI in diagnosing obesity, particularly for individuals in the intermediate BMI ranges, in men and in the elderly (Romero-Corral et al. 2008), the BMI is the measure used by the GP practices in the study to evaluate degrees of weight loss over time.

NICE (2006) recommends using BMI to classify degrees of obesity (see Figure 6.12) but also recommends that practitioners use clinical judgement. For example BMI may be less accurate in highly muscular people, risk factors may be of concern at lower BMI in Asian people and for older people risk factors may become important at higher BMIs.

Figure 6.12: Classification of people who are overweight or obese

Classification BMI (kg/m2)	BMI (kg/m^2)
Healthy weight	18.5-24.9
Overweight	25-29.9
Obesity I	30-34.9
Obesity II	35-39.9
Obesity III	≥40

Adapted from (National Institute for Health and Clinical Excellence 2006b)

Figure 6.13 shows the mean BMI of people in the participating surgeries at the beginning and end of the study. Although weight loss is one of the main priorities for people with Type 2

diabetes, these results show that weight loss strategies are difficult to maintain. The overall gain in mean BMI was 0.34 kg/m^2, with people in only 3 out of 7 practices managing to achieve a reduced mean BMI by the end of the study. This compares with an Oxford study (Rosell et al. 2006) that found the mean annual weight gain in a health-conscious cohort of more than 20000 people in the UK was approximately 400 g. This equates to a BMI increase of 0.5 kg/m^2 over three years in a 60 Kg woman of average height, demonstrating that weight gain over time is inevitable for many, not just those with diabetes.

Figure 6.13: Mean BMI of participants at March 2005 and January 2008

Surgery	Mean BMI start	SD	Collected data start	Mean BMI end	SD	Collected data end
1	30.38	6.332	60/83	29.17	6.761	71/83
2	29.54	6.109	48/65	29.56	6.494	48/65
3	27.62	5.241	54/82	29.44	5.571	67/82
4	28.57	5.883	62/77	28.06	5.547	60/77
5	31.36	6.394	40/56	30.88	7.826	47/56
6	28.48	5.436	65/73	30.41	5.185	48/73
7	27.90	4.974	12/61	29.53	4.877	61/61
Total	29.16	5.924	341/497	29.50	6.079	402/497

6.2.4.4.   Smoking status

There were differences across surgeries in the way in which smoking data were recorded. Some surgeries recorded whether the patients smoked, and if so, whether they received smoking cessation advice. Other practices recorded whether the patient smoked, and how many cigarettes/ounces of tobacco were smoked per day and did not necessarily record whether advice about cessation had been given.

Smoking status was recorded by either searching for free text in the diabetes screen, or by Read Code. Codes used with most frequency were 137R (current smoker); 137S (ex-smoker); 1373 (light smoker 1-9 cigarettes/day); 1374 (moderate smoker 10-19 cigarettes/day) and 1375 (heavy smoker 20-39 cigarettes/day). The code 137G was used for someone who keeps trying to stop smoking, and 8CAL for smoking cessation advice given.

For the purposes of this study, Read coded smoking status and free text entries were amalgamated for each participant, and coded as follows in Figure 6.14.

Figure 6.14: Codes used for smoking status

Code	0	1	2	3
Smoking status at start	Does not smoke at start of study	Smokes at start of study	Smokes at start of study	Smokes at start of study
Smoking amount at start	-	Light smoker (0-5/day)	Moderate smoker (5-19/day)	Heavy smoker (≥20/day)
Smoking status at end	Does not smoke at end of study	Smokes at end of study		
Smoking amount at end	-	Light smoker (0-5/day)	Moderate smoker (5-19/day)	Heavy smoker (≥20/day)

Figure 6.15 shows the number of participants in each practice who were smoking in March 2005.

Figure 6.15: Smoking status at March 2005

Smoking status at start of study					
Surgery	Non-smokers		Smokers		Collected data	% missing
1	57	79.2%	15	20.8%	72/83	13.3%
2	33	68.8%	15	31.2%%	48/65	20.8%
3	46	85.2%	8	14.8%	54/82	34.1%
4	41	87.2%	6	12.8%	47/77	38.9%
5	39	83.0%	8	17.0%	47/56	16.1%
6	51	85.0%	9	15.0%	60/73	17.8%
7	50	82.0%	11	18.0%	61/61	0%
Total	317	81.5%	72	18.5%	389/497	21.7%

Overall the percentage of people who were smoking at the start of the study is 18.5% of those for whom there was a record of smoking status. Considering that smoking can considerably worsen kidney disease and cardio-vascular risk in diabetes, these figures are of concern, although better than the latest figures for 2005, that showed that around a quarter

(24%) of the British population aged 16 and over smoke cigarettes (Goddard, 2006).

Figure 6.16 shows the number of people who smoke light to heavy amounts (≥20 cigarettes per day) at the start of the study. The number who smoke more then 20 cigarettes/day is cause for concern (n=33), but is mostly confined to surgery 2. Surgery 2 is considered to be in an area of social deprivation compared with the other practices, and data suggests that 29% of adults in manual occupations smoked compared with 19% of those in non-manual occupations (Goddard, 2006). Further analysis of these data with respect to social deprivation can be found in Chapter 7.

Figure 6.16: Smoking amount at March 2005

Smoking amount at start of study				
Surgery	Number of smokers	Light	Moderate	Heavy	Collected data
1	15	1	7	7	72/83
2	15	1	1	13	48/65
3	8	4	2	2	54/82
4	6	1	2	3	47/77
5	8	3	1	4	47/56
6	9	2	5	2	60/73
7	11	2	7	2	54/61
Total	72	14	25	33	382/497

Figure 6.17 shows the smoking amount at the end of the study. At the end of the study, the numbers of people who still smoked were less, and in surgery 2 there was a reduction in the number of people who were heavy smokers.

Figure 6.17: Smoking amount at January 2008

Smoking amount at January 2008					
Surgery	Number of smokers	Light	Moderate	Heavy	Collected data
1	9	3	5	1	62/83
2	11	3	4	4	32/65
3	7	4	2	1	43/82
4	6	2	3	1	58/77
5	8	4	2	2	46/56
6	7	3	4	0	48/73
7	10	2	5	3	56/61
Total	58	21	25	12	345

In the three years from the start to the end of the study, there was a decrease in the number of people who smoked. The total number of smokers had decreased by 14 (almost 20% of those who had smoked at the start), and the majority of heavy smokers in surgery 2 had reduced their smoking amount to becoming moderate smokers.

This reduction in smoking amount may reflect the publication of 'Smoking Kills' (Department of Health 1998) that has seen increased spending on mass media anti-smoking campaigns, a ban on tobacco advertising and promotion, more prominent health warnings and wider access to stop smoking services (National Institute for Health and Clinical Excellence 2006a). In addition in 2004, a public health white paper (Department of Health 2004) confirmed that all NHS premises and government departments would be smoke-free from the end of 2006 and a ban on smoking in enclosed public spaces in England by summer 2007.

The reduction in smoking amount may also reflect the Department of Health targets for smoking cessation introduced in 2004, that aimed to achieve a reduction in smoking rates from 26% in 2002 to 21% of the general population by 2010 (Department of Health 2004). These targets resulted in the introduction of primary care support services for people who wished to give up smoking, such as the NHS Stop Smoking services with £112 million over two years (2006-2008) allocated to PCTs.

6.2.4.5.   Exercise level

At the start of the study data on exercise levels were collected from the six participating surgeries. Unfortunately this had to be abandoned early on during the study because of poor data recording. The majority of surgeries were simply recording whether advice on exercise had been given, and in a minority of cases how much (self-reported) exercise had been undertaken. Because it was unlikely that any firm conclusions could be drawn from these scant data it was decided at time period three to stop collecting these qualitative measures.

6.2.4.6.   Progression of CKD

It is also important to consider the progression of kidney disease during the study, although it was never hypothesised that the self-management pack could directly affect kidney disease progression because of the relative short-time period of the study. Kidney damage can be quantified by amount of albuminuria (ACR) and also by measurement of estimated glomerular filtration rate (eGFR). eGFR can be equated to the stages of CKD (see Glossary for an explanation). Both parameters were measured at each of the six time points. Figure 6.18 shows the percentage of people with stages 1-5 CKD in the six participating surgeries over the period of the study.

Figure 6.18: % participants with different stages of CKD

Stage of CKD	Mar 2005	Oct 2005	Mar 2006	Nov 2006	June 2007	Jan 2008
1	2.6	1.6	1.4	5.0	5.2	5.2
2	38.6	33.2	35.2	36.2	40.0	36.8
3a	24.1	25.2	21.7	18.7	24.5	23.5
3b	11.3	12.9	12.3	10.1	11.1	11.1
4	2.8	3.2	3.4	2.2	3.2	4.0
5	0.4	0.4	0.2	0.2	0.6	0.2

It is difficult to interpret these data very easily as over the period of the study a large proportion of people (84/436) moved away, died or commenced dialysis. See Figure 6.8. What can be said for this cohort is that there were not large numbers of people reaching stage 4 CKD, or requiring dialysis/transplantation. In the course of the study only four people required dialysis. It must also be reiterated that people in the participating practices with microalbuminuria at the start of the study were excluded if they had already been referred to the renal unit. This meant that those at risk of progressive disease, who may have already

reached stage 3b or stage 4, were not included at the start. It is possible that if this high-risk group had been included then a greater proportion of people may now be requiring renal replacement therapy, although it is known that people with CKD stages 3b-4 are also at higher cardio-vascular risk and as a consequence have high mortality rates (Bilous 2008).

It is known that proteinuria is a risk factor for cardio-vascular morbidity and mortality (Wali et al. 2005). An interesting discussion might be whether those participants with proteinuria (ACR≥70), compared with those who had microalbuminuria, did have faster deteriorating kidney function and/or experienced earlier mortality. This will be discussed further in Chapter 7.

6.3. Distribution of packs

Before an analysis of how far the self-management package was able to influence blood pressure, blood sugar control, weight management and smoking status can be carried out, the powering the study will be discussed.

6.3.1. Powering of study

In Chapter 5, a description was given of how the study was powered. The study was powered on an outcome measure of blood pressure. It was calculated on the numbers of participants who had reached a target blood pressure of 135/75 mmHg (National Institute for Health and Clinical Excellence 2002) at baseline compared with the numbers who might be expected to achieve this target at the end of the study.

In order for the study to have 90% power with 5% significance, it was necessary to distribute the self-management packs to 42 patients in each surgery, that is, 252 packs in all.

6.3.2. Numbers not possible or suitable for self-management pack

Ultimately it was not possible to distribute this number of packs, with only 116 packs being distributed across the 6 intervention surgeries. There were two main reasons why participants were not offered the pack: non-possibility and non-suitability. Figure 6.19 shows the reasons why it was either not possible or not suitable for participants to be offered the self-management pack.

Figure 6.19: Reasons why participants could not receive the pack

Not possible	Not suitable
Moved away	Referred to renal unit (with progressive CKD)
Died	No protein in urine and eGFR ≥60
	In residential care
	Learning difficulties
	Malignancy and receiving active/non-active treatment/unwell

It was either not possible to give people packs (people who died or moved away), or it was not appropriate to do so. It was not appropriate to give packs to people who had no protein in their urine and who also had an eGFR ≥60 at the time of distribution as this group could not defined as being at risk of CKD. This was a surprisingly large group with 92/436 (21.1%) in this category.

Those who had been referred and were nearing renal replacement were not suitable either. There were also a large group of patients for whom educational intervention was considered not appropriate in discussion with practice staff – either if very elderly and/or in residential care or if suffering learning difficulties. A small number of people had other long-term conditions, such as cancer, and in these cases the practice nurses advised against pack distribution.

A summary of the numbers of people possible and suitable to receive the pack is shown in Figure 6.20. In each practice there were a high percentage (mean 60%) to whom the pack could not be distributed.

Figure 6.20: Participant possibility and suitability for the self-management pack

SURGERY	Total number of possible participants	Number not possible	Number not suitable	Total not possible/suitable	Total available to participate
1	83	15	36	51	32
2	65	14	33	47	18
3	82	13	28	41	41
4	77	13	38	51	26
5	56	8	24	32	34
6	73	21	20	41	32
Total	436	84	179	263	173

Figure 6.21 shows the reasons for non-distribution of packs in more detail, and further analysis of the issues involved will be discussed in section 7.2.

Percentage of patients in each surgery not suitable or possible for education pack
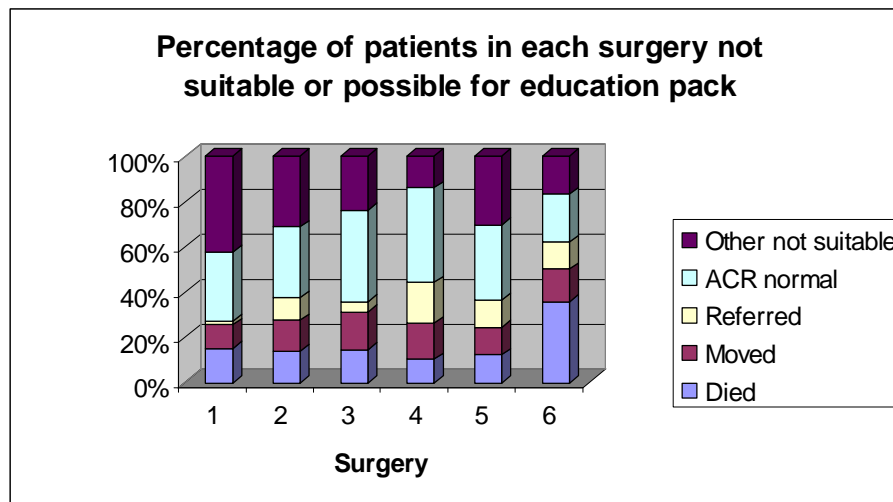
Once the number of patients for whom the pack was either not suitable or possible was taken into account (Figure 6.20), there were only 173 people to whom the pack could have been given, that is, pack distribution was achieved in 67% (116/173) possible patients.

Of those who were suitable to receive packs, there was still difficulty in achieving full distribution. Despite excellent support from the participating practices, it proved challenging to reach all suitable patients. 134 patients in total were contacted, and of these 18 people refused to participate. Reasons for non-participation included being 'not interested', 'too old for that sort of thing' and literacy problems (including native English speakers). It proved difficult to contact younger people who were employed especially if the participant was well and was not due at an imminent annual review appointment. If a participant was not due at a clinic within the timeframe for distribution of packs, then they were contacted by me on two occasions, once by mail and then followed up with a telephone call. If there was no response then I did not try again. Further analysis on the reasons for non-distribution of packs will be discussed in the next chapter. Figure 6.22 shows the percentage of people who received a pack of the total who were eligible.

Percentage of packs given/not given to those eligible (n=173)

- Pack given by 14.09.07
- Pack not given
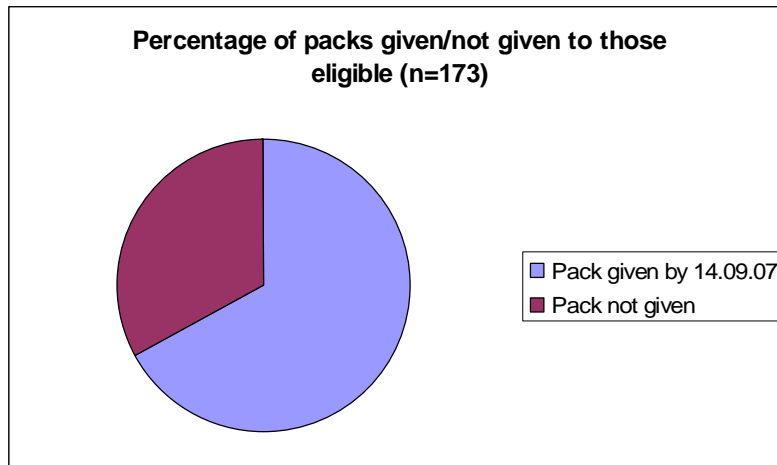
Pack distribution was achieved in 67% of those who were eligible.

6.4. Outcomes

6.4.1. Effects on study of national policy

It is important to consider the possible effects of national policy initiatives that occurred during the study time period. The main initiatives and policy changes during this time were the publication of the National Service Framework for Renal Services (Part 2) in January 2005; the publication of national guidance on CKD in December 2005, followed by local guidance in early 2006; the quality indicator for CKD in the QOF in April 2006 and the introduction of estimated GFR (eGFR) recording in this PCT in February 2006. Figure 6.23 shows the timelines for the six data collections alongside the publication of CKD policy initiatives. These policy changes are important because they may have affected clinical practice in the participating surgeries, which in turn may have had a direct effect on participants' blood pressure, HbA1c and BMI during this time period.

Figure 6.23: Data collections and CKD policy changes
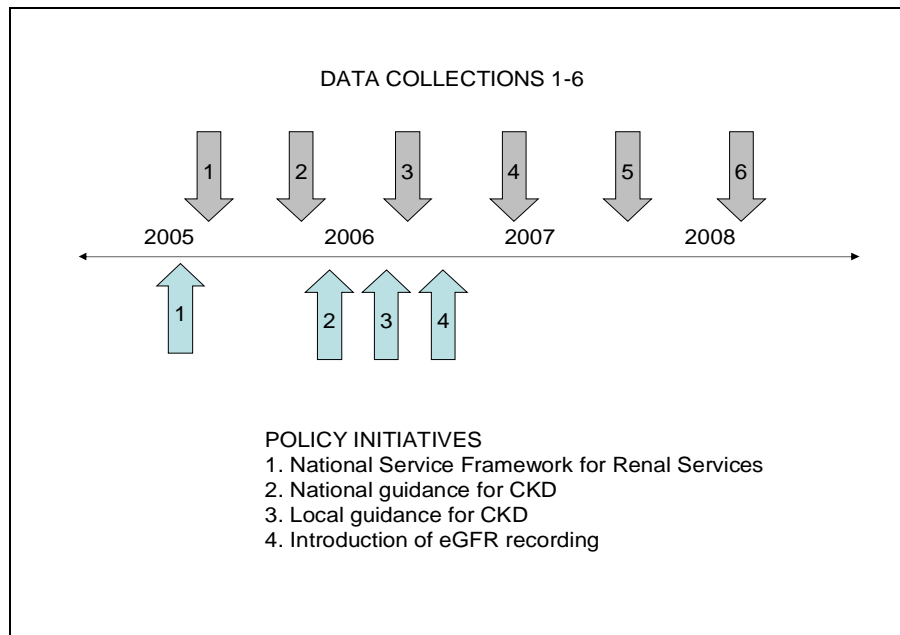
Data were analysed across two different groups. The analysis was carried out in SPSS using repeated measures analysis of variance. The groups were:

- Group 1 – patients from participating practices who did receive the self-management pack
- Group 2 – patients in the control group

Analyses were undertaken for the six time periods, and compared blood pressure (systolic and diastolic), glycated haemoglobin (HbA1c) and Body Mass Index (BMI) across the intervention and control groups. It is possible that, if self-management initiatives are to impact on specific outcome measures, then these outcome measures are the most likely to be influenced. For example, blood pressure control might be influenced by people understanding the need to take regular medication, reducing salt intake and/or self-monitoring blood pressure. Diet and exercise can influence HbA1c readings and body mass index.

6.4.1.1.   Systolic blood pressure

Systolic BP was compared across the two groups during the six data collection periods. Figure 6.24 shows the analysis.

Figure 6.24: Changes in mean systolic blood pressure over six time periods between intervention and control groups
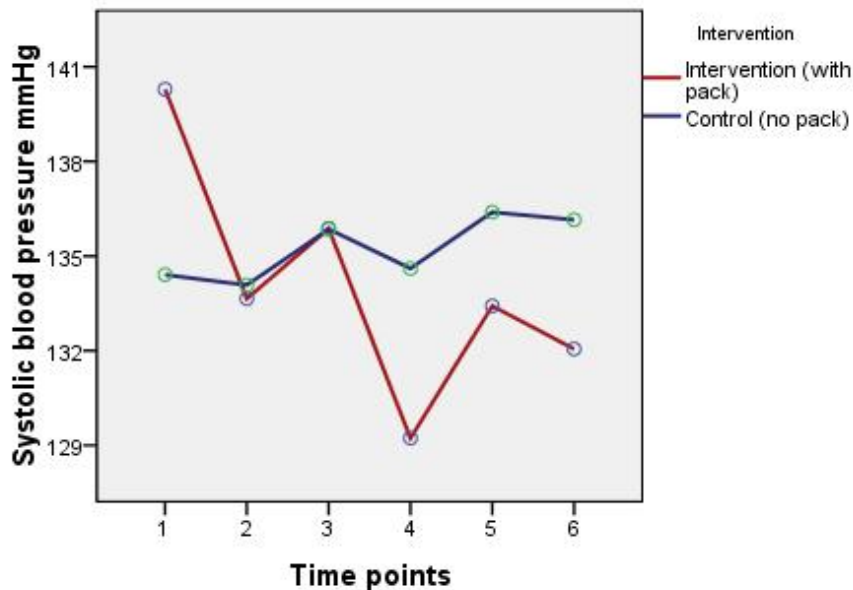
In the intervention group, systolic blood pressure was reduced after the first four data collection periods compared with the control group, but this fell just short of statistical significance. 140.3 ± 16.0 mmHg vs. 134.4 ± 14.4 mmHg in March 2005; to 129.2 ± 19.2 mmHg vs. 134.6 ± 15.0 mmHg in November 2006 (p=0.057 for systolic BP).

At the end of the study period in January 2008 the patients who had received the self-management package had a mean systolic BP of 132.1 ± 14.2 mmHg vs. 136.2 ± 16.4 mmHg in the control group (p=0.15). Although not statistically significant, the group who received the self-management pack had a mean blood pressure that is much nearer the NICE (2008) target of 130/80 mmHg. This may have important clinical implications in terms of cardio-vascular risk reduction.

It was interesting to note the 'rebound' in blood pressure in the 5th data collection period in June 2007, in the participating practices visited by the researcher. There may be a variety of reasons for this finding. Two main possibilities are:

1. Following the publication of policy guidance during 2006, practices had immediate interest in controlling blood pressure in this group, yet this interest began to wane during 2007.

2. That I stopped making appointments to visit the primary teams in the practices during the summer of 2007, after the final batch of packs had been distributed. Following September 2007 I only returned once to the practices for the final round of data collection in January 2008. It is possible that there was a positive effect on blood pressure control following the visits.

Further analysis of these findings will be discussed in the next chapter.

6.4.1.2. <u>Diastolic blood pressure</u>

Figure 6.25 shows the analysis for diastolic blood pressure. Here the diastolic blood pressure showed a decreasing trend in the group that received the pack, until a mean diastolic blood pressure of 74.9 ± 8.5 mmHg was reached at the end of the study. Interestingly diastolic blood pressure appeared to rise in the control group following time period 3 and 2 respectively, yet this did not happen in the group that received the pack.
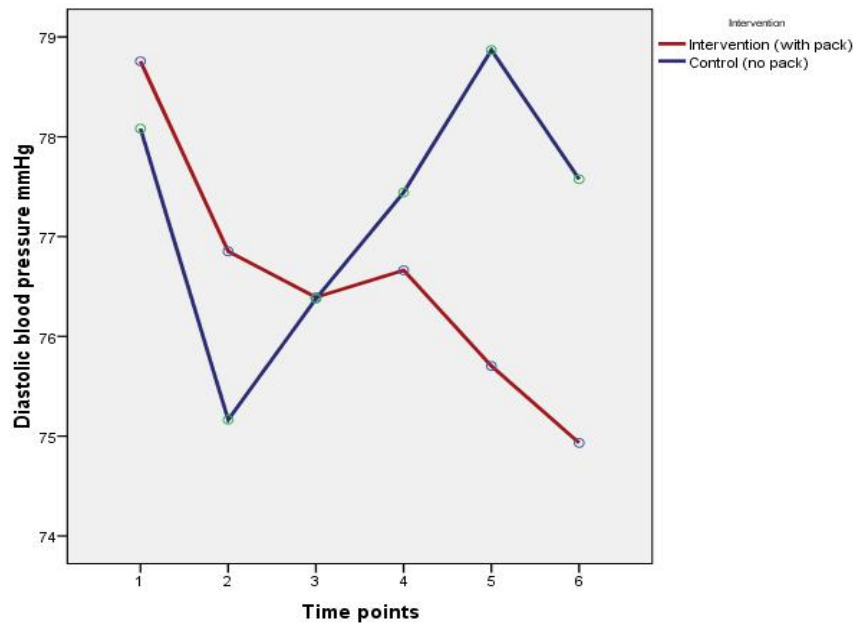
There was no significant difference in diastolic blood pressure between the participants in the control practice and the participants who received the pack, apart from marginal significance at time period 5 (p=0.053). However at the end of the study, mean diastolic blood pressure was 74.9 ± 8.5 mmHg in the intervention group. This compares with a mean diastolic blood pressure of 77.6 ± 9.1 mmHg in the control group. Although not statistically significant a difference of almost 3 mmHg in diastolic blood pressure may have implications for reduction in cardio-vascular risk. This assertion will be discussed in detail in Chapter 7.

6.4.1.3.   HbA1c

Figure 6.26 shows the differences in glycated haemoglobin between the two groups. In general terms, HbA1c dropped in the intervention group from time points 3-5, but then rose. The control group had a higher HbA1c throughout and experienced the same fall until time point 5. There was no significant difference between the intervention group (with pack) and the control group at any time point. The most significant time point was time point 4, when p=0.108.
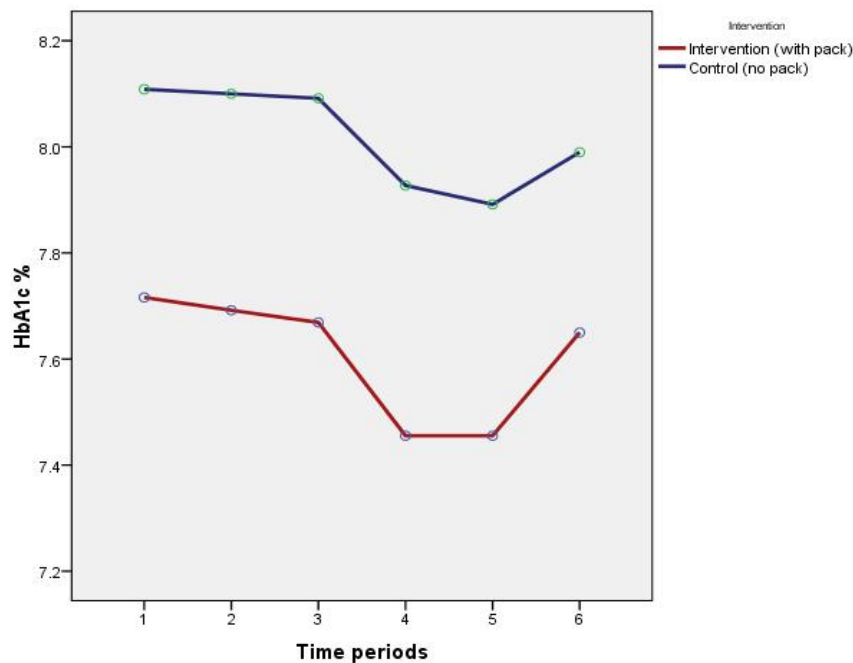
Although these data are difficult to interpret it can be said that mean HbA1c values in the control surgery were well above the recommended target of 6.5-7.5% (National Institute for Health and Clinical Excellence 2008b) at the start of the study. Although NICE (2008) recommends that people should be involved in decisions about their individual HbA1c target level, and this may lead to an agreed target well above that of 6.5% set for people with Type 2 diabetes in general, the mean value of 8.1% could contribute to an increased risk of clinical grade proteinuria and rising serum creatinine (Bilous 2008).

There was also a fall in HbA1c for both groups between time points 1-4, possibly as a result of QOF incentivisation, yet interestingly there was a rebound in HbA1c for both groups, after time point 5.

6.4.1.4. Body Mass Index

Figure 6.27 shows the differences in Body Mass Index between the intervention and control groups.
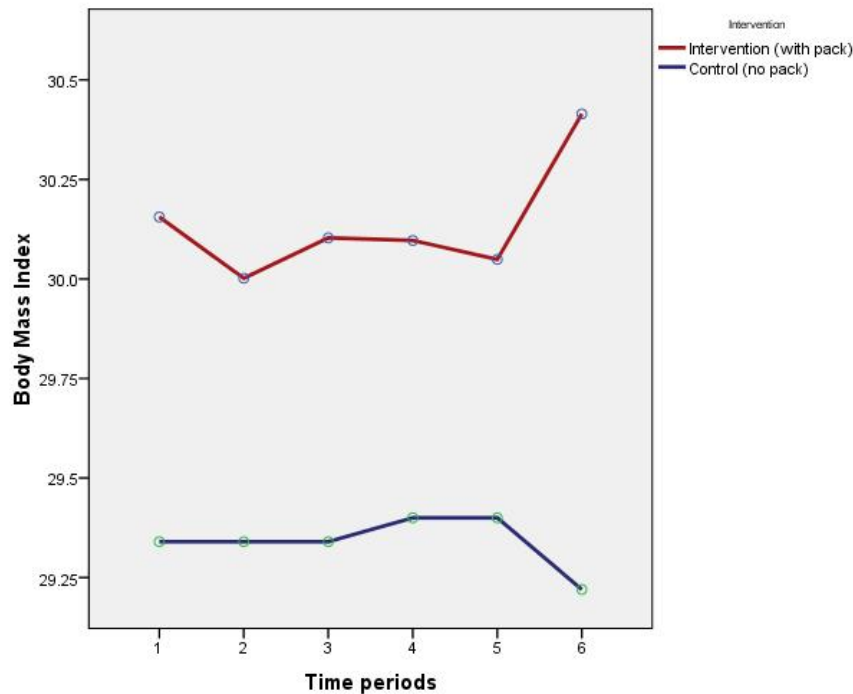
Overall the findings show that the group who received the self-management pack started and ended the study with a higher BMI than those who did not receive the pack or those in the control group. It is difficult to draw any firm conclusions from these findings, especially because a large amount of data (80.3%) for the control group at time period one is missing (49/61 records missing). This is because the BMI data that were collected with MIQUEST software only collected the latest 5 readings for BMI. This is an error on my part, as when I compiled the dataset I assumed that the latest 5 BMI readings would capture readings for the previous 3 years. This was clearly not the case in the majority of cases, as for most participants the latest 5 readings only captured data that covered the previous two years. In other words, the majority of participants had a weight and BMI calculated at least twice per year.

It is clearly challenging to support and help people to lose weight. Self-management strategies have been shown to be effective in weight management (Deakin et al. 2005) although it is possible that a group-based approach is needed for a significant change in body mass index.

6.5. Chapter summary

One of the main aims for primary care management of diabetes is to minimise the risk of cardio-vascular complications. The main finding from this study is that self-management techniques such as understanding of, and subsequent concordance with, prescribed medication may provide the opportunity for an individual to control their own blood pressure. It is also possible that active involvement from a renal nurse in identifying abnormal ACR results and subsequent initiation of medicines that modify the renin-angiotensin pathway, may also have an effect on blood pressure control. This assertion is supported by the downward trend in both mean systolic and diastolic blood pressure recordings in the participating practices during time periods 1-4, prior to the intervention being rolled-out. The importance of maintaining blood pressure to target is that it can slow the rate of CKD progression and reduce cardio-vascular risk (Bilous 2008).

Similar effects have not been seen for control of blood sugar and weight loss. This may be because blood sugar and body weight are more difficult to control from an individual's perspective, and rely much more on behaviour change (diet, exercise) than change in concordance with medication. The following chapter will analyse the findings and discuss the assertion that "diabetes self-management is a multi-faceted process involving much more that helping patients to monitor their blood glucose or take their medication as prescribed." (Clark 2008)(p. 118).

7. DISCUSSION

7.1.   Introduction

The focus of this study has been the development and evaluation of a self-management package for people with diabetes at risk of kidney disease. The research question was:

"Can an innovative self-management package control the parameters that contribute to the progression of kidney disease caused by diabetes?"

The aims of the study were:

- To develop a self-management education package which informs patients with diabetes about the risks of kidney disease
- To test the self-management package by comparing with a control group
- To evaluate the self-management package and consider ways to disseminate the package to a wider audience

This chapter discusses the second and third aims of the study and will focus on five main areas: the findings set within a context of recent published literature, the possible shortcomings of the method, the use of self-management initiatives in practice, the study implications and my reflection on the research process.

7.2.   The findings

The study's findings need to be put into context before any recommendations can be made. The study population will now be scrutinised in terms of age, gender, ethnicity and social deprivation, and compared with national data and recently published literature where available. In the second part of this section, the study's clinical data will be reviewed and evaluated.

The study population: demographics

      7.2.1.1.   Age and gender

Deteriorating kidney function occurs normally with the ageing process (Maertens and Van Den Noortgate 2008). It is therefore interesting to review whether the participants in this study, who were at risk of CKD, were more likely to have microalbuminuria as they get older. Firstly there needs to be a comparison of the age distribution of those in this study with the general population in the PCT. Figure 7.1 shows the age profile for men and women in 2007 in the same PCT as the intervention/control practices (London Health Observatory 2008).

Figure 7.1: Age profile of PCT inhabitants in 2007 (Adapted from London Health Observatory 2008)
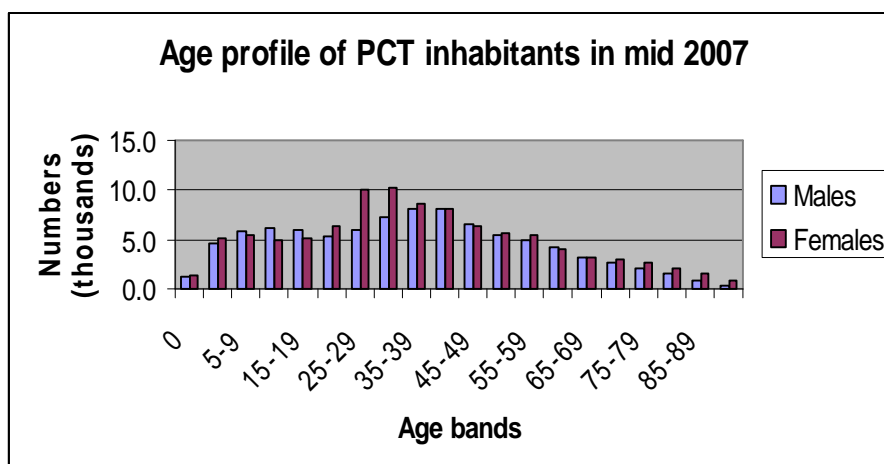
Figure 7.2 shows the age profile for men and women in the study within the participating practices, including the control practice.

Figure 7.2: Age profile of participants in 2007
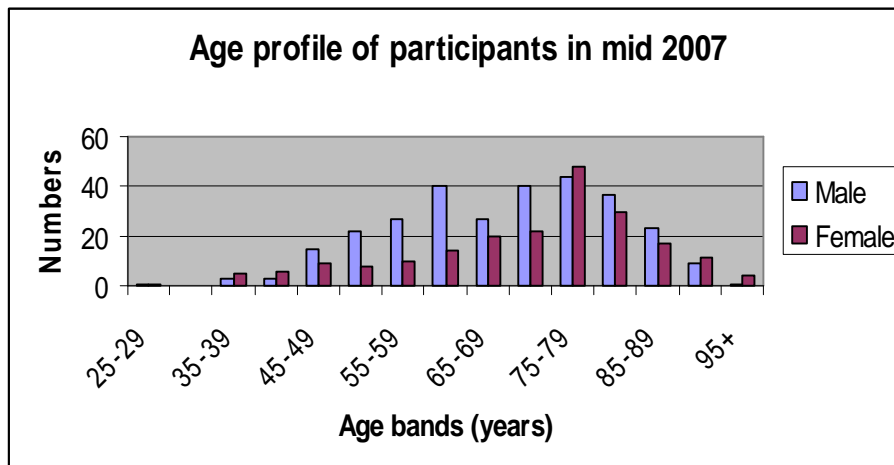
If Figure 7.1 and Figure 7.2 are compared it appears that women in this study are more likely to have diabetes with microalbuminuria (MA) as they get older, with the greatest likelihood of having microalbuminuria in the 75-79 year band. In contrast, men in this study appear to have microalbuminuria much earlier than women, shown by a steeper gradient from age 40 years, up to age 65, then dipping slightly before peaking at 75-79 years, as with women.

It is clear that more men in certain age groups have diabetes. A recent publication from Diabetes UK (Diabetes UK 2009) reported that 6% (around 197,050) of men aged 45-54 have diabetes compared with 3.6% (around 120,670) of women their age. In the older age groups (55–64 years) there are 8.5% of men with diabetes compared with 6.0% of women, and in the 65–74 age group 15.7% of men have diabetes compared with 10.4% of women.

However it is not clear whether MA appears sooner in men after diagnosis of diabetes. This question has to be considered in view of the mean screening rate of 71% (for both men and women) at the start of the study (ie. 29% of people with diabetes had not been tested for MA) and a mean screening rate of 86% in 2006. In the six intervention practices in 2006, 23% of people with diabetes were identified as having abnormal ACR values and of those approximately 60% were men. Although claims cannot be made about progression of proteinuria in the wider diabetes population, it is interesting to consider why men in this study had microalbuminuria (MA) at a younger age than women. No published evidence could be found which demonstrated that there were differences in MA progression due to gender alone, although one study was identified that found that risk factors for MA in Type 2 diabetes, did include poor glycaemic control and male gender (Kohler et al. 2000).

As MA progression is correlated with blood pressure and blood glucose control (Yamada et al. 2005) it is possible that there are differences in the way in which men and women take on health care advice regarding blood pressure and blood sugar control. One study (Heo et al. 2008)found that higher perceived control and better knowledge were related to better self-care behaviours in men (p<0.001), while higher self-care confidence and poorer functional status were related to better self-care behaviours in women (p<0.001).

However another study group (McCollum et al. 2005) found that women with diabetes scored lower on measures of health status and functioning-factors when compared with men. The authors proposed that these lower scores were likely to affect self-care activities, and concluded that gender differences should be considered when developing screening and treatment programmes for people with diabetes.

The implications for this study regarding gender differences are twofold. Firstly, men may be at risk of MA at an earlier age than women, so the educational intervention may need to come sooner. Secondly, that men may take on health-care advice in different ways from women, and these differences need to be considered when developing educational resources. For example, men may need to be given strategies that help them feel that they are controlling their condition, such as ensuring that dietary advice is consistent across different health care professionals. Women may need constant reassurance that their self-care behaviours are indeed helping their condition.

One study (Leeman et al. 2008) recognised that older people may learn in different ways from younger people and tailored a diabetes self-care programme to this group. The content of the educational intervention was individualised to experience of symptoms, self-care practices, and coping strategies, all delivered in a story-telling format. An initial pilot of the intervention with 43 older women over 75 years found high levels of participant satisfaction with the intervention, improvements in diabetes self-care practices, and a trend toward greater metabolic control.

7.2.1.2. Ethnicity

There was poor ethnicity recording in the study practices (36% missing data overall) at the time of this study, although LHO data have since been published. At the time of the analysis it was not possible to draw conclusions about how far people from different ethnic groups were more likely to engage in self-care practices or not.

Authors of a recent study into prevalence of CKD (de Lusignan et al. 2009) recommended that there needs to be an improvement in ethnicity recording. In their study, ethnicity recording was present in only around 25% of people with CKD. Although substantial investments have been made in other parts of the country to achieve much higher rates of ethnicity recording (Kumarapeli et al. 2006), this has not happened in all practices. However, even if ethnicity recording had been better, there are still relatively low numbers of people from black and minority ethnic (BME) groups in this study's primary care trust (PCT), compared with other parts of London (QRESEARCH and The Health and Social Care Information Centre 2008). Due to small recorded numbers of people from BME groups in this PCT, it will be difficult to show that any differences in self-management behaviours across different ethnic groups.

However it is important to consider the possible effects of ethnicity on self-management. In a survey of more than 6000 people with diabetes in the USA (Oster et al. 2006), African-Americans were significantly less likely than whites to monitor their diet, take exercise and not smoke; while Hispanics were less likely to monitor their diet than other groups. However all racial/ethnic groups had low levels of self-management behaviours. The authors recommended that further research was warranted to identify why racial disparities remain in settings where services are universally available.

Another study team (Glasgow et al. 2007) found that problem solving, an important patient skill for executing self-management behaviours, appears to be present across all racial and

ethnic groups. However it is possible that differences in self-management behaviours could be attributed to the type of facilitation and learning resources provided for self-management. Further work into what method of learning and teaching (written materials; one-to-one facilitation; peer support etc) might work best for different ethnic groups is clearly warranted. On reflection, more emphasis could have been placed on whether this study's self-management pack was culturally appropriate, not just in terms of content (advice on diet, medicines etc) but also with respect to learning style and health beliefs.

Practice Recommendation

Consideration must be given to cultural appropriateness of the learning materials in the self-management pack (such as dietary advice) and these will be reviewed before the final edition of the pack is published.

7.2.1.3. Deprivation

There are commonly used methods for calculating practice-level deprivation found in the literature, for example the Townsend scoring system (Townsend et al. 1988). However this method requires patient-level geographical data (identifiable data such as whole postcodes), which were not collected in this study because of data protection issues. Another method can use the deprivation score associated with the small area in which the practice resides, but this only provides a proxy for the socioeconomic deprivation experienced by the practice population as a whole. Given that the majority of a practice's registered patient population live in areas surrounding the practice that may have deprivation scores different from that of the area in which the practice is located or not, this assumption has its limitations (Strong et al. 2007).

However this second method was used as an approximation of social deprivation in this study, as identifiable data were not available. Data on the social grades of inhabitants of the ward (a small geographical area selected for electoral purposes) in which the practices are located were used. This may of course be different from the actual population of the practice, which may be from a wider geographical area.

Although it is recognised that there are difficulties in assigning deprivation scores through the social grades of inhabitants, this is one measure of deprivation that can be easily used. Social deprivation across the participating practices is varied. Fig 7.2 shows the percentage of social grades in the population in each ward where the participating practices are located. Data are from the 2001 census.

Figure 7.3: Social grades in participating practice populations

Social grades in practice populations
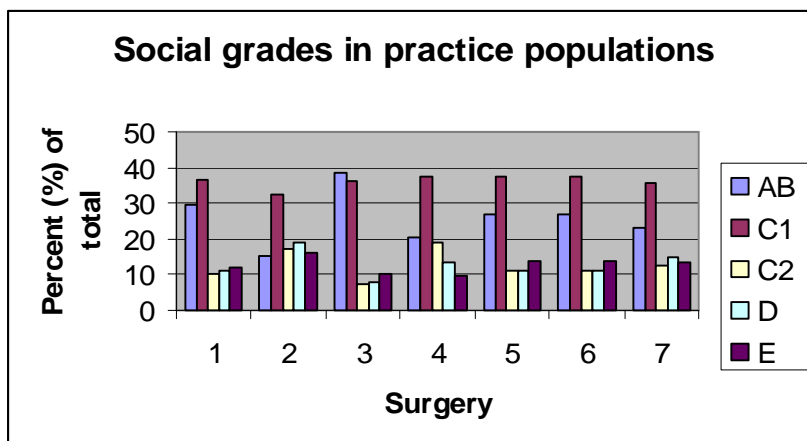
Key to Figure 7.3

| AB Higher and intermediate managerial / administrative / professional |
| C1 Supervisory, clerical, junior managerial / administrative / professional |
| C2 Skilled manual workers |
| D Semi-skilled and unskilled manual workers |
| E On state benefit, unemployed, lowest grade workers |

Surgeries 1 and 3 have many more inhabitants in social grades AB and C1, whereas surgery 2 has more people in grades C2-E, which implies a higher level of deprivation in surgery 2. This assertion is supported by my own observations and experience of working in this PCT. Surgery 2 is situated within an area of high levels of social housing, whereas surgery 3 is situated in a desirable leafy suburb known for attracting wealthy professionals.

Prevalence of diabetes in the participating practices in 2005 (according to the Quality and Outcomes Framework (QOF) returns) is shown in Figure 7.4.

Figure 7.4: Size of practice and prevalence of diabetes in participating practices in 2005

Surgery	Practice size	Number diagnosed with diabetes	Diabetes prevalence (%)
1	10536	315	3.0
2	7958	219	2.8
3	14241	393	2.8
4	9405	336	3.6
5	9041	247	2.7
6	10810	436	4.0
7	7629	267	3.5

There are differences between prevalence rates of diabetes in the participating practices (range 2.7-4.0%), although in these practices, prevalence does not appear to be correlated with deprivation. For example, it might be expected that surgeries 1 and 3 might have a lower prevalence of diabetes, with surgery 2 having a higher prevalence, and this is not the case.

The observed prevalence rates across deprivation quintiles found in the National Diabetes Audit (The Information Centre National Clinical Audit Support Programme 2006) provides a different picture. Data from the National Diabetes Audit (NDA) is based on 28% of the 1.8 million people who make up the registered diabetic population of England. Figure 7.5 shows prevalence rates of diabetes by deprivation quintile.

Figure 7.5: Prevalence rates by deprivation quintile

Deprivation Quintile	Prevalence rate
Quintile 1 (least deprived)	2.78%
Quintile 2	2.90%
Quintile 3	3.46%
Quintile 4	3.45%
Quintile 5 (most deprived)	3.70%

There is a difference of almost 1% in the observed prevalence of diabetes between areas which are least (Quintile 1) and most deprived (Quintile 5) having the highest prevalence of diabetes.

However, the difference in prevalence between the practices in the present study could be due to differences in people reporting symptoms of diabetes (thirst, urinary frequency) and

attending for diagnostic tests. Prevalence could also be correlated with the mean age of the practice population. Interestingly though, surgery 5 and 6 share the same building and have the same practice population, yet the prevalence of diabetes in 2005 between these two practices differed by 1.3%. There may also be clinical coding variations at practice level that also have to be taken into account.

There is also evidence that deprivation can affect clinical parameters such as blood pressure (QRESEARCH and The Health and Social Care Information Centre 2008). However, it has been suggested that blood pressure differences in people with diabetes between areas of high and low deprivation, have been eradicated since the introduction of the Quality and Outcomes Framework in 2004 (Ashworth et al. 2008). Since the reporting of performance indicators for blood pressure monitoring and control were introduced, there have been substantial improvements in achievement, that have been accompanied by the near disappearance of the achievement gap between least and most deprived areas (Ashworth et al. 2008). The following section will explore differences in clinical parameters across the participating and control practices, followed by an evaluation of the differences between intervention and control groups.

7.2.1.4. <u>Summary</u>

This section has compared the study population with national data where available, in terms of age, gender, ethnicity and social deprivation. It has been found that in the study population, men had microalbuminuria (MA) at a younger age than women, although it was not clear why this was the case.

Due to the poor ethnicity recording in the study practices (36% missing data overall), it has not been possible to draw conclusions about the effects of ethnic diversity on the findings. Social deprivation across the participating practices is varied, although differences in deprivation are not correlated with diabetes prevalence rates as expected.

7.2.2. <u>The study population: clinical parameters</u>

7.2.2.1. <u>Blood pressure</u>

Nationally collected data from primary care databases (QRESEARCH and The Health and Social Care Information Centre 2008) showed that mean systolic/diastolic blood pressure in

the general population in 2006/7 was 129/77 mmHg. Mean systolic and diastolic blood pressures in 2006/7 did not vary with level of deprivation.

The National Diabetes Audit (NDA) of 2005-2006 (The Information Centre National Clinical Audit Support Programme 2006) scrutinised the records of more than 650,000 people with diabetes, with 85% of these records being submitted from primary care.

Analysis of these data from primary care only showed that 26.8% of people with diabetes achieved the NICE (2002) blood pressure target of less than 135/75 mm Hg which was an increase of 2.62% on the previous year. 88% of people achieved the target of <160/100 mmHg. By comparison, 58% of participants in the present study in 2005, had achieved the NICE target of 135/75 mmHg. It is difficult to compare these data directly, as all of the participants in this study had microalbuminuria and the percentage of those with microalbuminuria in the national audit sample was not stated. However it appears that overall blood pressure control in the participating practices at the start of the study was better than in the national sample.

7.2.2.2. Blood sugar control: HbA1c

In the NDA period of 2005-2006, 22% of people with diabetes achieved the lower HbA1c target of <6.5%, and 60% achieved the target of <7.5% recommended by NICE at that time (National Institute for Health and Clinical Excellence 2002). In 2006 in the present study, 57% of people in the participating practices had an HbA1c result of <7.5%, a similar finding to the national sample.

7.2.2.3. Body Mass Index

Obesity is defined as having a body mass index (BMI) of 30 or above. In the QResearch report (QRESEARCH and The Health and Social Care Information Centre 2008) 26% of people in the general population had a BMI>30, and this included 11% of registered patients who had BMI>30 plus a diagnosis of coronary heart disease (CHD), hypertension or diabetes. In 2006/7 the highest proportion of obese patients was in Wales (31%) and the lowest was in London (22%). In the present study, baseline data found that 128 out of 342 patients (37%) of the study population in the intervention practices had a BMI>30, a much higher percentage compared with the national sample. This is to be expected as being obese, particularly at younger ages, substantially increases the lifetime risk of being diagnosed with

diabetes (Narayan et al. 2007). The NDA of 2005-2006 did not collect data on BMI so a comparison with a diabetic population is difficult.

7.2.2.4. Smoking cessation

The QRESEARCH study (QRESEARCH and The Health and Social Care Information Centre 2008) identified that in March 2007, 80% of registered patients aged 16+ had smoking information recorded within their electronic health record in the past 5 years. 22% of these were recorded as being current smokers. Smoking is more common among patients from the most deprived areas. For example by the end of March 2007, 34% of patients from the most deprived areas were current smokers compared with 14% of patients from the most affluent areas.

In 2006/7 the percentage of patients recorded as smokers in the past 5 years was highest in the North-East and London (25%) and lowest in the South-East and South-West (20%) (QRESEARCH and The Health and Social Care Information Centre 2008).

The present study's findings showed that the percentage of people who were smoking at the start of the study was 18.5% of those for whom there was a record of smoking status. This is a smaller percentage than in the general population although surgery 2, which could be considered to be in an area of social deprivation compared with the other practices, recorded more than 30% of the participants as smokers.

7.2.2.5. Kidney disease progression

Data which compare the rates of kidney disease progression can be difficult to analyse with respect to severity of CKD, as staging of CKD was only introduced into the UK in 2006, and retrospective data are difficult to find. For the purposes of this study, retrospective serum creatinine results were converted into eGFR readings using the Modification of Diet in Renal Disease (MDRD) formula, found on the Renal Association website http://www.renal.org/eGFRcalc/GFR.pl.

The Information Centre (The Information Centre National Clinical Audit Support Programme 2006) has published data on risk of renal failure (stage 5 CKD) in people who have diabetes. The prevalence in the population with diabetes is 0.21%, whilst the prevalence in the general population is 0.05%.

The highest prevalence rates for renal failure (stage 5 CKD) are found in the middle age bands, starting with a sharp rise at age 25-39 years. There is a higher complication rate of kidney failure in males (0.34%) compared with females (0.23%). There is little variation in prevalence rates of renal failure across the country (The Information Centre National Clinical Audit Support Programme 2006). The authors suggest that known preventive care interventions in people with diabetes from a young age should result in a reduction in these rates.

In the present study period of 3 years, there was little evidence of kidney disease progression, with only small numbers of people reaching stage 4 CKD, or requiring dialysis/transplantation. In the course of the study only four people required dialysis. However people were excluded from the study at the start if they had already been referred to the renal unit. This meant that those at risk of progressive disease, who may have already reached stage 3b or stage 4, were not included. It is possible that if the high-risk group had been included then a greater proportion of people may now be requiring renal replacement therapy.

It is likely that the high number of deaths during the study (around 10%) may have been due to cardio-vascular disease, a well-documented independent risk factor in CKD (Go et al. 2004). This means that many people with CKD may die of cardio-vascular disease before they progress to dialysis dependence. It is possible that this conclusion is also applicable to this study, although data on cause of death were not collected.

In the general population, a recent study in Surrey (de Lusignan et al. 2009) found that CKD (stages 3-5) is a condition which is more common with increasing age, and is more common in females than males. The data in the Surrey study were taken from 14 practices as part of a quality improvement initiative and were anonymised and extracted using MIQUEST software.

The prevalence of CKD in the Surrey study was much higher in women than men. However, as renal function declined, the proportion of men with CKD increased. Just over a quarter of people with stage 3A CKD were men. Men account for just over one-third of people with stage 3B CKD and nearly half of those with stage 4 and 5 disease. This may provide some insight as to why CKD is much more prevalent in females but renal replacement therapy is more common in men (de Lusignan et al. 2009). Interestingly in the present study, more men had microalbuminuria at an earlier age. However as this cohort did not include people who had already been referred to a renal unit at the start of the study, it has not been possible to give an accurate comparison of how many men with MA had further CKD progression and eventually required renal replacement therapy.

7.2.3. The intervention versus control group: clinical parameters

The results chapter outlined the findings by comparing the intervention and control groups. Some analysis about differences between the two groups took place in the results chapter, but further discussion is warranted here. There now follows a discussion about the group of patients that did not receive the pack, but were registered at the participating surgeries.

7.2.4. Characteristics of the group that did not receive the pack

This group were not given the pack either because they could not take part (moved away or died n=84) or because they were not suitable (n=179). Reasons for clinical non-suitability can be divided into renal causes or non-renal causes.

7.2.4.1. People who did not receive the pack: renal causes

Renal causes were either because they had no microalbuminuria (n=92) at the start of the intervention period, or they had been referred to the renal unit for progressive CKD (n=26).

The high percentage (21%) of people who were not suitable because they had normal ACR results was surprising, yet very pleasing, to me. On reflection this may be due to two reasons. First that a small percentage of people may not have been accurately documented as having microalbuminuria and were therefore wrongly included in the study. This may be because of false positives such as infection. However despite published guidelines and expert consensus opinions recommending the exclusion of a urinary tract infection (UTI) if a test result for urinary albumin is positive, findings from a systematic review (Carter et al. 2006) concluded that it is unnecessary to screen asymptomatic patients with demonstrable proteinuria or albuminuria for UTI. It is therefore likely that infection did not contribute to people being wrongly diagnosed with MA, therefore the number of false positives might be small.

What is more likely is that there are differences in progression of microalbuminuria (MA) which had not been completely understood by me at the start of the study, partly because of the lack of epidemiological evidence on MA progression. A more recent search identified three pertinent studies that illustrated progression and reduction. First, in a study of people with Type 1 diabetes (Ficociello et al. 2007), microalbuminuria was often found to progress to proteinuria in those who were treated with ACEi/ARBs (n=373). Poor glycaemic control and elevated serum cholesterol were the major determinants/predictors of this progression.

However in a smaller study of people with Type 2 diabetes (n=26) the converse appeared to be true (Atmaca and Gedik 2006). In this study the albumin excretion rate had been reduced significantly in each group over a twelve month period after initiation of ACEi/ARB. In another small study (n=20) (Cotter et al. 2008) regression towards normoalbuminuria occurred in 11 patients (35.5%) taking ARBs vs. 9 (22.5%) patients taking ACEis (NS between groups). A review paper (Araki et al. 2008) supports this assertion by suggesting that in people with Type 2 diabetes treated with ACEi/ARB, a reduction in microalbuminuria was more frequent than progression to overt proteinuria. They concluded by suggesting that a multi-factorial approach was important in reducing microalbuminuria in this group.

The conclusion is that rapid initiation of ACEi/ARBs in people with MA can reap rewards in especially if implemented alongside other measures such as strict blood pressure and blood sugar control. The results from this present study suggest that it is likely that the participating practices were provided improved care to this cohort of people at risk of CKD following the case study period. The practices did this by improving the screening rates for MA and by timely prescribing of appropriate medication to those at risk.

<div style="border:1px solid">

Practice recommendation

CKD education programmes for primary care health-care professionals to focus on importance of MA screening to identify those at risk, in order that timely prescribing of ACEi/ARBs can be initiated.

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7.2.4.2. People who did not receive the pack: non-renal causes

Some were not suitable because of another clinical condition (malignancy and receiving active/non-active treatment or being unwell with a long-term condition (n=25)). There were also social reasons, such as in residential care or learning difficulties (n=36), for why people in the participating surgeries did not receive a pack.

It is therefore difficult to draw conclusions about this group because of its diversity, although it might be useful to some extent to draw comparisons between this group and the group from the intervention practices that did receive the intervention, to see if any researcher effect could be identified. This will be discussed further in section 7.3.

It is pertinent to discuss some characteristics of this group that have relevance to long-term sustainability of the self-management pack. Firstly, in any practice there is always a transient

population, especially in inner-city areas, so long-term care and follow-up can be challenging. Secondly, people with diabetes and kidney damage are at increased cardio-vascular risk, so increased morbidity and mortality is likely. An important question is when education and self-management support should be initiated in this high-risk group.

There are implications from the findings of this study for initiation of self-management programmes for other long-term conditions. Apart from the renal causes of non-participation, there was still a sizeable number of people (n=61)(14%) who could not participate because of clinical or social reasons.

Despite searching the literature it was not possible to compare these figures for non-participation with other self-management studies or projects, as data on non-participation were rarely reported. The recommendation from this study is that development of future self-management programmes have to be considered in light of the number of people who are not suitable for self-care, either because of clinical or social reasons.

Practice Recommendation

It is important to recognise that any newly-developed self-management package or programme may not be suitable for people who either do not want, or are not able to self-care. The recommendation is that packages or programmes cater for a range of self-care abilities, from simple messages (eg. how many tablets to take each day) to complex interventions, such as monitoring and managing insulin requirements.

7.2.5. People who did not want to participate

In this study 18 people refused to take part and it is possible that some people took part but did not actually use the pack at all. An important question is how far the general public and those with long-term conditions believe that self-management or self-care is beneficial. In this study there was a minority (around 10%) who did not wish to have a pack, so presumably did not wish to self-manage.

The Department of Health commissioned Ipsos-MORI in 2008 to undertake a longitudinal study, exploring attitudes of the public towards self-care (Department of Health 2008a). The study aimed to investigate the general public's perceptions and behaviour with regard to self care of their health, and more importantly aimed to capture the attitudes and behaviour of

people with long-term health conditions. Overall the study found that the vast majority of British adults (89%) think that people should take responsibility for their own well being.

However, for those with a long-term condition, the results are somewhat different. Of those questioned (n=1975), 5% reported that they had diabetes, and over three-quarters of adults with diabetes and other long-term health conditions say they play an active role in treating their condition 'all or most of the time'. More than four in five older people aged 55-64 say they take care of their long term condition 'all or most of the time' (85% compared with 80% aged 15-24) as do those in the higher social grades (89% compared with 76% social grades DE). However respondents from ethnic minority groups were *less* likely to take an active role 'all' or 'most' of the time (59%), as were Londoners (48%).

Another important issue which was raised was how many with a long-term health condition (22%) were unable to perceive an advantage in taking a greater role in care of their health and condition and a further 15% did not know whether or not there were any advantages. The potential is clearly there to increase awareness amongst these groups of the advantages of self-care, and a recommendation for this thesis is that people with diabetes and CKD need to have a full explanation of the advantages, especially potential slowing of kidney disease progression.

Practice recommendation

The written information in the self-management pack should have an introductory paragraph that explains the benefits of self-care.

In the same study undertaken for the Department of Health (Department of Health 2008a) the results found that four in five adults with a long term health condition said they had *not heard* of a training course that would help them learn skills to self care for their health and condition. Although this present study has developed a self-care package, and not a training course, this finding has implications for this study in terms of dissemination; that is making sure that as many people as possible at risk of CKD have access to the package. This could be either in the original paper/DVD version, or on-line. Widening access for everyone with diabetes at risk of CKD is discussed in section 8.5.

Another important part of the study (Department of Health 2008a) compared data with figures from a similar study in 2004-2005 (two years before). In 2006-2007, three in five people with a long-term health condition said that they prepare questions 'all' or 'most' of the time for when they visit health or social care professionals such as doctors, nurses or social workers (60%). This has increased since 2004-05 when only around half said they prepared questions for health professionals (52%). A recommendation is that further emphasis is put

on preparing questions for the GP or practice nurse before the consultation, as preparing questions in advance can improve self-management skills (Sturt et al. 2006b).

Practice recommendation

The written information in the self-management pack should contain a suggestion that patients prepare questions for their GP or practice nurse prior to a consultation visit.

7.2.6. Health-care professionals and self-management

An important message is how far health-care professionals themselves encourage self-management. In the same study (Department of Health 2008a) people reported that when visiting their practice nurse they are more likely than those visiting GPs, hospital doctors or pharmacists to be encouraged to self care and play a more active role in caring for their long term condition. More than four in five of those visiting their practice nurse said that they were encouraged to self-care (83%). A significant proportion (62%) who visited their local pharmacist was encouraged to self care.

However for most people, the preferred source of information and advice about long-term health conditions in the future is the GP (66%). Other preferred sources of information are practice nurses (23%), local pharmacists (17%) and hospital doctors (17%). The implication is that GPs may need further training and support in facilitating self-care, as people with long-term conditions may not engage in self-care if their doctor does not support or encourage it.

In summary, this section has provided some recommendations for the way in which people who did not want to participate in self-management might be encouraged to do so. These include explaining the benefits of self-care more explicitly, advertising the pack more widely to make it more accessible, providing people with examples of questions they might ask of their health care professionals during consultation, and encouraging and training health-care professionals in this approach.

7.2.7. Characteristics of the group that did receive the pack

116 people (the intervention group) received the pack, although it cannot be assumed that everyone who was given the pack then read or viewed the contents, or acted on the advice given. When the pack was developed the aim was that it should be self-supporting, that is, that it did not require any additional explanation or information from the person giving out

the pack. What cannot be controlled was how far different practices or health care professionals supported or reinforced the advice given therein. Through observing the way in which different practice nurses took on the project, the nurses in practices 5 and 6 were the most enthusiastic for self-care. This observation was supported during my participant observation at the start of the study (see Chapter 2), such as conducting patient-centred consultations (*"how are you coping with your diabetes?"*) and encouraging people to identify individualised targets for weight loss and smoking cessation. However, a number of different health-care professionals in each practice distributed the packs and some were given out by me either in the surgery or in the patient's home. The conclusion is that there was variation in the way in which the packs were given out, and how far subsequent self-care strategies were supported and implemented in each case. Although these differences are recognised, they cannot be controlled for. Indeed, the package is likely to be much more useful if its benefits are found to be independent of who delivers it. If the pack is to be distributed in future without supporting information from the person who provides it, one important consideration is how far the pack is understood by the user.

However it would be useful if the person who delivers the pack is provided with some supporting information regarding aims, content and possible frequently asked questions (FAQs) that patients may ask once they have received the pack. A recommendation is that the pack includes supplementary information for health-care professionals that outlines the aims, content and potential FAQs.

Practice recommendation

The written information in the self-management pack should include supplementary information for health-care professionals.

7.2.8.   Health literacy

Since the start of this research study, there has been a growing interest in *health literacy*. Health literacy can be defined as

> *"the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."*
> (Department of Health and Human Services (HSS) (USA) 2000).

A number of reviews (Ishikawa and Yano 2008, Keller et al. 2008, Schaefer and Schaefer 2008) have evaluated the effect of health literacy on health outcomes. Most authors conclude that further research is needed to explore the impact that low health literacy may have on patient outcomes. However, it is agreed that health literacy goes beyond the commonly held belief that simply giving information in an understandable and readable format is enough to facilitate self-management. Although practical issues such as font size are clearly important, other factors which enable people to process and understand health information must be considered. One pertinent study (Sarkar et al. 2006) suggested that further study of the determinants of, and barriers to, self-management were warranted, whilst a review of health literacy and CKD (Devraj et al. 2009) concluded that despite the increasing prevalence of CKD and the considerable interest in health literacy, there has been limited research examining the role of health literacy in individuals at all stages of CKD.

Although the research study presented in this thesis does go some way to address the deficit in information resources for diabetic kidney disease, further work needs to be carried out in understanding the ways in which people take in and process heath care information.

Recommendation for further research
As little is known about how people with early CKD take-in and process health information, a qualitative study is recommended that investigates how people interpret the information in the self-management pack and use this to change their health behaviour. Semi-structured interviews with people who have received the pack could be undertaken. Interview topics could include baseline knowledge about risk of CKD, the aspects of the pack that were most useful, and the behaviours that were altered as a result of the information received.

7.2.9. Differences between groups: clinical parameters

7.2.9.1. Blood pressure

The most important finding was that both systolic and diastolic blood pressure did fall in the intervention group compared with the control group although the differences were not significant. At the end of the study period in January 2008, the patients who had received the self-management package had a mean systolic BP of 132.1 ± 14.2 mmHg vs. 136.2 ± 16.4 mmHg in the control group (p=0.15). Although not statistically significant, the group who received the self-management pack had a mean blood pressure that was much nearer the NICE (2008) target of 130/80 mmHg. The lowest mean blood pressure recording of the

intervention group was at data collection period 4 (November 2006). At this time point, mean systolic BP was 129.2 ± 19.2 mmHg and the mean systolic BP in the control group was 134.6 ± 15.0 mmHg (p=0.057). It was 3 months prior to time point 4 and during time point 5, that the self-management packs were being distributed. The statistical analysis shows mild significance but it would have been helpful to compare mean BPs in the intervention group with national data if those data had been available.

In the only study found that can be used for comparison (de Lusignan et al. 2009) the mean systolic blood pressure in people with CKD was 136.0 ± 17.5 mmHg, as compared with a mean of 126.8 mmHg in the rest of the population. Blood pressure control was no better in people with diabetes and CKD than without diabetes and CKD. The mean systolic BP in people with CKD with and without a positive proteinuria test (including dipstick tests) were 136.9 and 137.1 mmHg respectively (p=ns). The systolic blood pressure in the intervention group at the end of the present study was 132.1 mmHg. This compares with 136.2 mmHg in the control group which is the same mean BP as in the CKD group in the de Lusignan (2009) study.

It is therefore likely that changes to BP in the intervention practices have occurred as a result of this study's interventions rather than external influences. What cannot be explained is the exact reason for these resulting reductions in mean BP. It is possible that effects came about because of direct patient behaviour, such as individuals understanding of the risks of high blood pressure and being more concordant with prescribed anti-hypertensive medications. It is possible there was an effect resulting from my visits to the intervention practices. This could have been because my frequent visits increased practice nurses' understanding of the importance of BP control in this high-risk group, and this awareness prompted more diligent monitoring, recall and prescribing of anti-hypertensive medication.

It was interesting to observe that there was a 'rebound' in mean BP in the intervention group at time point 5 (133.4 ± 12.8 mmHg), although mean BP did fall again at time point 6 (132.1 ± 14.2 mmHg). The reasons for this are not clear but it is possible that BP control may relate to QOF incentivisation, with practices recalling patients for blood pressure checks and subsequent prescribing if the BP was over the QOF targets, towards the end of the financial year. Time point 5 occurred in June 2007 (after the end of the financial year) whereas time point 6 occurred in January 2008, just prior to the end of the financial year and QOF visits.

It is also possible that an intervention might have an immediate effect on learning and subsequent change on behaviour, but this effect diminishes with time (Boren et al. 2007).

Diastolic blood pressure in the intervention group also had similar reductions during the data collection period, but did not have a 'rebound' at time point 5. At the end of the study, mean diastolic blood pressure was 74.9 ± 8.52 mmHg in the intervention group. This compares with a mean diastolic blood pressure of 77.6 ± 9.01 mmHg in the control group (p=ns). Interestingly there was a difference that fell just short of being significant (p=0.053) at time point 5, with a mean BP in the intervention group of 75.7 ± 7.4 mmHg vs. 78.9 ± 10.6 mmHg in the control group.

The findings show that it is possible to achieve the NICE (2008) diastolic BP target of 130/80 mmHg for people with CKD and diabetes. This is in contrast with some other studies that found BP in people with diabetes difficult to control. One review (McLean et al. 2006) found that fewer than one in eight people (n=47964) with diabetes and hypertension have adequately controlled BP (defined by BP 130/85 mmHg), and recommended that there was an urgent need for multidisciplinary, community-based approaches to manage this high-risk cohort. A primary care study in Nottingham (Bebb et al. 2007) found that only 46% of participants had well-controlled blood pressure (defined by BP <145/85 mmHg).

In terms of cardio-vascular risk reduction the reduced blood pressure in the intervention group has important implications. Numerous studies have shown that BP control is an important modifiable risk factor for cardiovascular events (Mourad and Le Jeune 2008). Blood pressure control with angiotensin-converting enzyme inhibitors in the MICRO-HOPE study showed significant reductions in the risk of vascular complications, and blockers of the renin-angiotensin system produced substantial renal protective effects in patients with hypertension and diabetes (Gerstein 2002). An intensive multi-factorial intervention, including BP control, achieved sustained reduction in the risk of vascular complications and death in patients with Type 2 diabetes in the Steno-2 study (Gaede et al. 2003).

Although the BP endpoints from this current research study did not reach the NICE (2008) recommendations of <130/80 mmHg, a differential of >3mmHg compared with the control group might have significant effects on cardio-vascular risk reduction.

7.2.9.2. <u>Self-monitoring of blood pressure</u>

This study has not been able to investigate whether self-monitoring of blood pressure has contributed to the reductions in mean blood pressure in the intervention group, due to the very small number of people (n=4) with home monitoring machines who concluded the study. Studies into self-monitoring of BP are gaining interest especially because of increasing evidence of their role in reducing blood pressure (Cappuccio et al. 2004, Ogedegbe and

Schoenthaler 2006). Unfortunately the reasons behind this assertion are not clear (Cappuccio et al. 2004).

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Recommendation for further research

A study that aims to understand the effects/outcomes of using a home blood pressure machine by people with diabetes and MA is recommended.

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7.2.9.3.   HbA1c

It was found that HbA1c did drop during time points 1-4 in all groups including the control group. It is possible that the fall in HbA1c could be due to QOF incentivisation, as GPs and practice nurses aimed for tighter glucose control through more intensive prescribing of insulin and medication. This study did not find any significant differences between the intervention and control group, and this finding has been replicated in other studies.

In a recent Health Technology Assessment (HTA) (Loveman et al. 2008a), seven studies that had glycaemic control as an outcome measure were reviewed. One study (Kaplan et al. 1987) found that an intervention combining diet and exercise produced significantly lower HbA1c than in a control group who received only didactic education. The diet plus exercise intervention produced a sizeable reduction in HbA1c (–1.48%), whereas the drop was small in the diet group (–0.46%). HbA1c increased from baseline in the exercise group (+1.3%) and education group (+0.36%). The diet plus exercise intervention was the most intensive intervention involving 20 hours of contact, but it lasted only 10 weeks. Therefore, this effect was reasonably long-lasting as the outcome was measured at 18 months.

In another similar study where both dietary advice and exercise were included in the intervention (Uusitupa et al. 1993) mean levels of HbA1c did not differ between the intervention and control groups (there was a marginal difference at 12 months), although the proportion of patients with HbA1c <7.0% was greater in the intervention group. This was true at both the 12- and 24-month evaluations. In a larger study of 104 participants (Gilliland et al. 2002) there was an increase in HbA1c but two intervention groups combined (group plus one-to-one education) showed a significantly smaller rise in HbA1c than the control group. Five further studies did not report any differences in measures of HbA1c between intervention and control groups or between different interventions.

The studies that showed a change in HbA1c required intensive intervention, usually over a sustained period of time and often by specialist team members such as dieticians or a psychologist. The HTA concluded that some studies showed a statistically significant effect of education on HbA1c, whilst others did not. They did not conclude what type of intervention was most likely to offer a positive outcome. However, they did ascertain that in the case of reduction in HbA1c, statistically significant effects were in the region of a 1% change in many of the studies, and this reflected a clinically significant effect.

In a systematic review of 31 studies (Norris et al. 2002a), it was found that self-management education improves HbA1c levels at immediate follow-up, and increased contact time increases the effect. However the benefit declines 1-3 months after the intervention ceases, and the authors suggest that learned behaviours change over time.

The implications for this study are that reduction in HbA1c is particularly difficult to obtain, even when specialist resources are used to intervene. Good glycaemic control can be challenging for many people (Ockleford et al. 2008) yet there is some evidence that intensive education and support can be of benefit.

7.2.9.4. <u>Weight loss</u>

In this current thesis, baseline data found that 128 out of 342 patients (37%) of the study population had a BMI>30. At the end of the study, 165/402 patients (41%) had a BMI of >30. It must be re-emphasised here that these data include the control group with a large amount of missing data at time point 1, so comparisons in BMI pre- and post-study may be difficult. However the results show it can be very challenging for people with diabetes to lose weight, especially as there can be side-effects of weight gain with the use of insulin (Russell-Jones et al. 2007) and glitazones (Kushner et al. 2009).

Other studies have also shown the challenge for health care professionals to support people with diabetes to lose weight, regardless of the intervention. A Health Technology Assessment (Loveman et al. 2008a) did find that a number of studies showed significant effects of education on weight loss but fewer showed significant effects on BMI. The type of intervention that was most successful in reducing weight was a group intervention, and reasons for this could be that weight loss is best maintained through a number of crucial activities applied together, namely a change in diet, increase in exercise, but also support from others in the same situation and a realistic target and action plan. This is perhaps why Weightwatchers® is so successful (Heshka et al. 2003), as it combines each of these

activities. Also a recent study (Sacks et al. 2009) found that attendance at a weekly group session was strongly associated with weight loss.

This assertion is also supported by the findings of the DESMOND study (Davies et al. 2008) which evaluated the effectiveness of a structured group education programme on biomedical, psychosocial, and lifestyle measures in people with newly diagnosed Type 2 diabetes. The results showed that the intervention group had a greater weight loss (-2.98 kg) compared with 1.86 kg in the control group (p=0.027 at 12 months). Interestingly the DESMOND study did not find a significant difference in HbA1c levels up to 12 months after diagnosis, between the two groups, but this may be due to the problems with using HbA1c as an outcome measure as discussed in section 3.9.3.

A number of authors have hypothesised why people with diabetes do not change their behaviour despite understanding the consequences of not doing so. One interesting study (Ockleford et al. 2008) interviewed 36 people newly-diagnosed with Type 2 diabetes who were participating in the randomised controlled-trial of methods of education, with the intervention arm based on the DESMOND programme. The research team discussed the importance of a 'diabetic identity' (Bury 1982) in accepting the diagnosis and making subsequent behavioural changes. As an example, people who were categorised as 'acceptors' fully accepted their diagnosis, and were committed to changing their behaviour in response. 'Resisters' found it difficult to accept they had diabetes, and were not able to make any changes either to their identity or lifestyle. However acceptance of the 'diabetic identity' is no guarantee that they would always follow health-care advice, and many spoke of times when they would lapse away from recommended advice.

It is possible that people who took part in this doctoral study were more likely to be 'acceptors' than 'resistors', as presumably the 'resistors' were more likely to be the people who refused to take part. However as Ockelford et al (2008) suggested, acceptance of the diabetic identity alone is insufficient to bring about subsequent behaviour change following an educational intervention. Their findings support other research that identified that some people with Type 2 diabetes may not believe that it is a serious disease (Lawton et al. 2005). Perhaps most importantly for this thesis, Ockelford et al (2008) concluded that one type of educational approach is unlikely to suit all people with diabetes.

The conclusion is that weight loss, and more particularly a significant reduction in BMI is very difficult to achieve. It is possible that education has an effect on helping people deal with their condition, rather than bringing about changes in biomedical markers. Although this

present study's intervention did not show any benefit in terms of weight loss, there were data collection errors in the control group which have to be taken into account (see Chapter 6).

7.3.   Shortcomings of method

7.3.1.   Recording of data

It is recognised that there may be issues concerning validation of the collected data. As discussed in the methods chapter, there may be inaccuracies in the manual method used for data collection, that is, data were copied from practice computer screens to paper then inputted back into a computer programme. Data were cleansed as far as possible for obvious inputting mistakes.

A more important consideration is the quality of the data that were inputted at source, by the practice nurses or GPs, such as blood pressure recordings that are inputted manually. Other data collected in this study, such as blood results (HbA1c, serum creatinine and eGFR) were transferred electronically from the hospital laboratories.

Some studies have highlighted the difficulty with blood pressure end-digit preference (EDP). One study (Kim et al. 2007) found that that low-quality BP data, reflected in EDP, remains common in primary care of adults with diabetes. The authors found that EDP was highly prevalent in the BP measurements taken by non-physicians (in 4,333 readings, 50% of systolic and 50% of diastolic readings ended in zero; $p < 0.001$) and in physicians (in 1,347 readings, 69% of systolic, 64% of diastolic readings ended in zero; $p < 0.001$). Another study (Broad et al. 2007) found that 64% of systolic and 62% of diastolic blood pressure recordings ended with a zero end-digit, despite guidelines recommending measurement to the nearest 2 mmHg. They concluded that zero end-digit preference significantly decreases a patient's likelihood of being classified as eligible for drug therapy to reduce cardio-vascular risk.

At first glance it appeared that one practice (surgery 2) appeared to be using a manual sphygmomanometer, as 49 % BP recordings at time point 1 had a preference for end-digits ending in 0 or 5. Upon closer inspection, it was found that a greater than expected % of recordings throughout all the practices (including the control) at time point 1 also recorded an EDP of either 0 or 5 (167/399 (41.9%)). In these other practices BP was usually taken on an electronic device, although some individual practice nurses and GPs preferred to use a manual sphygmomanometer. It has not been possible to identify the proportion of BP recordings in each practice that have been taken either by a manual or an electronic device.

In total at time point 1 there were 42/399 (10.5%) people with a systolic blood pressure recorded exactly as 140mmHg and 39/399 (9.8%) people with a systolic BP recorded exactly as 130 mmHg. This phenomenon might be explained by the findings of another study (Burnier and Gasser 2008).

This study in Switzerland (Burnier and Gasser 2008) found that despite the use of electronic BP machines, end-digit preference remained a common feature of BP measurements. The authors investigated the frequency of end-digit preference and evaluated the impact of this bias on BP, which was measured either with an electronic device or with a conventional sphygmomanometer. Very marked digit preferences were observed for both the conventional and the automatic measurements, being most prominent for the digit 0 (52% and 25%, respectively) followed by a preference for the digit 5 (19% and 15%).

Although the authors explained the use of the electronic device could reduce the frequency of the bias to a certain extent, they suggested that the problem remains if professionals have to transfer the BP values into computer records. This might be the case in practices 1 and 3-7 where GPs and practice nurses take an electronic reading but then round down the systolic and diastolic pressures to the nearest 5 or 10 mmHg.

The implications are that patients may not be given optimal care for blood pressure management because true blood pressure readings are not being recorded. In the case of this present study it is possible that this practice was occurring in one surgery, with a high proportion of BP readings being rounded down to an EDP of 0 or 5 results in consistent achievement of the NICE (2008) blood pressure target of <130/80 mmHg. In this practice, mean systolic blood pressure was 129.4 mmHg at time point 3, 128.6 mmHg at time point 4 and 128.7 mmHg at time point 5. At time point 6, mean systolic BP in this practice was 131.2 mmHg. This was the only practice that managed to achieve the <130/80 mmHg target at three different time points, and it is possible that this target was achieved through the end-digit preference bias.

Another consideration is the possibility that the mean fall in blood pressure was related to the QOF incentivisation, particularly since the introduction of the BP target of 145/85 mmHg for those on the diabetes register occurred just before the start of the study in 2004. It is unlikely that the fall in BP seen in the intervention group was related to the QOF as the control group did not see similar effects, but it may be true to say that clustering of BP readings just below the QOF target may be a likely effect of incentivisation.

One study (Carey et al. 2009) found this to be the case, as they found that there was a trend towards recording systolic values just below, rather than just above the 150 mmHg systolic BP cut-off for diagnosing hypertension. In 2000–2001, before the QOF, 2.3% of patients had 148–149 recorded and 1.8% had 151–152. In 2004–2005, the figures were 4.2 and 1.3%, respectively. By smoothing the distribution the authors estimated that the true percentage of patients with systolic BP>150 mm Hg in 2004–2005 was 23%, rather than the 19% recorded. However they concluded that although BP readings were being clustered just below the QOF target, there was no evidence of adverse effects of this on clinical management. It is possible that this phenomenon also occurred in this study but because BPs were generally much lower than the QOF target, it is less likely.

Practice recommendation

For practitioners to record blood pressure to the nearest 2 mmHg when using a manual sphygmomanometer and to record the exact reading when using an electronic device.

7.3.2.   Powering the study

In order for the study to have 90% power with 5% significance, it was necessary to distribute the self-management packs to 42 patients in each surgery, that is, 252 packs in all. As described in Chapter 7, it was not possible to distribute this number of packs (only 116 were distributed), so the study is underpowered, and results should be viewed with caution.

As the study was underpowered it was not possible to identify significant differences between the intervention and control groups. At time points where there were marginal significant differences in systolic blood pressure between the two groups it is possible that, if the study had been powered, then significant differences may have been identified.

7.3.3.   Influences on the study

7.3.3.1.   National policy

As stated in other sections of this thesis, the care of people with CKD in primary care has changed dramatically over the past five years. This has mostly been due to four important national initiatives, namely:

- the publication of the National Service Framework (NSF) for Renal Services (Part Two) in February 2005, followed by local and national guidance for managing people with early CKD
- the General Medical Services (GMS) contract for 2006/07 including a new Quality and Outcomes Framework (QOF) domain for CKD (amended in 2008 and 2009)
- the recommendation that all hospital laboratories should report estimated glomerular filtration rate (eGFR) as a measure of kidney function (alongside serum creatinine) from April 2006
- NICE guidance for CKD, published in September 2008

The question is whether the differences in clinical parameters found in the intervention group in this study might have happened as a result of the national initiatives, although the amendment to the method to include a control group did aim to eradicate the effect of the policy changes. Although there was a downward trend in mean systolic and diastolic blood pressures in the intervention group which was not seen in the control group, it is possible that national policy changes did affect the management of patients in the participating practices observed by the falling mean BP recordings that occurred before the intervention was rolled-out.

7.3.3.2. Researcher influence

It is important to consider the effect that I had on the intervention practices, specifically the effect on blood pressure control. I was visiting the practices throughout the implementation of the above policy changes, and clearly recall the numerous questions from practices about proteinuria, prescription of ACE inhibitors and ARBs, and GFR reporting, especially following introduction of the QOF domains. It is possible that my presence in the practices during the policy changes influenced the care that practice nurses gave to the patients. Care may have changed in the following ways:

1. More rigorous monitoring of microalbuminuria
2. More immediate prescription of ACE inhibitors/ARBs once microalbuminuria was found.
3. More aggressive prescription of ACE inhibitors/ARBs to achieve lower blood pressure targets.

It is difficult to find evidence that supports these assertions, although to some extent the QOF results for 2005/2006, 2006/2007 and 2007/2008 can be utilised to underpin these points. The QOF targets for diabetes are:

DM12: The percentage of patients with diabetes in whom the last blood pressure is 145/85 or less

DM13: The percentage of patients with diabetes who have a record of micro-albuminuria testing in the previous 15 months (exception reporting for patients with proteinuria)

DM14: The percentage of patients with diabetes with proteinuria or microalbuminuria who are treated with ACE inhibitors (or angiotensin receptor blockers)

Figures 7.6-7.8 show the QOF returns for the intervention and control practices.

Figure 7.6: QOF returns for DM 12: blood pressure less than 145/85 mm Hg

Surgery	2004/2005 (%)	2005/2006 (%)	2006/2007 (%)
1	100	100	100
2	100	100	100
3	100	100	100
4	100	100	100
5	100	100	100
6	100	100	100
7	100	100	100

Figure 7.7: QOF returns for DM 13: microalbuminuria testing

Surgery	2004/2005 (%)	2005/2006 (%)	2006/2007 (%)
1	76.6	84.4	81
2	100	100	100
3	72.1	100	100
4	100	100	100
5	91	100	100
6	67.5	79.6	81
7	100	100	100

Figure 7.8: QOF returns for DM 15: ACE inhibitor/ARB prescription

Surgery	2004/2005 (%)	2005/2006 (%)	2006/2007 (%)
1	100	100	100
2	100	100	100
3	100	100	100
4	100	100	100
5	100	100	100
6	100	100	100
7	100	100	100

In summary all practices were reaching QOF targets in blood pressure control and prescription of ACE inhibitors/ARBs in all three years of QOF returns shown here. There were some differences in microalbuminuria testing, although the control surgery was testing 100% of patients, even in 2004/2005. It can be assumed that the QOF policy changes stated above had the same effect on all practices, even the control which was not visited by me during the study period.

These data might still have to be interpreted with caution in light of the number of people who have been exception-reported for each of the domains, that is, the number of people for whom the target has not been applied. This is because patients with specific diseases can be excluded from the denominators of individual QOF indicators if the practice is unable to deliver recommended treatments to those patients (Health and Social Care Information Centre 2005). For example if the domain DM12 (number of people with BP <145/85 mm Hg) is scrutinised, then the percentage of people exception-reported is variable. Across all participating practices, the percentage of people exception-reported for DM12 in 2006/2007 is almost 20% (range 18-23%).

Even bearing this in mind, it is likely that the effect on blood pressure seen in the study is an effect that has been achieved by the education pack rather than the effect of my visiting the intervention practices. It was not possible at the outset of the study to predict the huge changes in national policy and publicity surrounding the management of kidney disease in primary care during the study period 2004-2009. If this had been known at the start an alternative method could have employed, such as a cluster randomised trial (CRT). Practices could be recruited as before, but randomised (at practice level) to the intervention or to usual practice. If data are collected by a non-clinician (not a renal nurse) or data are collected retrospectively, this will remove the possible researcher effect on clinicians which could result in tighter blood-pressure control in patients.

Recommendation for future research

For this study to be replicated as a cluster-randomised trial, ensuring that the professional staff (practice nurses and GPs) in the practices randomised to usual practice are not visited by a clinical researcher during the study. Intervention practices should only be visited for data collection and pack distribution.

7.3.4. Summary

The process by which people take on health care advice and then translate this advice into behaviour change is a very complex process, with several inter-connecting components. This can present a challenge for evaluation and also for the interpretation of any demonstrated effects. It can be difficult to establish what exactly the 'active ingredient' causing any such effect is, and, in this case, it may be that a number of variables contributed to the effect of reducing blood pressure.

It may be, for example, that patients did receive more knowledge about blood pressure tablets from the pack, which translated into improved adherence to their prescription. It may be that the effect of my visits to the intervention practices raised the profile of CKD management so that practice nurses were more vigilant with BP control. There is also the effect of national policy and the QOF incentivisation to consider.

It is clear that this intervention has had an effect, although it is not possible to identify the key variable that is responsible for the effect. It may be that a subtle combination of factors are responsible, which might be difficult to reproduce beyond the setting in which this intervention was undertaken.

7.4. Self-management initiatives in practice

It is important to evaluate the findings in the context of results from research studies that have been published since the start of this thesis.

7.4.1. Commentary on wider use of self-management education packages

The overall rationale for the study was that there were no published data or published evidence on the use of self-management packs for people with, or at risk of chronic kidney disease. Since the start of the study in 2004, there has been increasing interest in self-management, in terms of self-management techniques, self-management programmes and an increasing commentary on how health-care professionals can facilitate a self-management approach. This section will review the findings in light of recently published literature, and will discuss the ways in which self-management initiatives should be planned, implemented and evaluated.

7.4.2. Planning of self-management programmes and interventions

Although briefly discussed earlier, there are differences between the ways in which self-management programmes are organised and implemented. A systematic review on risk-reducing interventions as part of diabetes self-management (Boren et al. 2007) concluded that there are many multi-faceted self-management programmes which have been shown to produce clinically important benefits, but the "specific elements of the programme that produce these benefits are difficult to determine." (Boren el. 2007)(p.1075). Of the 33 studies that were reviewed, there were some commonly featured interventions, such as education and counselling sessions, and follow-up, reminders and feedback via telephone. There were also a variety of educational resources, such a booklets, letters, newsletters, videos and personal reports.

In the same review there were found to also be a variety of outcome measures, most commonly HbA1c (15 studies), cholesterol (10 studies), blood pressure (8 studies) and BMI (6 studies). 85% of the reviewed studies indicated that at least one outcome measure was significantly better in the intervention group than the control group. The main recommendation from this review was that there is some evidence for the beneficial effects of self-management interventions in diabetes, but future published studies should specify the content of the intervention, patient sample and materials used to ensure that findings can be compared with other similar projects. The review concluded that future research should focus on "diabetes risk reduction in areas where evidence is lacking, such as diabetic nephropathy...." (Boren et al. 2007)(p. 1075).

This present study implemented a self-management initiative that focussed on giving information that promoted the self-care ideology, rather than an intervention that emphasised behavioural and psychosocial strategies. These strategies are clearly important and a number of self-management programmes have drawn on social, cognitive and behavioural theories during their development (Barlow et al. 2002). As discussed before, it is difficult to extrapolate which aspect of a multi-faceted intervention is the most effective. For this study, one of the most crucial considerations in developing of the package was how far the intervention could be incorporated into 'real life', that is, an intervention that was not only clinically-effective but also cost-effective. As the Barlow et al (2002) review concluded, one of the major issues with individualised approaches involving one-to-one contact with health professionals relates to cost.

7.4.3. Methods to support implementation of self-management initiatives

It has been suggested that if self-management programmes and initiatives are to be successfully integrated into primary care, there needs to be a system put in place to support

this (Crespo and Shrewsberry 2007). In a study that evaluated the introduction of a self-management programme in four rural health centres, the health centres that fully implemented the self-management programmes made targeted efforts in organisational change. These efforts included a commitment to keep self-management on the agenda in management meetings, with clinical staff setting an example by adopting self-management behaviours themselves. They also implemented patient self-management support in multiple patient care venues.

In practice this means that the 'senior leaders' in GP practices need to commit to integrating self-management in their surgery, and that a core group of staff members might become self-management champions. Most importantly health care professionals need to be trained in self-management skills, and also be encouraged to employ self-management techniques themselves (Crespo and Shrewsberry 2007).

Practice recommendation

If self-management programmes are to be successfully implemented in primary care then each practice needs the support of the senior partner, learning opportunities in how to promote self-management skills for patients, and identification of 'self-management champions'.

7.4.3.1. Staff training

Training for staff in self-management techniques is recommended, as there sometimes may be a tension between a health-care professional's (paternalistic) approach to managing a long-term condition and an individual patient's aspiration for empowerment. Although it has been recognized as a critical linkage, the explicit impact of health care professional support on self-care management in chronic illness has attracted a relatively scant body of research (Thorne and Paterson 2001). As an example, there has been recent debate on health-care professionals' misunderstandings about the concept of self-management (Lau-Walker and Thompson 2009). Lau-Walker and Thompson (2009) suggest that effective patient self-management (self-efficacy) support from health-care professionals needs to address patients' confidence in their ability to manage specific activities rather than just convincing patients of the value of such activities.

For this present study, the relevance might be that it is not enough just to tell people of the importance of blood pressure control, but rather that their confidence in managing their own blood pressure needs to be assessed and discussed.

Some centres are beginning to evaluate their current capacity to support and implement consistent patient-centred self management practices (Brownson et al. 2007). The Primary Care Resources and Supports for Chronic Disease Self-Management (PCRS) instrument is a user-friendly self-assessment tool, and initial evaluation has indicated that the PCRS is applicable across different types of primary care teams and chronic illness conditions (Brownson et al. 2007).

7.5. Summary of recommendations

A number of recommendations from this study have been discussed, and these are now summarised.

7.5.1. Recommendations for practice

7.5.1.1. Recommendations for format and content of the self-management package

- To include supplementary information for health care professionals, explaining the aim, content and FAQs.
- To include an introductory paragraph that explains the benefits of self-care.
- To check suitability of font size and colour of written materials for older people.
- To check cultural appropriateness of the learning materials.
- To cater for a range of self-care abilities, from simple messages (eg. how many tablets to take each day) to complex interventions, such as monitoring and managing blood pressure.

7.5.1.2. Recommendations for MA screening and blood pressure management

Education programmes on CKD for primary care health-care professionals to focus on importance of annual MA screening to identify those with diabetes at risk, in order that timely prescribing of ACEi/ARBs can be initiated.

For practitioners to record blood pressure to the nearest 2 mmHg when using a manual sphygmomanometer and to record the exact reading when using an electronic device.

7.5.1.3. Recommendations for the implementation of self-management initiatives in primary care

Successful implementation is dependent on the support of the senior leader/partner in the practice and identification of 'self-management champions'.

Facilitator skills for empowering self-management techniques should be made available for health care professionals who care for people with diabetes mellitus.

7.5.2. Recommendations for further research

1. Further research is needed to explore the natural progression of microalbuminuria, especially whether male gender is a factor in progression of the condition.

2. A qualitative study that investigates how people might take the information in the self-management pack and use this to change their health behaviour is recommended. Semi-structured interviews with people who have received the pack could be undertaken. Interview topics could include baseline knowledge about risk of CKD, the aspects of the pack that were most useful and the behaviours that were altered as a result of the information received.

3. A study that aims to examine the effects/outcomes of using a home blood pressure machine is recommended.

4. Replication of the present study as a cluster-randomised trial is recommended.

7.6. Dissemination and spread

The findings of this study have important implications for people with diabetes at risk of kidney disease and the implications of disseminating this intervention to a wider audience will be considered.

The specific dissemination of the self-management package to the study and control practices, and to the local PCT will be discussed in Chapter 8 (the artefact). Although the

project has been developed locally, it is important to consider how it can be disseminated on a national level.

Dissemination (now termed spread) means taking the learning that has taken place and sharing it with other parts of the organisation, whilst sustainability can be defined as holding onto the improvements and evolving the improvements as required (NHS Institute for Innovation and Improvement 2007). The terms 'spread' and 'sustainability' are current terms commonly used in implementing improvement initiatives and have been defined in the NHS Sustainability Model published in 2003, and revised in 2007 (NHS Institute for Innovation and Improvement 2007). The NHS Sustainability Model consists of ten factors relating to process, staff and organisational issues that play a very important role in spreading and sustaining change in healthcare. See Figure 7.13.

This Model has been designed for use at a local project level and also for use at the beginning, during and at the end of a project. Although it could be argued that this thesis is a research project rather than a quality improvement initiative, the Model can act as a checklist to identify and understand key barriers to spread and sustainability.

The model used as a theoretical framework in Chapters 2 and 3, Silverman's (1970) action approach to organisations (Figure 7.9), complements the NHS Sustainability Model. Silverman (1970) asserted that change is dependent on the interrelationship of a number of factors, including the knowledge, attitudes and beliefs held by the wider society, by the organisational structure, as well as by individuals (patients and practitioners). Two of these categories are replicated by those of the NHS Sustainability Model, namely 'Staff' and 'Organisation'.

Figure 7.9: Silverman's (1970) action approach to organisations
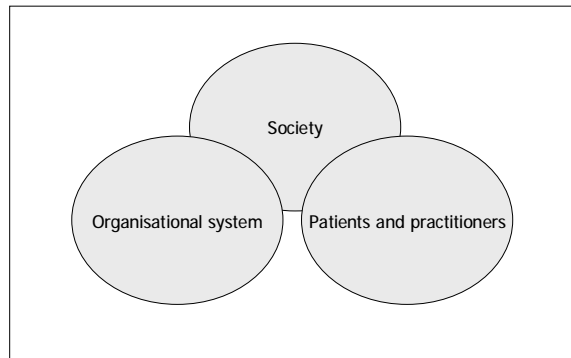
7.6.1. The Spread Acceleration Model

The Spread Acceleration Model (Fraser 2002) describes how any innovator needs to consider the way in which an idea can be implemented in areas that have not used it before. The key factors that must be considered when spreading an innovation are shown in Figure 7.10. Those factors identified with a **ü** are those which have been considered and supported by the innovation, that is, the self-management pack developed and tested in the present study. Those identified with a **û** are those which require further work.

Figure 7.10: Key factors for spread of self-management pack into clinical practice

Relative advantage ü

How clear and how much is this new idea/practice better then current situation?

Current lack of consistency for incorporating self-management initiatives into diabetes annual reviews

Compatibility û

How closely does new idea/practice reflect beliefs and values of adopter(s)?

Most practitioners support self-care philosophy in principle, but only some support in practice.

Complexity ü

How easy is it to understand the new practice/idea?

Self-management pack easy to use – see Chapter 8 for patient evaluation

Communicability û

How easily can it be shared with others?

Not shared with others at present

Observability û

How visible is the new practice or idea and its results?

Not visible at present

Trailability ü

How easy is it to test the new idea?

Already tested

Reversibility û

How easily can the adopter revert to the old ways?

New ways have not been implemented yet

Uncertainty û

How certain can an adopter be of positive results from the change?

Positive results need to be spread

Adapted from Fraser (2002) Accelerating the spread of good practice , Kingsham Press, Chichester, England

For the findings from this thesis to be adopted into usual practice it is crucial that attention is paid to 'communicability' and 'observability' factors. One way in which these findings can be communicated and made visible on a wider scale is through conference presentations and journal publications.

Appendix 10 shows relevant presentations and publications related to the study's method and findings. For this study, it was important to not only disseminate the research findings via conference presentations and journal publications, but to communicate the findings to the practice nurses and GPs who would not usually attend these events or read these publications.

There is often a tension between spreading the findings to an academic community and spreading the findings to those who are caring for people who are affected by the results. For me, both arenas are equally important.

7.6.2. Study findings and translation into national programmes and initiatives

Since the study began, I have been involved in a number of national initiatives that aim to improve the care and management of people with early CKD in primary care. These initiatives have developed as a direct and also indirect result of the findings. These initiatives can be broadly divided into the areas of patient empowerment and also education of health professionals.

7.6.3. Patient empowerment

Since March 2007 I have worked as the project co-ordinator for the Quality Improvement in CKD study (QICKD), a Health-Foundation funded study, which is due to be completed in March 2010. One of the interventions focuses on patient empowerment and my thesis findings have contributed to shaping this intervention.

A multi-disciplinary expert group was formed to develop the intervention, including patients, primary care staff, experts in self-care and renal healthcare professionals. There was a high degree of concordance of aims and objectives within the group, who worked exceptionally well together, motivated by a shared commitment to enhance patient empowerment in CKD. In terms of defining the intervention, research around initiatives underway in other disease areas, such as diabetes, was examined, including the findings from the present study.

A package of different tools has been developed for this empowerment programme aimed at people with stage 3b CKD and is being tested in a large GP practice. Tools include a self-efficacy questionnaire (measures patient confidence in self management) and a patient concerns sheet (on which patients set out their concerns). These will be used to establish a baseline before an empowerment programme begins.

Subsequently, patients are provided with information in the form of 'Frequently Asked Questions' (FAQs) and a DVD. A care plan will be completed in partnership with the health care professionals. There will also be a group education session for patients. Crucially the practice nurses facilitating the empowerment approach needed to be taught not only how to manage and care for people with CKD, but also, how to empower people to manage their condition. Therefore a separate part of the intervention focuses on the healthcare professionals themselves and I am giving them education sessions about CKD. Group facilitation skills training is also being carried out.

Evaluation will be via a post self-efficacy questionnaire to help establish any interim and longer-term changes. There will also be a questionnaire about the group sessions to determine the effectiveness of the sessions and a staff questionnaire to find out about the success of the new service development (used in conjunction with the confidence questionnaire).

7.6.4. Education of health care professionals

I am the Chair of the CKD Forum, a project group of the British Renal Society. The main aim of the Forum is to provide leading-edge professional development and education in early CKD for health care professionals. Some activities of this Forum have been shaped by my PhD study findings, specifically the finding that patients need more information about CKD and also need to be taught about opportunities for self-management.

7.6.5. Collaboration with the DH Kidney Care team

The CKD Forum was contacted by the Kidney Care team at the Department of Health to see if Forum members could collaborate with, and contribute to, two special issue journals on CKD, for health care professionals working in primary care. The Journals are the British Journal of Primary Care Nursing (BJPCN) and the Primary Care Cardiovascular Journal (PCCJ), and they have a joint circulation of 25000 readers.

The Editor of the BJPCN said

"I want to thank the Renal Tsar, Dr Donal O'Donoghue, and NHS Kidney Care, led by Beverley Matthews, for recognising the importance of practice nurses in improving the detection and management of CKD in primary care and supporting this special issue of BJPCN. Thanks also to the members of the CKD Forum who have very willingly (even gladly!) given their time and writing skills to ensure that the articles in this issue are absolutely on target to help us improve the primary care management of CKD throughout the UK." (BJPCN 2009, Special Issue on CKD, p. 5)

An article on self-management in this issue was included as a direct result of the thesis findings. A summary of the interview findings was also included in the 'Evidence in Practice' section. An information sheet for patients was also devised (see Appendix 11 for all these publications).

7.6.6.   Development of learning resources: ckdonline

As there has been tremendous change to the management of CKD in primary care since 2005, the CKD Forum wanted to find out the impact of the introduction of national and local CKD Guidelines. In Spring 2007, 10,000 questionnaires were sent to GPs in each of the ten Strategic Health Authorities in England, and it was hoped that the findings would help shape the CKD Forum's future strategy and educational philosophy.

A two-page questionnaire asked them for their opinions on the eGFR, the Quality and Outcomes Framework (QOF) and management of CKD. The results shown below are from the questionnaires that were returned in Summer 2007. It is possible that views of GPs might have changed in the intervening period, especially since there have been further amendments to the QOF and publication of NICE guidance for CKD since then.

The return of the questionnaire on a single mail shot was 15 % (approximately 1500 returns). There were a number of interesting findings. Those most relevant to this thesis were those concerning proteinuria and blood pressure control. A large percentage of respondents had poor understanding of the difference between albumin:creatinine ratios (ACRs) and protein:creatinine ratios (PCRs) to quantify proteinuria. Over 60% strongly agreed with the statement that "I find the distinction between ACRs and PCRs confusing." With regards blood pressure control, almost 70% responded that they found a blood pressure target of < 130/80 mmHg in people over 70 years old unrealistic.

The GPs were asked about their own education and it was found that only 50% of GPs felt

that they had had sufficient education about CKD. In terms of ongoing education the majority would prefer local half days (38%), local evening sessions (30%) or online material (29%) as opposed to national meetings (3%). The overwhelming majority would prefer this to be given by the local nephrologists and specialist nursing staff. See Figure 7.11.

Figure 7.11: Results of GP survey: where/how education on CKD should be delivered
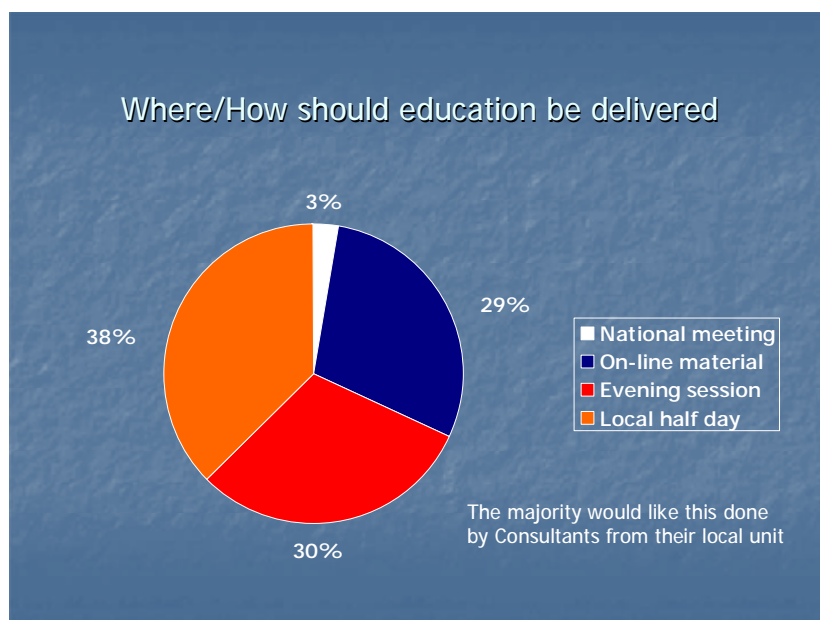
7.6.7.   Development of an on-line learning module

As a result of the questionnaire findings, the CKD Forum went about developing an on-line resource to supplement education provided by renal units to local primary care teams. The development was undertaken in collaboration with OCB Media, based at the University of Leicester. This company runs medical educational activities, provides multimedia production services and specialises in e-learning development.

The module is called *Chronic kidney disease - a guide for primary care* and is available at www.CKDonline.org. Content of the module is shown in Figure 7.12, and was developed as a result of the questionnaire findings which showed that greater understanding of eGFR, CKD progression, proteinuria, and *information for patients* was warranted. The section on how to inform and educate patients was included as a direct result of the findings from this thesis.

<u>Figure 7.12: Content of on-line learning module</u>

- CKD - Why it has become an important issue

- Causes of CKD

- Medicines Management

- Management of hypertension

- Nutrition

- What to tell patients *including self-management opportunities*

- Primary care

- Issues for the future

I wrote the section on 'what to tell patients' and the learning objectives for this section were:

- To identify the main points to convey to patients when first diagnosed with CKD

- To review the ways in which self-management of CKD can be promoted

- To identify and evaluate a variety of patient learning materials for CKD

Each section is presented in an easy to use and engaging manner, populated throughout with illustrations and videos and underpinned with a cross-referenced glossary. There are multiple choice questions (MCQs) included after each section to review the learning that has taken place.

This resource is free to use as a reference tool, however, different levels of educational training certificates are available for a small administration fee. The on-line resource was launched at the end of 2008, and efforts are being made to advertise the modules to primary care. The website is recording the number of hits that have been made to the site, and asks respondents to provide feedback after completion. By March 2009 (three months after launch) there were 539 registered users, with 327 visits to the site in one month. In August 2009 there were 300 visits to the site, with 67% of those visiting the site for the first time. An advertising flyer is shown in Appendix 12.

7.6.8.   Other publications and presentations to primary care professionals

I was commissioned to write the following article:

Thomas, N (2009) Diabetes and CKD: what does the new NICE guidance say?
Journal of Diabetes Nursing, 13, 4, p126-136.

I included a section on the opportunities for people with chronic kidney disease (CKD) to exercise self-management. See Appendix 13.

I was asked to contribute to the on-line NHS Choices resource. NHS Choices is a Department of Health website where people can find out about medical services, medical advice for specific conditions, topical news stories and what to do (such as pandemic flu) and most importantly how people can help themselves to manage their conditions or concerns. The CKD section was being updated in 2007/8 and I worked with a medical writer to write some 'questions to ask' for people with early kidney disease. I also recorded a film for the site and this can be found at
http://www.nhs.uk/conditions/Kidney-disease-chronic/Pages/Introduction.aspx

In addition I am asked frequently asked to contribute to continuing professional development activities external to City University. With regards teaching, I have recently provided education sessions on early CKD to St Georges University of London, University of Warwick and Southmead Hospital, Bristol. I have also been asked to update care managers employed by NHS Direct on managing people with CKD. I was invited to present a 45 minute session at the *Primary Care Live* exhibition and conference in October 2009. In all these sessions I have included discussions on 'what to tell patients' and have identified 'self-management opportunities'. I frequently describe direct quotes from the interviews undertaken from this thesis to illustrate my points.

7.7.   Sustainability

The Sustainability Model identifies factors that can influence sustainability, and includes process, staff and organisational factors, see Figure 7.13.

Figure 7.13: The NHS Sustainability Model
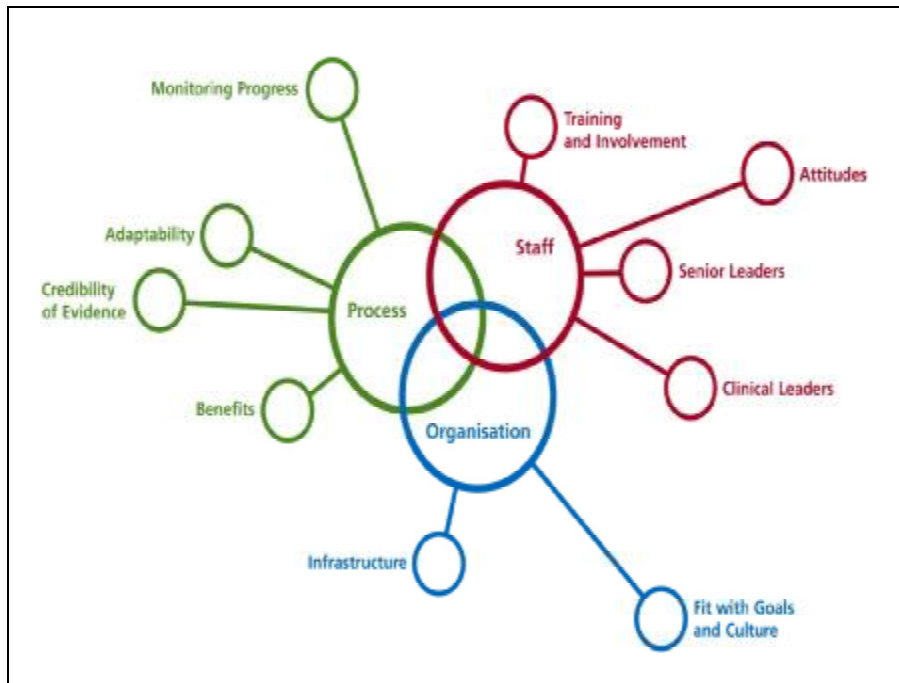
©NHS Institute for Innovation and Improvement 2006

For the self-management pack to be successfully implemented and sustained, the following specific factors need to be considered in the participating practices and in the local PCT.

7.7.1. Staff

Staff factors that need consideration include staff training (how to identify who would benefit from a pack/how to distribute the pack during a usual consultation), staff attitudes to sustaining the improvement, and senior leadership engagement.

7.7.2. Process

Factors concerning process include identifying the benefits of using the pack and assessing the credibility of those benefits. Also how easy it is to adapt to the process of pack distribution and how effective is the system that has been put in place to monitor the results.

7.7.3. Organisation

Issues that require consideration are how far the change fits with organisation's strategic aims and culture, and whether there is an infrastructure for sustainability in place. All of these issues will be discussed in more detail in Chapter 8.

7.8. My reflection on the research process

7.8.1. Relationship with practices

At the start of the study I was not familiar with the workings of primary care. I was naïve about how people with long-term conditions were managed, such as timings of clinics, management templates, patient education initiatives, the QOF and the system for recall of non-attendees. I did not understand the role of the practice nurse, and the working relationships between practice nurses and GPs. As described in Chapter 2 these issues became the main aims of the case study, so were subsequently resolved during the period of participant observation in 2004.

Although these practice issues were resolved there remained some misunderstanding at the outset about my role in the participating practices, partly because I had not thought through the boundaries of being a practitioner-researcher (Meyer et al. 2003). On reflection, my naivety in both the complexities of primary care teams, and also my role as a researcher, led to the misunderstandings. I was insecure in both the role of researcher and the context of the research environment, so probably clung to what I knew best, that is, my role as a specialist renal nurse. When I first began to visit the six participating practices, I introduced myself as a renal nurse (not researcher), and emphasised my experience in managing people with chronic kidney disease. Whilst observing consultations with patients, the practice nurses and GPs would sometimes ask my opinion, and occasionally would ask me to explain renal issues directly to the patient. This was within my comfort zone, and I willingly gave of my expertise. Sometimes the practice nurses would telephone me to discuss referral of patients to the renal unit, and again I was very willing to support them.

7.8.2. Ethical issues

Having expert knowledge can have both benefits and disadvantages. Although there is a possibility for ethical issues to be raised when a researcher becomes involved in patient care, researcher involvement can lead to a therapeutic interaction for the participant (Eide and Kahn 2008) as described above. However these potential benefits for the patient have to be balanced with possible detrimental effects on the research process. As discussed in Chapter 4, my ingrained clinical knowledge could have posed a threat to identifying the true patient perspective, as my clinical knowledge was deep-rooted and often subconscious and intuitive (Wilson and Wilson 2008).

Whilst the difficulties of being involved in patient care are recognised, participation can bring about change in the researcher bringing out new observation, while this new observation in turn can change how the researcher participates (Bailey 2007). In other words, being involved in care can produce serendipitous findings that would not have necessarily evolved if the observation period had been truly non-participatory.

An example was when I was observing a consultation between a lady and her husband and a practice nurse. The patient was having difficulties in understanding one aspect of dietary advice. It appeared that she had been given conflicting messages about eating fruit and vegetables, and I was asked directly if I could help clarify the advice. On gentle questioning it transpired that she had been referred to a renal dietitian, who had given the advice (rightly or wrongly) on reducing fresh fruit intake, because of rising serum potassium levels. Although I am not sure that I was able to advise the patient successfully, it starkly demonstrated to me the importance of giving consistent advice to patients. Inconsistent advice leads to uncertainty and less possibility for control and empowerment (Lowery and Ducette 1976).

On balance I think that my participation in the 'non-participation' observation period did allow a better working relationship with the practice nurses, who valued my advice and support in times of changing CKD practice and management. Although my interactions with practice nurses and patients may have gone some way to influence the mean reductions in BP found in the participating practices, it would never have been possible to differentiate those influences from the effects of the intervention.

As the study moved on, I became more comfortable in my researcher role, and when the time came for me to end my secondment with the local renal unit, I was ready to relinquish my 'specialist nurse' persona. Today I am still struggling with my insecurity as a non-clinical nurse, but I have grown in my role as researcher. The doctoral journey has been so very enjoyable and rewarding, and has contributed enormously to my personal and professional development.

7.8.3. <u>Challenges of undertaking a part-time Doctorate</u>

To date the Doctorate has taken five and a half part-time years. During this time my employment has changed a number of times, although my main base has continued at City University. At the start of my Doctorate in February 2004, I was employed on a secondment within a hospital trust. Three years into the study, I returned to City University three days per week. In April 2007 I secured another secondment opportunity to Kidney Research UK, a charity based in Peterborough, to work as a project co-ordinator for two days per week on a

national Quality Improvement project, funded by the Health Foundation. This work has given me the opportunity to work within a multi-professional research team based within another academic institution, a hospital trust and a charity.

My research funding continued for most of the project from June 2004 to November 2008, and covered my salary for one day per week. Additionally during this time I have carried out external consultancy to a number of hospital Trusts, academic institutions and pharmaceutical companies.

Although it might have been more comfortable for me to have stayed within the hospital trust for the duration of the Doctorate, in retrospect, the growth in my academic maturity might have been curtailed if this had been the case. The benefits of working within a multi-professional research environment, as within the Kidney Research UK team, cannot be underestimated. Within this team I have learnt to appreciate wider ethical issues, the economics of undertaking research, aspects of project management and the difficulties associated with multi-site working. Most importantly I have been the opportunity to make national and international contacts in the subject area of self-management, and already have had opportunities to apply for further research funding.

7.9.   Chapter summary

This chapter has analysed the findings set within a context of recent published literature. The chapter discussed the possible shortcomings of the method, which included the challenges of distributing the intervention in order to power the study and the quality of the data such as end-digit preference in blood pressure recordings.

The discussion on the use of self-management initiatives in practice suggested that the implications of the study could be replicated for other long-term conditions, although the simple action of self-management pack distribution needs to be accompanied by a commitment to a self-care ideology. A culture change from a passive, to an active self-care philosophy, requires the support of 'self-care champions' and lead clinicians responsible for diabetes practice.

The main implication of the study is that there is a place for implementing self-management packages or programmes in primary care for people with diabetes mellitus at risk of kidney damage. The study has shown that the main outcome measure, mean systolic blood pressure, can be reduced to a level near to that recommended by the National Institute for Health and Clinical Excellence (2008).

The main recommendation for practice is that there are parts of the self-management pack that need to be amended prior to further dissemination.

The main recommendations for further research are twofold. First, the undertaking of a qualitative study, which investigates how people might take the information in the self-management pack and use this to change their health behaviour. In other words assessing the problem-solving and decision-making skills that enable a person to apply new information in order to function successfully as a health-care consumer (health literacy)(Nath 2007).

Secondly, that replication of this study as a cluster-randomised trial (to remove researcher bias) is undertaken.

8. THE ARTEFACT

8.1. Introduction

A requirement of this thesis has been to develop an 'artefact'. The artefact is the final version of the self-management package that has been developed, tested and evaluated as the study has progressed. This thesis has described each of these stages, and a summary is now included.

8.2. Summary of artefact development

The self-management package was developed for and with patients. The development of the pack was informed by the observations made during the case study visits to GP practices, the findings of the literature review and the interviews with people who have diabetes and were at high risk of progression of CKD. The pack contains a variety of educational learning materials (written information, 20 minute DVD, a fridge magnet (with key messages), a monitoring diary and a blood pressure machine (if required), the aim being to cater for different people with a variety of learning styles.

8.2.1. Summary of how the artefact was tested

Testing of the package was undertaken in six GP practices, with one additional control practice. Patients with Type 1 or Type 2 diabetes at risk of kidney disease (defined by the presence of microalbuminuria) were included. Data on renal function (serum creatinine, eGFR and proteinuria) systolic and diastolic blood pressure, glycated haemoglobin (HbA1c), body mass index (BMI) and smoking status were collected at six time points: before, during and after the intervention. Outcomes in patients in the participating surgeries who did receive a pack (n=116) were compared with patients in the control group (n=61).

8.2.2. Results of the testing phase

At time point 4 mean systolic BP in the intervention group was 129.2 ± 19.2 mmHg vs. 134.6 ± 15.0 mmHg in the control group (p=0.057). At time point 5 there was mild significance (p=0.053) in mean diastolic BP. At the end of the study (time point 6) the intervention group had a mean systolic BP of 132.1 ± 14.2 mmHg vs. 136.2 ± 16.4 mmHg and mean diastolic BP of 74.9 ± 8.5 mmHg vs. 77.6 ± 9.1mmHg in the control group (p=ns). There were no significant differences in HbA1c and BMI at any time period.

The main focus of this chapter is to explain how the self-management package was evaluated at the end of the study by users and professionals, and how their comments were used to amend the package prior to final dissemination.

8.3. Evaluation of artefact and subsequent changes made

It was important to gain a qualitative understanding of whether people were able to understand the content of the pack, whether they found the pack useful, and whether they took the messages from the pack and changed their behaviour as a consequence.

The original aim was to evaluate the pack (content, ease of understanding, usefulness) in four ways:

1. Ongoing feedback from patients: Each pack contained a feedback form that gave my contact number and address. I requested that if anyone had questions or comments they were to contact me directly.

2. Post-study feedback from patients: Through a short questionnaire sent by post to 15 people who had received the pack, and by 3 face-to-face interviews.

3. Post-study feedback from practice nurses.

4. Post-study update of educational resources that may have changed as a result of national policy/guidance.

8.3.1. <u>Ongoing feedback</u>

Of the 116 packs that were distributed only two people contacted me with questions. Of course it is possible that other questions were asked of the primary care practitioners and were answered face-to-face during consultations, although practice nurses did not report that this was the case when questioned.

One question concerned the use of blood glucose monitors and the need for monitoring in people with Type 2 diabetes. One man telephoned me and asked whether it was necessary for people with Type 2 diabetes on tablets to monitor their blood glucose at home. Unfortunately this was at the same time period at which there had been local and national

debate about the use of self-monitoring of blood glucose (SMBG) in people with Type 2 diabetes. At the time of the enquiry (July 2007) the Diabetes UK website stated that

> *"People with Type 1 and Type 2 diabetes should have access to self-monitoring of blood glucose (SMBG) based on individual clinical need, type of diabetes, personal circumstances and informed consent - not on ability to pay. 95 per cent of diabetes care is self-care."*

At the same time the website was also carrying a 'news item' on a recently published study. This study (Farmer et al. 2007) concluded that there was no convincing evidence of an effect of self monitoring blood glucose, with or without instruction, in improving glycaemic control compared with usual care, in reasonably well controlled non-insulin treated patients with Type 2 diabetes.

The local PCT at that time had recently sent guidance to GP practices which stated that people with diabetes, not treated with insulin, should not be recommended to undertake SMBG, presumably because of lack of evidence and also cost. This was a confusing picture for this one particular patient, and he had therefore sought clarification. The issue was not easily resolved despite my contact with the patient's GP, who told me that the health care professionals themselves were uneasy about the PCT's decision. I contacted the patient again and told him that I have been advised by his GP that SMBG was not necessary for people with diabetes controlled on oral medication.

In my opinion this was an unsatisfactory outcome but unfortunately I was not in a position to question the PCT decision. Since 2007, the issue of SMBG in people with Type 2 diabetes is still attracting debate over the evidence base (Welschen et al. 2005) and also the cost (Belsey et al. 2009), with mean national expenditure on home BGM being £73.64 per patient per year. The current position statement from Diabetes UK on SMBG (Diabetes UK 2006), states that people with Type 2 diabetes who control their condition with healthy eating, physical activity and with or without oral medication, should have their glycaemic control monitored through regular HbA1c testing based on NICE (2002) guidelines. However the position statement also specifies that   "people with diabetes who prefer to monitor their blood glucose to proactively review and inform lifestyle changes should be able to do so."

For the purposes of this self-management package, the advice on SMBG needs to be made more explicit, with further information on the evidence/cost debate and Diabetes UK guidance.

Another patient enquired whether the troublesome tickly cough that he was experiencing might be due to the BP medication (ramipril) that he was taking. I confirmed that this might be likely but that he should visit his GP for advice and assessment.

In summary, the opportunity for patients to contact me about the pack did not produce many questions although the query about SMBG did raise a pertinent debate, which has alerted me to provide more information on this in the artefact.

8.3.2. Post-study feedback from patients

8.3.2.1. Questionnaire

At the end of the distribution period, it was planned that a small number of people who had received the pack would help me to evaluate the contents of the pack for ease of understanding. The original study protocol stated that evaluation of the pack would be carried out with 15 patients and a short questionnaire (see Appendix 14) was developed. The aim was to find out whether they understood the content of the pack and whether they could make any recommendations for improvement.

Patients were randomly selected from the 116 who had received the pack and then it was checked with practice nurses in the participating practices that these patients were not acutely unwell or suffering any sort of life crisis. Questionnaires were distributed by post and if not returned within three weeks people were sent a reminder.

I received only 5 replies despite the reminders. The results are shown in Figure 8.1.

Figure 8.1: Summary of patient replies to evaluation questionnaire

Patient number	Did you look at the pack?	How soon after receiving did you look at it?	Which parts did you look at?	Which parts were most useful?	Was there anything you did not understand?	Any further suggestions or comments?
1	Yes	One week	DVD	"Nothing said that I did not know already"	No	"Everyone sounded most miserable and down-beat about it all"
2	"I do not recall receiving a pack"					
3	Yes	Immediately	All	"DVD reminded me what I needed to do. The fridge magnet least useful."	No	No recommendations
4	Yes	Within one week	All except DVD	"DVD was fiddly and required too much effort – no compelling reason to watch"	No	No recommendations
5	Yes	Immediately	All	All	No	

Because of the small number of respondents, and subsequent small amount of qualitative data, it was recommended by my first supervisor to undertake 3 face-to-face semi-structured interviews with patients, to elicit further in-depth evaluation.

8.3.2.2. Interviews

Three patients who had received the pack were randomly selected from one practice, and agreed to meet me at a forthcoming diabetes clinic. The semi-structured interview was based on the questions in the paper questionnaire. Two men (one white man aged 77 years and one Asian man aged 66 years) and one woman (white, aged 64 years) were interviewed.

During the interview with the female patient I made some notes. This became a little problematic as she talked quite quickly and I was not confident that I was able to capture all her thoughts and recommendations. Subsequently both interviews with the male interviewees were taped, with their permission. Figure 8.2 shows a summary of the interview findings.

Figure 8.2: Summary of post-study interview findings

Patient number	Did you look at the pack?	How soon after receiving did you look at it?	Which parts did you look at?	Which parts were most useful?	Was there anything you did not understand?	Any further suggestions or comments?
1. Female	Yes	Immediately	All of it	DVD	No	Good to keep everything in a box
2. Male	Yes	A few days later	Could not get the DVD to work on my computer	Written information	No	Elaborate on how serious diabetes can be
3. Male	Yes	Straight away	All of it with my wife	I do not use the book (monitoring diary) as my machine records it (blood sugar) all	Everything to me is OK	Nothing to improve

Some of the comments from the interviews are now described in detail.

NT: Which bits of the pack were most useful?

"I have always been a big reader, so I like the written information. If you see a film you can miss bits, so I would always prefer the piece of paper."

"The bit about BP control, I took note of that. My BP is always high so that was very interesting."

NT: Would you find it useful to have a BP machine at home?
"Not really. I know it is high......so if it high, what can you do about it, apart from taking the tablets?"

NT: What about the fridge magnet?
"Well it is still on my fridge! I do glance at it, but it is a bit gimmicky I suppose!"

NT: Was there anything that was not in layman's language that you did not understand?
"Not that I can remember – it all seemed fine."

I asked some additional questions based on the comments received from the questionnaire. I was concerned that some parts of the DVD might be distressing.

NT: Did you find the DVD depressing?
No, not at all!
NT: What about the part which shows people on the kidney machine?
No I did not find that at all, everything was perfect. I understood what it meant, and what that bit meant to say.

NT: Do you remember the bit about the dialysis machines? Was it frightening?
I don't think it was frightening at all....you should tell people the worst that can happen.

NT: I was thinking about putting the DVD on-line. Would you be able to access it?
"Well I go to the library to access my emails. I don't have a phone line at home."

NT: Did you do anything differently after looking at the pack?
"I did not realise how important the monitoring of the diabetes and also the blood pressure was, for kidney damage. But apart from taking the tablets then I'm not sure what I can do about that."

"I am quite pleased with myself as I've given up smoking now."

NT: Is there anything else you can recommend for me to change in the pack?

"You could elaborate on the seriousness of it all. People don't realise how important it is."

8.3.3. Post-study feedback from practice nurses

I visited 5 out of the 6 practice nurses in the participating surgeries in the beginning of 2008. The practice nurse in practice 4 had recently left and a replacement had not yet been employed. I asked them about their experiences of distributing the pack, and for any suggestions they might have for improving the pack.

I have categorised their comments into themes, namely, ease of distribution, evaluation of developed resources and ideas for dissemination.

8.3.3.1. Ease of distribution

Overall none of the practice nurses found it difficult to incorporate the pack distribution into a usual consultation. The obtaining of the consent took time, but this of course will not be necessary in the future if it becomes part of usual practice. None of the nurses could remember if they had been asked to clarify or explain any of the information in the pack. Two practice nurses commented that the box that contained the resources was very useful, as the contents did not become damaged and the packs were easy to store and locate when required.

8.3.3.2. Evaluation of developed resources

All the nurses thought it necessary to have a variety of resources to cater for a variety of learning styles and varying levels of required information. One practice nurse particularly liked the 'key messages' on the fridge magnet, and suggested it was important to keep the overall message simple. One practice nurse suggested that the leaflet should have the key message on the first page: "Are you at risk? If so, what can you do about it?"

Two practice nurses said that the DVD was too long for some people to sit through, although recognised that some individuals required that level of knowledge.

8.3.3.3. Ideas for dissemination

All the practice nurses were enthusiastic about having a range of resources to help inform people about CKD. Ways in which they could continue to have access to these resources included:

- Having a (master) paper copy that could be photocopied
- Uploading the DVD to a well-recognised and easily accessed website, such as Diabetes UK. The website link could then be incorporated into the written information.
- Writing an article for the Diabetes UK patient magazine to reach a wider audience.

Other issues included continuing education of practice nurses and GPs about CKD, including suggestions about when to start giving information about self-management of CKD. There was also a suggestion that the practice computer database could be searched to identify people with CKD and microalbuminuria and each identified patient record flagged to ensure that the self-management pack/resources are given when the patient attends clinic.

8.3.4. Post-study update of national guidance that has affected pack content

In 2008 the NHS published specific guidance for the development of patient information materials (Department of Health Branding Team 2008). This guidance includes recommendations for writing style (writing from patient's point of view and use of everyday language) and optimum engagement. Other pertinent recommendations include advice on

- Short sentences: in general, no more than 15 to 20 words long.
- Lowercase letters: are easier to read, although uppercase is always required for the first letters of names and sentences.
- Question and answer format: will help divide up your text.
- Bulleted or numbered points: will help to break down complicated information, and will help patients to digest it.
- Small blocks of text: long paragraphs can look daunting on the page; use headings and paragraph breaks to divide your information up.
- Large bold font: very useful for highlighting and emphasising text, whereas uppercase letters, italics and underlining can make text more difficult to read.
- Font size of at least 12 point (14 point for older people)
- Use Frutiger Roman for professionally produced materials. If this is not available, use Arial instead.

- For the best print contrast, set dark print against a light background.

'Your health, your way - a guide to long term conditions and self care' (Department of Health 2008b) was launched on NHS Choices on 2 November 2008, setting out the support that patients should expect to receive from their Primary Care Trusts and local authorities. 'Your health, your way' is not new policy, but draws together all the strands of work and information that already exist.

The core aims are to empower and support people with long term conditions to understand their own needs and be able to make an informed choice about the self care support they wish to access from the resources available. Five key areas of self care have been identified to achieve these aims. These are:

1. Information
2. Skills and knowledge training
3. Tools and self-monitoring devices
4. Healthy lifestyle choices
5. Support networks

This artefact provides information on a long-term condition and healthy lifestyle, and also ways in which individuals can self-monitor. It does not overtly provide skills for self-management, or provide support networks, so a recommendation is that health care professionals involved in the subsequent use of the artefact provide opportunities for individuals to acquire these skills.

Partly as a result of this DH initiative, the NHS Kidney Care team launched the 'Kidney Care Plan' in March 2009. Every adult patient with chronic kidney disease will now be given a personal folder, 'My Kidney Care Plan'. The Plan is to 'help you get involved in your own care by helping you to think about the things that are important to you.' People with CKD will be able to use the Plan to discuss in detail their needs and concerns with a specialist nurse or other trained member of their kidney team and keep notes in their folder. The care plan folder shows examples of topics that people with kidney disease may wish to talk about during a consultation or care planning meeting. Examples are food and drink, my blood test results, my kidney disease. There is an insert which has the heading "I would like to talk about...."

As there is overlapping content with the Kidney Care Plan and this artefact, it is important that the two resources are compatible, especially as the Care Plan will have a national implementation plan. Although the Care Plan has only been piloted with people who have already been referred to a renal team, there are possibilities for it to be used by people with early CKD. As a consequence, it is possible that some parts of the Kidney Care Plan could be incorporated into this artefact.

During the study period 2004-2009, there was one change to guidance on blood pressure targets. This came as a result of NICE (2008) recommendations for the management of CKD in primary care. The blood pressure target recommended for people with diabetes and CKD is now 130/80 mmHg, compared with 135/75 mmHg at the start of the study (NICE, 2002).

As a result the BP targets contained within the written information and DVD had to be amended.

8.4. Overall changes to design of pack as result of thesis findings

There were a number of recommendations that arose from the findings and discussion chapters in this thesis. Firstly the structure of the pack will be changed to cater for requests for differing amounts of information. This will mean inclusion of three different pamphlets within the pack, rather than just one. These are: key messages, benefits of self-care and further information. Key messages will also be further highlighted within the DVD, with changes made to the opening sequence.

The importance and possible benefits of self-care were highlighted as not receiving enough emphasis, so this is the reason for supplementary information. The different ways in which men and women take on health-care advice has been reviewed. It appears important that women are given encouragement to believe that self-care strategies do work – another reason for including more encouraging text on the benefits of self-care. For men, consistency of message appears important to enable good control of their condition. Consistency of message across all learning materials has been checked.

The cultural appropriateness of the materials has been checked, and studies (Sanders Thompson et al. 2008, Schouten et al. 2006) that have recommended strategies to enhance cultural issues have been reviewed, and recommendations incorporated.

The suitability of the font size/font colour of the written information for older people has been checked against national guidance (Department of Health Branding Team 2008), and subsequently amended.

Further information about self-monitoring of blood glucose has been included. Information about medicines (ACEis and ARBs) now contains further information about harm and benefit, especially adverse effects that could arise (Raynor et al. 2007). Recently published NICE guidance (National Institute for Health and Clinical Excellence 2009) on medicines adherence has been reviewed and recommendations have been incorporated. These include a clear explanation of what the medicine is and likely benefits; possible side-effects; a suggestion where patients might find reliable information after a consultation, such as on the NHS Choices website.

8.4.1. Detailed changes to self-management pack

Figure 8.3 shows the specific changes that have been made to the self-management pack. The final version of the pack is contained in Appendix B.

Figure 8.3: Specific changes made to self-management pack

Learning material	Overall Presentation	Format	Content	Available media
Box	No change		Include background information for health-care professionals	
Written information	Change from one A5 folded sheet, to three A5 sheets/booklet	Change font size to Arial 14 point and include more bullet points rather than text. Change text to question and answer format	Key Messages As before except for BP target, and include questions: Are you at risk? If so, what can you do about it? Self-care • Benefits • Questions to ask Further information • Kidney disease • Screening • Blood Pressure 　Ways it can be controlled 　Side effects of medication 　Blood pressure machines • Blood sugar monitoring 　especially in Type 2 diabetes • Lifestyle • What can happen	Paper On-line *Seeking permission to include on NHS Choices website*
Film	No change	Change opening sequence to include key messages	BP target changed from 135/75 to 130/80 mmHg	DVD On-line *Seeking permission to include on NHS Choices website*
Fridge magnet	Not included in final version	Content added to written information	BP target changed from 135/75 to 130/80 mmHg	
Monitoring diary	Not included in final version	Recommendations for monitoring added to written information		
Blood pressure machine	Not included in final version	Recommendations for buying a BP machine added to written information		

8.5. Dissemination

8.5.1. <u>Local dissemination</u>

Communication with the six intervention practices has been ongoing throughout the study. In each practice there has been one named contact person, usually the most senior practice nurse or nurse practitioner in the practice. During the data collection and intervention periods I formally communicated with the practices every three months by letter (sent by post). It was important to ensure written communication with one named person during the duration of the study as sometimes, when I visited the practice, the named contact was not present. I asked the named contact to ensure that information was communicated to other key practice staff for the entire study period. In all practices except one, I had the same named contact for the duration of the study.

At the start of the study my letter updated the practices on the aims of the study, the different phases of the study, and when to expect my visits. I also communicated details such as what was expected of the practice, what exactly would be carried out, such as length of time spent in the practice with patients, and what would happen next. I always ensured that they were comfortable with the amount of feedback from me and what was expected of them.

After the end of the pack distribution period (October 2007) I visited the practices once more, at the last data collection period in January 2008. Since then, I have communicated by letter only: once in September 2008 and again in June 2009 to inform them of the results.

In September 2008 I sent them a copy of the paper that had been published in the Journal of Renal Care (see Appendix 16), outlining the development of the package. In June 2009 I wrote to the practices for the final time explaining my results. I also requested that they contact me if they had immediate questions, and subsequently visited each practice in September 2009 to give a formal thank-you for all their assistance and to distribute 30 copies of the amended self-management pack (DVD and written information only).

8.5.1.1. <u>Sustainability</u>

In Chapter 7 there was a discussion about how far this artefact could be sustainable, and a check-list for sustainability was identified (NHS Institute for Innovation and Improvement 2007). There now follows a discussion about the recommendations for sustaining the incorporation of the artefact into the participating surgeries and in the local PCT.

Attention needs to be paid to the process of incorporating the artefact into everyday practice. This includes convincing the practice nurses and GPs in participating practices of the benefits of using the artefact, beyond helping patients. It is also crucial to ensure that it is easy to adapt to the improved process and how effective is the system that has been put in place to monitor the results. This means that I must spend time with the practice nurses in the participating practices, discussing ways in which the artefact can be introduced to the people at risk and perhaps more importantly how the process can be sustained and evaluated.

Possible ideas include the use of the EMIS system to flag people who are at risk (by flagging abnormal ACRs), and to introduce practices to the NICE (2008) audit support toolkit that shows how current practice in CKD management can be measured against NICE recommendations. For example audit criterion 10 in the toolkit is:

"In people with CKD and diabetes aim to keep the systolic blood pressure below 130 mmHg (target range 120-129 mmHg) and the diastolic blood pressure below 80 mmHg."

Staff factors that need consideration include staff training in facilitating self-care. The DH document 'Your health, Your Way' (Department of Health 2008b) outlines an example of good practice from NHS Kirklees. This example of a self-care pathway for practitioners working with people with a long-term condition shows how the patient and health care practitioner together can use the care plan to identify self-care support and resources. This artefact serves as a suitable information resource, although could benefit from additional knowledge and skills training such as DESMOND or the Expert Patient Programme.

It is also crucial that senior leaders in each practice engage with the recommendations of this thesis, so a summary of the thesis's findings and recommendations have been sent to the senior partners and practice managers in the participating practices.

Finally it is important to consider how far the integration of the artefact into usual practice (the change) fits with the practice's strategic aims and culture. Although it is not always possible as an outsider to evaluate the culture of an organisation, the case-study observation period did give me some insight into the services offered to patients. Overall the culture in the participating practices did seem to be one that tried to do its best for the patients, and all the practice nurses involved did respond to suggestions and practice changes as a result of national CKD management policy. It is five years since I first had contact with the practices and an excellent relationship with them has developed. I am hoping that my final visit to the

practices will result in a positive outcome, that is, one that takes my recommendations and improves patient opportunities for self-management.

8.6. The Medical Research Council (MRC) Framework for Complex Interventions

8.6.1. Introduction

The difficulties in isolating the 'active ingredient' of the self-management package (the intervention) were discussed in section 7.3.4. As the intervention developed in this thesis included a variety of components, including organisational and delivery methods (Bradley et al. 1999), the intervention could be described as complex. The MRC (Medical Research Council 2000) described a complex intervention as follows:

"Complex interventions in health care, whether therapeutic or preventative, comprise a number of separate elements which seem essential to the proper functioning of the intervention, although the active ingredient that is effective is difficult to specify." (Medical Research Council 2000)

It has been recommended that complex interventions should be carefully planned and designed and to help researchers, the MRC in 2000 published a five-phase framework for developing and evaluating complex interventions.

There are a number of reasons why a framework might be necessary. If the intervention is relatively simple, clearly defined and can be standardised (as in randomised controlled trials (RCTs)) then differences can be confidently attributed to interventions. In an intervention which includes multiple intervention components, attributing differences to one part of the intervention can be more difficult (Victoria et al. 2004). In addition, standardising the intervention is more challenging if the intervention is aimed at changing behaviours and may consist of multiple interrelated and interdependent components, such as practitioner and patient behaviours (Blackwood 2006). It has also been suggested that as the components of interventions are not always reported, it is very difficult to draw conclusions or comparisons across different studies (Lindsay 2004). It has also been recognised that there are challenges facing systematic reviewers of complex interventions although a recent paper has suggested several ways of addressing them (Shepperd et al. 2009).

The MRC Framework was first published in 2000 and later revised in 2008 (Medical Research Council 2008). One framework (Bradley et al. 1999) particularly contributed to the

development of the original MRC Framework, whilst later publications (Hawe et al. 2004, van Meijel et al. 2004) informed the subsequent development of the Framework.

The original MRC Framework drew on the principles developed by the earlier frameworks, and includes five phases: preclinical, modelling, exploratory, definitive RCT and long-term implementation. Figure x shows the original MRC Framework for Complex Interventions (2000).

Figure 8.4: The MRC Framework (2000) for the design and evaluation of complex interventions

THEORETICAL	MODELLING	EXPLORATORY TRIAL	DEFINITIVE RCT	LONG TERM IMPLEMENTATION
Prior theory and empirical evidence used to formulate the intervention and how it would work in theory	Practicalities and concrete structure of the intervention are developed and refined	Intervention is refined in an exploratory trial	Refined intervention is subject to a definitive RCT	Following successful RCT the intervention is implemented in routine clinical practice
Preclinical	Phase I	Phase II	Phase III	Phase IV

Continuum of increasing evidence

The original Framework (Medical Research Council 2000) with an accompanying paper (Campbell M et al. 2000) was updated in 2008 (Medical Research Council 2008) to provide a more flexible, less linear model. The rationale for updating the Framework was described in the introductory paragraph:

"It updates the advice provided in the 2000 MRC Framework ......taking account of the valuable experience that has accumulated since then, and extending the coverage in the guidance of non-experimental methods, and of complex interventions outside the health service. It is intended to help researchers to choose appropriate methods, research funders to understand the constraints on evaluation design, and

users of evaluation to weigh up the available evidence in the light of these methodological and practical constraints." (Medical Research Council 2008)(p.4)

The updated Framework includes questions to be asked during the stages of development, feasibility/piloting, evaluation and implementation.

8.6.2. Review of papers using the MRC Complex Intervention Framework

This section reviews papers that have been published within the topic areas of diabetes, cardio-vascular disease and other long-term conditions. Following the publication of the Framework in 2000, a number of researchers started using the Framework in their studies.

8.6.2.1. Diabetes

Three have been identified that have used the Framework in the field of diabetes. One study group in Germany (Muhlhauser and Berger 2002) examined the available evidence for diabetes treatment and teaching programmes implemented in Germany over the previous 20 years. They concluded that although a number of researchers had developed programmes for people with diabetes that had used elements of the Framework, the majority had not used the Framework in a systematic way. They recommended the use of the Framework to develop and report such interventions, which in turn will enable systematic appraisal across different methodologies.

In contrast to the apparent lack of systematic use of the Framework in the German review, one UK study (Sturt et al. 2006c) used the MRC Framework to systematically develop and evaluate a Self-Efficacy Goal Achievement nursing intervention for Type 2 diabetes. The Preclinical study included literature analysis and findings from parallel studies. The Phase I study was a small trial of the intervention, evaluation of its feasibility and identification of appropriate outcome measures. The important message from this phase (demonstrating the utility of the Framework) was that parts of the intervention were adjusted to remove the less effective components and enhance the more effective. It was only when Phase I had been evaluated and redefined that the Phase II (exploratory) and Phase III RCT was developed (Sturt et al. 2006a).

Paul (2007) also used the MRC Framework to shape a complex intervention of peer support for people with Type 2 diabetes for a randomised control trial in a primary care setting. The

Preclinical Phase included a review of the literature relating to Type 2 diabetes and peer support. In Phase I the theoretical background and qualitative data from four focus groups were combined to define the main components of the intervention. The preliminary intervention was conducted in Phase II. This was a pilot study conducted in two general practices and amongst twenty-four patients and four peer supporters. Focus groups and semi structured interviews were conducted to collect additional qualitative data to inform the development of the intervention. Four components (peer supporters; peer supporter training; retention and support for peer supporters and peer support meetings) were identified from the Preclinical Phase and Phase I. The preliminary intervention was implemented in Phase II. Findings from this phase allowed further modelling of the intervention, to produce the definitive intervention (Paul et al. 2007). In some ways this sequence mirrors the method developed in the current thesis and this comparison will be discussed further in section 8.6.4.

8.6.2.2. <u>Cardio-vascular disease</u>

In the area or cardio-vascular disease, four published papers were found. One paper (Byrne et al. 2006) described how the MRC Framework assisted in the development and evaluation of a complex primary health care intervention that aimed to promote the secondary prevention of coronary heart disease. The authors explained how the Framework helped clarify how the intervention could be tailored to individual practices, practitioners and patient needs, while at the same time preserving the theoretical functions of the components. In a practical sense, findings from the pilot phase informed further modelling of the intervention, such as reducing administrative time, increasing the practical content of training and omitting unhelpful patient information.

In another study (Robinson et al. 2005) the researchers used the Framework to develop an intervention that facilitated coping skills in new carers of stroke patients. As in the Byre (2006) study the intervention was modified after Phase I and Phase II. A systematic review of complex interventions for stroke care (Redfern et al. 2006) was undertaken. The MRC Framework was used to structure the review and overall the authors asserted that few complex interventions in stroke care had been adequately developed or evaluated. They suggested that these issues may explain failures to demonstrate efficacy and recommended that greater attention is needed to theoretical development and methodological quality.

Another study (Corrigan et al. 2006) aimed to examine the contribution of qualitative research in developing a complex intervention for secondary prevention of heart disease. The

authors described how focus groups undertaken in Phase I could identify components of the intervention that had not been considered beforehand, such as practical approaches to minimising administration and providing information about stress management. The important message was that use of the Framework enabled tailoring of the intervention components to individuals' needs in different healthcare systems.

8.6.2.3. Long-term conditions

Other published papers in the general field of long-term conditions were identified (Wong 2004, Eldridge et al. 2005, Thompson and Weiss 2006, Murchie et al. 2007, Klinkhammer-Schalke et al. 2008). In these studies the Preclinical stage ensured that the interventions were based on sound evidence; Phase I was extremely valuable in identifying the barriers that could have derailed the successful implementation of the interventions; whilst Phase II identified problem implementation areas such as administrative or practical aspects.

8.6.3. Critique of the MRC Framework

There have been a number of advantages identified by researchers. In the systematic review of stroke care (Redfern et al. 2006), the authors explained how the Framework can set standards for theoretical and methodological development within an RCT design. Other authors have discussed how it is useful to apply the Framework even when planning and implementation has taken place (Rowlands et al. 2005), whilst it has been argued that the stages of Framework may be useful even if they are not systematically applied (Eldridge et al. 2005, Greenhalgh et al. 2005)

There has however been some debate about the possible limitations of the Framework, such as whether all the recommended stages are indeed crucial. One review (Treweek and Sullivan 2006) asked whether Phase II testing made a difference to outcome. The findings were not that conclusive with two-thirds (22/34) of those testing their interventions not believing that more or different testing would have produced a more effective intervention. The authors suggest that conclusions are difficult because testing is often not described in trial reports, and this makes it hard to judge whether a trial result could be improved with a better intervention, or whether further work with a different intervention is required.

Other authors have described difficulties with the modelling phase (Lovell et al. 2008); have asserted that an RCT may not be necessary if an intervention is feasible and soundly-developed (van Meijel et al. 2004); and that long-term implementation, although

recommended by the MRC as a separate study, may be difficult in terms of funding/resources (Blackwood 2006).

There has been recent debate about the specific difficulties in defining, developing, documenting, and reproducing complex interventions that give rise to the challenges for researchers in systematically reviewing complex interventions (Shepperd et al. 2009). One review (Redfern et al. 2006) has claimed that there is no convincing evidence that a well-developed complex intervention in stroke care has improved outcomes. In addition, it appears that a decade after the MRC Framework was published that some researchers are still developing complex interventions without using a rigorous approach (Shepperd et al. 2009).

8.6.4. <u>Reflection on the use of the Framework in different stages of this thesis</u>

On reflection use of the MRC Framework to guide development of the complex intervention developed and evaluated in this thesis would have been extremely helpful. Looking back at the work of this thesis, some of the recommended phases of the suggested Framework were undertaken but these were not explained in an explicit way. Figure 8.5 shows where the development stages of the intervention in this thesis are related to those within the MRC Framework. In addition, the updated MRC Framework guidance recommends that researchers ask specific questions of the intervention during each phase (Medical Research Council 2008). The questions which relate to the different phases of the Framework and which also relate to the different aspects of the thesis are shown in Figure 8.5.

Figure 8.5: MRC Framework (2000 and 2008): the main elements of the process and key questions to be asked

Stage	Section in thesis	Questions to be asked
Preclinical: Theoretical	Case study Literature review	Does your intervention have a coherent theoretical basis?
Phase I: Modelling	Development of intervention: - Theoretical frameworks - Interviews - Integration of case study, literature review and interview findings to develop intervention	Have you used this theory systematically to develop the intervention?
Phase II: Exploratory Trial	Testing of intervention: - Six practices and control group - Dataset - Data analysis	Have you done enough piloting and feasibility work to be confident that the intervention can be delivered as intended? Can you make safe assumptions about effect sizes and variability and rates of recruitment and retention in the main evaluation study?
Phase III and IV: Definitive RCT and long-term implementation	Discussion - recommendations for future studies	What design are you going to use, and why? Is an experimental design preferable and if so, is it feasible? If a conventional parallel group randomised controlled trial is not possible, have you considered alternatives such as cluster randomization or a stepped wedge design?

8.6.4.1.   Preclinical: Literature review

The theoretical basis could be improved. Firstly there was some debate (p. 50) on how far the literature review could be systematic especially in view of the identified qualitative/grey literature that was pertinent to the review. In retrospect the literature review should have been more systematic and based more closely on the CRD (2009) guidance. The review should have had more explicit aims and specific inclusion/exclusion criteria. A discussion of how far qualitative/grey literature can be appraised should have been included, especially as there are published methods for synthesising qualitative studies in systematic reviews (Thomas and Harden 2008, Dixon-Woods et al. 2007). Finally the review should have been updated more thoroughly prior to submission.

It is important that the findings of the review are used to develop the intervention. Further discussion that identified and explained the gaps in the theoretical basis should have been included such as the evaluation of the different stages between receiving an educational intervention and the possible subsequent behaviour change.

8.6.4.2.   Phase I: Modelling

The use of the underpinning theory was not entirely clear especially as the work of both Kirkpatrick and Funnell & Anderson was cited. On reflection the Kirkpatrick Model (1967) had the potential to be extremely useful but it was not used in the thesis to its fullest extent. It could have been used more constructively to form a basis for the review search strategy and could have provided a framework for reviewing the findings, as the Kirkpatrick Model outlines a hierarchy of levels of evaluation as follows:

- RESULTS: Effect on learning environments

- BEHAVIOUR: Transfer of learning into behaviour

- LEARNING: Effects on knowledge, attitudes and beliefs

- REACTION: Evaluation of the learning experience

The literature review could have been structured around this hierarchy, that is, studies with outcomes that simply measured the learning experience would be evaluated together in one section. This could be followed by studies that measured the effects of the intervention on knowledge, attitudes and beliefs. Higher level studies that analysed how an intervention

translated learning into behaviour change would then be scrutinised, followed finally by those that changed learning environments.

The work of Funnell and Anderson (1995, 2000, 2004, 2005, 2008) was alluded to in this thesis but the use of their measurement instruments such as the Diabetes Empowerment Scale (Anderson et al. 2000) could have been scrutinised to a greater extent. In retrospect their empowerment philosophy (Funnell and Anderson 2004) should have been introduced at the start of the thesis and key concepts within the philosophy should have been used to check that any part of the resulting intervention adhered to their recommendations. One example is that the words 'should' and 'ought' (as mentioned in the DVD) are not conducive to an approach which purports to support empowerment.

8.6.4.3. Phase II: Exploratory trial

The exploratory trial was undertaken in six GP practices and 116 patients received the intervention. On reflection the external influences that could have affected the outcomes were not considered fully enough. One possible influence was the differing practitioner explanations of the self-management pack when it was given out. For example some practitioners may have used a facilitative approach when explaining the aims of the pack (emphasising what the patient can do to help themselves) whilst others may have focussed on what should be done or not done, such as stopping smoking. Although further evidence is needed to clarify how far the performance of diabetes educators can influence outcomes (Loveman et al. 2008b), further guidance for practitioners would have been beneficial. In addition, a guide for practitioners that explained how to answer patients' questions that arose as result of the intervention, may also have contributed to removing practitioner bias.

It is also recognised that there are a number of stages between the giving of information (the intervention) and possible changes in outcome, such as reduced BP and HbA1c, which were not explored fully in the thesis. The American Diabetes Association (Funnell et al. 2008) has published national standards for diabetes self-management education. Standards 1-6 give best practice guidance for the practical aspects of the education such as the use of an advisory group and the qualifications of instructors. Standards 7-10 are concerned with patient aspects, most importantly individualised assessment, goal setting and effectiveness of the programme. Goal setting in diabetes education often relates to Social Cognitive Theory (Baranowski et al. 2002), and includes the process of identifying behaviours (self-control), greater confidence to perform behaviours (self-efficacy) (Krichbaum et al. 2003), positive reinforcement and other constructs presumed to maximize goal (behaviour) attainment (Sprague et al. 2006).

The intervention developed for this thesis did not explicitly include the assessment and goal setting stages, although these stages might have been included in generic one-to-one discussions with practice nurses during annual review clinics or regular check-ups. It is recognised that the omission of these stages is a limitation of this current study. Recommendations for changes to the current intervention are discussed further in section 8.6.4.3.

It could be argued that some assumptions written up in earlier parts of the thesis are unsound. For example on p.212 I concluded that:

"It is therefore likely that the changes to BP in the intervention practices have occurred as a result of this study's interventions rather than external influences".

Blood pressure control improved during the course of the study, yet it is not entirely clear which parts of the intervention might have affected blood pressure. It is possible that the practitioners' confidence in managing blood pressure to target improved as the study progressed, and this in turn improved blood pressure control. This increased confidence may have resulted as a consequence of my visits to the practice or as a result of QOF incentivisation (Carey et al. 2009). It is difficult to extrapolate whether practitioners' titrated blood pressure medication to maximum levels to achieve QOF targets, whether they invested more time in explaining the benefits of blood pressure tablets to slow down kidney disease progression, or a mixture of the two. A refinement to the intervention could be the inclusion of a 'Confidence in Managing CKD' questionnaire (personal communication) undertaken before and after the intervention, which would identify in part whether changes in outcome were directly due to practitioner interventions.

Another issue that required further analysis was the assertion that people who did not want to take part in the study did not want to self-manage (p.208). There are of course numerous reasons why people may not wish to take part in research studies. Pertinent reasons for this thesis might include a general mistrust of participation in research studies and misunderstandings about the nature of the project itself (Williams et al. 2007). A refinement to the intervention should be that more care is taken to explain the precise nature of participation. In addition, the study information sheet should go beyond standardised guidelines for its design and instead proactively seek out and address areas of concern or potential misunderstanding (Williams et al. 2007).

8.6.4.4.   Phase III and IV: Definitive RCT and long-term implementation

It is recognised that there were difficulties in identifying the key variable that effected changes in BP in the intervention group. It was important to eradicate the effects of national policy on CKD management as far as possible by including a control group, but this was very challenging in the time period 2004-2008 because of new QOF targets for CKD and the publication of NICE guidance for CKD.

A definitive RCT in the future is recommended, although it is not possible to undertake an RCT (at patient level) because of practitioner effects in one GP practice. If the intervention was randomised at patient level then practitioners might find it difficult to provide the intervention in one patient followed by unchanged usual practice in the next. In addition, individual practices might have differing populations, differing QOF achievement scores or differing approaches to self-management. A cluster-randomised trial (CRT) (at practice level) would be the method of choice. However it is recognised that it is not possible to fully account for all effects such as practitioner confidence in managing diabetes/CKD and practitioner confidence in facilitating a self-management approach, although if these measures are incorporated into the design of the Phase III study, then the effects of these variables might to some extent be reduced.

8.6.5.   Next steps

The following recommendations are based on selected 'Further questions' of the MRC Guidance (2008, p.14).

'Have you conducted a systematic review?'
I aim to revisit and update the literature review as discussed above in section 8.6.4.1 and aim to submit for publication as the first stage of the MRC Framework (preclinical) by September 2010.

Who is the intervention aimed at?
As the intervention seeks to achieve change in more than one area (both patients and practitioners), processes and outcomes need to be identified and measured at both levels. As discussed in section 8.6.4.3, the intervention needs to include a patient-centred measure such as self-efficacy, measured prior to and after the intervention. From a practitioner perspective, the intervention should also include a way to measure confidence in promoting an empowering approach (practitioners). Both of these patient and practitioner aspects are

being measured and evaluated in another study (Jain et al. 2009) that I am involved with. Once validated for CKD, the instruments could be incorporated within the current intervention although it is recognised that inclusion of too many additional measures could overcomplicate the method and result in inconclusive findings.

Can you describe the intervention fully?

The intervention needs to be described fully to allow reproducibility in different settings and to enable comparison with other studies, as in a systematic review. I aim to publish the refined exploratory trial protocol by registering the study in the NIHR Clinical Research Network Portfolio.

How variable is the intervention? Can you describe the context and environment in which the evaluation is being undertaken?

Further discussion on context needs to be considered before developing the intervention further. The exploratory study was undertaken in a suburban PCT with a low ethnicity mix compared with other areas. The challenges of reaching so-called 'hard to reach groups' need to be considered, especially the challenge of developing an intervention for people who do not have English as their first language.

Have you reported your evaluation appropriately?

To date some aspects of the Phase I part of the study have been reported (Thomas et al. 2008). The Preclinical stage (literature review) will be reported as in section 8.6.4.1 above, whilst the Phase II study could be published once further refinements to the exploratory trial have been undertaken. Phase III evaluation would be published according to CONSORT criteria for cluster-randomised trials (Campbell et al. 2004).

8.6.6.   <u>Conclusion</u>

The question is now whether wider dissemination and application of the intervention is at present merited. Dissemination of the findings to date has only been within the six participating practices within one PCT. The next stage will be to publish the theoretical basis for the study (the evidence from the case study and literature review). Further refinement of the intervention is required before another exploratory trial is undertaken. This refinement will include additional measures such as validated instruments to measure practitioner and patient confidence.

It has been most useful to reflect on the thesis with respect to MRC Framework for Complex Interventions. The reflection has provided the opportunity to consider additional work that needs to be carried out prior to future publications and grant applications. These activities will contribute to the refinement of the intervention prior to another exploratory trial being carried out in a different cohort of intervention and control practices.

8.7. Chapter summary

This chapter has summarised the way in which the artefact has been developed, and has described the changes that have to be made to the final version. These include changes to the design, format and content. The ways in which the artefact now needs to be disseminated and sustained have been examined and some of these activities will continue to facilitate sustainability. The final section reviewed the potential use of the MRC Framework for Complex Interventions in this thesis.

9. FINAL CONCLUSIONS AND RECOMMENDATIONS

9.1. Introduction

This final chapter will review and analyse the conclusions that have been drawn from the different parts of this Doctorial thesis, namely the case study, literature review, research project and artefact. The use of the theoretical frameworks that have been used in this thesis will be evaluated. The chapter will review and develop the recommendations that have been made in Chapter 7 and will identify potential areas for wider dissemination of the artefact.

9.2. Conclusions: the case study

The case study was undertaken in 2004 and it is recognised that diabetes management in primary care is likely to have changed and developed since then. The introduction of the QOF targets for both diabetes (2004) and CKD (2006) has certainly made practitioners aware of how they might improve the care of people at risk of CKD.

However, at the time of writing the conclusions that were drawn provided a very useful framework upon which to base the literature review and resulting research project. The main conclusions were that practice nurses and GPs were finding some aspects of CKD management difficult. These aspects were measurement and monitoring of microalbuminuria and measuring blood pressure and controlling to target. My observations concluded that the educational strategies used by the practice nurses to facilitate self-management of diabetes were varied. Patients were given information verbally but this was not backed up with written materials or other educational media. Despite there being a national drive (Department of Health 2004) at this time to facilitate self-care, these recommendations were not necessarily being implemented at practice level, especially when managing people with CKD.

9.3. Conclusions: the literature review

The literature review was first developed and written in 2004/5 and it is recognised that the number of articles and research papers that have been published on the effectiveness of educational interventions for people with diabetes have risen since then. Reports on the effectiveness of general self-management programmes such as the Expert Patient Programme (National Primary Care Research and Development Centre 2007) and specific

programmes such as DESMOND (Davies et al. 2008) have been published. There have also been reports on who might benefit from such programmes (Reeves et al. 2008, Skinner et al. 2008). There have been systematic reviews of diabetes education models undertaken (Loveman et al. 2008a, Vermeire et al. 2009) although the question of whether any particular type of education or intervention is more effective than another remains unanswered. The suggestion is that some educational interventions can produce improvement in diabetic control in Type 1 diabetes, but there are mixed results for Type 2 diabetes (Vermeire et al. 2009).

I also found it difficult to draw firm conclusions from my own literature review partly because it is challenging to judge the size of the effect of the intervention, when results are based on very different reported outcomes. Some outcomes were measured by how well the participants evaluated the learning experience (were the facilitators friendly, were the learning resources easy to read), some were measured by change in knowledge (can participants explain what might happen with a low blood sugar), whilst some studies measured the transfer of learning into behaviour. With studies into diabetes, the most common measurable outcome utilised by researchers is a physiological measure, that is, the effect on HbA1c, although this too can have shortcomings (Herman et al. 2009).

9.4.   Conclusions: the research project

The underlying rationale for the research project was that despite the evidence that the course of diabetic kidney disease can be slowed by managing blood pressure to target, improving glycaemic control and giving advice and support on lifestyle changes, it appeared that management of this condition in primary care was less than optimal. Health-care professionals have a role in supporting people to manage their own diabetes, yet at the start of the research project there were no evidence-based educational resources available to help people achieve the aim of slowing CKD progression through self-care.

The main aim of the research project was to develop and test a self-management education package that educates people with diabetes about the risks of kidney disease and empowers them to self-manage their condition. The findings from the case study, literature review and patient interviews informed the development of the package. The package was tested in six participating and one control practice.

The main conclusion from the research project was that self-management techniques such as understanding of, and subsequent concordance with, prescribed medication may provide the opportunity for an individual to control their own blood pressure. It is also possible that active

involvement from a renal nurse in identifying abnormal ACR results and subsequent initiation of medicines that modify the renin-angiotensin pathway, may also have an effect on blood pressure control. The importance of maintaining blood pressure to target is that it can slow the rate of CKD progression and reduce cardio-vascular risk (Bilous 2008).

The implications are that the methods used in this study could be replicated for other long-term conditions, although the simple action of self-management pack development and distribution needs to be accompanied by a commitment to a self-care ideology. A culture change from a passive to an active self-care philosophy requires the support of lead clinicians responsible for managing long-term conditions.

9.5. Conclusions: the artefact

There were parts of the self-management pack that required further amendment following patient evaluation and these changes have now been made. I still have slight reservations however about the emphasis of the film (DVD). Within the film there is an underlying message that kidney function can deteriorate if the condition is not managed well and this could result in serious consequences such as the need for dialysis. Despite some interviewees being convinced that the best way to change behaviour was to use a shock tactic:

> *"They perhaps don't frighten people enough."*

I am still not certain that this is the best method for everyone. Sections of the DVD contain interviews with people on dialysis and this may be upsetting for some. Clearly further evaluation of the package and research into how far the package could potentially change behaviour is required.

9.6. Evaluation of the theoretical frameworks used in the study

The theoretical framework utilised in the literature review was Silverman's action approach to organisations (Silverman 1971). This theory suggests that change is dependent on the interrelationship of a number of factors, including the knowledge, attitudes and beliefs held by the wider society, by the organisational structure, as well as by individuals. See Figure 2.3 .

As discussed in Chapter 7 this framework has a number of overlapping themes with the NHS Sustainability Model (NHS Institute for Innovation and Improvement 2007) and I am

confident that despite the fact that the Silverman model was published over 30 years ago, this model is still relevant and useful today.

The Kirkpatrick model (Kirkpatrick 1967) used to evaluate some of the papers used in the review was of great value, especially as on reflection it could be usefully utilised to evaluate self-management programmes/packages in future studies. See Figure 9.1.

Figure 9.1: The Kirkpatrick Model (1967)
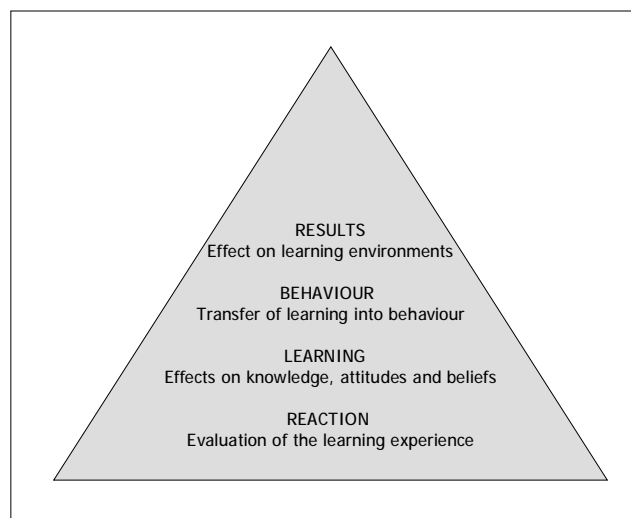
In practical terms this would mean taking each of the four components (reaction, learning, behaviour and results) and using these to evaluate self-management programmes/packages.

- reaction of participant - what they thought and felt about the training/education

- learning of participant - the resulting increase in knowledge, skills or attitudes

- behaviour of participant – the extent of behaviour change

- results of programme/package – wider effects on the programme/package such as the effect of reducing BP on cardiovascular risk

If the package developed and tested in this present study is successfully rolled-out to a wider cohort, subsequent evaluation of the package based on these four components is recommended.

9.7. Summary of recommendations

Chapter 7 identified the main recommendations for practice, education and research arising from this present study. The main recommendations for clinical practice are concerned with rapid initiation of ACEi/ARBs in people with MA and recommendations regarding blood pressure management (practitioners should record blood pressure to the nearest 2 mmHg when using a manual sphygmomanometer and record the exact reading when using an electronic device). It is also recommended that a study that aims to understand the effects/outcomes of using a home blood pressure machine by people with diabetes and MA is undertaken.

The main practice recommendation for the artefact is that it should contain an introductory paragraph that explains the benefits of self-care and should cater for a range of self-care abilities, from simple messages (eg. how many tablets to take each day) to complex interventions, such as monitoring and managing insulin requirements. The written information in the self-management pack should also contain a suggestion that patients prepare questions for their GP or practice nurse prior to a consultation visit.

To promote practice nurse and GP engagement with self-management techniques there are recommendations for education and training in how to promote self-management skills for patients. The written information in the self-management pack should include supplementary information for health-care professionals to explain the approach.

The main recommendations for further research are twofold. First, to undertake a qualitative study which investigates how people might take the information in the self-management pack and use this to change their health behaviour. Secondly, that replication of this study as a cluster-randomised trial (to remove researcher bias) is undertaken.

9.8. Further development and dissemination of the artefact

There are two main issues to be resolved before the artefact can be further disseminated and sustained across a wider location: one issue concerns practical implementation support from the PCT and the other, which may be harder to achieve, is GP and practice nurse support for a self-management philosophy.

Firstly, for the artefact to be disseminated across a wider geographical area it has to be implemented across the PCT in which it was piloted. At the time of thesis submission, I was in contact with the PCT Head of Commissioning for Equalities and Patient/Public

Engagement. This PCT has outlined two strategic goals for the future direction of health policy:

- to maximise the quality of life of the population through the provision of the earliest and most clinically and cost-effective care provided in the least intrusive way

- to reduce health inequalities (health promotion, and preventative health agendas), thereby improving life expectancy and to achieve greater health gain focused on deprived communities.

These goals aim to focus in particular around eight areas of identified need, two of which are diabetes and coronary heart disease. At the time of the submission of this thesis the Head of Commissioning had been in touch with me and discussed the following initiatives:

i) To incorporate the self-management pack materials within the PCT patient education programme for people who have been diagnosed with Type 2 diabetes.

ii) To run a disease-specific Expert Patient Programme for diabetes and explore the possibility of incorporating the learning materials in the pack as a learning resource for patients.

Secondly there has been increasing evidence that health care professionals are having difficulties in integrating a self-management approach into day-to-day practice. One study (Blakeman et al. 2006) found that although GPs valued increased patient involvement in their health care, this was in conflict with other values concerning professional responsibility. The authors concluded that providing GPs with training in consultation skills is required in order to encourage the delivery of effective self-management.

Another study that explored practice nurses' involvement in facilitation of self-management for long-term conditions (Macdonald et al. 2008) found that nurses seemed to lack resources beyond personal experience and intuitive ways of working for encouraging effective self-care. The authors concluded that the practice nurses' identified ways of working are unlikely to be sufficient to support patients' self-management. This in turn points to a need for education to equip nurses with techniques to work effectively with patients dealing with longer-term effects of chronic illness.

It appears that there is support for patients having increased involvement in their care but sometimes health-care professionals need specific training to help them engage with and promote self-management. Researchers from the National Primary Care Research and

Development Centre (Kennedy et al. 2005) have reported on a complex self-management intervention in a randomized controlled trial (RCT) involving 700 patients with established inflammatory bowel disease (IBD) attending outpatient clinics. They described how this training could be undertaken, which included a demonstration video, role-play, and video-feedback training. Results confirmed and highlighted the value of training in patient-centred communication and its potential for promoting self-management effects.

No other UK studies that have evaluated self-management training for health-care professionals could be found, although one American paper was identified (Siminerio and Siminerio 2006). Clearly there is a need for training of self-management in this PCT and elsewhere in the UK if GPs and practice nurses are to support and facilitate self-care effectively. I am hoping to discuss the possibility of PCT training for health-care professionals in facilitation skills for empowering self-management with the PCT Head of Commissioning for Equalities and Patient/Public Engagement.

9.9. Conclusion

The University guidelines for submission of this type of Doctorate state that the emphasis is on developing a thesis that contains one or more reflective accounts of case study work, a critical review of literature, a main research area and a dissemination artefact and plan. I have undertaken each of these components separately but I have ensured that they have been written up as one coherent and reasoned whole. The aims were to carry out a case study in six general practice surgeries, to perform a literature review on diabetes and self-care and to undertake a research project that developed and tested a self-management package. All of these aims were achieved and it is hoped that self-management training for health-care professionals and further dissemination of the self-management package to a wider audience will continue after this thesis has been examined.

If self-management can change an individual's attitude to their condition then there is the potential for improved clinical outcomes such as delaying progression of kidney disease

> *"I think if I had taken it seriously in those days and learnt what I know now, I would be a completely different person."*

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APPENDICES

Appendix 1
Local Research Ethics Committee Approval

27th November 2003

Ms Nicola Thomas
Research Lead Nurse
:

Dear Ms Thomas

Re: Can an innovative patient-centred education programme prevent the deterioration of renal function due to diabetic nephropathy?

Thank you for your recent letter regarding the above study. I am happy to note that all points raised by the Committee have been fully addressed and I can now give final approval on behalf of the LREC Committee for your study to proceed.

LREC approval is given on the understanding that:
- The study is commenced within the next 12 months. Should the start be delayed beyond this time, a re-application to the Committee will be required.
- Any change or amendment to the protocol will be reported to the Committee
- The Committee should be sent one copy of any publication arising from your study, or a brief report after completion if there is to be no publication. If the study last for more than a year a brief annual report should be provided

Best Wishes

Yours sincerely,

Dear Ms Thomas

Title: Can an innovative patient-centred education programme prevent the deterioration of renal function due to diabetic nephropathy?
Reference: 03/87

Amendment: 1
Date: 26.03.06

The above amendment was reviewed at the meeting of the Sub-Committee of the Research Ethics Committee held on 29 March 2006.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

- Letter to Dr   dated 26 March 2006

Research governance approval

All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects research governance approval of the research.

Appendix 2
Successful grant applications 2004-2007

Award	Date received	Total awarded	Use
Hospital Savings Association	Jun-04	£5,000.00	Doctoral fees
Insulin Dependent Diabetes Trust	Dec-04	£6,381.00	Artefact development
St Helier Association of Kidney Patients	Feb-05	£5,000.00	Artefact development
SW Thames Kidney Fund	Feb-05	£5,000.00	Artefact development
British Renal Society/Kidney Research UK	Jun-04	£19,871.68	Salary 0.2 WTE
British Renal Society/Kidney Research UK	Jan-07	£25,449	Salary 0.2 WTE
Total		£66,701.68	

Appendix 3
Patient information sheet (interviews)

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

The research project is looking at ways in which the development of kidney damage can be slowed down in patients with diabetes. The researcher is a renal (kidney) nurse who is interested in working with individuals like you, who may be at risk of kidney damage.

Diabetes is a condition that affects around 3% of the population in this country and in order to keep healthy, every person with diabetes needs good and regular healthcare. As you know, the control of diabetes and the early detection and treatment of any possible problems is very important. Complications of diabetes include foot and eye problems.

You may know that another of the complications of having diabetes is kidney damage. Whilst many people with diabetes are not affected, those with high blood pressure and/or high blood sugar levels, and those who smoke, are at risk.

I would like to ask you a few questions about how much you understand about diabetes and kidney damage, and how much you know about blood pressure and blood sugar control. I would also like to ask you about the ways in which people can best learn about their diabetes in terms of sugar and blood pressure management.

I expect that these interviews will take around 20-30 minutes and I would like to tape our discussion using a small tape-recorder so that I can listen to your answers afterwards. I would like to talk with you at your GP surgery, perhaps before or after your routine appointment with your GP or practice nurse.

I would also be working alongside your GP and practice nurse to understand how they manage diabetes in the surgery, and I would also need to review your case notes and blood results from time-to-time. It is not necessary for you to have any extra blood tests or appointments if you take part in the study.

Overall the study will take around four years to complete and at the end of the project I hope to be able to show that kidney damage can be slowed down with intensive education, blood sugar and blood pressure management. I would only need to ask you the questions on one occasion, but I may be visiting your surgery on a regular basis to follow up your care. At the end of the study I hope to be able to produce some information leaflets and educational materials for other patients who are at risk of kidney damage. If you take part then you will be helping me with the development of these materials therefore contributing to the care of other people with diabetes.

You may of course not want to participate, and I understand completely if this is the case. If you do decide to take part, then you will be free to withdraw at any time without giving a reason, and if this happens your care will not be affected in any way. All information about you will be kept confidential and you will not be identified in any report that may be published after the research has been completed.

You are most welcome to ask me questions at any time. My contact number is below.

I would like to thank you for your time in considering my request for you to participate in the study. If you decide to take part, then it will be necessary for you to sign a written consent form.

Nicola Thomas
Lead Nurse for Research
Telephone:

Appendix 4
Patient interviews: planning checklist

SURGERY	NUMBER	INTERVIEW	NOTES	CLINIC DATE	TIME	PLACE	LETTER	PHONE CALL	AGREED?	ROOM ARRANGED?	Completed?
1	3379		OK			Surgery	letter Sept 05				
	4039	13	Referred								
	6740		OK	31.10.05	09:15	Surgery	24.10.05	yes	yes	surgery OK	Y
	8561		OK			? home					
	9921		OK			Surgery			now seen at diabetes centre		
	10745		unwell								
	15260		OK	16.09.05		Surgery					
	16521	1 (pilot)	OK			Surgery			not possible for me		
	16019		refused before	Nov-05		Surgery			yes	surgery OK	Y (pilot)
	17213		unwell			?home	14.09.05	21.09.05	no		
	19792		non attender	Jan-06		Surgery					
	22169		OK	14.09.05		Surgery					
	25003		wife unwell			Surgery	missed				
2	707		unwell								
	4469		died								
	5238	4	OK	27.06.05	10:00	?home	13.06.05	yes	yes	Home	Y
	6822		OK	no appt 12/8							
	10177		OK ? Referred								
	12513		severe learning difficulties								
	14713		left practice								
	16122		wife died recently								
	16238	3	OK	24.06.05	11:30	surgery	13.06.05	yes	yes	surgery OK	Y
	17465		ACR<10								
3	18622		? Referred								
	2435		non attender								
	4241	10	OK	08.07.05	10:30	Surgery	symposium	no	yes		
	5524		OK		11:30	Home	1.09.05	yes	yes	home 11:30 8.09.05	Y
	6075		referred diabetes centre								
	6958		no appt								
	7161	7	OK	12.08.05	09:00	Surgery	29.07.05	yes	yes	surgery OK	Y
	26549	11	OK	16.09.05	09:30	Surgery	1.09.05	yes	yes	surgery OK	Y
4	30166	2	OK	24.06.05	09:40	Surgery	13.06.04	yes	yes	surgery OK	Y
	111		already referred								
	1980	12	OK	14.10.05	10:10	Surgery	1.10.05	yes	yes	surgery OK	Y
	2191		referred								
	4016		unwell								
	7702		ACR now <10								
5	14192		ARF								
	16631	9	OK	26.08.05	12:30	Surgery	15.08.05	yes	yes	surgery OK	Y
	349		Very deaf								
	11374	5	OK	12.07.05	14:15	Surgery	7.07.05	yes	yes	surgery OK	Y
6	18370		OK	13.07.05	10:10	Surgery	7.07.05	yes	refused	surgery OK	Y
	24023	6	OK	21.07.05	15:10	Surgery	7.07.05	yes	yes	surgery OK	Y
	5465	15	OK	20.07.05	10:00	Surgery	7.07.05	no	yes	surgery OK	Y
	6228		OK	31.05.05			AL	no			
	18701		ACR now <10								
	25031	8	OK	20.07.05	10:45	Surgery	7.07.05	yes	yes	home	Y
	34204	14	OK	Jun-05		Home			will take part - ring mid August	home	Y

Appendix 5
Consent form

CONSENT FORM

TITLE OF PROJECT:

Can an innovative patient-centred education programme delay the deterioration of kidney function caused by diabetes?

Name of Principal Investigator:
Nicola Thomas

Please initial box

The subject (or parent/guardian for a paediatric project) should complete the whole of this sheet himself/herself

1. I confirm that I have read and understood the information sheet for this project.

2. I confirm that I have had an opportunity to ask questions and discuss this project.

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

4. I agree to take part in this project.

_____   _____   _____
Name of Patient   Date   Signature of Patient (or Parent/Guardian)
(BLOCK CAPITALS)

_____   _____   _____
Name of Investigator   Date   Signature of Investigator
(BLOCK CAPITALS)

1 copy for patient; 1 copy for researcher; 1 copy to be kept with medical notes
Version dated 06/12/02

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Appendix 6
Identified interview codes (themes)

INTERVIEW THEMES (CODES)

Master (M) codes		First level (F) codes		Second level (S) codes	
M1	Impact of diabetes	F1	Complications of diabetes	S1	Lack of libido
				S2	Lack of energy
				S3	Loss of vision
		F2	'Restrictions'	S4	Dietary
				S5	Trying to lose weight
				S6	Alcohol
				S7	Taking tablets/injecting
				S8	Non-concordance
M2	Barriers to control	F3	Physiological barriers	S9	Poor memory
				S10	Lack of dietary choices
		F4	Health beliefs	S11	Cultural beliefs
				S12	Beliefs about ideal weight
				S13	Fatalism
				S14	Diabetes is not a serious condition
		F5	Inability to take-on health care advice	S15	Inconsistency of message
				S16	Unrealistic and unattainable advice
M3	Self-management	F6	Risk of kidney disease	S17	Did not know of risk
				S18	Not told of risk
		F7	Poor knowledge of self-management activities	S19	Providing annual urine test; blood pressure control; smoking cessation; exercise
		F8	Ways to get key messages across	S20	How: film, internet, individual sessions, group sessions, reading, family support
				S21	Who: practice nurse, specialist nurse
				S22	Where: in special clinic
				S23	When: as soon as possible
		F9	Ways to change behaviour	S24	To shock
				S25	To make kidney disease sound serious
		F10	Individual responsibility	S26	Important to help yourself

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Appendix 7
Artefact (DVD) costs

media pool

08/02/2006

PRE PRODUCTION		Quantity	Individual Cost	Total Cost
1 PRE PRODUCTION - Scripting / Production set-up				
Producer	2.5 day/s	2.5	£ 290.00	£ 725.00
Production Manager	1.0 day/s	1	£ 200.00	£ 200.00
SUB TOTAL				£ 925.00

PRODUCTION				
2 FILMING				
Camera (incl. sound) + operator	3.0 day/s	3	£ 490.00	£ 1,470.00
Producer	3.0 day/s	3	£ 290.00	£ 870.00
Raw Stock (DV CAM) @ 60 mins each		6	£ 20.00	£ 120.00
Subsistence / Expenses (per person, per day)		6	£ 20.00	£ 120.00
SUB TOTAL				£ 2,580.00

POST PRODUCTION				
3 EDITING (OFFLINE / ONLINE)				
Offline/ Online				
Edit suite	3.0 day/s	3	£ 210.00	£ 630.00
Editor	3.0 day/s	3	£ 290.00	£ 870.00
Producer	3.0 day/s	3	£ 290.00	£ 870.00
DV CAM Deck (Digitising)	6.0 hour/s	6	£ 30.00	£ 180.00
Music (non-broadcast Europe - up to 1000 copies + internet) per 30 sec		4	£ 85.00	£ 340.00
Music (MCPS) admin charge		1	£ 11.00	£ 11.00
DV CAM Deck (Record)	1.0 hour/s	1	£ 30.00	£ 30.00
Stock (DV CAM) @ 22 mins each		1	£ 14.00	£ 14.00
Approval material (VHS) - Layoff + Stock		2	£ 12.00	£ 24.00
SUB TOTAL				£ 2,969.00

4 ENCODING / DVD AUTHORING / DUPLICATION				
Encode to Mpeg 2 (DVD)		1	£ 100.00	£ 100.00
Author DVD		1	£ 250.00	£ 250.00
Design DVD facia		1	£ 100.00	£ 100.00
Burn 1st DVD (including printed facia & case)		1	£ 20.00	£ 20.00
Additional DVDs, 1000 or above (including printed facias & cases)		200	£ 3.50	£ 700.00
SUB TOTAL				£ 1,170.00

Master Sub-Total				£ 7,644.00
5 PRODUCTION FEE				
General administration / insurance / accounts		1	£ 1,528.80	£ 1,528.80

TOTAL				£ 9,172.80

All costs exclude VAT and are subject to final client specification.

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Appendix 8
DVD shooting schedule/script

DVD SHOOTING SCHEDULE (Amended after 080306 meeting)

Project: Kidney disease through diabetes DVD
Shoot date: from March 13 2006
Locations: 1. Hospital xxxxx 2. xxxxx Surgery;
3. Patients home

SHOOT DAY 1 – Hospital 13/03/06

1. Urine sample being tested
2. On-camera interview with Nicola Thomas, Research Lead Nurse
3. Establishing shots of Nicki walking in corridor, through waiting area, into her office, seated at desk/computer
4. Exteriors of hospital
5. Signage to hospital Renal unit
6. Wide views of kidney patients in hospital, sitting in waiting area
7. Wides and CUs of staff or patients smoking outside hospital doorway (can they do this same way office workers do?)
8. "Shock" shots of disabled and/or seriously ill patients on the ward
9. Customers in café eating fatty food (subject to permission from café owner)

SHOOT DAY 2 – GP Surgery 20/03/06

1. On-camera interview with GP (from 2 pm)
2. Exterior patient arriving at surgery
3. Signage to surgery, patient walking past
4. Patient delivering sample, chatting to receptionist/nurse
5. Close up (CU) of sample
6. Possible vox pop (short interview in situ) with patient if willing
7. Patient arriving for blood pressure test, sitting down
8. Nurse applying blood pressure equipment
9. Close-ups and semi-views of equipment being pumped up
10. Close-ups nurse examining reading
11. Reaction close-up of patient's face
12. Wide general view of nurse talking to patient about the result

SHOOT DAY 3 – Hospital 21/03/06

1. Short interviews with one or more patients about what happened to them their regrets, what they should have done

2. Wides and CUs of dialysis equipment in operation, dialysis being administered to patient

3. On-camera interview with nephrologist (1-2 pm)

4. Any shots we failed to do on Day 1 above (e.g. café scenes).

SHOOT DAY 4 – Home 22/03/06

1. Nicki Thomas arriving at home of patient

2. Patient greeting Nicki

3. Patient at home

4. GV Patient taking medicine

5. Close-ups of prescribed medicine, label, label, medicine being administered

6. Patient at home checking his/her own glucose levels

7. Patient going for brisk walk or jog in sports gear/trainers.

IN-HOUSE GRAPHICS

1. Graphic for "know your numbers (section 1)
2. Graphic of blood pressure readings and what they mean (e.g. what's high, what's low, what's desirable) (section 5)

3. Graphic displaying blood glucose data(section 6)
4. Text graphic of various bullet points (last section – main messages)

ANIMATED GRAPHICS FROM 3RD PARTY SOURCES (IF AVAILABLE)

1. Animated graphic of kidney function (section 3)
2. Animated graphic of diseased kidney

Appendix 9
Data collection pro-forma

Surgery	Number	Time point	Age	Gender	BP systolic	BP diastolic	ACE	ARB	Other HT agent	HbA1c	BMI	Exercise	Smoker?	Smoking amount	Date last ACR	Result ACR	Date last Cr	Result Cr	eGFR

Appendix 10
Publications and presentations related to Doctoral thesis

Publications

Thomas, N (2009) Diabetes and Chronic Kidney Disease: what does the new NICE guidance say? <u>Journal of Diabetes Nursing</u>, 13, 4, 126-136.

Thomas, N (2009) Thomas, N (2009) Identification and management of chronic kidney disease. <u>Journal of Renal Nursing</u>, 1, 2, 13-16.

Thomas, N and John, I (2009) What works: an online CKD module for primary care. <u>British Journal of Renal Medicine</u>, 14, 1, 5.

Thomas, N (2009) Chronic Kidney Disease – promoting self-management. <u>British Journal of Primary Care Nursing</u>. Special issue, CKD. 34-35.

Thomas, N (2009) Patient information leaflet. <u>British Journal of Primary Care Nursing</u>. Special issue, CKD. p.36.

Thomas, N, Bryar, R and Makanjuola, D (2008) Development of a self-management package for people with diabetes at risk of chronic kidney disease <u>Journal of Renal Care</u>, 34, 3, 151-5.

Thomas, N (2005) Can we delay the progression of CKD by improving collaboration between renal units and primary care teams? <u>EDTNA-ERCA Journal</u>, XXXI (4) 178-181.

Thomas, N (2004) Collaboration between hospital and primary care can improve the management of diabetic nephropathy, <u>Br J Diabetes and Vascular Disease</u>, 4, 3, 202-204.

Conference presentations, posters and films

Kidney Research UK Fellows Day, Henley Business School, September 2009, poster

Health in Transition, Adelaide Australia, August 2009, oral presentation

British Renal Society, Birmingham, June 2009, poster

European Dialysis and Transplant Nurses Association, Prague, September 2008, guest speaker

Kidney Research UK Fellows Day, Oxford, October 2007, poster

World Congress for Nephrology Nursing, Rio de Janeiro, April 2007, guest speaker

Kidney Research UK/British Renal Society, 2007, DVD, Living with Kidney Disease. On NHS Choices <u>http://www.nhs.uk/video/</u>

Kidney Research UK Fellows Day, London, October 2006, oral presentation

British Renal Society/Renal Association, Harrogate, May 2006, oral presentation

Kidney Research UK, London October 2005, video presentation (interview with Lawrence McGinty) <u>www.kidneyresearchuk.org</u>

Kidney Research UK Fellows Day, Belfast, April 2005, oral presentation

Appendix 12
Flyer: CKD online resource

Appendix 14
Artefact evaluation questionnaire

You may remember that in the past you were given a pack about diabetes and the risk of kidney damage. The pack was called 'Kidney Disease: Reducing the Risk' and the contents are pictured here.
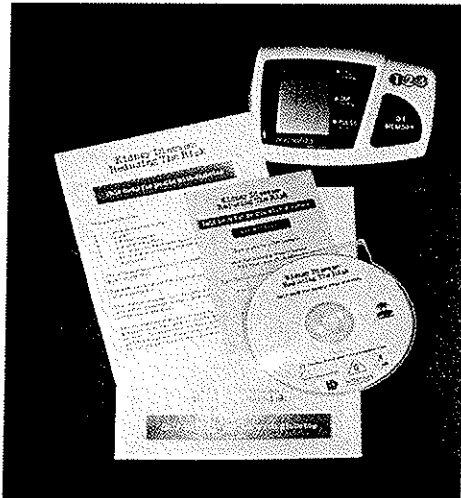
The box contained

- written information
- a DVD
- a 'fridge magnet'
- a monitoring diary
- some people were also given a blood pressure machine to try at home

There are a number of questions that I would like to ask you about the pack and I can either telephone you to chat the questions through, or you are most welcome to return your answers to the questions in the enclosed envelope (the questions are over the page).

It may be difficult for you to remember what you first thought about the pack as it may have been given to you some months ago. I also appreciate that you may not have been interested in the information or have not yet have a chance to look at it. If this is the case please be honest! I would prefer to know if it has not been useful to you, or if you have not had time to look at it.

The questions are over the page.

Did you look at the pack? Yes   No

If no, please could you explain why you did not look at it?

If no, did any members of your family/friends look at the pack?

Yes   No

If no to either of the above, then thank you very much for your time and please return the questionnaire in the stamped envelope

If yes to the first question, please answer the following

If you can remember, approximately how soon after receiving the pack did you look at it?

Immediately   Within one week   Within one month

Which parts of the pack did you look at? Tick all that apply

Written information ☐   DVD (film)   ☐

Fridge Magnet   ☐   Monitoring diary ☐

Which parts did you find most useful (if any)?

Which parts did you find least useful?

Was there anything that you did not understand in the pack?

Do you have suggestions on how to make the pack better/clearer/more useful?

If you had a blood pressure machine included, did you use it?

Yes   No

If you did not have a blood pressure machine included, would you have found a blood pressure machine useful?

Yes   No

If yes, could you explain why you might have found it useful?

Many thanks once again for all your help – if you have any questions then please do not hesitate to contact me