An evaluation of a Diabetes Specialist Nurse Prescriber on in-patient services

by

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Statement of Originality

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Abstract

Background
Concerns have been raised about the quality of the diabetes in-patient service. Nurse prescribing creates an opportunity to improve care for these patients.

Aim
The aim was to compare in-patients with diabetes who received standard care and an intervention group who had their medicines managed by a Diabetes Specialist Nurse prescriber.

Methods
A quasi-experiment was conducted using six wards in a single hospital trust. In-patient care of a convenience sample of patients was evaluated before (n=187) and after (n=265) a Diabetes Specialist Nurse prescriber provided a medicines management intervention. Prospective data were collected to measure insulin and oral hypoglycaemic medication errors and length of stay. Using a smaller sub-sample of participants, sample 2 (n=56), additional data were collected to evaluate the intervention on self-efficacy, patients information needs, and to determine the types of medicines information important to patients. Data collection methods included documentary evidence, modified retrospective case-record review and questionnaires.

Findings
Errors were significantly reduced by more than 50% in the intervention group (p<0.05). The median length of stay was reduced by two days. The total number of errors and length of stay were affected by admission category (p<0.001). In sample 2, self-efficacy scores were increased but the extent to which patients information needs were met was inconclusive. Participants rated similar categories of medicines information as important.

Conclusion
A medicines management intervention provided by a Diabetes Specialist Nurse prescriber can have a positive effect on patient safety and quality of care in-patients with diabetes receive. This model of care has important implications in terms of maximising resource use and providing a more flexible and accessible model of service delivery. In order that the contribution of nurse prescribing can be fully realised further evaluation of the intervention is required.

Key words
Diabetes, nurse prescribing, in-patient services, quality, safety
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Chapter 1: Introduction

1.1 Background

Diabetes Mellitus is one of the most common chronic diseases in both western and developing countries (Passa 2002). During recent years concerns have been raised about the prevalence of this disease in the developed world (Clark 1998). It is estimated that 194 million people worldwide or 5.1% of the population currently have diabetes, and by 2025 this will rise to 300 million (6.3%) (Deakin et al. 2005). The prevalence of diabetes in the United Kingdom (U.K) has also risen dramatically. Recent figures indicate that 2% of all men and 1.67% of all women in the U.K have a diagnosis of diabetes (Harvey et al. 2002, National Collaborating Centre for Chronic Conditions (NCCCC) 2008, Passa 2002).

Diabetes occurs as result of insulin deficiency, or resistance to the actions of insulin (Alberti & Zimmet 1998). Abnormalities of carbohydrate, fat, and protein metabolism subsequently occur as a result of the deficient action of insulin. Diabetes is diagnosed when a patient has a fasting blood glucose, or glucose tolerance test result ≥7.0mmol (British Medical Association (BMA) 2004, NCCCC 2008). The disease is classically associated with symptoms of thirst, polyuria (passing large amounts of urine) and if severe enough weight loss.

The majority of patients are diagnosed with either type 1 or type 2 diabetes: type 1 diabetes has an auto-immune basis and is characterised by an absolute deficiency of insulin (Alberti & Zimmet 1998). It is classically a disease of rapid onset which tends to occur in the young (BMA 2004). In contrast, type 2 diabetes, the most common form of diabetes, tends to have an insidious onset and is characteristically a disease of the middle aged or elderly (BMA 2004). Prevalence of type 2 diabetes increases
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with age and more than 90% of people are diagnosed with this category of the condition (Nathan et al. 1997). In the U.K the prevalence of diabetes has been significantly affected by the changing ethnic mix of the population. People from black and minority ethnic communities are six times more likely to develop this disease. Ten percent of people aged over 65, and more than a quarter of people aged over 60 and of Asian origin, have this disease (Audit Commission 2000, International Diabetes Federation (IDF) 2006).

Diabetes is a progressive condition which is associated with a number of long-term complications (BMA 2004, Parving 1999). The risk of macro-vascular diseases such as coronary heart disease (CHD), hypertension, stroke (CVA) and peripheral vascular disease (PVD) are all increased. Additionally, patients with long-term and or poorly controlled diabetes may also experience micro-vascular complications including retinopathy, nephropathy and neuropathy (BMA 2004, Deakin et al. 2005). The care of people with diabetes is therefore complex. A quarter of people living with this disease experience three or more long term conditions (Audit Commission 2000). In addition to the personal effects of diabetes related co-morbidities the costs to the National Health Service (NHS) are considerable.

Over five percent of total healthcare expenditure (approximately £25 million a day) is spent on the management of diabetes and its associated costs (Healthcare commission (HCC) 2007a). The combination of increased incidence and prevalence of diabetes and its associated complications means that diabetes presents an increasingly serious clinical and financial challenge for service provision both in the hospital and community setting (Bagust et al. 2002, Department of Health (DH) 2008a). Much of the expense associated with diabetes is due to complications which could be reduced with good healthcare and good self-management (DH 2003a, HCC 2007b). In addition to relieving acute symptoms (King 2003), the aim of disease
management is to minimize the risk of long-term complications by achieving optimal control of blood glucose, blood pressure and lipids (Cox & Keogh 2004, Rachmani et al. 2002). Blood pressure is the pressure of the blood within the arteries, primarily produced by the contraction of the heart muscle. Adult blood pressure is considered normal at 120/80mmHg where the first number is the systolic pressure and the second is the diastolic pressure (BMA 2004). The term ‘lipids’ refers to the measurement of the two main types of fat in the blood, triglycerides and cholesterol. Ideally the level of cholesterol should be less than 5.0mmol/l, and fasting triglycerides less than 2.0mmol/l (Watkins 2003). There is considerable evidence from the Diabetes Control and Complications Trial (DCCT) which indicates that for every one percent reduction in the glycosylated haemoglobin (HbA1c) the risk of micro-vascular and neuropathic complications are reduced by 40-50% (DCCT 1993). Glycosylated haemoglobin, the primary measure used to monitor control in patients with diabetes, is based on the average plasma glucose concentration over a prolonged period of time (BMA 2004). A person with an HbA1c of less than 7% is recognised as having good diabetic control (NCCCC 2008).

The use of medicines is an important component of the care of patients with diabetes and their use in clinical practice is directed by national guidelines provided by the government (National Institute for Health and Clinical Excellence (NICE) 2008). Drugs used in the management of diabetes are designed to increase insulin resistance, increase insulin responsiveness or modify intestinal absorption of carbohydrate and exogenous insulin. Insulin injections and or oral anti-diabetic medicines correct and manage the symptoms in both type 1 and type 2 diabetes. Evidence from a systematic review however, suggests that a number of lifestyle factors including smoking, diet and body mass index, also play a significant part in the development of diabetes related complications (Deakin et al. 2005). Body mass index (BMI) is used
in the assessment of obesity and is the body's weight divided by the square of the height in metres. Adults with a BMI greater than 25 are classed as being overweight (BMA 2004). Additionally, there is a growing body of evidence which suggests that care is enhanced when patients receive a combination of drugs and non-pharmacological support (i.e. education and support for self-care and modification of lifestyle behaviours (e.g. diet, smoking and exercise)) (DH 2007, 2008b, Kroker 2004, Rapley et al. 2003).

It is recognised that self-efficacy (SE), the belief (confidence) that one can carry out behaviour necessary to reach a desired goal, is a central concept of self-management theory and a good predictor of self-care in chronic diseases such as diabetes (Bandura 1977, Glanz et al. 1997, Holloway & Watson 2002, Marks et al. 2005a). It is evident that patients with diabetes who are more confident about their condition (i.e. have higher levels of SE), and are satisfied with the health care they receive (Kavanagh et al. 1993, Westaway et al. 2003), are also more likely to adhere to their prescribed treatment regime and self-manage their condition (Norris et al. 2001). Additionally, they demonstrate improved health outcomes (Clark & Dodge 1999, Marks et al. 2005a). Evidence suggests however, that less than 50% of patients are adherent to their medication regime, which decreases further with multiple chronic conditions (Anderson et al. 2005, Hugtenburg et al. 2005, Williams et al. 2009). Healthcare professionals must therefore make every effort to work in partnership with patients, ensure that they are knowledgeable about the disease and support patients' ability to self-care.

Despite this, concerns have been raised about the quality of care (Audit Commission, HCC 2007a), and healthcare costs associated with the management of in-patients with diabetes (BMA 2004, DH 2008a). Patients with diabetes occupy approximately 10-25% of beds (Audit Commission 2000, DH 2008b), and account for over nine
percent of current hospital costs (BMA 2004). Compared to patients without diabetes these admissions cost six times as much, and are on average 2.6 days longer (DH 2008b). In-patients with diabetes have reported a number of concerns about the care they receive including insufficient access to diabetes health professionals, doctors and nurses lack of knowledge about diabetes and its treatment, a lack of information from health professionals during admission, a lack of control over self-management during admission and unnecessary side-effects from medicines (Audit Commission 2000, HCC 2007a). In-patients with diabetes also experience high numbers of insulin and oral hypoglycaemic (OHA) medication errors that chiefly result in prolonged admission (DH 2004, 2008b, National Patient Safety Agency (NPSA) 2007), and are a common cause of significant morbidity and complications (Hellman 2001, NPSA 2007). There is therefore a need to improve the care and services that in-patients with diabetes receive.

1.2 Rationale for the study

In order to improve the quality of care that patients receive the NHS has undergone a radical process of reform and modernisation, a key component of which is to provide services that are both flexible and accessible to patients (DH 1999a, 2000, 2008c). Nurse-led care is seen as one means to improve healthcare provision (DH 1999a, 2000, 2003b) and nurses have established key roles in the delivery of care in several areas, especially chronic diseases (Campbell 2004, McKee & Nolte 2004, Raftery et al. 2005). It is recognised that nurses have an important role to play in the services that in-patients with diabetes receive (DH 2003a, 2008b), and the prescription of medicines by nurses should help optimize this role (DH 2006).

Policy surrounding the prescription of medicines by nurses in the U.K has undergone several recent changes (DH 2002, 2003c, 2005, 2006, 2009). This has effectively
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provided around 18,000 nurses with virtually the same prescribing rights as doctors (Nursing and Midwifery Council (NMC) 2010). Provided medicines are within the nurses’ area of competence, Nurse Independent Prescribers (NIPs) can independently prescribe any licensed medicine and some controlled drugs, and any medicine as a supplementary prescriber (but only after a diagnosis has been made by a doctor and a patient specific clinical management plan (CMP) been drawn up for the patient) (DH 2003c). Recent evidence suggests that nearly a third of these nurses prescribe for patients with diabetes, with the majority prescribing oral hypoglycaemic medication, insulin and antihypertensive drugs (Courtenay & Carey 2008a). Findings from a national survey of U.K. Diabetes Specialist Nurses (DSN) in 2007 also indicate that in recent years the role of the DSN has undergone significant development (James et al. 2009) whereby nearly 60% are now involved with prescribing medicines.

Although there is some evidence to suggest that nurse prescribing is being used to support and enhance patient services in a number of practice settings (Bradley & Nolan 2007, Carey et al. 2010, Courtenay & Berry 2007, Courtenay et al. 2009a), little is known about how nurse prescribing affects diabetes in-patient care (James 2004). This is important given the increasing number of DSNs who are undertaking the prescribing role, and the need to improve the diabetes in-patient service.

This study aims to evaluate the effect of a Diabetes Specialist Nurse prescriber on in-patient services.

1.3 Aim of the study

The aim of the study was to compare in-patients with diabetes who received standard care and an intervention group who had their medicines managed by a DSN prescriber.
1.4 Research Questions

The issues and gaps highlighted from the review of the literature, as discussed in chapter 2, helped to formulate the research questions and hypotheses outlined below:

1. Do hospital in-patients, who receive a medicines management intervention from a diabetes specialist nurse prescriber, experience a reduction in a) the number of insulin and oral hypoglycaemic (OHA) medication errors and, b) length of stay (LOS)?

2. Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, report improved levels of self-efficacy (SE)?

3. Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, report an improvement in the extent to which their medicine information needs are met?

4. What types of information do patients consider important about their medicines?

Hypotheses

Hospital in-patients with diabetes who receive a medicines management intervention (MMI) from a DSN prescriber:

- will experience a reduction in the number of insulin and OHA medication errors (H1)
- will experience a reduced length of stay (H2)
- will report improved levels of self-efficacy (H3)
- will report an improvement in the extent to which their medicine information needs are met (H4)
1.5 Rationale for research approach and methodology

An experimental approach was deemed the most appropriate research methodology to answer the research questions. Experimental studies in medicine and healthcare aim to assess the effects of specific interventions and compare those with other established modes of treatment and patient management. The assumption in experimental research is that there is some model of cause and effect, such that the manipulation of one variable results predictably in a change of another (Watts et al. 2001). The assumption in this study is that by manipulating medicines management (from doctors and nursing staff to a medicines management intervention delivered by a DSN prescriber), in-patients with diabetes will experience a reduction in the number of insulin and OHA errors, a reduction in LOS, report improved levels of SE and report an improvement in the extent to which their medicine information needs are met. A more detailed discussion of the epistemological approach taken by the study and the philosophical basis of experimental design is presented in Chapter 4.

1.6 Personal interest in the area

Initial interest in non-medical prescribing arose through my experience as a practice nurse and nurse practitioner in general practice. During this time the process of providing care to patients was frequently interrupted or delayed when I had to request a General Practitioner to prescribe the medicine for my patients. The costs of diabetes in terms of the burden of care to the National Health Service (i.e. provision of care), and medicines to manage the condition were also underlined by this experience. In addition to the progressive nature of the disease and its multiple associated complications, I learnt that good diabetic control was underpinned by encouraging and supporting patients to self-manage their condition.
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My interest and involvement in advanced nursing practice followed, but a lack of prescriptive authority continued to cause me frustration and limit my clinical practice. Whilst I was studying to become a nurse independent and nurse supplementary prescriber a few years later, I really began to appreciate how nurse prescribing could contribute to service delivery and make a difference to patient care. Awareness of the mixed response to nurse prescribing by colleagues in the medical profession and mixed reports in the media heightened my interest in this area. Since 2005, I have been involved in a number of research projects in non-medical prescribing including: diabetes, dermatology, paediatrics and the development of multi-professional prescribing. Although these experiences have provided a wealth of knowledge in this area, they have also highlighted the urgent need to demonstrate the contribution nurse prescribing can have on the services that patients receive.

This study arose from a joint working partnership between Peterborough and Stamford Hospital NHS Foundation Trust and the University of Reading (the university where I was registered as a student at the time). The Diabetes team at the hospital approached the University of Reading to undertake a collaborative study as part of their service improvement programme for in-patients with diabetes.

My study was designed as part of a broader collaborative study conducted by the hospital. The hospital team included Jonathan Roland (JR), Consultant Diabetiologist at Peterborough & Stamford Hospital NHS Foundation Trust, Mimi Hills (MH), a Service Improvement Manager, June James (JJ), a Senior Diabetes Specialist Nurse and qualified nurse prescriber, and Jenny Amps (JA), a nurse experienced in diabetes research.

In addition to the research questions described in Chapter 1.4, the broader study was designed to evaluate the medicines management intervention on a number of
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additional outcomes including: i) doctors and nurses levels of diabetes knowledge and skills; ii) patients ability to self-manage their diabetes whilst in hospital; iii) patient satisfaction with in-patient care; and iv) the number of readmissions experienced by patients. The hospital team (JR, JJ and MH) were responsible for each stage of the process by which these additional measures were evaluated.

1.7 Contributions to the study

The broader study was endorsed, and sponsored by JR, the clinical lead for the project. The hospital trust designated MH as project lead and seconded JJ to be the DSN prescriber who would deliver the MMI.

Supported by the hospital team (i.e. JR, JJ, and MH) and my academic supervisor, Professor Molly Courtenay, I was responsible for the overall study design; the development and piloting of tools used during data collection (e.g. the insulin and OHA medication error extraction chart and three questionnaires) and collection of questionnaire data used to answer research questions 2, 3, and 4, described in Chapter 1.4. During data collection I was also responsible for monitoring the progress of the study, keeping study records and maintaining regular contact with JJ and MH.

The documentary evidence and patient documents, described in Chapter 5.3 and 5.44 respectively, were collected by JJ and MH, who also provided support recruiting patients to sample 2. JA was responsible for examining the anonymised charts of all patients admitted onto the six study wards during the period of data collection, as described in Chapter 5.4.1. I was responsible for the analysis of data used to answer my research questions.
1.8 Structure of the thesis

The thesis is organised into seven chapters. The first chapter introduces the study and reasons as to why it should be undertaken. Background information about the condition of Diabetes Mellitus, the complications that can arise and concerns over the quality of care that in-patients receive are described. The aim of the study, research questions and hypotheses are then presented. A rationale for the research approach and methodology is provided.

Chapter two reviews the literature relating to the roles and responsibilities of nurses who care for patients with diabetes, the effects of nurse-led care on service delivery and the impact that nurse-led care has on patient outcomes. Gaps in the literature are highlighted from which the research questions are formulated. Chapter three discusses the theory of medication errors, the theoretical framework used in the study. A rationale for the medicines management intervention and, anticipated benefits are then discussed.

A discussion of the epistemological approach of the study and philosophical basis of experimental design is presented in Chapter four. The use of a quasi-experiment, study design, sample selection, research setting and content of the medicines management intervention are then addressed in this chapter. Ethical considerations of the study are outlined. Chapter five discusses the methods of data collection and data analysis for each of the research questions. Practicalities, access, and the use of documentary evidence to collect demographic data are considered. Following this the rationale for methods of data collection (i.e. retrospective case record review and questionnaires) and tools used to collect the data are presented. The methods used in the pilot work and main study are then reported along with the research process and analysis of the data for each research question.
Chapter 6 presents the results from the analysis of data collected from the documentary evidence, modified retrospective case record review and three questionnaires. Following a description of the participants the effect of the medicines management intervention on each outcome measure is examined. The results are presented under each of the four research questions. Chapter seven provides a discussion of the findings in relation to the literature and a critical review of the methodology, study strengths and limitations. The contributions the study makes to the body of knowledge are presented. A number of recommendations are made. A conclusion of the main points is then provided.
Chapter 2: Review of the Literature

2.1 Overview

In order to address concerns over medication errors and shortfalls in service provision, guidance suggests that diabetes specialist nurses should have an integral role in the care that in-patients with diabetes receive (Audit Commission 2000, DH 2003a, 2008b). In order to understand this role further, the literature evaluating the activity and effects of nurse-led care in diabetes is reviewed in this chapter. Literature is analysed from a global perspective and key methodological issues identified, before examining each individual study. Gaps in the literature are highlighted and from these, research questions, as discussed in Chapter 1.4, are identified for my own study which seeks to further knowledge in this area.

Specific questions that the review addresses are:

1) What are the roles and responsibilities of nurses who care for patients with diabetes?

2) What are the effects of nurse-led care on diabetes service delivery?

3) What is the impact of nurse-led care on the outcomes of patients with diabetes?
2.2 Search Strategy

Systematic searches of CINAHL and MEDLINE were conducted for the period January 2000-18\textsuperscript{th} June 2010. PsycINFO and the British Nursing Index were also searched but did not yield any additional results. The on-line search was supplemented by a hand search of the literature through references identified from retrieved articles. Key words (alone and in combination) included: 'nurse-led', 'care', 'clinics', 'diabetes', 'prescribing', 'activities', 'effectiveness', 'impact' and 'patient outcomes'.

2.2.1 Inclusion Criteria

- Primary research studies in the last 10 years, published in the English language from any country.

Studies that specifically explored the role of nurses based in primary care, or were conducted purely on patients in primary care settings were excluded, as the focus of the search was to evaluate the literature on nurses working in secondary care settings (including hospital in- and out-patients).

2.3 Findings

A total of 668 results were identified from the searches. However, many of these were duplicated citations through combining search terms. Additionally many did not meet the inclusion criteria. A total of twenty three relevant publications representing twenty one research studies met the criteria for inclusion in the review. The methodological quality of all included studies, specifically the design, sample size considerations, participant details, reliability, validity, and study findings were considered. As suggested by Neill (2000), this approach ensures that papers are reported accurately, bias avoided, validity assessed, and areas of agreement and disagreement across study findings identified.
Table 2.1 provides an overview of each study, including where appropriate the content of the intervention, main outcome measures, and strategies used to address reliability and validity (Polit et al. 2001). Using guidance produced by the Centre for Reviews and Dissemination (2006) the quality of each study was assessed against the following criteria:

1) Is consideration given to the size of the sample, and / or a sample size calculation reported?
2) Does the study include a comparison group, and / or apply a randomisation procedure to the sample?
3) Is a sufficient description of the intervention provided, where appropriate, and / or the study processes?
4) Are relevant outcome measures reported?
5) Are methods to address the reliability and validity of the study adequately reported i.e. content validity, pilot testing and previously validated tools?

The extent to which these five aspects of quality were met is presented as a star rating in Table 2.1. A five star rating indicates that the each aspect of quality was present in the study.

The studies reviewed used a mixture of quantitative methods, predominantly randomised controlled trials (RCTs) and quasi-experiments. Seventeen were based in secondary care (including hospital in-patients (n=6) and out-patients (n=10)) and four across primary and secondary care.
### Table 2.1 Summary of study designs 2000-2010

<table>
<thead>
<tr>
<th>First author, year, (country)</th>
<th>Method</th>
<th>No of participants/ response rate</th>
<th>Sample/ Participants</th>
<th>Approach/</th>
<th>Main objective</th>
<th>Methods used to support reliability &amp; validity (including previously validated tools)</th>
<th>Study quality (star rating)</th>
</tr>
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<tbody>
<tr>
<td>Nurses who care for patients with diabetes</td>
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<tr>
<td>Courtenay, 2008 a,b Carey, 2008 (U.K)</td>
<td>Questionnaire</td>
<td>439/1400 qualified NISP who prescribed for patients with diabetes</td>
<td>Randomised sample of NISP.</td>
<td>Survey</td>
<td>To examine NISP for people with diabetes and the extent to which nurses feel prepared for this role and the prescribing practices of these nurses</td>
<td>1. Pilot testing 2. Previous survey (Courtenay et al. 2006) 3. Double check of data entry</td>
<td>5*</td>
</tr>
<tr>
<td>James, 2009 (U.K)</td>
<td>Questionnaire</td>
<td>159/361 (44% response rate)</td>
<td>Lead DSN in U.K diabetes centres.</td>
<td>National Survey</td>
<td>To review working practices of DSN, specific clinical roles and examine changes since 2000</td>
<td>1. Pilot testing</td>
<td>2*</td>
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DSN-Diabetes specialist nurse; NISP-nurse independent & supplementary prescriber; U.K-United Kingdom
<table>
<thead>
<tr>
<th>First author, year, (country)</th>
<th>Method</th>
<th>No of participants/ Response rate</th>
<th>Sample/ Participants</th>
<th>Approach/ intervention</th>
<th>Content of intervention</th>
<th>Main outcome measures</th>
<th>Methods used to support reliability &amp; validity (including previously validated tools)</th>
<th>Study quality (star rating)</th>
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<tr>
<td>Grey, 2002 (U.S)</td>
<td>Prospective repeated measures</td>
<td>Baseline &amp; 3 months n = 227 Sub-sample baseline, 3 &amp; 6 months n = 135/227</td>
<td>Convenience sample, newly referred patients with diabetes to life care programme. Patient Education.</td>
<td>3 x 4 hr education sessions on diabetes self management. Assessment with nurse, nutrition counselling, extra appointments and telephone calls as required for management. Patients enrolled for 3-6 months.</td>
<td>HbA1c, adherence to ADA guidelines, resource utilization. Not discussed</td>
<td>2*</td>
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<td>Flanagan, 2008 (U.K)</td>
<td>Retrospective audit</td>
<td>28,016</td>
<td>Convenience sample, hospital in-patients.</td>
<td>Staff Education.</td>
<td>Education sessions for all healthcare staff. Awareness improvement programme. Daily visit and support from DSN. Amount of contact and education each patient or staff member received is unknown.</td>
<td>LOS, bed occupancy, quality of care. 1. Pilot test</td>
<td>1*</td>
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<tr>
<td>James, 2004 (U.K)</td>
<td>Audit (adverse events) Questionnaires</td>
<td>42. 9/42 (21%) response rate for questionnaire. 19/ 28 (67%) response rate for questionnaire.</td>
<td>Convenience sample, hospital in-patients. Medical staff.</td>
<td>Patient &amp; staff education.</td>
<td>Amount of contact and education from DSN unknown. Glycemic control, adverse events, patient and staff satisfaction. 1. Previous audit (James et al. 2003)</td>
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DSN-Diabetes specialist nurse; HbA1c- glycosylated haemoglobin; ADA- American Diabetes Association; LOS-length of stay
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<th>Methods used to support reliability &amp; validity (including previously validated tools)</th>
<th>Study quality (star rating)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavan, 2001 (U.K)</td>
<td>Prospective study</td>
<td>819</td>
<td>Convenience sample, hospital in-patients.</td>
<td>Education and adjustment of insulin and oral hypoglycaemiac medicines. (average 2 visits from DSN)</td>
<td>DSN assessment, Advice on diet, blood glucose machine, insulin pens, discharge planning. Telephone contact for 3 months for new insulin treated patients. Weekly teaching sessions for staff.</td>
<td>LOS, number of occupied bed days, number of staff using DSN for support</td>
<td>Not discussed</td>
<td>3*</td>
</tr>
</tbody>
</table>

DSN-Diabetes specialist nurse; RCT-randomised controlled trial; HbA1c- glycosylated haemoglobin; ADA- American Diabetes Association; QOL-Quality of life; LOS-length of stay; BP-blood pressure; U.S-United States
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<tr>
<td>Denver, 2003 (U.K)</td>
<td>Quasi-experiment</td>
<td>120 116/120 (97%) completed study</td>
<td>Randomised sample, hospital out-patients, type 2 diabetes &amp; BP≥ 140/80 mmHg</td>
<td>Disease management protocols &amp; titration of medicines.</td>
<td>Routine primary care and nurse assessment monthly for 3 months, then 6 weekly for 3 months. Lifestyle advice, education re BP, titration of medicines, and adherence of drug regime. Patients enrolled for 6 months.</td>
<td>BP, 10yr CHD and stroke risk.</td>
<td>1. Framingham equation used to calculate 10yr CHD and stroke risk</td>
<td>3*</td>
</tr>
<tr>
<td>Kim, 2007 (South Korea)</td>
<td>Quasi-experiment</td>
<td>60 51/60 (85%) completed study</td>
<td>Hospital outpatients with type 2 diabetes, randomised into control or intervention group.</td>
<td>Education, and titration of medicines using web based approach.</td>
<td>Continuous access to website with education, reinforcement of diet, exercise and medicine adjustment, and self-monitoring. Regular feedback on medicine regime and adjustment via web and texting. 12 week intervention. Patients had to enter details at least once week.</td>
<td>HbA1c, fasting blood glucose, 2 hr post meal glucose.</td>
<td>Not discussed</td>
<td>4*</td>
</tr>
<tr>
<td>New, 2003 (U.K)</td>
<td>RCT</td>
<td>1014 (506 intervention) 638 (345 intervention)</td>
<td>Randomised sample, hospital out-patients, BP≥ 140/80 mmHg, total cholesterol ≥ 5.0mmol</td>
<td>Education and titration of medicines (average 2 visits for intervention groups).</td>
<td>Routine care and 45 minutes with specialist nurse. 30-45 min every 4-6 weeks until target achieved. Lifestyle advice and education, titration of medicines, drug action and side effects. Patients enrolled for up to 1 year.</td>
<td>BP or cholesterol, all cause mortality.</td>
<td>Not discussed</td>
<td>4*</td>
</tr>
</tbody>
</table>

DSN-Diabetes specialist nurse; RCT-randomised controlled trial; HbA1c- glycosylated haemoglobin, LOS-length of stay; BP-blood pressure; CHD-coronary heart disease
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<tr>
<td>Sampson, 2006 (U.K)</td>
<td>Prospective study</td>
<td>14,722</td>
<td>Convenience sample of hospital in-patients.</td>
<td>Education and adjustment of insulin and oral hypoglycaemic medicines.</td>
<td>DSN assessment. Medication review, dose titration. Lifestyle advice and education. Pre-discharge review. Group education for ward nurses. Amount of contact and education each person received unknown.</td>
<td>LOS.</td>
<td>Not discussed</td>
<td>2*</td>
</tr>
<tr>
<td>Young, 2002 (U.K)</td>
<td>Prospective audit</td>
<td>43/51 eligible patients</td>
<td>Hospital out-patients, insulin treated patients HbA1c &gt; 7.5%.</td>
<td>Education and insulin dose adjustment.</td>
<td>Two 20 minute appointments with DSN. Advice on lifestyle, complications, injection technique. Insulin dose alterations. Telephone contact over 6 months as required. Patients enrolled for 6 months.</td>
<td>HbA1c, BMI, Insulin dose.</td>
<td>Not discussed</td>
<td>2*</td>
</tr>
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</table>

**Disease Management Protocols**

| Davidson, 2003 (US)           | Quasi-experiment        | 504 (252 intervention)            | Randomised sample, minority population, hospital out-patients. | Disease management protocols. | Amount and type of contact from DSN unknown Patients enrolled for 1 year | 10 standards of care (outlined by the ADA). | Not discussed                                                                          | 2*                      |

DSN-Diabetes specialist nurse; HbA1c- glycosylated haemoglobin; ADA- American Diabetes Association, LOS-length of stay; BMI-Body mass index
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<tr>
<td><strong>Evaluation of nurse interventions on patient outcomes</strong></td>
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<tr>
<td><strong>Patient self-care</strong></td>
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<tr>
<td>Kim, 2003 (South Korea)</td>
<td>RCT</td>
<td>50</td>
<td>Randomised sample, type 2 diabetes, hospital out-patients</td>
<td>Telephone support and medicine adjustment recommendations.</td>
<td>Routine care and 30 minute assessment, information booklet and daily log instructions, Education/diet reinforcement, exercise, risk factors, drug therapy, management of hypo-/hyperglycaemia, medicine adjustments recommendation. Average 16 calls @ 25minutes for 12 weeks Patients enrolled for 12 weeks.</td>
<td>Self-report adherence questionnaire, HbA1c.</td>
<td>1. Self-report adherence questionnaire (Kim 1999) 2. Content validity 3. Internal consistency</td>
<td>4*</td>
</tr>
<tr>
<td>Wong, 2005 (China)</td>
<td>RCT</td>
<td>101/120 eligible patients completed the study</td>
<td>Randomised sample, hospital in-patients, patients deemed fit for discharge except for their glycemic control</td>
<td>Regular telephone support.</td>
<td>Routine care, Patient discharged 1-2 weekly telephone contact with DSN over 24 weeks Patients enrolled for 24 weeks</td>
<td>HbA1c, LOS, emergency department attendance, adherence and patient satisfaction.</td>
<td>1. Content validity 2. Inter-rater reliability adherence assessment form</td>
<td>5*</td>
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DSN=Diabetes specialist nurse; RCT=randomised controlled trial; HbA1c- glycosylated haemoglobin; LOS=length of stay
## Chapter 2: Review of the Literature

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</table>
| Davies, 2001 (U.K)           | RCT    | 300                               | Randomised sample, hospital in-patients. | Patient education. | Routine care & individual structured education and information. Amount of contact from DSN unknown. | QOL, LOS, time in days to readmission, patient satisfaction, diabetes knowledge, use of community resources. | 1. Audit of Diabetes Dependent Quality of Life (Bradley 1994)  
2. Diabetes Knowledge Questionnaire (Dunn et al. 1984)  
3. Diabetes Clinic Satisfaction Questionnaire (Wilson & Home 1993) | 4*        |
| Shibayama, 2007 (Japan)       | RCT    | 134/309 eligible patients  
61/67 completed intervention (91%) | NIDDM attending hospital out-patients, aged 20-75 years, HbA1c: 6.5%-8.5%. | Patient counselling and education. | Routine care & monthly appointment with DSN (range 8-76 minutes) with individual structured information and education, lifestyle assessment and advice. Patients encouraged to problem solve, set realistic goals, & identify barriers to behaviour. Patients enrolled for 1 year. | QOL, HbA1c, modification of cognition & behaviour. | 1. Piloting  
2. Content validity  
5. Japanese version of problem areas in diabetes survey (PAID) (Ishii et al. 1999) | 5*        |

DSN-Diabetes specialist nurse: RCT-randomised controlled trial: NIDDM-non insulin dependent diabetes mellitus: HbA1c- glycosylated haemoglobin: QOL-Quality of life: LOS-length of stay
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DSN—Diabetes specialist nurse; HbA1c—glycosylated haemoglobin; QOL—Quality of life
2.3.1 Methodological issues in the research reviewed

Research Tools
The available research evaluating nurse-led activities in diabetes is entirely questionnaire surveys (Carey & Courtenay 2008, Courtenay & Carey 2008a, 2008b, James et al. 2009, Winocour et al. 2002). Although participants in each of the studies reviewed were asked to self-report the areas of diabetes care in which they were involved, they were not asked to indicate the frequency or amount of time they spent on these activities each week. Consequently, it is not possible to determine the extent of their involvement in these activities.

Fourteen of the eighteen studies that evaluated an intervention used standard clinical measures, such as blood pressure (BP) and HbA1c, to report the effect of the intervention on patients' health. Studies reporting on patient outcomes (Davies et al. 2001, Kim & Oh 2003, Shibayama et al. 2007, Vrijhoef et al. 2001, Vrijhoef et al. 2002, Wong et al. 2005) predominantly used surveys to assess patient satisfaction, knowledge and self-care practices. Given the range of variables and previously validated tools that were used to assess these outcomes, it is difficult to generalise the findings from this aspect of work.

Study Quality
Overall study quality is poor. Using the quality assessment criteria, described in section 2.3 of this chapter, studies received an average three star rating. The quality of three studies was low (Flanagan et al. 2008, James 2004, Winocour et al. 2002). In contrast, four studies (Chan et al. 2006, Courtenay & Carey 2008a, Shibayama et al. 2007, Wong et al. 2005) were classified as being high quality and received a five star rating. All studies reported on relevant outcome measures. However, there was less consistent reporting on considerations regarding sample size and methods to support reliability and validity.
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Reliability & Validity


Studies exploring in-patient care have predominantly undertaken a prospective design (Cavan et al. 2001, Sampson et al. 2006) or been conducted as an audit (Flanagan et al. 2008, James 2004). However, scant methodological information is provided and it is unclear how the work was carried out. While it is likely that further details of these studies could be obtained by contacting the authors, it is important to note that factors such as editorial policy or space restrictions in these more medically based journals may have precluded detailed reporting. Consequently, less confidence can be placed in the evidence that the nurse intervention was causally related to outcomes, as relationships found may be explained by confounding factors.

Sampling

Sample size calculations were conducted in seven studies (Chan et al. 2006, Davies et al. 2001, Kim 2007, Kim & Oh 2003, New et al. 2003, Shibayama et al. 2007, Wong et al. 2005). However, sample size in each of the studies reviewed is variable (range= 40 to 28,016) and in some cases small (James 2004, Kim & Oh 2003, Young et al. 2002). The demonstration of statistical significance in studies with a small sample size should therefore be interpreted with some caution.
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Location of data collection

Eleven of the twenty one studies were based in the U.K. Of the six studies (Cavan et al. 2001, Davies et al. 2001, Flanagan et al. 2008, James 2004, Sampson et al. 2006, Wong et al. 2005) that were conducted on hospital in-patients only one (Wong et al. 2005) explored the effect of a nurse-led intervention on patient outcome measures. The generalizability and application of the findings from the review are therefore limited by the different types of healthcare provision and settings in which this work has been carried out (e.g. study country, hospital in-patient or out-patient clinic).

Description of the Interventions

Studies evaluating nurse-led interventions, and patient evaluation of these interventions, are predominantly RCTs (Barr-Taylor et al. 2003, Kim & Oh 2003, New et al. 2003, Shibayama et al. 2007, Wong et al. 2005). Generally, studies provided relatively little information about the DSNs who delivered the intervention. These studies also frequently lack information about the content of the intervention (Davidson 2003, Flanagan et al. 2008, James 2004, Sampson et al. 2006). As previously mentioned, while it is likely that further details of these studies could be obtained by contacting the authors, a lack of clarity regarding the content of interventions means it could be difficult to repeat the studies, and therefore reduces the reliability of this research.

Design of the Interventions

al. 2005, Young et al. 2002). The frequency of these encounters ranged from a total of five to twenty minutes, once or twice a week on the telephone, to twelve weekly clinic appointments. Study duration and follow-up are also variable and inconsistent ranging from three months up to one year. Studies reporting on in-patients with diabetes (Cavan et al. 2001, Davies et al. 2001, Flanagan et al. 2008, James 2004, Sampson et al. 2006) primarily examine measures relating to the admission period. The inconsistency in the content of the interventions and short follow-up periods make it difficult to determine the most effective approach to care.

Additionally, the majority of participants in out-patient intervention studies (Barr-Taylor et al. 2003, Chan et al. 2006, Davidson 2003, Denver et al. 2003, Grey et al. 2002, Kim 2007, Kim & Oh 2003, New et al. 2003, Shibayama et al. 2007, Vrijhoef et al. 2001, Vrijhoef et al. 2002, Young et al. 2002) appear to have received additional medical input during the study period and consulted their regular physician at least once during the trial period. It is possible that this additional input may have had some influence on the findings.

Specific methodological issues relating to the individual studies are addressed within the main body of the review.

2.4 Themes from the literature

The following key themes were identified from the review:

- Nurses who care for patients with diabetes (n=3)
- Evaluation of nurse interventions on service delivery (n=12)
- Evaluation of nurse interventions on patient outcomes (n=6)
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Each theme is explored below.

2.4.1 Nurses who care for patients with diabetes

Several studies report findings that describe the activities of nurses who care for patients with diabetes. Within this theme several sub-themes emerged: ‘nurses’ roles’, ‘prescribing practice’, and ‘specialist knowledge’.

Nurses’ roles

Two surveys have explored the main areas of care that nurses caring for patients with diabetes are involved (James et al. 2009, Winocour et al. 2002). The main areas of care linked to their role and function include education, patient management, promotion of self-care, acquisition of physical skills and psychological support.

It is unclear from Winocour et al.s (2002) study as to whether consultant physicians or nurses reported on the activities of the DSN. However, subsequent sections of the questionnaire did require physicians to collect additional information from other healthcare professionals including nurses. This additional information collected from 75% of the sample, indicated that DSNs were involved in adjusting hypoglycaemic agents. More than 95% reported that DSNs were involved in patient management and education. Where a telephone help line was in place, over 90% of respondents reported that DSNs were involved with this service.

Evidence from a more recent national survey (James et al. 2009) suggests that since 2002 the role of nurses caring for patients with diabetes has undergone significant development. Specifically examining the working practices of DSNs in the U.K in 2007, James et al. (2009) reported that, in addition to their more traditional roles such as education of healthcare professionals and patients, dose titration, and providing a telephone help-line, 90% offer independent nurse-led clinics: clinics that
frequently provide a specialist service to renal and antenatal patients with diabetes. Insulin pump training was also reported to be an important area of activity by over 50% of respondents. Importantly, nearly 60% of DSNs reported they were involved with prescribing medicines.

*Prescribing practice*

Specifically exploring the prescribing practices of nurse independent and nurse supplementary prescribers (NISP) in more detail, Courtenay & Carey (2008a) conducted a national survey in 2006, and reported that nearly a third of all qualified NISPs in the U.K. prescribe for patients with diabetes. Whilst the majority of nurses were based in general practice (e.g. practice nurse and nurse practitioners), it is evident that nurses working in a variety of roles (e.g. midwives, children’s nurses and community psychiatric nurses) and settings also prescribe medicines to this group of patients. Further examination of the prescribing patterns of these nurses suggests that the majority prescribe more than six items a week and frequently prescribe oral hypoglycaemic medication, insulin, antihypertensive, and lipid regulating drugs (Carey & Courtenay 2008, Courtenay & Carey 2008b).

*Specialist knowledge*

Winocour *et al.* (2002) and Courtenay & Carey (2008a) also assessed nurses’ level of specialist training in diabetes. Findings from Winocour *et al.*’s (2002) survey indicate that over 90% of DSNs had received training to educate patients and staff about diabetes. A basic course in general diabetes was reported by over 85% of respondents as a desirable criterion in the job specification for a DSN. More recently, Courtenay & Carey (2008a) report over 80% of NISPs who prescribe for patients with diabetes have a degree level qualification or higher. However, only 55% had undertaken a diploma, degree or masters level module in diabetes. Although another
23% had undergone informal training in diabetes (including visits to a specialist nurse or Diabetiologist, in-house training, and training provided by drug companies), 20% had not undertaken any specialist training in diabetes. Importantly, nurses with specialist education in diabetes found the prescribing programme met their needs to a greater extent than those without, and prescribed a greater number of items per week for patients with diabetes compared to those without specialist training (Courtenay & Carey 2008b).

Summary

There are specific areas of care in which nurses caring for patients with diabetes are frequently involved. These areas include education, individualised care, patient management, promotion of self-care, acquisition of physical skills and psychological support. Recent evidence suggests that over the last few years the role of the diabetes nurse has expanded quite considerably whereby large numbers of specialist nurses now provide specialist nurse-led clinics. It is evident from the findings that the majority of nurses appear to be actively involved in titration of insulin dose and medicine adjustment for patients with diabetes. Furthermore large numbers of both specialist and non-specialist nurses appear to have incorporated the prescribing role into the care they provide for this group of patients. Having formal education and training in diabetes appears to increase the extent to which nurses use their prescribing qualification for patients with diabetes.

2.4.2 Evaluation of nurse interventions on service delivery

This theme examines twelve studies that have evaluated the effect of a nurse-led intervention on service delivery of patients with diabetes. A number of sub-themes
emerged from the literature including 'patient and staff education', 'education and management of patients', and 'disease management protocols'.

Patient and staff education

There is some evidence to suggest that an increased amount of education for diabetic patients has a positive effect on a number of areas of diabetes management (Flanagan et al. 2008, Grey et al. 2002). These areas include glycemic control, emergency admissions, clinic attendance rates and length of hospital stay.

Grey et al. (2002) conducted a prospective repeated measures study to examine the effects of a patient education intervention on patients with diabetes in a minority population. In addition to regular quarterly attendance at the Diabetes Life Care programme and appointments with their physician, any further patient contacts with the nurse over the remaining period were then determined by individual need. Outcome measures included glycemic control, adherence to standards of service provision, hospital admissions and visits to the emergency department. At three months, significant improvements in HbA1c were identified in 142 out of 227 patients. At six months, these improvements remained for 66 patients. Adherence to the standards of care for annual eye and foot examination were also significantly improved.

More recently, Flanagan et al. (2008) explored the effect of an educational intervention provided by a team of five specialist diabetes nurses on length of stay and the number of emergency admissions. Focussing on early identification and treatment of patients with diabetes, an education programme for each hospital ward was established. A rolling programme of diabetes related education sessions for healthcare professionals was also provided. Although the intervention is poorly
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described by the researchers it is evident that a specialist nurse visited each ward daily. Overall length of stay was reduced but not to a significant level. However, there was a significant reduction in length of stay for diabetes emergency admissions.

The effect of education provided by a DSN (and qualified supplementary nurse prescriber) on glycemic control was also explored by James (2004). Additional measures included the number of hypoglycaemic events, patient satisfaction and staff knowledge. Hypoglycaemia, occurs when blood glucose drops below 3.0mmol/l. This causes a number of symptoms such as dizziness, sweating, shaking and palpitations that usually go away 10 to 15 minutes after eating sugar. If left untreated it can lead to seizures, coma, and even death (IDF 2006). Data collected included information on the medication used to treat diabetic patients, changes to medication and adverse events. Patients and staff also completed a short questionnaire. These questionnaires measured patient and staff satisfaction with the role of the DSN prescriber and staff knowledge with regards to the management of diabetes.

James reports a reduction in the number of hypoglycaemic events and improved glycemic control. However, it is unclear how much contact or education patients and staff received from the DSN prescriber. Only nine out of the forty two patients and nineteen out of the twenty eight staff completed questionnaires. Staff were found to be highly supportive of the project and reported that their knowledge of how to manage diabetes had improved. Similarly, patients reported high levels of satisfaction with the role of the DSN prescriber.

*Education and management of patients*

(combining education, the adjustment (or changes) to patient medications and or the use of the telephone or web) provided by a DSN, on length of stay, number of occupied bed days, HbA1c, lipids, BMI, symptoms of hypoglycaemia, patient and physician satisfaction, and quality of care.

Over a two year period, Cavan et al. (2001) examined the effect of an educational intervention provided by a DSN advisor, and subsequent adjustment of insulin and hypoglycaemic medications using medicine protocols on hospitalised diabetic patients. Advice on discharge planning was also provided. During their hospital stay patients received an average of two visits from the DSN. Outcome measures included length of stay, number of occupied bed days and the number of doctors and nurses who used the DSN advisor to support their decisions.

Compared to computer records from the previous year, median length of hospital stay was significantly improved for both medical and surgical patients. Although not at a significant level, bed occupancy rates for patients with diabetes were reduced representing a net saving of 4,171 bed days. The average length of stay for surgical patients showed marginal improvement. However, the average length of stay for medical patients increased. All twenty eight doctors surveyed reported that they had used the DSN advisor and found it a useful service. Additionally, nursing staff reported that the DSN had enabled them to access appropriate and rapid advice on patient management.

The effect of a intervention involving education and insulin dose adjustment provided by a DSN was also examined by Young et al. (2002). Using poorly controlled and insulin treated diabetic patients these researchers conducted a prospective audit. Interventions took place on initial referral to the DSN and two weeks later. Any additional patient contacts with the DSN over the remaining six month period were
then determined by individual need. Outcome measures included HbA1c, BMI, and insulin dose. Twenty seven of the forty three patients seen by the DSN improved with regards to lowered HbA1c and increased insulin dose. BMI did not show any rise. The remaining sixteen patients showed no corresponding improvement with regards to HbA1c and there were no significant changes in insulin dose or BMI.

Sampson et al. (2006) examined the effect of an educational and clinical intervention provided by a DSN on in-patients with diabetes. Combining adjustment of insulin and oral hypoglycaemic medications and discharge planning with patient and staff education these researchers analysed bed occupancy data for medical and surgical in-patients for six years, with the intervention in place for the final two years. Comparing bed occupancy data of in-patients with diabetes to matched groups of patients who did not have diabetes, before and after the intervention, mean excess bed days was the only outcome measure reported. Although information on the number of visits the DSN made to each patient and the amount of education provided to staff members is not provided, following the intervention mean excess bed days were significantly reduced with a resultant net saving of 700 bed days for those aged under sixty, and 1330 bed days per year for those aged 61-75 years.

Barr-Taylor et al. (2003) used a RCT to determine the effect of a DSN intervention on HbA1c, BP, lipids, quality of life, physician visits, hospital admissions, emergency room visits, patient satisfaction and physician satisfaction. In this study, patients with poorly controlled diabetes and one or more major co-morbid conditions were randomised to either the intervention or control group. Patients in the control group received written information encouraging them to maintain contact with their physician and to attend general diabetes education classes. In addition to regular
scheduled telephone calls any further contact for patients in the intervention group, was then determined by need.

Patients in the intervention group attended on average three and a half group sessions, received on average thirteen phone contacts, and five changes to their medication regime from the DSN. Self-report forms were completed by patients before and after the study. Sixty one intervention patients and fifteen physicians (with two or more intervention patients in the study) were invited to complete a survey to assess their satisfaction with the programme (fifty seven patient and thirteen physician completed questionnaires were returned).

The effect of the intervention on BP was inconclusive and there were no significant changes to the number of physician visits, admissions to hospital, or emergency room visits. Overall, a significantly higher number of patients randomised to the intervention group achieved their HbA1c goal. Additionally, mean reductions in HbA1c, and cholesterol were significantly greater in these patients. Patients in the control and intervention group reported improved mood and a high level of confidence to engage in self-care behaviour. The majority of patients reported high levels of satisfaction with the programme reporting that the programme was very helpful in preparing them to self-manage their condition. Similarly, staff were found to be highly supportive of the DSN intervention with 70% strongly recommending that the programme be adopted by their healthcare system.

These findings are further supported by Chan et al. (2006) and Kim (2007). Chan et al. adopted a quasi-experimental design to determine the effect of a diabetes nurse clinic intervention on patients with poorly controlled type 2 diabetes on glycemic control. Other outcome measures were BP, weight, healthcare utilization and quality of care. Patients attending a regional out-patient clinic were randomised to either a
control or intervention group. The emphasis of the intervention was to promote self-management behaviours, communicate the importance of lifestyle changes, and provide regular attention and feedback on patient's monitoring.

At twelve weeks, the HbA1c, and systolic BP of patients in the intervention group had improved significantly when compared to baseline measures. Healthcare utilization had also significantly decreased (i.e. admission or emergency room attendance). A questionnaire completed by participants before and after the intervention identified a significant improvement in the overall quality of care of patients in both groups. A possible explanation for this provided by the researchers was that patients in both intervention and control groups felt more engaged and ultimately more satisfied in the care that was provided.

Using a RCT, Kim (2007) explored the effects of a twelve week web-based nurse intervention on glycemic control. In this study, hospital out-patients with type 2 diabetes who were able to self-test blood glucose, inject insulin if necessary, had access to the internet at home and owned a cellular phone, were randomized to either the intervention or control group. Patients in the control group maintained usual contact with their diabetes specialist doctor and were provided with the usual recommendations about medication, education and lifestyle modification.

Patients in the intervention group participated in web-based education, medication adjustment and frequent self-monitoring of blood glucose. Additionally they were asked to electronically record their blood glucose levels and medication dosage information on the web at least once a week. Based on this information the nurse then used the internet and short message service of the cellular phone to recommend any necessary dose adjustments. Glycemic control was significantly improved in patients whose HbA1c was $\geq 7.0\%$ at baseline. Additionally, in patients
whose baseline HbA1c was <7.0%, fasting glucose, and two hour plasma-glucose were also reduced; however this was not at a level of statistical significance.

Two further studies (Denver et al. 2003, New et al. 2003) provide additional evidence with regards to the positive effects of a specialist nurse intervention combining education and adjustment of patient medications. New et al. (2003) used a RCT to examine the effect of specialist nurses on raised BP, raised total cholesterol and mortality. Eligible diabetic patients who presented at their annual review with raised BP (> 140/80 mmHg), raised total cholesterol (> 5.0 mmol), or both were randomized to the nurse-led hypertension clinic, the nurse-led hyperlipidemia clinic, or usual care. Participants attended a mean number of two visits for both intervention groups.

A higher number of patients randomized to the specialist nurse-led clinic achieved their treatment targets. However, the effect of the intervention on hypertensive patients was not significant. The authors suggest that this can be explained to a large extent by the concurrent implementation of local hypertension guidelines, whereby an ongoing reduction in BP in the whole study population was identified. In contrast the hyperlipidemia-only intervention group demonstrated significantly improved attainment of targets. Additionally, the two intervention groups demonstrated a significant reduction in patient mortality.

These findings are further supported by Denver et al. (2003). These researchers used a RCT to determine the effect of a nurse-led hypertension clinic on systolic BP, diastolic BP, lipids, HbA1c, and ten year CHD and stroke risk scores. Patients attending a hospital clinic with type 2 diabetes, treated hypertension, and a seated BP ≥ 140/80 mmHg were randomly assigned to the intervention or control group. Patients in the intervention group were three times more likely to reach a target systolic BP < 140 mmHg and experienced a significant reduction in ten year CHD and
stroke risk scores. However, there were no significant differences between the two groups in the reduction of diastolic BP, lipids, or HbA1c.

*Disease management protocols*

One study (Davidson 2003) examined the effects of a DSN-led service on enhanced patient compliance and patient management. Using a number of DSN-led protocols to manage and titrate medicines, this researcher examined the effect of nurse-led care, on the ten standards of service provision, (as outlined by the American Diabetes Association (ADA)), for a randomised sample of diabetic patients in a minority population. Standards of care were significantly improved in seven out of the ten areas described by the ADA for patients who had received the intervention. These areas included diabetes education, nutrition counselling, HbA1c, lipid and renal profile, foot and eye examination. Additionally, patient HbA1c levels improved.

*Summary*

Improved glycemic control, cost effectiveness and decreased length of hospital stay are the main benefits of nurse-led interventions in diabetes care. Other positive benefits include improved patient satisfaction, improved glucose monitoring, improved quality of care and increased clinic attendance. Additionally the rate patients were re-admitted to hospital was also reduced. The findings of research examining nurse-led care on BP and cholesterol are inconsistent. It is evident that healthcare staff are supportive of the DSN. However, the effect of the role of the DSN on staff knowledge and patient management is currently unreported.

Disease management protocols are the main mechanism by which nurses adjust and titrate medicines for patients with diabetes. The scope of professional practice and nurses’ involvement in the adjustment and titration of medicines are varied. This appears to be related to the nurses’ area of clinical practice and competence in the
management of diabetes. There is negligible evidence exploring the effect of nurse prescribing.

2.4.3 Evaluations of nurse interventions on patient outcomes

The final theme reports on six studies that have been conducted to evaluate a nurse intervention on patient outcomes. Several sub-themes emerged in this area of the review: 'patient self-care', 'quality of life', 'quality of life and self-care'.

Patient self-care

Two studies (Kim & Oh 2003, Wong et al. 2005), both RCTs, have been conducted to examine the effect of a nurse intervention on patient self-care, glycemic control, and patient satisfaction.

In order to examine the effect of a nurse intervention on diabetes adherence and glycemic control, Kim & Oh (2003) randomised patients with type 2 diabetes from a city hospital clinic to either the intervention group or routine care. Each participant received on average sixteen calls from the nurse, each lasting on average twenty five minutes. Patients who had received the intervention demonstrated significantly increased levels of self-care with regards to glucose monitoring and diet adherence. Additionally, patients' HbA1c levels were significantly improved.

Similar findings are reported by Wong et al. (2005). This researcher randomly assigned patients in a regional hospital, who were deemed fit for discharge by a doctor (except for their glycemic control) to receive the intervention or routine care. Patients in the control group remained in hospital and continued to receive routine care. Data was collected at baseline, twelve and twenty four weeks. This data included HbA1c, length of stay, emergency department attendance, adherence and
Chapter 2: Review of the Literature

patient satisfaction. At twenty four weeks the HbA1c of patients in the intervention group had significantly improved. Additionally these patients had significantly higher blood monitoring and exercise adherence scores (at twelve and twenty four weeks) and a shorter hospital stay with estimated savings of HK$11,888 (£960) per patient. Both groups of participants reported similar high levels of patient satisfaction with nurse-led diabetes care and education.

Quality of life

Four studies (Davies et al. 2001, Shibayama et al. 2007, Vrijhoef et al. 2001, Vrijhoef et al. 2002) looked at the effect of a DSN intervention on quality of life (QOL). Davies et al. (2001) used a RCT to examine the effect of a DSN led intervention on in-patients referred to the DSN service. Other effects examined by these researchers included length of hospital stay, time (in days) to readmission, use of community resources, patient satisfaction, diabetes knowledge and disease specific quality of life. Patients were randomised to receive either the intervention or routine care. Those randomised to the intervention group, received individual structured patient education from the DSN who also provided practical management advice to ward-based doctors and nurses. Although the amount of contact time between patients in the intervention group and the DSN is unclear, it is clear that the intervention was delivered by a team of four DSNs.

Diabetes knowledge and quality of life were assessed using questionnaire surveys at the point at which participants were randomised, and one week following hospital discharge. Additionally a patient satisfaction questionnaire was distributed one week post-discharge. Overall quality of life remained unchanged. Patients in the intervention group were significantly more satisfied with the care they had received, significantly less likely to use community resources and were more knowledgeable
about their diabetes. When compared to the control group, the median length of stay was significantly lower in patients in the intervention group, producing an average saving of £436 per patient.

Shibayama et al. (2007) similarly adopted a RCT to determine the effect of one-to-one lifestyle counselling intervention provided by a DSN on quality of life, glycemic control and modification of cognition and behaviour. Patients in the control group received routine care. Those in the intervention group received routine care plus monthly appointments (of eight to seventy six minutes duration) with the DSN over a one year period, where they received individualised structured information, education and lifestyle advice. Additionally they were encouraged to problem solve, set goals, and identify barriers to behaviour.

Health related quality of life, and cognitive and behavioural modification were assessed using a combined questionnaire at baseline and one year follow-up. Patients in the intervention group showed significantly higher scores in both cognition and behaviour modification. However, glycemic control and quality of life remained unchanged.

Quality of life and patient self-care

The effect of a DSN intervention on quality of life and patient self-care has also been examined in the Netherlands by Vrijhoef et al. (2001, 2002). A quasi experimental design was used by these researchers to examine the effect of a shared care model (with the DSN as the main care provider) for patients with stable type 2 diabetes. During the year long studies, data on clinical status and glycemic control were collected at baseline, six and twelve months.
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The group based protocols directed the DSN through several areas of patient care including consultations, interpretation of laboratory results, management, advice and education. Quality of life remained unchanged. In both studies, improved levels of knowledge were found in patients who received the intervention. This was also a significant finding in those patients who had participated in the pilot study. Self-regulation in both studies had also significantly improved. The level of patient self-care in these studies remained unchanged.

The most significant effect of the research conducted by Vrijhoef et al. (2001 & 2002), was the significantly improved level of glycemic control. In both studies a significant improvement in total cholesterol was also identified. Further positive and significant findings in the pilot study include improved mean diastolic BP, and triglycerides. Satisfaction rates were high and fairly stable across both studies.

Summary

Patient evaluations of nurse-led care report improved self-care and patient knowledge. Additionally, marginal improvements to quality of life and, patient satisfaction have been reported. The impact on several different measures has been explored including diabetic symptoms, HbA1c, length of hospital stay, and costs. The effects on these outcomes are variable and inconclusive. In each intervention, a strong emphasis was placed on education and support provided by a DSN. Disease management protocols were the main mechanism by which nurses were able to adjust and titrate medicines for patients with diabetes.
2.5 Gaps in the literature

This review has examined the literature by exploring the role and responsibilities of nurses who care for patients with diabetes and the contribution that nurses make to the care of this group of patients. There are gaps within the literature with respect to knowledge and understanding, methodology and theory, each of which is explored below:

a) Gaps in knowledge and understanding

The review of the literature has established that patients with diabetes experience a number of benefits when they receive nurse-led care including improved glycemic control, reduced length of stay, improved glucose monitoring, improved knowledge and higher levels of patient satisfaction. The care nurses provide to patients with diabetes includes a strong emphasis on patient education, support, advice and medicines management.

The literature reveals that although national policy highlights the importance of reducing medication errors and improving the quality of care that in-patients with diabetes receive, the effect of diabetes nurse-led care on medication errors is unreported. The majority of studies use standard clinical measures to report the effect of the intervention on patients' health e.g. BP and HbA1c. Few studies have reported on patient outcome measures related to quality of care e.g. patient satisfaction, ability to self-care, and only one Hong Kong based study reported on patient outcome measures for in-patients with diabetes.

Medicines protocols appear to be the main mechanism by which nurses have traditionally been responsible for the management of diabetes care. However, the literature in relation to nurses' roles indicates that nurses are increasingly
incorporating the prescribing role into the care they provide to patients with diabetes. While nurse prescribing has been introduced as a means to improve access to healthcare professionals and service provision little attempt has been made to evaluate this role on diabetes services. Therefore, there is a need for evaluative research to explore the benefits of nurse prescribing and to provide objective data on in-patient outcome measures such as medication errors and length of stay. Intervention studies need to provide a rationale for their content and incorporate the prescribing role into their design. Additionally there is a need to explore the effects of nurse-led care on other quality of care measures that in-patients with diabetes experience such as their ability to self-care, and the extent to which their information needs are met.

b) Gaps in methodology

There is a lack of outcome studies on in-patients with diabetes which require an experimental approach and a lack of data looking at long-term study effects. Clearly, there is a need therefore for future studies on in-patients with diabetes to adopt both an experimental approach and a longitudinal design.

c) Gaps in theory

The literature reveals that research in this area tends to adopt an experimental approach and is highly medically orientated. Consequently it is not underpinned by theory or located within a critical framework. Intervention studies primarily report clinical measures such as cholesterol, BP and HbA1c. Attempts are made to report on patient satisfaction, but this is not explored in any detail.

The issues and gaps highlighted within the review of the literature form the basis of the research questions formulated within the quasi-experiment as described in
Chapter 2: Review of the Literature

Chapter 1.4. The next chapter of the thesis explains the theory of medication errors, the theoretical framework used in this evaluative study of a diabetes specialist nurse prescriber on in-patients with diabetes.
Chapter 3: Theoretical Framework

3.1 Overview

The roles and activities of nurses who care for patients with diabetes and the contribution that nurses can make to this group of patients were demonstrated in the previous chapters. While the number of DSNs involved with prescribing medicines is increasing (James et al. 2009), little attempt had been made to explore how the prescribing role can be used to improve diabetes in-patient services, or reduce the number of medication errors that this group of patients experience. Given that national guidance highlights that DSNs should have an integral role in improving diabetes in-patient services (DH 2008b), evaluation of the prescribing role is required.

This chapter will discuss the theoretical framework used. The rationale for the medicines management intervention used in the study and, anticipated benefits to patient care will be explained.

3.2 Theory of Medication Errors

Based on the theory of medication errors (Leape 1994, Reason 1990), a general systems theory (von Bertalanffy 1968), this study aimed to develop an intervention led by a DSN prescriber that would address a number of factors associated with medication errors (ME) and shortfalls in service provision that in-patients with diabetes experience (DH 2003a, 2008b, HCC 2007b).

There is substantial evidence to suggest that most MEs involve a chain of problems, and a variety of systemic features such as the level of the task, team, work environment and the wider organisational context (Dean et al. 2002, Hellman 2001,
Chapter 3: Theoretical Framework

2004, Leape 1999, Reason 1990, Vincent 2003). Reason (1990), Vincent et al. (1998) and Dean et al. (2002) describe two types of error; slips and lapses, and mistakes. Slips and lapses are errors of action and occur when there is a break in routine and attention is diverted. In comparison, mistakes which are more difficult to detect are rule and knowledge based errors, and are errors of conscious thought. Mistakes commonly result from a lack of knowledge or mis perception of the situation with the subsequent application of the wrong rule to the situation.

It is recognised that ME occur when human system factors interact with the process of delivering medicines to produce an unintended or potentially harmful outcome (Vincent 2003). The system of providing medications to patients is complex with multiple sub-processes and as a result errors can occur at each stage of the process by which patients receive their medication e.g. prescribing (including transcribing or physician ordering), dispensing, preparation, administering and monitoring (Clancy 2004, NPSA 2007). The rate at which errors occur at each stage of the medication process also varies. For example, a recent review of 59,802 ME reported to the National Reporting and Learning System (NRLS) in the U.K between January 2005-2006 (NPSA 2007) identified that 59% of errors occurred during the administration of medicines, 18% preparation or dispensing, 16% prescribing and 9% monitoring.

Many specific factors have been repeatedly associated with errors i.e. slips, lapses and mistakes that occur in the system of delivering medicines to patients including a lack of knowledge of the drug and the patient, poor history taking, a high work load, failure to follow policy and procedure, miscalculations of drug dose, errors in decimal points, medications with similar names, use of abbreviations and complicated dosage regimes (DH 2004, Leape et al. 1995, Lesar et al. 1997, NPSA 2007, O’Shea 1999, Wilson et al. 1995).
Although errors are an intrinsic part of mental functioning and cannot be totally eliminated (Anderson & Webster 2001, Ioannidis & Lau 2001, Reason 1990), there is considerable evidence to suggest the fundamental cause usually lies in a variety of systemic features operating at the level of the task, the work environment and the wider organisational context. The primary objective of a system designed to deliver medicines safely is to make it difficult for individuals to err (Leape 1994). Ideally, a system as Leape (1994) suggests, will automatically correct errors or have mechanisms in place to at least detect errors in time for corrective action. A structured and systematic approach to reducing medication errors means that instead of focusing on the individual the focus is on the conditions under which individuals work and how these conditions predispose individuals to err (DH 2004).

3.3 The Medicines Management Intervention
Insufficient access to diabetes health professionals, doctors and nurse lack of knowledge about diabetes and its treatment, a lack of information from health professionals during admission, a lack of control over self-management during admission and unnecessary side-effects from medicines are nationally recognised shortfalls in diabetes in-patient services (Audit Commission 2000, HCC 2007a). Similar shortfalls in service provision were identified in the study hospital following an audit conducted as part of an ongoing programme to improve the care in-patients with diabetes receive (James 2003). It was evident that the shortfalls identified in the study hospital by James (2003) were rooted across several parts of the process by which they received their insulin and OHA medication i.e. prescribing, administration and monitoring.
Chapter 3: Theoretical Framework

The medicines management intervention (MMI) was therefore developed to improve the care in-patients with diabetes receive. It was anticipated that combining key components from the established role of the DSN (e.g. medicines management, education, support and promotion of self-care) (Carey & Courtenay 2007) with the relatively new role as a prescriber would help improve the prescribing, administration and monitoring stages of the process by which in-patients with diabetes received their insulin and OHA medication.

There were 3 stages to the MMI:

1) Medication review by a DSN prescriber
2) Education and support for patients and healthcare professionals i.e. doctors and nurses
3) Encouraging patients (and their families) to self-care and manage their condition

A rationale for each stage of the MMI is presented below:

1. Medication Review by a DSN prescriber

There is considerable evidence to suggest that regular medication review is one effective way to optimize drug therapy, check compliance and concordance, improve patient understanding, improve health outcomes, and reduce the likelihood of medicine related problems i.e. adverse events, medication errors and unnecessary side-effects (Cohen et al. 2005, HCC 2007a, Medicines Partnership 2002). Importantly, it is recognised that the effect of medication review is maximised when it is undertaken in a systematic way and conducted by a competent person (Medicines Partnership 2002).
Chapter 3: Theoretical Framework

In addition to providing a systematic approach to care, it was believed that if the DSN prescriber conducted a medication review diabetes in-patients would have access to a knowledgeable and experienced diabetes health professional during their admission. It was anticipated that the DSN prescribers’ high level of technical competence and knowledge of diabetes medicines management would help optimize drug therapy, improve patient understanding and reduce the number of medicine related problems. It was expected that this in turn would help reduce the number of medication errors and length of stay that in-patients with diabetes experience.

2. Education and support for patients and staff

Evidence suggests that the education and knowledge of healthcare professionals are key factors that contribute to the errors experienced by in-patients with diabetes (DH 2004, Kowiatek et al. 2001, NPSA 2007). Additionally, the literature suggests that patients with diabetes who are knowledgeable about their condition are more likely to adhere to their prescribed treatment regime, self-manage their condition (National Prescribing Centre 2005, Norris et al. 2001) and demonstrate improved health outcomes (Clark & Dodge 1999, Marks et al. 2005b).

Therefore, it was envisaged, that if the DSN prescriber provided structured individual ward-based patient education sessions appropriate to need (including information on the patient’s condition, management of medicines, medication changes and self-management) patients would report improved self-efficacy: additionally the extent to which their information needs met would also be enhanced.

Furthermore, it was expected that if medical and nursing staff received individual high quality education sessions appropriate to need, (including information on the treatment regime of each patient, drug actions and dose, drug interactions and
adverse effects), this learning would be applied to the practice setting, and patient care would improve with the number of medication errors potentially being reduced.

3. **Encouraging patients (and their families) to self-care and manage their condition**

It is evident from the literature that patients with diabetes who are more confident about their condition are also more likely to adhere to their prescribed treatment regime and self-manage their condition (Norris *et al.* 2001). This stage of the intervention was based on the chronic disease self-management programme (CDMP), developed by Lorig *et al.* (1996), a well established framework which encourages patients to self-care and manage their condition. The CDMP incorporates cognitive and behavioural modification strategies suggested by Bandura (1977). These strategies are designed to enhance self-efficacy and include weekly action planning, group problem solving, and individual decision making. Additionally, information from a well qualified and highly credible person appears to have a greater impact on efficacy expectations than messages from a less credible source (Marks *et al.* 2005b).

Several experimental studies (Dongbo *et al.* 2003, Hammond *et al.* 1999, Lorig *et al.* 1999, Wright *et al.* 2003) have explored the effect of the CDMP on patients with a variety of chronic diseases including arthritis, diabetes, and asthma. The findings indicate that improved health behaviour, psychological well-being, quality of life, self-efficacy, and reduced hospital admissions are all benefits from interventions that adopt this programme. Additionally, it is evident that interventions which adopt a format similar to the CDMP are more successful than those that use traditional methods of managing patients (Marks *et al.* 2005b).
Chapter 3: Theoretical Framework

It was envisaged therefore that the support and encouragement provided by the DSN prescriber would have a positive effect on patients' ability to self-care and improve self-efficacy and the extent to which their information needs were met.

An experimental approach was identified as being the most appropriate research methodology to support this theoretical framework and answer the research questions. The use of the experimental approach is discussed in the following chapter.
Chapter 4: Methodology

4.1 Overview

This chapter explores the epistemological approach of the study and the philosophical basis of experimental design, specifically focusing on quasi-experiments. The study design, sample selection, research setting, and content of the medicines management intervention are then considered. Finally, ethical considerations of the study are discussed.

4.2 Epistemology

Contemporary healthcare and medicine in particular prides itself on its objective status which has been achieved through longstanding scientific accomplishment. Objectivism is the epistemological view that things exist as meaningful entities independently of experience. Thus, the aim of research is to attempt to find objective truth and meaning. This is the epistemology underpinning the positivist stance.

During the three distinct generations of positivist philosophers e.g. Locke, Hume and Comte in the early 18th and 19th centuries, Ayer (1936) and Carnap (1932) in the early 20th century, and Hemple (1965) in the post war period, the ideas associated with positivism have been developed, challenged and restated a number of times. The key elements of this approach remain however, largely unchanged (Crossan 2003, Outhwaite 1987). Therefore, there are a number of implications for research based on this approach as explained by Hughes & Sharrock (1997), Easterby-Smith et al. (2001), and Crossan (2003).

Positivism adopts a clear quantitative approach to investigation as the belief is, this is the only research from which valid generalisations can be made. Positivism assumes
that things can be studied as hard facts and the relationship between these facts can be established as scientific laws (Crossan 2003, May 1993). Any data collected within positivism is therefore theory driven and designed to test the accuracy of the theory under investigation (Black 2003). Consequently, rather than using human beliefs or interests, objective criteria tend to be used to determine the topic of interest and how to study it: the aim of which is to identify causal explanations. In addition to the topic of interest being operationalised in a way that enables facts (data) to be measured objectively, the role of the researcher is also believed to be independent of the subject under examination. Furthermore, it is believed that if problems are reduced to the simplest elements they will be better understood.

A major criticism of the positivist approach is that it does not provide the means to examine human beings and their behaviours in an in-depth way (Crossan 2003, Playle 1995, Whall & Hicks 2002). As Playle (1995) and Crossan (2003) assert, humans are not objects and are subject to many influences on behaviour, feelings, perceptions and attitudes that positivists would reject as irrelevant. Consequently, there is a denial of the importance of influence and context of the relationship between the researcher and research participant. Data are seen as being gathered rather than created and the researchers own influence is not acknowledged (Playle 1995). Critics of the positivist approach also argue that it yields useful but limited data on the phenomenon under investigation (Crossan 2003, Playle 1995).

Post-positivism however, provides an alternative to the traditions and foundations of positivism, and aims to describe and explore in-depth phenomena from a qualitative perspective (Crossan 2003, Parahoo 2006, Playle 1995). In contrast to positivism, the post-positivist approach recognises the intricate relationship between individual behaviour, attitudes and external structures. It additionally assumes that reality is multiple, subjective and mentally constructed by the individual. The approach fits well
with nursing which has historically dealt with understanding patients' values and meanings (Playle 1995, Whall & Hicks 2002). The subjective experience of the patient and ensuring an individualised, holistic approach to care are also key components of modern healthcare services (DH 2008c, Whall & Hicks 2002).

A key criticism of the post-positivist approach however, is the subjective nature of the inquiry and lack of control over researcher bias (Crossan 2003, Parahoo 2006). Other limitations of this approach generally relate to the interactive and participatory nature of the qualitative methods used during data collection. Furthermore, it is argued that qualitative research lacks both reproducibility and generalizability (Crossan 2003, Polit et al. 2001).

Given the multifaceted, complex and dynamic nature of nursing practice it is evident that neither positivism nor post-positivism should be the sole approach to scientific inquiry. While there is a danger in the acceptance of objectivity that not only will there be a continuing dehumanization of the research process but also the subjects of the research themselves (Playle 1995), it is evident ascribing to only one view will lead to an incomplete nursing science (Crossan 2003, Giddings & Grant 2007, Whall & Hicks 2002). Positivistic views in medical science are strong and enduring and at a time of increasing skill mix and interdisciplinary practice these views may greatly affect the continued development of nurses' roles. With this in mind, positivism was deemed to be the most the appropriate philosophical approach to test the hypotheses and answer the research questions as discussed in Chapter 1.4.
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4.3 The Experimental Approach

Experiments allow comparisons between different approaches to treatment and interventions across all areas of healthcare. Rooted in traditional scientific method, and aiming to remain impartial and objective, the emphasis is on the investigation of what may be directly observed (Watts et al. 2001). Using a set of orderly disciplined procedures, the researcher systematically moves from defining the research question to data collection and analysing the findings.

In the late 19th century, John Stuart Mill and his followers were instrumental in the development of experimental methods (Wilson-Barnett 1991). Unhappy with simply counting the observations (variables) of interest, they wanted to change things and put nature to the test and evaluate the results. The chief premise of the approach is that groups of similar subjects are selected and treated the same apart from at least one factor which is introduced or manipulated to influence the outcome. By comparison and evaluation of the different groups, factors can be identified which help to infer a causal link. Advantages of this approach include the ability to test hypotheses, and the capacity to compare effects of interventions to generate a level of confidence for estimated values uncovering influences and patterns of interactions (Wilson-Barnett 1991). Experimentalists seek to achieve consistency in observations, reliability in measures across subjects, and reproducible findings. However, if the observations are not systematic and replicable, the theory can lack scientific rigour and robustness. The experiment by nature of the study design can be replicated by other investigators and by consistency of findings achieve some degree of confidence in generalisations (Poole & Jones 1996).

Substantial knowledge in healthcare has been built through experiments, and significant advances in understanding have been provided through experimental
Chapter 4: Methodology

evidence, including the role of psychological and physical rehabilitative interventions in aiding adaptation and recovery after major illness (Wilson-Barnett 1991). Increasingly, the results from randomised controlled trials are the foundation on which good practice guidelines have evolved. However, there are still limitations and disadvantages of this approach. In addition to the difficulties in observing and understanding human behaviour, Seaman & Verhonick (1982) point out that there are only a few valid criterion measures of the dependent variable available to indicate the effects of the independent variable upon human subjects. Additionally, in the current health service philosophy of encouraging participation in care i.e. fully informed consent and freedom of choice, some controlled experiments may increasingly seem both unacceptable and unethical.

Concerns have also been expressed by the nursing discipline over the fundamental issue regarding the suitability of scientific enquiry for investigating nursing interventions (Poole & Jones 1996). Consequently, experiments have often been deemed inappropriate for the advancement of nursing. Despite this, the field experiment is still considered to be a viable option for testing new techniques and procedures for nursing care (Wilson-Barnett 1991). The concise analysis of specific variables (techniques or treatment) under investigation is a key advantage of the experimental approach. The results from the analysis can then be used to determine the effects of nurse-led interventions on patient care.

It is evident from the literature reviewed in Chapter 2 that there is a paucity of experimental research investigating the effects of care provided by a DSN prescriber on in-patients with diabetes or its impact on outcome measures. This was an important fact that was considered during the formulation of the research questions and during the initial stages of the research design.
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4.4 Quasi-Experiments

The design of this research is a quasi-experiment. A true experiment consists of two equivalent groups of participants who are randomly assigned into either an experimental group or control group (Babbie 1998). In comparison to participants in the control group, those randomised to the experimental group are exposed to an intervention. However, in contrast to a true experiment, in a quasi-experimental design experimental and control groups may not be equivalent or randomized or there may be no control group (Polit et al. 2001).

Consequently, in a quasi experiment, as all the factors that might affect the outcome are not controlled, the researcher is more limited in drawing wider conclusions. Despite this, quasi-experiments are still associated with a high level of rigour (Polit et al. 2001). Consequently, the degree of confidence and level of causation which can be inferred from analysis of the data collected using this approach are also high.

In this study, which was conducted on six wards in one hospital in the East of England, it was neither possible nor practical to randomize the participants. A quasi-experimental design was chosen as a realistic and practical method to successfully evaluate the MMI. It enabled the intervention to be delivered without randomization, and prevented interaction between participants in the control and intervention groups (thus reducing the risk of bias within the results, and minimizing the rate of attrition).
4.5 Study Design

A longitudinal study design was adopted. During the study there were three data collection points, on admission, discharge, and three months follow-up. The researcher, DSN prescriber and Consultant Diabetologist agreed that a three month follow-up period was an appropriate time frame for patients to have recovered from their hospital admission and for the final data collection point.

Whilst it is accepted that the act of research and data collection (in itself an intervention) can affect the data (Becker et al. 2003), a time series involving the collection of data over an extended period of time allows data to be tested for change over time. As a result of participation however, during the period of data collection the testing effect can occur whereby participants improve their scores and or change their behaviour. Despite these limitations this was still deemed the most appropriate study design in order to assess the effect of the MMI provided by a DSN prescriber on the number of insulin and OHA medication errors, LOS, SE and patients' medicine information needs.

Participants who met the inclusion criteria for the study (explained in more detail in section 4.7 of this chapter) and were recruited in the first three months were assigned to the control group (pre-intervention group). Following a one month period designed to enable ward staff to adjust to a nurse-led service, data was collected for a further three months. Subsequent participants who met the inclusion criteria, recruited between months 5-7, were then assigned to the intervention group. Participants in the control group received standard care i.e. their medicines were prescribed and managed by medical (i.e. House Officers, Senior House Officers and non-diabetes Specialist Registrars) and nursing staff other than a DSN prescriber. In comparison, participants in the intervention group, in addition to standard care, received the MMI
delivered by the DSN prescriber (See chapter 3 and section 4.8 of this chapter for a more detailed description of the MMI). Figure 4.1 below provides a diagrammatic overview of the study design and the three data collection points used in the study.

![Figure 4.1: Study Design and Data Collection Points](image)

### 4.6 Research Setting

The research setting was six medical and surgical wards in a District General Hospital in the East of England. As part of a service improvement programme for inpatients with diabetes, the Diabetes team at the hospital approached the University of Reading (the university where the researcher was registered as a student at the time) to undertake a collaborative study. This setting supported the quasi-experimental design of the study and allowed a detailed exploration and comparison of the delivery of two different models of care for in-patients with diabetes to be conducted.

Participants were recruited between May to December 2005 and data collection was completed in March 2006. The study wards were identified by the hospital as those where patients with diabetes were most likely to be admitted. Hospital staff including managers, consultants, the DSN and ward-based doctors and nurses confirmed that they would be willing to support the study.
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4.7 Sample Selection

Subjects were a convenience sample of patients with diabetes i.e. all patients admitted on to one of the six wards during the three month pre-intervention phase and three month intervention phase who met the inclusion criteria. Convenience sampling is the selection of the most readily available subjects as participants in a study (Polit et al. 2001). Although convenience sampling can limit generalizability and cause problems with representativeness, bias and erroneous findings, it is an inexpensive and efficient way of ensuring sufficient participants (Polit et al. 2001). The use of a convenience sample in this study ensured that all participants who met the inclusion criteria were in-patients with diabetes on one of the study wards at the hospital.

Data collected from all eligible patients admitted on to one of the six wards during the three month pre-intervention phase and three month intervention phase were specifically used to address question 1 (Sample 1) i.e. ‘do hospital in-patients, who receive a MMI from a DSN prescriber, experience a reduction in a) a the number of insulin and OHA medication errors and, b) LOS?’

Initial inclusion criteria were:

- Patients who were prescribed insulin and or OHA medication
- Patients who were not self-medicating

Figure 4.2 below provides a diagrammatic overview of the study design, sample selection and data collected from sample 1.
Chapter 4: Methodology

Pre-Intervention group (Months 1-3)

Diabetic patient admitted to medicine, surgery, orthopaedic, vascular surgery, amputation or medicine (renal) ward

Intervention group (Months 5-7)

Eligibility criteria checked
Not self-medicating
Prescribed insulin and or oral hypoglycaemic medication

Eligible to participate?

Yes

Details added to study records (no further action taken)

No

Participate in Sample 1

Data collected to answer Question 1:
Do hospital in-patients, who receive a medicines management intervention from a diabetes specialist nurse prescriber, experience a reduction in a) the number of insulin and oral hypoglycaemic (OHA) medication errors and, b) length of stay (LOS)?

On Admission
Collect demographic data: admission type, type and management of diabetes, age & sex

At Discharge
Admission and Discharge Date recorded, hospital medication chart, insulin chart, and insulin infusion chart copied made anonymous and sent for assessment of insulin and OHA errors

Data collection complete

Figure 4.2: Sample 1
Chapter 4: Methodology

Additional inclusion criteria were then applied in order to generate a smaller sub-sample of patients (Sample 2):

- does the patient have a predicted length of stay of at least 3 days (to ensure they were in hospital long enough to receive the MMI)?
- is the patient admitted to the medical ward (specialising in renal disease), the vascular surgery ward or the vascular amputation ward?
- is the patient conscious, alert and not confused, not acutely ill or in pain?
- does the patient have an adequate command of English?
- does the patient have any special needs or communication problems?

Patients who met the additional inclusion criteria were then approached on admission regarding willingness to participate in the additional elements of the study designed to answer question 2: 'do hospital in-patients, who receive a MMI from a DSN prescriber, report improved levels of SE?'; question 3: 'do hospital in-patients who receive a MMI report an improvement in the extent to which their medicine information needs are met?' and question 4: 'what types of information do patients consider important about their medicines?' Figure 4.3 below provides a diagrammatic overview of the study design, sample selection and data collected from sample 2.

Prior to identifying the inclusion criteria for sample 2, the admissions department of the hospital were asked to provide data on the average length of stay for patients admitted to the six study wards. It became evident from this information that patients admitted to the renal medicine, vascular surgery and amputation wards were more likely to be admitted to hospital for at least three days i.e. long enough to receive the MMI. Therefore data for sample 2 were only collected from these three wards.
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Pre-intervention group
Months 1-3: All participants received routine care

Further eligibility criteria checked
Predicted length of stay at least 3 days?
Admitted to medicine (renal), vascular surgery or vascular amputation ward
Conscious, alert and not confused
Adequate command of English
No special needs or communication problems

Eligible to participate?
Yes
No

Details added to study records

Patient information leaflet given and left for 24 hrs

Patient willing to participate & consent obtained?
Yes
No

Refusal recorded

Participant in Sample 2

Additional Data collected to answer Questions 2, 3 & 4
Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, Q2) report improved levels of self-efficacy Q3) report an improvement in the extent to which their medicine information needs are met? Q4) What types of information do patients consider important about their medicines?

On Admission
Administer Questionnaire 1
Collect additional demographic data: marital status, employment, ethnicity, housing, length of diagnosis, other chronic disease

At Discharge
Administer questionnaire 2

Normal care resumed

3 Month follow up
Administer questionnaire 3

Data collection complete

Figure 4.3: Sample 2
4.7.1 Sample size

Sample size was determined using the previous year's admissions data from the six study wards and evidence from a review of medication error intervention studies (Ioannidis & Lau 2001). Reviewing data from 37 studies these researchers identified that regardless of sample size (range 90-11,000) large treatment effects were almost always present in the reviewed studies. An estimated sample size of 500 was therefore deemed adequate to ensure accurate and reliable statistical conclusions for sample 1.

Further consideration was given to determining the size of sample 2, and in order to answer research questions 2, 3 and 4. This was based on the information provided by the hospital admissions department described in section 4.8 and sample size (range 30-110) of the studies used in the psychometric testing of the diabetes management self-efficacy scale (DMSES) (Kappen et al. 2001, Kara et al. 2006, McDowell et al. 2005, Moens et al. 2001, van der Bijl et al. 1999); the scale used to measure diabetes self-efficacy described in Chapter 5.5.3. It was estimated that reasonable study effects would be detected if the size of sample 2 was around 80 patients. However, an unexpected decrease in eligible patients admitted to the three relevant study wards during data collection, meant only 56 patients were recruited to sample 2.

4.8 Medicines Management Intervention

A DSN prescriber who was experienced and well regarded in the hospital was used to deliver the MMI to all patients in the intervention group. This included an initial patient assessment by the DSN prescriber (including a review of their medicines regime), one to three structured individual ward based patient education sessions appropriate to need (information was provided on the patient's condition,
management of medicines, medication changes and self-management), and on-going review of patients medicines regime. Additionally, family members were included in the education sessions so they could also improve their knowledge and understanding of diabetes. The frequency of education sessions and their content were based on the initial patient assessment.

During the intervention period the DSN prescriber also provided medical and nursing staff with one to two individual education sessions appropriate to need. These sessions comprised information on the treatment regimes of each patient including drug action and dose, drug interactions and adverse effects. After discharge both groups of patients (i.e. pre-intervention and intervention) received routine care for their diabetes. Nurse supplementary prescribing was instigated in the absence of medical staff, in an emergency or if a delay in prescribing would adversely affect the patient.

4.9 Ethical Considerations
This research utilized the three primary ethical principles on which standards of ethical conduct in healthcare research are based: beneficence, respect for human dignity, and justice (Hendrick 2000, Polit et al. 2001). These principles helped ensure that the rights of participants were protected and were used to guide each stage of the research process. Each ethical principle is discussed in more detail below:

a) Principle of beneficence
Beneficence is the requirement to benefit the research participant. It is imperative that the researcher ensures that participants do not experience any harm (Hutchinson 2009). In this study, no risk was identified with regard to the physical, psychological or emotional involvement that could be caused by involvement in the study. In accordance with the NHS research and governance framework, data collected to answer research question 1 was classed by the Research Governance
Chapter 4: Methodology

Committee at Peterborough and Stamford Hospital NHS Foundation Trust as an audit i.e. information was gathered with the intention of evaluating the effectiveness of efficiency of a care or treatment plan which lies within current professional practice (National Research Ethics Service 2006). This committee granted Research and Development approval for the study to be conducted in the hospital trust.

The study was also considered by the University of Reading Ethics Committee (the university where the researcher was registered as a student at the time) (a copy of the approval letter can be found in Appendix 1) who granted ethical approval for the study to be conducted.

b) Principle of respect for human dignity

This principle includes the right to self-determination and the right to full disclosure. Self-determination means that participants have the right to decide voluntarily whether to participate in the study (Polit et al. 2001). As research question 1 was classed as an audit, only those participants who met the inclusion criteria for sample 2 had the right to decide whether to take part in the additional element of the study i.e. completion of the three questionnaires.

Full disclosure means that the researcher has fully described the nature of the study, the person's right to refuse participation, and the likely risks and benefits that would be incurred by the participant (Hutchinson 2009, Polit et al. 2001). This was achieved in the following way: on admission, all potentially eligible patients for sample 2 were approached and given an information sheet and contact details of the researcher (Appendix 2). The researcher returned at least 24 hours later and if the patient agreed to participate, full details of the study and required level of involvement were then provided. Time was spent with each potential participant answering questions
and providing detailed information about the required level of involvement. A consent form (Appendix 3) was then signed by the patient and the researcher.

c) Principle of justice
This principle requires the researcher to be fair to participants and maintain their right to privacy. This includes maintaining confidentiality and anonymity of data (Office of Public Sector Information 1998, Polit et al. 2001). In addition to the above procedures, and those described in more detail in chapter 5.3, the demographic details and medication charts used to extract data to answer research question 1 were anonymised and coded in accordance with the Data Protection Act (1998).

The inclusion criteria, presented in section 4.7 of this chapter, ensured participants received fair treatment and a selection process based on the research requirements. The information sheet and consent form both emphasised the fact that completion of the questionnaires during the study was voluntary and participants could withdraw at any time if they wished to do so (Appendices 2 & 3). Patients were reassured that the study was anonymous and that no identifying information would be included in the report or publications emanating from the research. In case participants needed to access the researcher at any point during the study, each participant was given the contact details of the researcher.

The study was conducted in accordance with the approval of the University of Reading Ethics Committee and the Research Governance Committee at Peterborough and Stamford Hospital NHS Foundation Trust. The hospital also supported the researcher's application to obtain an honorary research contract.

The following chapter explores the methods of data collection used in the study and analysis of data for each research question.
Chapter 5: Methods

5.1 Overview

This chapter explores the rationale for the methods of data collection and data analysis for each of the four research questions. It commences with a description of practicalities and access, and the use of documentary evidence to collect demographic data. The methods of data collection (i.e. retrospective case record review and questionnaires), tool development, methods used in the main study and analysis of data used for each research question are then considered.

5.2 Practicalities and Access

For an innovation or change in practice such as the MMI to be accepted, Lewin (1952) and Heifetz (1994) recommend that the process needs to be carefully planned and effectively communicated at each level of the organization. Additionally, it has been recognised that communicating clear role definitions and objectives is an essential part of the process which supports the effective implementation of specialist and advanced nursing roles (Lloyd Jones 2005).

In order to prepare the staff who worked in the hospital trust, a series of staff meetings were held prior to the pre-intervention phase at which details (including information sheets) about the research were disseminated. These meetings created an opportunity to improve doctors, nurses and senior hospital managers understanding about nurse prescribing and allowed them to discuss any concerns or queries they had about the MMI. All ward staff were invited to attend the meetings and also an additional meeting at which the interim findings would be presented. Medical staff and the senior management team of the hospital were also invited to a presentation of the interim findings. It was hoped that these interim meetings, as Kotter (1996) suggests, would provide an opportunity to provide feedback on the first
stage of the project and help secure continued support from leaders of the organisation (i.e. senior management team). The researcher was also introduced to the medical and nursing staff on each ward and was provided with the opportunity to explain the research to staff in person.

Before and during the study regular meetings between the researcher, DSN prescriber and Service Improvement Manager were organised in London between September 2004 and January 2006. These meetings allowed discussion and support regarding the development and content of the research instruments, study design and progress of the study during data collection and analysis. Additionally, ongoing communication was maintained between the researcher, DSN prescriber and Service Improvement Manager through the use of regular e-mail and telephone contact.

5.3 Documentary Evidence

Documentary evidence, including both hospital and individual patient records were used to collect information on patients' length of stay and demographic data. Documentary evidence is classed as any evidence (or document) which is used to extract data (Babbie 1998). A number of demographic variables of interest associated with diabetes related outcomes were identified from the literature including age, gender, type of diabetes, management of diabetes, duration of diabetes, co-morbidities, ethnicity, employment status and marital status (BMA 2004, Deakin et al. 2005, NCCC 2008). Information extracted from these documents were used to support analysis of the data collected from the retrospective case record review and questionnaires, discussed in sections 5.4.6 and 5.5.7 of this chapter: detailed descriptions of which are provided in the following sections of this chapter.
5.4 Q1: Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, experience a reduction in a) the number of insulin and OHA medication errors and, b) LOS?

5.4.1 Retrospective case record review

In order to collect data to answer research question 1a) a modified version of retrospective case record review was used. Although there are numerous approaches to collecting data on error events (including spontaneous voluntary reporting, solicited voluntary reporting, direct observation and computerized screening algorithms) (Karson & Bates 1999, Woloshynowych et al. 2003), retrospective case record review is a well established technique used to identify medication errors (Classen et al. 1997, Leape et al. 1991, Vincent et al. 2001, Wilson et al. 1995, Woloshynowych et al. 2003).

The basic methodology for this approach was developed in the early 1970s in the U.S for the Californian Insurance Feasibility Study (Woloshynowych et al. 2003). It is a two-stage process. During stage 1, medical records are screened according to predefined criteria (e.g. unexpected death, sepsis or unplanned returned to the operating theatre) in order to identify records of patients more likely to have suffered an adverse event. Records meeting one or more of the criteria are then forwarded for clinical review by a trained clinician i.e. stage 2. Each case record in the second stage is examined in detail to determine whether or not an adverse event has occurred and information about the nature and cause of the adverse event e.g. medical history and physiological measurements is extracted. An adverse event (AE) is an umbrella term used to describe errors in healthcare that patients experience. More specifically it is defined as ‘an unintended injury to patients which prolongs hospitalization or produces disability’ (Karson & Bates 1999).
Retrospective case record review has a number of advantages (Vincent et al. 2001, Wilson et al. 1995, Woloshynowych et al. 2003). It provides a more complete indication of the incidence of AE than other types of reporting systems. The review documents provide a robust standardised method of recording and collecting data. However, the whole process is wholly dependent on the accuracy, completeness and legibility of patient records. Often the AE itself is not explicitly stated in the record and may not be recognised. Low to moderate inter-rater reliability has also been reported (Wilson et al. 1995). Furthermore, it can be time consuming and expensive. Despite these limitations however, several key studies have successfully used this method to improve patient safety and inform government policy (Classen et al. 1997, Vincent et al. 2001, Wilson et al. 1995, Woloshynowych et al. 2003).

Due to the time and financial limitations of this study, it was not possible or practical to review the full case records of each participant. A modified version of this technique was therefore adopted. An experienced and trained researcher in diabetes examined the anonymised medication records, insulin charts and sliding scale charts of all patients admitted onto the six study wards during the period of data collection. Each set of charts were assessed in order to determine whether or not the participant had experienced any insulin and OHA medication errors during their admission.

5.4.2 Tool development

In order to identify whether in-patients who receive a MMI from a DSN prescriber experienced a reduction in the number of insulin and OHA medication errors, a medication error chart (Appendix 4) was developed. Medication errors were identified from the literature (Kowiatek et al. 2001, Lesar et al. 1997, Manley et al. 2003), and work previously conducted in the study hospital (James 2003, 2004).
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Using the evidence from this literature, the errors were classified into fourteen different categories and reflected the three stages of the medication process targeted by the MMI i.e. prescribing, administration, and monitoring (Woloshynowych et al. 2003). Validity of the error categories was further confirmed by an expert panel based at the study hospital.

In order to support the reliability of the insulin and OHA errors that were recorded, the process by which errors were identified and extracted from the medication charts was conducted blind by an experienced diabetes researcher. Additionally, the first twenty error charts (and medication charts from which these errors were extracted), were reviewed blind by a Consultant Diabetiologist. There was agreement between the two reviewers (i.e. an experienced diabetes researcher and Consultant Diabetiologist) with regards to the insulin errors extracted from the medication charts and those recorded on the insulin and OHA medication error charts.

5.4.3 Pilot work

The medication error chart was piloted on the medication charts of twenty in-patients with diabetes i.e. insulin and OHA medication errors were extracted from the patient documents (i.e. hospital medication chart, insulin and or insulin infusion chart) and recorded on the medication error chart. This process was undertaken to ensure that all errors identified in the patient documents would ‘fit’ within the categories described on the error chart and thus further validate the error categories. Although some minor refinements were made to the description of some error categories, it was evident that the format and content of the chart was appropriate.
5.4.4 Methods used in Main Study

During the study, admission and discharge dates and demographic data (i.e. admission type, type and management of diabetes, age and sex) were collected from patient and hospital records on all participants. Following discharge, patient documents (i.e. hospital medication chart, insulin chart and insulin infusion chart) were assessed for the fourteen insulin and OHA medication errors i.e. errors were extracted from the patient documents and recorded on the error chart.

5.4.5 Recording and Organising Data

Microsoft Excel© was used to organise, collate and record the data from each patient. Upon discharge, in preparation for review and in order to maintain patient confidentiality and comply with the Data Protection Act (Office of Public Sector Information 1998), the hospital medication charts, insulin charts and / or the insulin infusion charts of each patient were photocopied and anonymised. These documents were then coded and the same code was given to the medication error chart used to record the fourteen insulin and OHA medication errors for each patient. In accordance with local policy and procedure, the photocopies and medication error charts (used to record the fourteen insulin and OHA medication errors) will be stored at the study hospital until 2016.
5.4.6 Data analysis

Data were collected from a total of 452 participants (Sample 1). The basic demographic data collected for sample 1 supported a general analysis of the frequency and distribution of the fourteen insulin and OHA medication errors across the three stages of the medication process. More detailed demographic data were collected from the participants in the smaller sub-sample 2 (n=56) (see Chapter 4, Figure 4.1). This additional demographic information supported a separate and more detailed analysis and exploration between the frequency and distribution of the fourteen insulin and OHA medication errors and a number of additional variables e.g. marital status, employment status, ethnicity, length of time since diagnosis, accommodation and any other chronic disease or illness (see Appendix 5). These findings were then used to explore the relationship between insulin and OHA medication errors, SE and patients medicine information needs.

Microsoft Excel© and SPSS version 12 were used for data entry and data analysis. Descriptive statistics were used to describe the demographic nature of sample 1 and sample 2. To ensure that cell size reached the recommended minimum of five and in order to achieve a reasonable degree of statistical power to detect effect (Pallant 2005), in both samples the fourteen insulin and OHA medication errors were re-categorised into the three stages of the medication process (i.e. prescribing, administration, and monitoring). Median values for length of stay are presented as this not a normally distributed measure. For both samples chi-squared tests were used for categorical data when testing for association. A number of statistical procedures were then applied to each sample, the details of which are provided separately.
A general linear modelling (GLM) procedure was used at various stages of the data analysis procedures for sample 1 and sample 2. GLM is a popular generalisation of the linear regression model, such that effects can be tested for categorical predictor variables e.g. type of diabetes and sex, as well as for effects of continuous predictor variables e.g. total number of errors and length of stay (Hill & Lewicki 2007). The GLM allows a wide variety of research outcomes to be summarized. Following discussion with a senior statistician from the University of Reading, this was deemed to be the most appropriate procedure to explore which if any demographic factors contributed significantly to explaining the variation in the total number of errors, length of stay and diabetes self-efficacy.

For each research question, and all tests that were conducted the level of significance (p-value) was set at the conventional 5% mark. Where findings fail to reach the level of statistical significance and / or are of particular interest they are included in the text.

Sample 1 data analysis

A GLM was used to explore whether age, sex, type of diabetes, admission category, or management of diabetes contributed significantly to explaining the variation in the total number of errors and length of stay. The model was then checked for goodness of fit using residual analysis.

Sample 2 data analysis

The number of categories for several variables (e.g. management of diabetes, marital status, accommodation and ethnicity) were reduced in order to achieve a reasonable degree of statistical power to detect effect (Pallant 2005).
Independent-samples $t$-tests, a procedure used to establish whether the two means collected from the two groups differ significantly (Field 2005), were used to compare the total number of errors and total number of chronic diseases or illness between the pre-intervention and intervention group. A GLM procedure was used to explore which if any factors contributed significantly to explaining the variation in the total number of errors, the three stages of the medication process and length of stay. These factors included age, sex, type of diabetes, time since diagnosis, admission category, management of diabetes, employment, accommodation, having another chronic disease or illness. The model was then checked using residual analysis.

5.5 Q2: Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, report improved levels of self-efficacy?

Q3: Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, report an improvement in the extent to which their medicine information needs are met?

Q4: What types of information do patients consider important about their medicines?

A series of three questionnaires were used to collect data in order to answer research questions 2, 3 and 4. A copy of each questionnaire is presented in Appendices 6, 7, 8. Data collection methods and analysis for these three research questions are considered together below.

5.5.1 Questionnaires

Whilst questionnaires are primarily used in survey research they are also widely used in experimental research (de Vaus 1996). There are three main approaches to using questionnaires; mail (self-completion), telephone surveys, and face to face interviews. Although the type of population, nature of question, and resources available will determine the type of questionnaire to be used, literacy problems,
cognitive issues, language differences and cultural considerations need to be fully thought out with regards to each approach and adjusted for during questionnaire development (Beckett et al. 2000, Brener et al. 2003). Additionally, cost and manpower are other factors that will affect the choice of the distribution method. Consequently, before the questionnaire is designed, researchers need to satisfy themselves that the approach adopted will be the most effective for their study.

In order to ensure that the analysis is valuable and complete, questionnaires must be carefully and specifically designed. In addition to biased responses, poor questionnaire design will fail to provide accurate answers to the questions under investigation and produce much irrelevant information, wasting time and money (Bennett et al. 1994, Kelly & Long 2000, Oppenheim 2000). The layout of the questionnaire and format of questions therefore needs to be simple, clear and unambiguous. Furthermore, thought needs to be given to the questions asked, and how they will be interpreted.

Careful consideration was given to the design, format and layout of the questionnaires to ensure that the descriptive and analytic data generated would support appropriate analysis to answer the research questions. In order to generate good quality data sets, a combination of questionnaire approaches were used i.e. mail / self-completion and telephone.

1) Mail / self-completion questionnaires

In a mail / self-completion questionnaire the respondent completes the questionnaire and the researcher has little control of the process. There are several advantages to this method. As the answers are anonymous, there is consequently less bias than in a face to face interview. Additionally, participants are able to consider their responses and take their time to complete it. However, there are some significant limitations.
Whilst the nature, content and level of interest in the topic can affect the response rate, many postal questionnaires typically achieve only a 50% response rate (Babbie 1998). Poor response rates can cause problems with representativeness of the sample. However, this can be partially overcome by the use of reminder questionnaires. Incentives such as gifts, money or free samples, although not adopted in the current study, have also been shown to have a positive effect on the response rate (de Vaus 1996). Furthermore, there is no control over who completes the questionnaire or in what order, and the researcher is unable to probe and explore beyond the actual factual answer.

2) Telephone Questionnaires

Increasingly, telephones are being used as an approach to complete questionnaires (Smith 2005). Although the overall cost is similar to a mail survey, they are much quicker to complete and significantly improve the response rate (Smith 2005). The main advantage of this approach compared to mail / self-completion questionnaires is that the quality of data can be enhanced i.e. the researcher is able to develop a rapport with the participant and ensure the questions are understood. This can enhance the completion rate and quantity of data. However, given that concerns have been raised that responses may be shorter and less information may be divulged when this approach is adopted, it is important that interviewers ensure that they create an atmosphere of confidence and professionalism and reassure participants of their usefulness.

3) Questionnaires completed by Interviewers

When using interviews to complete a questionnaire the main issue surrounds standardization. Whilst visual interaction is unavoidable, interviewers need to be
consistent in their approach and interaction with participants. As with telephone questionnaires, the researcher is able to develop a rapport and make sure the questions are understood by the participant. This approach also tends to yield a high response rate. However, compared to other approaches it is more costly in terms of both time and money.

The structure and format of the three questionnaires used in this study were based on the design of those previously used in the field of diabetes SE and patients medicines information needs (Berry et al. 2006, van der Bijl et al. 1999).

Participants in sample 2 were asked to complete three questionnaires. Questionnaire 1 was given to participants following admission, questionnaire 2 at discharge and questionnaire 3 at three months follow-up. Questionnaire 1 and 2 adopted a self-complete approach (and were returned using a stamp-addressed envelope). Questionnaire 3 was completed by telephone. However, several patients (specifically those who were hard of hearing or had a breathing problem) chose to have the questionnaire mailed to them to complete.

5.5.2 Questionnaire structure and format

A set of three questionnaire booklets, each 4-6 pages in length, were developed for this part of the study. The first page of each questionnaire contained information about the study and simple instructions on how to complete the questionnaire.

Each questionnaire contained a series of fifteen 6-point Likert scale statements designed to assess diabetes SE, specifically participants' confidence in activities to self-manage their diabetes i.e. managing blood sugar, adjusting medication, diet,
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exercise and lifestyle in various settings. Details of the next stage of the study were then provided.

Questionnaire 2 repeated the first fifteen questions and also included an additional question (Q16). The additional question asked participants to rate on a 6-point Likert scale how well their information needs had been met during their hospital stay. Questionnaire 3 comprised all questions in questionnaire 2, plus a series of eleven statements which required participants to rate how important certain areas of information were to them in an explanation about their medicines (Q17).

5.5.3 Questionnaire development

The questions used to assess diabetes SE and patients' medicines information needs were developed using two previously well validated instruments (Berry et al. 2006, van der Bijl et al. 1999). A description and rationale for the choice of these instruments is provided below.

All questions used unipolar Likert attitudinal scales to record responses and were graded from one to six, where six was the most positive response. Compared to single questionnaire items that capture the variable of interest, attitudinal scales provide the opportunity to view responses within the context of an individuals' overall responses to scale items, thus minimising the possibility of misinterpretation (Howe 1995). Responses obtained from individuals at different points in time are also more likely to be stable when using attitude scales compared to individual item indicators, thus enhancing reliability (Babbie 1998). However, it is important to note individuals who achieve the same overall score can respond very differently to particular items. Despite this limitation, attitudinal scales are an established and widely used technique (Howe 1995).
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1) Diabetes Self-efficacy tool

As discussed in Chapter 1, SE has been identified as both an important determinant of health behaviour and a good predictor of self care in chronic diseases (Bandura 1977, Glanz et al. 1997, Holloway & Watson 2002, Marks et al. 2005a). The strength of SE expresses the strength of belief an individual has that they can attain the expected level of behaviour, whereas a lack of SE can be a perceived barrier to taking a recommended health action (O'Leary 1985). An individual may give up trying because they lack a sense of efficacy in achieving the required outcome. Ultimately, for a change in health behaviour to occur an individual must believe that the change will be beneficial, have belief in their ability to make the necessary change and that the change will result in a valued outcome. If the behaviour produces the desired outcome, the behaviour is more likely to be tried again (Bandura 1986, van der Bijl & Shortridge-Baggett 2001). Thus, adherence to difficult medical and/or lifestyle regimes are likely to be more consistent and longer lasting in those patients whose belief in their abilities to affect their health are strong (Bandura 1977, Clark & Dodge 1999). Given that SE is a temporary and easy to influence characteristic (Clark & Dodge 1999), which is situation and task specific (Holloway & Watson 2002), the best way to assess SE is using a scale that has been designed to measure narrowly defined domains of SE in specific populations of patients with diabetes (Clark & Dodge 1999, Holloway & Watson 2002, van der Bijl & Shortridge-Baggett 2001).

A search of the literature between 1995-2005 identified five scales designed to assess diabetes related SE (Anderson et al. 2000, Rapley et al. 2003, Talbot et al. 1997, van der Bijl et al. 1999, Weinger et al. 2005). During tool development each of the five scales was appraised with respect to content, appropriateness and psychometric properties. Overall suitability to support the design and answer the research questions in this study was also considered. It was evident from the
literature (Anderson et al. 2000, Rapley et al. 2003, Talbot et al. 1997, van der Bijl et al. 1999, Weinger et al. 2005) that each scale has been designed to measure a variety of factors that affect diabetes SE including cognitive and social factors, psychosocial issues, diabetes knowledge, confidence, self-management and self-care behaviours.

Following this review the Diabetes Management SE scale (DMSES) (van der Bijl et al. 1999) was considered to be the most suitable scale and therefore selected. The DMSES is designed to measure efficacy expectations towards diabetes self-care activities, and has undergone extensive testing and validation. Additionally, a range of self-care behaviours are explored including general diabetes management, medication use, diet, self-monitoring of blood glucose (SMBG), exercise and foot care.

Five studies (Kappen et al. 2001, Kara et al. 2006, McDowell et al. 2005, Moens et al. 2001, van der Bijl et al. 1999) have been conducted to evaluate the DMSES scale in different populations and healthcare settings across the world. Convenience samples have been used to collect data from a total of 423 patients with diabetes from the community and hospital out-patient clinics. The twenty item DMSES has been adapted to four different languages, including English, and reported to be internally reliable in each setting. A more recently modified and validated fifteen item version of the DMSES (Sturt 2005) has also been developed. Good internal reliability of the DMSES (alpha coefficients ranging from 0.71-0.88) has been consistently demonstrated in studies that have previously explored the psychometric properties of the twenty item DMSES (Kappen et al. 2001, Kara et al. 2006, McDowell et al. 2005, Moens et al. 2001, van der Bijl et al. 1999). In addition, two studies which explored the longitudinal psychometric properties of the twenty item DMSES (Kara et al. 2006,
van der Bijl et al. 1999) similarly reported satisfactory test-retest reliability / stability at four to five weeks (alpha coefficients 0.79-0.91 p<0.01).

The use of scales which focus on measuring different aspects of an attitude, as in the DMSES, reduces the possibility of misinterpretation based on a single item indicator and also enhances content validity (Babbie 1998). Satisfactory content and construct validity of the twenty item DMSES have previously been reported (Van der Bijl et al. 1999). As the intention in this study was to assess diabetes self-care activities and the self-management skills of patients with diabetes repeatedly, this was an important fact that was considered during the development phase of the questionnaire.

In order to measure diabetes SE in this study the DMSES was modified, whereby the number of ratings per each item of the fifteen point scale was reduced from ten to six. The modified version of the DMSES used in this study demonstrated good internal reliability at each stage of data collection (alpha coefficients ranging from 0.79-0.92).

The content of the fifteen item SE scale, used as the first fifteen questions of each questionnaire can be found in Appendices 6, 7 & 8.

2) Medicines Information Needs tool

There is some evidence to suggest that giving patients information increases adherence to treatment regimes, increases self-care, self-management behaviour and promotes adaptive coping (Donovan & Blake 1992, Payne 2002). Berry et al. (1995) originally identified sixteen categories of information that individuals want to know about their medicine. Following a number of more recent studies (Berry et al. 1995)
2006, Berry 2004, Berry et al. 2008, Berry et al. 1995, Berry et al. 1997), conducted to explore the medicine information needs of different groups of the population including members of the public, adults, young children and rheumatology outpatients, the number of categories relating to the information needs of patients has been refined to eleven.

In this study, the eleven refined categories of medicine information (Berry et al. 1995, 1997, 2006, 2008) were used in questionnaire 3 (including information on side-effects, interactions, alternatives, and risks of not taking the medicine), in order to assess the medicine information needs of patients with diabetes (see Appendix 8, Q 17): the content validity and reliability of which are supported by their development, refinement and successful use in these more recent studies.

5.5.4 Pilot Work

In order to pilot the questionnaire ten patients with diabetes from Peterborough and Stamford Hospital NHS Foundation Trust (both hospital in- and out-patients) were asked to complete it. To further support the content validity, it was also sent to a DSN, hospital manager, and three academic colleagues specialising in diabetes. Participants in the pilot work were asked to comment on its ease of completion, and if they experienced any difficulties understanding what was required of them. Following this and comments from professional colleagues (DSN, manager and academic colleagues) the following amendments were made for the main study:

The length of questionnaire 1 was reduced by removing the section on demographic information. This information was then collected from the patient records. To reduce confusion all questions using Likert scales were graded from one to six, where six was the most positive response. In each questionnaire the instructions for
participants, particularly the medicines information need categories (Q17) in questionnaire 3, were reworded to improve clarity. After further piloting of the revised instructions and questionnaires with three further in-patients with diabetes, the questionnaires were ready for dissemination in the main study.

5.5.5 Methods used in Main Study

It was anticipated that each questionnaire would take about ten minutes to complete. On admission questionnaire 1 was given to the participant with a stamped-addressed envelope (SAE) to the University of Reading. Participants were asked to complete the questionnaire in their own time and return it to the university using the SAE. Participants’ demographic information (including marital status, employment status, ethnicity, housing, other chronic disease or illness, and length of diagnosis and patient contact details) was collected from the patients’ records during hospital admission. Questionnaire 2 was distributed to patients upon discharge and participants were asked to return it to the university in the SAE provided.

A week before the final data collection point (three months after discharge), participants were contacted by telephone and asked if they were still willing to complete questionnaire 3. A convenient time and date was then arranged with participants to conduct the telephone interview. Each question on the questionnaire was read verbatim over the telephone and completed by the researcher. If a telephone number was not available, or participants preferred to self-complete the questionnaire, the questionnaire was mailed to them (Appendix 9), with a postal reminder (if not returned within 2 weeks) (Appendix 10). Thank-you letters were mailed to participants following completion of the final questionnaire (Appendix 11). All demographic information and data obtained from the questionnaires were anonymised, entered into a database and analysed. Each questionnaire was also
Chapter 5: Methods

coded. All the questionnaires are stored in a locked filing cabinet, secured against unauthorized access and will be kept at the University of Surrey until 2016.

5.5.6 Recording and Organising of Data

Microsoft Excel® was used to organise, collate and record the data from each patient. Consistent processing of the questionnaires was carried out and a clear record of the questionnaires returned by each participant was kept. Each participant was given the same number throughout the study to allow correlation between data on demographic information, insulin and OHA medication errors, SE and medicines information needs. A coding schedule was developed for each questionnaire and used during data entry.

5.5.7 Data Analysis

1) Self-efficacy

Microsoft Excel® and SPSS version 12 were used for data entry and analysis. Data were summarized using descriptive statistics. The maximum score for the series of fifteen statements used to assess SE in each questionnaire was 90 i.e. the higher the score the higher the level of SE. Independent-samples t-tests were conducted to compare SE at each data collection point between the pre-intervention and intervention groups. Paired samples t-tests were used to compare pairs of means for the SE scores. This was conducted to evaluate and compare the impact of the MMI on patients' SE scores between groups.
A GLM procedure was used to explore which if any factors contributed significantly to explaining the variation in the SE scores on the three questionnaires. These factors included age, sex, type of diabetes, employment, accommodation, and having another chronic disease or illness. The model was then checked using residual analysis.

The relationship between insulin and OHA medication errors, SE and data from the three patient questionnaires was also investigated using the Pearson product-moment correlation coefficient, a technique that is used to describe and explore the strength of the linear relationship between two variables (Pallant 2005). The Pearson correlation coefficient (r) can range from -1 to +1. The size of the value provides information on the strength of the relationship, where a correlation of zero indicates no relationship between the two values. Relationships investigated included sex, type of admission, type of diabetes, length of stay, total number of errors.

2) Patient information needs and Types of medicine information

Data collected via Likert scales are ordinal (Mogey 1999) i.e. they have an inherent order, but it cannot be assumed that the difference between the points on the scales are the same. Data collected via Likert Scales were therefore summarized using descriptive statistics, and the distribution of observations displayed with tables. The frequency of responses was examined by combining the number of people selecting 1 or 2, and 5 or 6, scores. The non-parametric Mann-Whitney test, which works on the basis of ranking (Mogey 1999), was used to compare the findings between the two groups.

The next chapter presents the findings from the analysis of data, which are presented under each of the four research questions.
Chapter 6: Results

6.1 Overview

The results represent the analysis of the data collected from the documentary evidence, modified retrospective case record review and three questionnaires. An initial descriptive overview of participants will be followed by examination of the variables in relation to the effect of the medicines management intervention on medication errors, length of stay, self-efficacy, the extent to which patients' information needs were met, and in determining what information patients consider to be important about their medicines. The results are described below under each of the four research questions.

6.2 Q1: Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, experience a reduction in a) the number of insulin and OHA medication errors and, b) LOS?

Data collected from the modified retrospective case record review and documentary evidence (i.e. demographic information and information on LOS) are presented below. The results from sample 1 and the smaller sub-sample 2 are presented separately.

6.2.1 Sample 1

Between May 2005 and December 2005, 452 patients were included in sample 1 across both the pre-intervention (n=187) and intervention (n=265) groups using the inclusion criteria described in Chapter 4.7. The basic demographic data collected supported a general exploration and analysis of several key variables associated with diabetes patient outcomes and the frequency and distribution of the fourteen insulin and OHA medication errors.
6.2.2 Sample 1: Demographic Data

Table 6.1 summarises the demographic data collected from patients across sample 1. Participants were male (n=258) and female (n=194), and were admitted under medicine (n=227), surgery (n=98), kidney disease (n=27), orthopaedics (n=52), vascular amputation (n=17) and vascular surgery no amputation (n=31). Over 75% of participants across the two groups had type 2 diabetes and over 55% were treated with insulin. Patients' age ranged between 18-93 years and over 30% were more than 75 years of age.

### Table 6.1: Sample 1: Patient characteristics

<table>
<thead>
<tr>
<th>Type of Diabetes</th>
<th>Pre-intervention (n=187)</th>
<th>Intervention (n=265)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>44 (23.9%)</td>
<td>60 (23.3%)</td>
<td>0.980</td>
</tr>
<tr>
<td>Type 2</td>
<td>140 (76.1%)</td>
<td>197 (76.8%)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>106 (56.7%)</td>
<td>152 (57.4%)</td>
<td>0.690</td>
</tr>
<tr>
<td>Female</td>
<td>81 (43.3%)</td>
<td>112 (42.3%)</td>
<td></td>
</tr>
<tr>
<td>Management of Diabetes</td>
<td></td>
<td></td>
<td>0.771</td>
</tr>
<tr>
<td>Oral hypoglycaemic agents</td>
<td>79 (44.9%)</td>
<td>109 (43.4%)</td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>63 (35.8%)</td>
<td>98 (39%)</td>
<td></td>
</tr>
<tr>
<td>Oral hypoglycaemic agents and Insulin</td>
<td>34 (19.3%)</td>
<td>44 (17.5%)</td>
<td></td>
</tr>
<tr>
<td>Type of Admission</td>
<td></td>
<td></td>
<td>0.021</td>
</tr>
<tr>
<td>Medicine</td>
<td>83 (44.4%)</td>
<td>144 (54.3%)</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>41 (21.9%)</td>
<td>57 (21.5%)</td>
<td></td>
</tr>
<tr>
<td>Kidney disease</td>
<td>11 (5.9%)</td>
<td>16 (6.0%)</td>
<td></td>
</tr>
<tr>
<td>Orthopaedics</td>
<td>21 (11.2%)</td>
<td>31 (11.7%)</td>
<td></td>
</tr>
<tr>
<td>Vascular amputation</td>
<td>12 (6.4%)</td>
<td>5 (1.9%)</td>
<td></td>
</tr>
<tr>
<td>Vascular surgery (no amputation)</td>
<td>19 (10.2%)</td>
<td>12 (4.5%)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td>0.197</td>
</tr>
<tr>
<td>&lt;=61 years</td>
<td>64 (34.2%)</td>
<td>100 (38.5%)</td>
<td></td>
</tr>
<tr>
<td>62-74 years</td>
<td>63 (33.7%)</td>
<td>77 (29.6%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 75 years</td>
<td>60 (32.1%)</td>
<td>83 (31.9%)</td>
<td></td>
</tr>
</tbody>
</table>
In order to rule out patient demographic influences upon study results, all baseline demographic variables were examined to check for parity between the pre-intervention and intervention groups. Patient characteristics across the two study groups were generally similar (Table 6.1), although a greater proportion of patients in the intervention group were treated with insulin, were aged less than 61 years and admitted under medicine. Results of chi-square analysis showed that there was a significant difference in admission category between the two groups: however, there were no significant differences in the other demographic characteristics i.e. sex, age, type of diabetes, and management of diabetes.

6.2.3 Sample 1: Insulin and OHA Medication Errors

Data relating to the frequency and distribution of the fourteen insulin and OHA medication errors across the three stages of the medication process experienced by patients in sample 1 are presented in this section. Findings comparing the frequency of errors in the pre-intervention and intervention groups, and at each stage of the medication process are then presented.

In total, insulin and OHA medication errors were recorded for 85.8% (n=388) of patients across both the pre-intervention and intervention groups (see Table 6.2). Some patients in both groups experienced multiple errors. The maximum number of errors recorded for one patient in the pre-intervention group was 130 compared to a maximum of 33 errors for a patient in the intervention group. Administration (42%) and prescribing errors (43%) were the most frequent categories of ME on the charts of participants in both groups. Nurse Supplementary prescribing i.e. medicines were prescribed using an agreed clinical management plan (as described in Chapter 1.2), was initiated for 30 patients.
Chapter 6: Results

It was evident from an independent-samples t-test that there was a significant reduction in the total number of errors between pre-intervention \( (M=13.4, \text{SD}=21) \) and intervention groups \( (M=3, \text{SD}=6.0; t(376)=7.45, p=0.00) \). The magnitude of the differences in the means was moderate \( (eta\text{-squared}=0.11) \). Patients in the pre-intervention group experienced on average more than four times as many errors as those in the intervention group.

(The T-statistic is the statistic that is used to test whether a regression co-efficient is significantly different from zero, in this case used to determine whether the differences between two means are significantly different from zero (Field, 2005). Eta squared, can range from 0 to 1, and represents the proportion of variance in the dependent variable that is explained by the independent (group) variable (Pallant, 2005.).)

Table 6.2: Sample 1: Insulin and OHA medication errors

<table>
<thead>
<tr>
<th>Type of Insulin &amp; OHA Medication Error</th>
<th>Pre-Intervention</th>
<th>Intervention</th>
<th>Difference</th>
<th>Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration errors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin doses not signed as given</td>
<td>410</td>
<td>207</td>
<td>-203</td>
<td></td>
</tr>
<tr>
<td>Inappropriate dose of short acting insulin administered in response to hyperglycaemia</td>
<td>91</td>
<td>9</td>
<td>-82</td>
<td></td>
</tr>
<tr>
<td>OHA medication not signed as given</td>
<td>53</td>
<td>28</td>
<td>-25</td>
<td></td>
</tr>
<tr>
<td>Sliding scale doses not signed as given</td>
<td>45</td>
<td>70</td>
<td>+25</td>
<td></td>
</tr>
<tr>
<td>Omission of insulin after hypoglycaemia</td>
<td>16</td>
<td>8</td>
<td>-8</td>
<td></td>
</tr>
<tr>
<td>Charts incomplete</td>
<td>9</td>
<td>7</td>
<td>-2</td>
<td></td>
</tr>
<tr>
<td><strong>Total Administration errors</strong></td>
<td>624 (40%)</td>
<td>329 (44%)</td>
<td>-295</td>
<td>-47%</td>
</tr>
<tr>
<td>Prescribing errors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of insulin incorrect</td>
<td>247</td>
<td>82</td>
<td>-165</td>
<td></td>
</tr>
<tr>
<td>Insulin chart not signed by prescriber</td>
<td>108</td>
<td>44</td>
<td>-64</td>
<td></td>
</tr>
<tr>
<td>Unit abbreviated to 'u' and unclear</td>
<td>89</td>
<td>113</td>
<td>+24</td>
<td></td>
</tr>
<tr>
<td>Insulin not written up</td>
<td>62</td>
<td>60</td>
<td>-2</td>
<td></td>
</tr>
<tr>
<td>Number of units of dose unclear</td>
<td>52</td>
<td>56</td>
<td>+4</td>
<td></td>
</tr>
<tr>
<td>Prescription chart not signed by prescriber</td>
<td>11</td>
<td>11</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total Prescribing errors</strong></td>
<td>569 (36%)</td>
<td>366 (49%)</td>
<td>-203</td>
<td>-36%</td>
</tr>
<tr>
<td>Monitoring errors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin/oral medication dose not adjusted when persistent BG &gt; 14mmols</td>
<td>246</td>
<td>45</td>
<td>-201</td>
<td></td>
</tr>
<tr>
<td>Insulin/oral medication dose not adjusted with persistent BG &lt; 4mmols</td>
<td>134</td>
<td>14</td>
<td>-120</td>
<td></td>
</tr>
<tr>
<td><strong>Total Monitoring errors</strong></td>
<td>380 (24%)</td>
<td>59 (8%)</td>
<td>-321</td>
<td>-85%</td>
</tr>
<tr>
<td><strong>Sum of Total errors</strong></td>
<td>1573 (100%)</td>
<td>754 (100%)</td>
<td>-819</td>
<td>-52%</td>
</tr>
</tbody>
</table>
Using an independent-samples t-test it was also evident that there was a significant reduction and difference in the total number of errors between the two groups at each of the three stages of the medication process targeted by the MMI (p<0.05). Patients in the pre-intervention group experienced more than twice as many administration, prescribing and monitoring errors as those in the intervention group (see Table 6.3). The frequency of monitoring errors was reduced by 85% in the intervention group.

Table 6.3: Sample 1: Group comparison of insulin and OHA medication errors at each stage of the medication process

<table>
<thead>
<tr>
<th></th>
<th>Pre-Intervention Mean &amp; SD</th>
<th>Intervention Mean &amp; SD</th>
<th>df</th>
<th>t</th>
<th>P value</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration errors</td>
<td>M=3.5, SD=9</td>
<td>M=1.3, SD=3.35</td>
<td>449</td>
<td>2.81</td>
<td>0.006</td>
<td>0.02</td>
</tr>
<tr>
<td>Prescribing errors</td>
<td>M=2.9, SD=9</td>
<td>M=1.4, SD=3.0</td>
<td>448</td>
<td>2.20</td>
<td>0.028</td>
<td>0.01</td>
</tr>
<tr>
<td>Monitoring errors</td>
<td>M=1.91, SD=8</td>
<td>M=0.2, SD=1.32</td>
<td>449</td>
<td>3.11</td>
<td>0.002</td>
<td>0.02</td>
</tr>
</tbody>
</table>

(Degrees of freedom (df) is defined as the number of independent observations in a sample of data that are available to estimate a parameter of the population from which that sample is drawn (Field 2005).)

6.2.4 Sample 1: Effect of admission category and group on insulin and OHA medication errors

In order to determine if any of the baseline demographic variables (i.e. age, sex, type of diabetes and admission category) contributed significantly to explaining the variation in the total number of errors, a general linear modelling (GLM) procedure (as described in chapter 5.4.6) was conducted.
Admission category was found to influence the number of errors patients experienced with the average number of errors varying across each admission category. Patients in the pre-intervention group admitted to the vascular amputation ward experienced nearly ten times as many errors as those in the intervention group (see Table 6.4).

Table 6.4: Sample 1: Effect of admission category and group on insulin and OHA medication errors

<table>
<thead>
<tr>
<th>Admission Category</th>
<th>Orthopaedic</th>
<th>Surgery</th>
<th>Medicine</th>
<th>Kidney disease</th>
<th>Vascular surgery (no amputation)</th>
<th>Vascular amputation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Pre-intervention</td>
<td>Intervention</td>
<td>Pre-intervention</td>
<td>Intervention</td>
<td>Pre-intervention</td>
</tr>
<tr>
<td></td>
<td>2.2</td>
<td>2.1</td>
<td>2.5</td>
<td>2.2</td>
<td>4.3</td>
<td>16.2</td>
</tr>
<tr>
<td></td>
<td>3.0</td>
<td>7.1</td>
<td>1.0</td>
<td>11.0</td>
<td>3.0</td>
<td>29.5</td>
</tr>
</tbody>
</table>

Using a GLM, it was apparent that the total number of errors was significantly affected by both group and admission type ($p=0.000$) (see Table 6.5). In the pre-intervention group patients admitted to the vascular amputation ward experienced the greatest number of errors. By contrast, patients in the intervention group admitted to the vascular surgery ward experienced the greatest number of errors.
Table 6.5: Sample 1: GLM: Effect of admission category and group on insulin and OHA medication errors

<table>
<thead>
<tr>
<th>Admission Category</th>
<th>Intervention</th>
<th>Pre-Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopaedic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney disease</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Medicine</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Surgery</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Vascular surgery (no amputation)</td>
<td>6</td>
<td>19</td>
</tr>
<tr>
<td>Vascular amputation</td>
<td>1</td>
<td>36</td>
</tr>
</tbody>
</table>

6.2.5 Sample 1: Length of Stay

In the pre-intervention group the median length of stay was 9 days (inter-quartile range 4-18) compared to a median of 7 days (inter quartile range 4-13) in the intervention group (p<0.05). A GLM procedure identified that LOS was significantly affected by both group and admission type (p=0.000). Patients in the pre-intervention group admitted to the vascular amputation ward had the longest length of stay (see Table 6.6)
Table 6.6 Sample 1: Effect of admission category and group on length of stay

<table>
<thead>
<tr>
<th>Admission Category</th>
<th>Pre Intervention</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopaedic</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>Medicine</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Surgery</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Vascular surgery (no amputation)</td>
<td>28</td>
<td>27</td>
</tr>
<tr>
<td>Vascular amputation</td>
<td>26</td>
<td>67</td>
</tr>
</tbody>
</table>

The Pearson product-moment correlation technique was used to explore the relationship between LOS, total number of errors, age and sex in more detail. A medium, positive correlation was found to exist between the length of stay and the total number of errors in the pre-intervention group \([r=0.43, n=107, p<0.01]\). As the total number of errors increased, so did length of stay. Although this effect was also present in the intervention group, it was less marked \([r=0.196, n=246, p<0.01]\). There was no correlation between length of stay and age or sex.

6.2.7 Sample 2

After applying the further inclusion criteria, described in chapter 4.7, fifty six patients were recruited to sample 2 across both the pre-intervention \((n=27)\) and intervention \((n=29)\) groups between May 2005 and December 2005.
6.2.8 Sample 2: Demographic Data

Table 6.7 summarises the demographic data collected across both the pre-intervention (n=27) and intervention (n=29) groups. Participants were male (n=35) and female (n=21), and were admitted under both medicine (specialising in renal disease) and surgery (including vascular amputation and vascular surgery). The majority of participants (over 75%) across the two groups had type 2 diabetes and over 50% were treated with insulin. Patients' age ranged from 26 to 81 years and 55.6% had been diagnosed with diabetes for less than fifteen years.

All baseline demographic variables were examined to check for parity between the pre-intervention and intervention groups in order to rule out patient demographic influences upon study results. Patient characteristics in the pre-intervention and intervention groups were generally similar (Table 6.7), although there is evidence that a greater proportion of patients in the pre-intervention group were treated with insulin, had been diagnosed with diabetes for more than fifteen years, and had another chronic disease. By contrast, a greater proportion of patients in the intervention group was admitted to the medical ward, and aged less than 70 years. However results of chi square analysis showed that although there was a significant difference in the type of admission between the two groups, there were no significant differences in the other demographic characteristics i.e. sex, age, type of diabetes, management of diabetes, ethnicity, employment status, marital status, accommodation and chronic diseases.
### Table 6.7: Sample 2: Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention (n=27)</th>
<th>Intervention (n=29)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>5</td>
<td>5</td>
<td>1.00</td>
</tr>
<tr>
<td>Type 2</td>
<td>19</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td>0.836</td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>11</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td><strong>Management of Diabetes</strong></td>
<td></td>
<td></td>
<td>0.206</td>
</tr>
<tr>
<td>Oral hypoglycaemic agents</td>
<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Insulin/ oral hypoglycaemic agents &amp; Insulin only</td>
<td>14</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td><strong>Type of Admission</strong></td>
<td></td>
<td></td>
<td>0.02</td>
</tr>
<tr>
<td>Medicine</td>
<td>9</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>17</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td>0.254</td>
</tr>
<tr>
<td>&lt; 50 years</td>
<td>3</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>51-69 years</td>
<td>11</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>&gt; 70 years</td>
<td>13</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>Married/living together</td>
<td>12</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Divorced/separate/single/widowed</td>
<td>15</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td><strong>Employment</strong></td>
<td></td>
<td></td>
<td>0.883</td>
</tr>
<tr>
<td>Not employed</td>
<td>20</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>7</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td>0.587</td>
</tr>
<tr>
<td>White</td>
<td>25</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Asian/Black/ British Asian/British Black</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>How long since diagnosed?</strong></td>
<td></td>
<td></td>
<td>0.300</td>
</tr>
<tr>
<td>0-15 years</td>
<td>15</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>&gt; 15 years</td>
<td>12</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td><strong>Other chronic disease/illness</strong></td>
<td></td>
<td></td>
<td>0.589</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>17</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td><strong>Accommodation</strong></td>
<td></td>
<td></td>
<td>0.217</td>
</tr>
<tr>
<td>Detached or semi detached house</td>
<td>23</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Terrace or flat</td>
<td>4</td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 6: Results

6.2.9 Sample 2: Insulin and OHA Medication Errors

A comparison of the frequency and distribution of the fourteen insulin and OHA medication errors between the pre-intervention and intervention groups of sample, and at each stage of the medication process is presented in this section.

Across both the intervention and pre-intervention groups, ME were recorded for forty two (75%) patients (see Table 6.8), many of whom experienced multiple errors. Administration (56%) and prescribing errors (44%) were the most frequent type of ME present on the charts of participants across both groups. Nurse supplementary prescribing was used to prescribe medicines for seven patients.

Table 6.8: Sample 2: Insulin and OHA medication errors
Chapter 6: Results

It was evident from an independent-samples t-test that there was a significant reduction in the total number of errors between pre-intervention \((M=26, SD=35.04)\) and intervention groups \((M=5.03, SD=7.79; t (47)=2.632, p=0.016)\). The magnitude of the differences in the means was moderate \((\text{eta-squared}=0.11)\). A mean reduction of 21 errors was identified in the intervention group.

Using an independent-samples t-test, it was evident that there was a reduction in the average number of errors at each of the three stages of the medication process targeted by the MMI. Patients in the pre-intervention group experienced more than four times as many administration errors as those in the intervention group \((p=0.05)\) (see Table 6.9). Administration and monitoring errors were both reduced by more than 75% in the intervention group.

Table 6.9: Sample 2: Group comparison of insulin and OHA medication errors at each stage of the medication process

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention Mean &amp; SD</th>
<th>Intervention Mean &amp; SD</th>
<th>df</th>
<th>t</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration errors</td>
<td>M=11.2, SD=20.9</td>
<td>M=2.5, SD=4.89</td>
<td>53</td>
<td>2.09</td>
<td>0.05</td>
</tr>
<tr>
<td>Prescribing errors</td>
<td>M=7.65, SD=13.2</td>
<td>M=2.4, SD=4.1</td>
<td>53</td>
<td>1.95</td>
<td>0.06</td>
</tr>
<tr>
<td>Monitoring errors</td>
<td>M=1.12, SD=2.9</td>
<td>M=0.17, SD=0.66</td>
<td>53</td>
<td>1.80</td>
<td>0.12</td>
</tr>
</tbody>
</table>

6.2.10 Sample 2: Effect of admission category on the number of insulin and OHA medication errors

In order to determine if any of the baseline demographic variables (i.e. age, sex, type of diabetes and admission category) contributed significantly to explaining the variation in the total number of errors, a GLM procedure was conducted.

The number of errors patients experienced was found to be affected by whether they had been admitted as part of the pre-intervention or intervention group. Patients in the pre-intervention group experienced up to three times as many errors as those in the intervention group (see Table 6.10).
Chapter 6: Results

Table 6.10: Sample 2: Effect of admission category and group on insulin and OHA medication errors

<table>
<thead>
<tr>
<th>Admission Category</th>
<th>Mean Number of Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>26.7</td>
</tr>
<tr>
<td>Medicine</td>
<td>9.8</td>
</tr>
<tr>
<td>Pre Intervention</td>
<td>3.6</td>
</tr>
<tr>
<td>Intervention</td>
<td>7.3</td>
</tr>
</tbody>
</table>

Using a GLM, admission category was identified as being a key factor (p=0.06) contributing to the variation in the total number of errors. Although admission category did not significantly affect the number of errors, patients who had been admitted to the surgical wards in both the pre-intervention and intervention group experienced more errors compared to those patients admitted to the medical ward (see Table 6.11).

Table 6.11: Sample 2: GLM: Effect of admission category and group on insulin and OHA medication errors

<table>
<thead>
<tr>
<th>Admission Category</th>
<th>Adjusted Mean Number of Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>35</td>
</tr>
<tr>
<td>Medicine</td>
<td>8</td>
</tr>
<tr>
<td>Pre Intervention</td>
<td>4</td>
</tr>
<tr>
<td>Intervention</td>
<td>9</td>
</tr>
</tbody>
</table>
6.2.11 Sample 2: Length of stay

In the pre-intervention group the median length of stay was 17.5 days (inter-quartile range 10-46), compared to median of 14.5 days (inter-quartile range 9-32) in the intervention group (p<0.05).

In order to determine if any of the baseline demographic variables (i.e. age, sex, type of diabetes and admission category) contributed significantly to explaining the variation in length of stay a GLM was performed. Using a GLM it was apparent that although admission type contributed to length of stay, this was not at a significant level (p=0.42). Patients admitted to the surgical wards in the pre-intervention group experienced an adjusted mean length of stay which was more than double that of patients admitted to the medical wards (see Table 6.12). In order to explore the extremely large difference between LOS and admission type in the pre-intervention group, a further independent sample t-test was conducted. It was evident from the results that admission type had a highly significant effect on LOS for this group of patients (p=0.0004).

Table 6.12: Sample 2: Effect of admission category and group on length of stay
6.4 Q2: Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, report improved levels of self-efficacy?

Across the pre-intervention and intervention group 100% of participants (n=56) completed and returned the first questionnaire. Four patients died prior to completing the second questionnaire and a further seven did not return this questionnaire. In total 45 participants (80%) returned the second questionnaire. The third questionnaire was completed by 41 participants (73%); two postal questionnaires were not returned and the remaining two patients were readmitted to hospital. The overall completion rate for the three questionnaires was 84%.

Data collected from the first 15 questions of all three questionnaires, designed to assess diabetes SE, are presented below.

Participants completing questionnaires on admission and at three month follow-up, in both the pre-intervention and intervention groups, reported similar SE scores. At discharge, participants in the intervention group scored on average nine more points compared to those in the pre-intervention group (see Table 6.13). Results of independent samples t-tests confirmed that there was no significant difference in the SE scores on admission (SE1), discharge (SE2) or at three month follow-up (SE3) between the intervention and pre-intervention groups (see Table 6.13).

| Table 6.13: Group comparison between self-efficacy on admission, discharge and three month follow-up |
|---------------------------------------|-------------------------------|-------------------------------|---|---|---|
| Independent samples t-test            | Pre-intervention Mean & SD    | Intervention Mean & SD        | df | t  | P value |
| SE1                                  | M=68, SD=18.2                 | M=70, SD=15.4                 | 54 | -0.445 | 0.66 |
| SE2                                  | M=62, SD=17.7                 | M=71, SD=14                  | 42 | -1.731 | 0.091 |
| SE3                                  | M=76, SD=8.4                  | M=73, SD=11.1                | 39 | 0.872  | 0.386 |
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In order to determine what if any effect the MMI had on SE, the SE scores reported by participants at each of the three data collection points in the pre-intervention and intervention groups were explored using paired samples t-tests (see Table 6.14). In the pre-intervention group a large significant increase \( (p=0.02) \) in SE was identified between discharge and at three month follow-up (See Table 6.14) i.e. a mean increase of fourteen points was identified in participants in the pre-intervention group who completed the three month follow-up questionnaire (see Table 6.13).

Table 6.14: Impact of the medicines management intervention on self-efficacy

<table>
<thead>
<tr>
<th>Paired-samples t test</th>
<th>Pre-Intervention</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>df</td>
<td>t</td>
</tr>
<tr>
<td>SE1-SE2</td>
<td>21</td>
<td>0.987</td>
</tr>
<tr>
<td>SE2-SE3</td>
<td>15</td>
<td>-2.548</td>
</tr>
<tr>
<td>SE1-SE3</td>
<td>19</td>
<td>-2.006</td>
</tr>
</tbody>
</table>

6.4.1 Factors affecting self-efficacy

A GLM was conducted in order to determine if any of the baseline demographic variables (i.e. age, sex, type of diabetes and admission category) contributed significantly to explaining the variation within each SE. Type of diabetes was found to contribute to the variation of SE scores. Patients with type 2 diabetes in both the pre-intervention and intervention group had lower levels of SE at discharge than patients with type 1 diabetes \( (p=0.04) \) (see Table 6.15).

Table 6.15: Effect of type of diabetes and group on self-efficacy at discharge

![Adjusted mean SE score at discharge chart]
Chapter 6: Results

The Pearson product-moment correlation technique was used to explore the relationship between SE, length of stay, total number of errors, patients' characteristics and demographic information in more detail.

Across both groups, a number of significant relationships were identified between SE, insulin and OHA medication errors, patients' characteristics and demographic information. In the pre-intervention group significant negative correlations were identified between SE2, age and admission category. Lower levels of SE were associated with older patients \( r=-0.46, n=21, p=0.034 \), and patients admitted under the surgical ward \( r=-0.43, n=21, p=0.05 \). Similarly, a significant negative correlation was identified in the intervention group between SE2 and the total number of errors. Lower levels of SE were associated with patients who experienced a higher number of insulin and OHA medication errors \( r=-0.44, n=22, p=0.039 \).
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6.5 Q3: Do hospital in-patients, who receive a medicines management intervention from a DSN prescriber, report an improvement in the extent to which their medicine information needs are met?

Data collected from question 16 in questionnaires 2 and 3 were used to determine whether patients who receive a MMI from a DSN prescriber report an improvement in the extent to which their medicine information needs are met.

Overall, 69% of participants reported that their information needs had been met (Table 6.16) and the overall median was 5.5 (inter-quartile range 3-6) (Table 6.17). Two people (7%) in the pre-intervention group indicated that their information needs had not been met. At three month follow-up, 77% of all participants reported that their information needs had been met compared to only 61% at discharge (Table 6.16).

Table 6.16: To what extent have your information needs been met?

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Pre-intervention</th>
<th></th>
<th>Intervention</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Needs not met</td>
<td>Needs totally met</td>
<td>Needs not met</td>
<td>Needs totally met</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 &amp; 2</td>
<td>5 &amp; 6</td>
<td>1 &amp; 2</td>
<td>5 &amp; 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Count</td>
<td>%</td>
<td>Count</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n</td>
<td></td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Discharge</td>
<td>14</td>
<td>1</td>
<td>7.1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7</td>
<td>57</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8</td>
<td>57</td>
<td>16</td>
<td>65</td>
</tr>
<tr>
<td>Three month</td>
<td>6</td>
<td>1</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>follow-up</td>
<td></td>
<td>6</td>
<td>82</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14</td>
<td>82</td>
<td>18</td>
<td>72</td>
</tr>
</tbody>
</table>

114
There was no significant difference between the pre-intervention or intervention group in the number of people whose information needs had been met ($p=0.50-056$) (Table 6.17).

### Table 6.17: Group comparison showing median, inter-quartile range & Mann-Whitney test

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention</th>
<th>Intervention</th>
<th>Mann-Whitney Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Inter-quartile range</td>
<td>Median</td>
</tr>
<tr>
<td><strong>Discharge</strong></td>
<td>5</td>
<td>3-6</td>
<td>5</td>
</tr>
<tr>
<td><strong>Three month follow-up</strong></td>
<td>6</td>
<td>5-6</td>
<td>6</td>
</tr>
</tbody>
</table>

### 6.6. Q4: What types of information do patients consider important about their medicines?

Data collected from question 17 in questionnaire 3 were used to determine what types of information patients consider to be important about their medicines. Participants were asked to rate how important eleven areas of information were to them in an explanation about their medicines (1 indicated 'not at all important' and 6, 'very important'). In both the pre-intervention and intervention group at least 75% of participants rated all eleven types of information highly (see Table 6.18). The overall median was 6 (inter-quartile range 5.25-6) (See Table 6.20). Results from the Mann-Whitney test confirm that overall participants, in both the pre-intervention and intervention groups, reported very similar levels of importance to the eleven types of information (range of $p=0.3-1.00$) (see Table 6.20).
Table 6.18: Importance of the different types of medicines information

<table>
<thead>
<tr>
<th>n=40 unless otherwise stated</th>
<th>Not at all /not important</th>
<th>Important/ very important</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>%</td>
</tr>
<tr>
<td>1. What the medication is (drug type etc)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2. What the medication does / how it works</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3. Probability medicine will be effective</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>4. Detailed questions about taking medicine (e.g. dosage)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5. Possible side effects</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>6. Interactions with other medicines</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>7. Any alternatives to medication</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>8. What to do if you forget to take it or take too much (n=39)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>9. How will you know if medication is working (n=38)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. Risks of not taking medication (n=38)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>11. How to contact the nurse/doctor (n=38)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Participants reported that the most important types of information were: detailed questions about the medicine (e.g. dose) (98%), how to contact the nurse/doctor (95%) and what to do if you forget (92%), followed by what the medication is (drug type etc.) and probability of the medicine being effective (each 90%). Information on what the medication does / how it works, possible side effects, and interactions, how to know if the medicine is working and risks of not taking the medicine and alternatives to medicines were found to be less important to participants (see Tables 6.18 & 6.19).
Participants in both the pre-intervention and intervention group rated three areas (probability medicine will work, detailed questions about taking medicine and risks of not taking the medicine) as very important (median=6, inter-quartile range 5.75-6). Overall, participants rated alternatives to medication as the area of information that is least important to them (median=6, inter-quartile range 4-6) (see Table 6.20).
Table 6.20: Comparison of groups: median importance ratings of information about the medicine listed in order of importance

<table>
<thead>
<tr>
<th>Information about the Medicine</th>
<th>Pre-intervention</th>
<th>Intervention</th>
<th>Mann-Whitney Test: z &amp; p values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Median</td>
<td>Inter-quartile range</td>
</tr>
<tr>
<td>Probability medicine will work</td>
<td>40</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>Detailed questions about taking medicine e.g. dosage</td>
<td>38</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>Risks of not taking medicine</td>
<td>38</td>
<td>6</td>
<td>5.75-6</td>
</tr>
<tr>
<td>What the medication is (drug type etc)</td>
<td>40</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>What the medication does / how it works</td>
<td>40</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>Interactions with other medicines</td>
<td>40</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>Possible side effects</td>
<td>40</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>What to do if you forget to take it or take too much</td>
<td>39</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>How to contact the nurse/doctor</td>
<td>38</td>
<td>6</td>
<td>6-6</td>
</tr>
<tr>
<td>How will you know if medication is working</td>
<td>38</td>
<td>6</td>
<td>5-6</td>
</tr>
<tr>
<td>Any alternatives to medication</td>
<td>38</td>
<td>6</td>
<td>4-6</td>
</tr>
</tbody>
</table>
6.6 Summary

This chapter presents data from the documentary evidence and modified retrospective case record review collected from the 452 participants of sample 1, fifty six participants of sample 2, and the three questionnaires also completed by sample 2. All participants were admitted to one of the six study wards of a district general hospital in the East of England between May and December 2005.

Patient characteristics in the pre-intervention and intervention groups of both sample 1 and sample 2 were generally similar. The majority of participants were diagnosed with type 2 diabetes and admitted to the medical ward. In both samples, there was a statistical difference in admission category between the two groups (p<0.05). However, there were no statistical differences in the other demographic variables i.e. age, sex, type of diabetes or management of diabetes.

In both samples, participants who received the MMI experienced significantly fewer insulin and OHA medication errors (p<0.001 & p<0.05 respectively). Errors were reduced at each of the three stages of the medication process targeted by the intervention, and in sample 1 these reductions were at level of statistical significance (p<0.05). In both samples, the majority of errors (42% and 56% respectively) occurred during the administration process by which patients received their medicines. Median length of stay was less for patients in the intervention group (by two days in sample 1, and three days in sample 2) (p<0.05). The total number of errors and length of stay that participants experienced were affected by group and admission category, and to a level of statistical significance in sample 1 (p<0.001). In both the pre-intervention and intervention groups of sample 1 a significant relationship was found between length of stay and the total number of errors, as the total number of errors increased so did length of stay (p<0.01).
Chapter 6: Results

Overall, SE scores of participants in the intervention groups were higher than those in the pre-intervention group (p>0.05). The SE scores of participants who received the MMI, during admission and at three month follow-up were more stable than those of participants in the pre-intervention group. In the pre-intervention group hospital stay had a negative effect on SE. At each data collection point SE was affected by a number of demographic factors (including age, type of diabetes and admission category), these relationships however were variable and inconsistent.

With respect to the extent to which the information needs of patients were met during admission and three month follow-up, there was no significant difference between the pre-intervention and intervention groups in the number of people whose information needs had been met (p>0.05). In both groups, participants were interested in similar types of information about the medicines, most interested in 'detailed questions about the medicines' (98%), and least interested in 'alternatives to medicines' (75%).

A discussion of these findings is presented in the following chapter.
Chapter 7: Discussion

7.1 Overview

This chapter commences with a discussion of the findings in relation to the literature. A critical review of the methodology, study strengths and limitations follow. A critical evaluation of the research process is presented. The contribution of the study to the body of knowledge, methodology and theory are discussed. A number of recommendations are made, and a conclusion of the main points is then provided.

7.2 Part 1: Discussion of the findings in relation to the literature

It is evident from the study findings that across the intervention group of sample 1 and sample 2, insulin and OHA medication errors were reduced by more than 50%, and length of stay reduced by a median of two days. The self-efficacy scores of participants in the intervention group of sample 2 also increased. The results provide empirical evidence that the prescribing role can be successfully used by a DSN to reduce medication errors, reduce length of hospital stay and improve self-efficacy.

A discussion of the key issues identified from these results is presented using the following sub-headings ‘new ways of working’, ‘improving the quality of care’ and ‘resource implications’.

New ways of working

Central to the success of this study was the opportunity created by the prescribing role for the DSN to work differently to overcome shortfalls in the diabetes in-patient service. Using new knowledge gained through prescribing, with the ability to work independently, the DSN was able to make more effective use of existing specialist skills and knowledge to support this new model of care. While a review of the literature (Carey & Courtenay 2007)
reports that care provided by hospital DSNs includes patient and staff education, support, advice and medicines management, Peters et al. (2001) suggests a lack of autonomy can restrict practice. Undeniably, the ability to practice autonomously is a defining characteristic of advanced nursing practice (Bonsall & Cheater 2008), and allows nurses to take on skills previously associated with medical practitioners, such as prescribing medications. The findings therefore suggest that having the capacity to prescribe medicines enhanced the role of the DSN. This is in-line with the anticipated benefits of nurse prescribing (DH 2006), primarily introduced in the U.K as a means to improve patient care and access to healthcare professionals, to make better use of the skills of healthcare professionals and to encourage more flexible working (Ball 2009, Buchan & Calman 2004, Miles et al. 2006).

In addition to supporting the anticipated benefits of nurse prescribing, expanding nurse's roles and developing new areas of practice is also a central theme of the NHS modernization agenda (DH 1999b, 2000). In this study, the increased autonomy associated with having the capacity to prescribe was used to develop nurse-led medication review, a new and extended area of practice for DSNs. While it is evident that nurses have been involved in assessing patients and advising doctors about patient's medicines in diabetes for some time (James et al. 2009), they were unable to implement their recommendations legally. Through practising autonomously, the DSN prescriber in this study was able to take responsibility for decisions and suggestions that were made during the process of medication review. As a result the potential for misunderstanding was reduced, and patients experienced less insulin and OHA medication errors, a reduced length of stay and increased self-efficacy. This concurs with recent qualitative reports (Carey et al. 2009a, Stenner & Courtenay 2008) which suggest that as a result of taking a more active role in medicines management, nurse prescribers are able to avert and or correct prescribing errors. However, this is the first study to formally describe and evaluate this area of practice on patient outcomes.
Chapter 7: Discussion

It appears therefore that DSNs who are qualified nurse independent and supplementary prescribers are ideally placed to use their increased autonomy to develop new models of care and to take a more active role in medication review. This is important given that developing new ways of working are vital to overcoming the constraints on doctors' availability caused by the restricted work hours of junior doctors, and the reduced number of hours worked by increasing numbers of female doctors (Royal College of Physicians 2005), and the need to improve diabetes in-patient services.

*Improving the quality of care*

Improving the quality of care in-patients receive by reducing the number of medication errors in prescribed drugs (DH 2004, NPSA 2007) and, providing adequate information, equitable, timely access to knowledgeable healthcare professionals, and continuity of care (DH 2003a, 2007) have become increasingly essential requirements of diabetes services. Despite this, a recent survey of people with diabetes indicates that only a quarter of in-patients with diabetes are reviewed by a specialist team during their stay (HCC 2007b). Adopting the MMI however, ensured a consistent approach to the care in-patients received. The DSN prescriber was able to increase patient contact, work with patients on an individual basis, review their medication regime and information needs, and encourage patients to self-care. Consequently, the care provided from an experienced diabetes specialist was less fragmented, more equitable and continuous. The findings from this study therefore suggest that implementing these changes had a positive effect on the quality of care patients received, and as a result medication errors were reduced. They also provide some evidence that nurse prescribing can produce benefits in line with current government policy on improving patient safety (DH 2004, NPSA 2007) and improving the quality of diabetes in-patient care (DH 2003a, 2007). Additionally, they highlight the central role of the DSN prescriber in supporting this policy and contribute to the emergent body of evidence exploring the feasibility and effectiveness of service
models for this group of patients (DH 2007, 2008b). Furthermore, they concur with previous qualitative reports which describe how continuity of care and safety are both improved when nurses adopt the prescribing role (Carey et al. 2009a, Courtenay et al. 2009a). It would seem logical that other DSNs who are prescribers and care for this group of patients consider adopting the MMI. Further evaluation of the MMI using DSN prescribers in other U.K hospital settings is therefore required.

Despite the more consistent approach to care provided by the MMI, and attention that the DSN prescriber gave to the information needs of patients, findings exploring the extent to which these needs were met over time were inconclusive. Whilst this is the first study to explore the information needs of hospital in-patients, this result is in contrast to the emergent evidence which suggests that the majority of patients are satisfied with the medicines information they receive from the nurse (Courtenay et al. 2009a, Courtenay et al. 2009b, Latter et al. 2005, Stenner et al. 2010). Stenner et al. (2010) for example, recently reported that patients with diabetes in the primary care setting were happy with the amount information the nurse prescriber provided about their condition and the need for treatment.

It is evident however, that the information needs of patients with diabetes can be affected by both individual and organisational factors (DH 2003a, 2008b, HCC 2006). Being hospitalised has a significant impact on this group of patients. Many patients report that they lose control over their own-self management and experience unstable glycemic control as a result of the problems they encounter e.g. timing and quality of meals, access to insulin and inadequate blood glucose monitoring (DH 2003a, 2008b). Consequently, when patients with diabetes are admitted to hospital they do need more information (HCC 2006). Despite this, patients with diabetes have repeatedly reported a lack of information from health professionals during admission (Audit Commission 2000, HCC 2007a). Whilst it is possible therefore that a lack of control over self-management during admission,
caused by illness or hospital medication policy, may well have affected the information needs of patients in the current study, the results also suggest that nurses need to pay greater attention to the information needs of this group of patients. Regular monitoring and review of information needs, using a well-validated instrument such as the medicines information tool used in this study, is one approach that could be adopted to improve this aspect of care.

Recent healthcare policy (Audit Commission 2000, DH 2003a) highlights how adequate provision of information supports patients’ ability to self-manage their diabetes. Interestingly, participants in both the pre-intervention and intervention groups rated similar categories of medicines information as important. They were most interested in information regarding the probability that the medicine would work, how to take the medicine, and risks of not taking the medicine. This is in contrast to previously reported studies (Berry et al. 2006, Berry et al. 2008, Latter et al. 2005). For example, the 74 members of the general population surveyed by Berry et al. (2006), 54 rheumatology patients surveyed by Berry et al. (2008), and 115 patients surveyed by Latter et al. (2005) indicated that side-effects and what the medication does / how it works, were the most important information required by patients about their medicine.

The findings from the present study provide an initial insight into what types of medicines information are important to patients with diabetes. The majority of participants had been diagnosed with diabetes for a number of years. It therefore seems likely that they would have already received information on side-effects and interactions. Patients with diabetes have previously described how the type of information they need changes during their life (Hiscock et al. 2001, Stenner et al. 2010). For example, a key finding, to emerge from focus groups and in-depth interviews of sixty one people with diabetes, reported by Hiscock et al. (2001), was the need for information to be provided in an ongoing and incremental way as the course of the disease evolved, and life circumstances change.
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More recently, Stenner et al. (2010) similarly found that patients desire for information varied over time, and was greater during transition periods to a new treatment. It seems likely that the findings from the present study simply reflect that the types of information patients are interested in does change during the course of a disease. Given the complexity of meeting the information needs of patients with diabetes highlighted above, this improved understanding is important if this area of practice is to be improved. In order that patients receive the right amount and type of information, nurses clearly need to be aware of this variation. For this to be achieved, it is important that diabetes education and training for nurses is reviewed to ensure the content is fit for purpose.

Recent guidance recommends that optimum care for patients with diabetes is best achieved through a combination of drugs and non-pharmacological support (DH 2007, 2008b, HCC 2007b). Encouraging patients with diabetes to self-manage their condition is a key component of this approach (DH 2001, 2003b). The improved self-efficacy scores of patients in the intervention group suggest that the MMI did have a positive effect on patients' confidence in their ability to perform diabetes related self-care behaviours. Given the important predictive nature of the relationship between self-efficacy and diabetes self-care (Bandura 1977, Marks et al. 2005a), the findings indicate that adopting the MMI could help patients increase control over their diabetes and, by avoiding concerns they have during admission such as a lack of information and unstable glycemic control, improve the quality of care they receive.

Although the findings suggest that the MMI provides a new and innovative strategy to enhance diabetes self-efficacy, investigation of the relationship between self-efficacy and demographic variables identified that self-efficacy was affected by a number of factors (including age, type of diabetes, admission category). At each data collection point these relationships were found to be variable and inconsistent. The inconsistent nature of the relationship between diabetes self-efficacy and a range of demographic variables (e.g.
employment status, ethnicity and marital status) has also previously been reported
& Bond 2002, Wu et al. 2007). Across these six studies data were collected from a total of
694 patients with diabetes in a variety of healthcare settings (including hospital outpatients
and the community). In-line with the current study findings, the relationship between
demographic variables and diabetes self-efficacy was variable and inconclusive. Although
care must be taken in interpretation of tendencies when running multiple correlations as
some associations will occur from chance (Field 2005), it is evident from the literature
exploring the theory and use of self-efficacy in healthcare interventions that self-efficacy is
a temporary and easy to influence characteristic (Bandura 1977, Clark & Dodge 1999,
Holloway & Watson 2002). Therefore, it is likely that despite the MMI, the inconsistent
relationships between the demographic variables and self-efficacy reported in this thesis
reflect normal behaviour of the self-efficacy construct.

Interestingly, in both the pre-intervention and intervention groups the highest levels of self-
efficacy were reported by patients at three month follow-up. Although there is currently no
evidence available with which to compare this result, it is feasible that this finding
represents a typical pattern of behaviour for diabetes self-efficacy, whereby self-efficacy
increases after a patient is discharged from hospital. On the other hand it could be
contended that this result represents the testing effect, whereby the improved self-efficacy
scores at three months follow-up merely reflect the act of participation rather than any real
change in behaviour (Becker et al. 2003). In order to understand this area in more detail
further evaluation of the Diabetes Management self-efficacy scale using longitudinal
intervention studies is required.

Resource implications

In addition to improving the quality of care, ensuring standards of care and the best use of
resources are also essential requirements of modern service delivery (DH 2008c). This
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study is the first to demonstrate that when a DSN prescriber works autonomously they are able provide a more efficient way of working and overcome previous inadequacies in the traditional healthcare system. These inadequacies include a lack of prescriptive authority. This meant that in order to initiate, and or titrate insulin and oral hypoglycaemic medicines DSNs had to work within the specific limits of a pre-arranged protocol. Additionally, care could only be delivered after each patient had been discussed with the medical team. This approach was problematic however, as many senior doctors are not available for clinical duties every day (Royal College of Physicians 2005), and hence were unable to ratify decisions that had been made. Consequently, patients experienced frequent delays in their diabetes treatments and inappropriate timings of their medications (Audit Commission 2000, DH 2003a, 2008b, James 2003). Giving nurses the capacity to prescribe overcomes such difficulties. As previously discussed, prescribing allows nurses to work independently and means that they are less dependent on the availability of doctors. Consequently, they are able to work more efficiently, the speed with which patients receive their medicines is increased and care provided is more responsive to need.

Significantly, the findings demonstrate that compared to traditional doctor-led models of care, a nurse prescriber can generate similar outcomes with respect to reducing medication errors (Ioannidis & Lau 2001), reducing length of hospital stay (Cavan et al. 2001, Sampson et al. 2006) and increasing self-efficacy (Corbett 2003). This is important for two reasons: firstly, the evidence generated in this study crucially demonstrates that nurse prescribers can provide a high standard of care. This is in contrast to concerns that doctors and other healthcare professionals have reported about nurse prescribers’ level of clinical experience (Carey et al. 2009b, Rana et al. 2009) and the level of pharmacology training nurses receive (Bradley et al. 2006). As the first study to report on this aspect of nurse prescribing practice, these findings may therefore help to alleviate the concerns of these healthcare professionals. Secondly, as the salary of a diabetes specialist nurse
prescriber (typical pay range £30-40,000 per annum) (NHS Careers 2010a) is considerably less than that of a hospital consultant (range £75-100,000 per annum) (NHS Careers 2010b) this model of care has the potential to reduce the direct costs of care.

There are also significant cost implications associated with the reduced length of stay experienced by patients in this study. The reduced length of stay of patients in the intervention group suggests that improving the process by which patients receive their medicines, and reducing the number of errors they experience has a positive effect on the speed with which they recover. A relatively strong correlation was found to exist in this study between length of stay and the total number of errors. As the total number of errors increased in participants in sample 1, so did length of stay (p<0.01). While it is possible that the number of errors simply increased if patients were in hospital longer, it is recognised that a range of factors can affect length of stay (i.e. nature and severity of illness, availability of investigations, and response to treatment). Furthermore, the detrimental effect of medication errors on increasing length of stay has been clearly demonstrated in several studies (Leape et al. 1991, Vincent et al. 2001, Wilson et al. 1995).

Based on the current study findings i.e. a median reduction in length of stay of two days per patient and a cost per day of £250 (DH 2010), over one year the reduction in length of stay is a potential cost saving of over £500,000. The potential cost savings demonstrated by the reduced length of stay in this study highlight how, in-line with national guidance (DH 2008b), a DSN prescriber delivering this intervention provides good value for money. At a time when doctors are increasingly unable to meet patient demand (Rosen & Dewar 2004, Royal College of Physicians 2005), and there are ongoing financial restraints within the NHS that continue to affect the availability of diabetes specialist in-patients teams (DH 2008b), this study has important implications in terms of maximising resource use, and providing this group of patients with a more flexible and accessible model of care.
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Considering that over 4% of total healthcare expenditure in the U.K is spent on diabetes (NCCCC 2008), 10% of hospital beds are occupied by patients with diabetes (DH 2008b), and admissions for patients with diabetes are on average 2.6 days longer than other patients (DH 2008b), this is a significant finding which may be of particular interest to those involved with service improvement and quality assurance.

It is important to note however, that in line with previous research on reducing medication errors (Anderson & Webster 2001, Ioannidis & Lau 2001, Reason 2000), it is likely that the current study effects will only be maintained, and errors controlled if ongoing support and funding is provided. Consequently, healthcare organisations intending to adopt a similar model of care would need to ensure ongoing support and funding is provided to those involved.

Given the implications of supporting this model of care in terms of manpower and resources it is important that the effects of the intervention are considered more closely. In both samples, monitoring and administration errors were substantially reduced whereas the effect on prescribing errors was less notable. There may well be a case therefore to strengthen the elements of the MMI directed towards the prescribing stage of the medication process. Additionally, it may also prove beneficial if the DSN received additional support from either a pharmacist or Diabetiologist in this area of practice.

The extent to which errors were reduced by the intervention was also affected by admission category. In sample 1 for instance, on four of the study wards (i.e. medicine, kidney disease, vascular surgery and vascular amputation) the average number of errors was reduced by nearly two thirds, whereas on the orthopaedic and surgical wards the number of errors increased. Patients on the orthopaedic and surgical wards tended to be admitted for planned and routine procedures, had a shorter length of stay and were less
likely to be treated with insulin, whereas the greatest intervention effects were found on wards such as medicine, kidney disease, vascular surgery and vascular amputation where patients tended to have unplanned and longer admissions. Consequently, there may well be a case for targeting the MMI to specific groups of patients such as those who have unplanned and longer admissions. In order to understand this area more fully, further evaluative research on patients who have unplanned and longer admissions is required.

Admission category also influenced the total number of errors and length of stay patients experienced. Compared to the other study wards (i.e. medicine, kidney disease, orthopaedics and surgery), patients admitted across the two vascular wards experienced the longest length of stay and greatest number of errors. Although caution should be used when interpreting this finding as only 10% of study patients were admitted to these two wards, it is useful to consider why this group of patients experienced the longest length of stay and greatest number of errors. Patients admitted to the vascular wards were generally older than those in the other admission categories (i.e. medicine, kidney disease, surgery, and orthopaedics) and possibly had a number of other co-morbidities requiring complex medicines regimes increasing the likelihood of errors occurring.

There is substantial evidence to suggest that the potential for error increases when patients have co-morbidities and medicine regimes that involve poly-pharmacy (DH 2004, NPSA 2007, Wilson et al. 1995). Evidence of a relationship between co-morbidities and medication errors has also previously been reported (Manley et al. 2003). In a review of the medical records of 133 patients undergoing ambulatory haemodialysis, Manley et al. (2003) reported the number of co-morbidities correlated positively with the number of medication error problems. The current study findings suggest that healthcare staff need to be more vigilant during the process by which this group of patients i.e. those admitted to the vascular surgery and vascular amputation wards receive their medicines. Additionally, it could be argued that even though the MMI provided one to two educational sessions to
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doctors and nurses, this may not be sufficient to meet the learning needs of healthcare staff that care for patients with more complex medication regimes. Healthcare staff working on vascular surgery or vascular amputation wards, where patients tend to have more complex healthcare needs, may therefore require extra educational sessions. A more formal assessment of diabetes knowledge before the intervention would help ensure that the content of the MMI is appropriate to the learning needs of healthcare staff working in different clinical areas.

7.3 Part 2: Discussion of Methodology

Overall, the study was successful in that each research question was answered. The experimental approach and methods of data collection generated objective data on the outcome measures of interest i.e. medication errors, length of stay, self-efficacy, the extent to which patients information needs are met, and the types of information patients consider to be important about their medicines. Hypotheses 1-3, as described in Chapter 1.4, were supported by the results. However, the evidence from this study does not support hypothesis 4, as hospital in-patients with diabetes, who received the MMI from a DSN prescriber, did not report an improvement in the extent to which their medicines information needs were met.

The inclusion criteria for sample 2 were based on data provided by the admissions department of the hospital regarding average length of stay, and the need to ensure patients were in hospital long enough to receive the MMI. During data collection difficulties were experienced identifying patients with a predicted length of stay of three days, and recruiting participants for sample 2. At the end of the pre-intervention phase only twenty people had been recruited to this sample. Therefore in order to increase numbers the pre-intervention phase was extended by an additional month.
During the development of the MMI it was estimated that patients, doctors and nurses would require one to two educational sessions. However, the DSN reported that sometimes their needs were greater. Although the DSN was able to devote twenty four hours a week to the MMI, it was reported that at times it was difficult to deliver the intervention to all participants in this time period.

In order to maintain the consistency and quality of the intervention, it may be useful if the educational sessions, for patients, doctors and nurses, were more structured. A summative assessment of participants’ knowledge before and after the intervention, including an assessment of the patient’s ability to self-manage their diabetes, would also support a more detailed evaluation of this aspect of the intervention. The amount and type of education and information received by patients and healthcare staff would be accurately recorded, and this in turn could be used to calculate the necessary level of manpower and resources.

7.3.1 Study Strengths

The study gives a clear and detailed description of the rationale and content of each stage of the intervention. Each stage of the MMI was based on evidence from the literature. The quality of this process is a strength of the study as it would be relatively easy for another researcher to use the MMI in a future study.

This study used one nurse to deliver the intervention. One of the drawbacks of this approach is the possibility of character bias which reduces the generalizability of the findings. In contrast, a key strength of this approach is that it helped the implementation, quality and standardisation of the intervention.
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A high number of participants completed each of the three questionnaires. Seventy three percent out of a sample of 56 patients originally recruited to sample 2 completed all three questionnaires. It is not possible to compare these completion rates as this is first study in this subject area to collect three sets of data from the same group of patients. A completion rate of over 70% is classed as reasonable (Polit et al. 2001). The low attrition rate therefore strengthens study findings and reduces the risk of bias.

A further strength of the study is the reliability of the instrument that was used to measure diabetes self-efficacy. At each data collection point, the internal consistency of the modified Diabetes Management self-efficacy scale was found to be high (alpha coefficients 0.79-0.92). This indicates that the self-efficacy scale reliably assessed efficacy expectations of sample 2 towards diabetes self-care activities.

The comparable effects of the intervention on outcome measures across sample 1 and 2 suggest that the study has good generalizability. The large size of sample 1 meant that these effects were at a level of statistical significance. This enhances the generalizability of the findings, and confidence that the results could be reproduced if the study was repeated.

7.3.2 Study Limitations

Although it has been shown that the research questions were successfully answered, there were limitations to the methods adopted. This study used a convenience sample of patients whereby all patients admitted to one of the six wards during the three month pre-intervention and three month intervention period were included in the study i.e. it was not a random sample. There is the possibility therefore that the sample is not representative of patients with diabetes, and hence a degree of caution should be used when interpreting the findings.
For example, the study recruited few ethnic minority patients to sample 2. As there are specific ethnic groups, such as South Asian and African Caribbean, who have a higher prevalence of type 2 diabetes (BMA 2004), the generalizability of the findings from this sample are somewhat reduced. An enhanced sampling frame would ensure that a greater proportion of patients with a black or minority ethnic background were recruited in future studies.

Additionally, the pre-intervention and intervention groups of both samples 1 and 2 were similar with regard to demographic information, apart from admission category. In both samples a greater proportion of patients were admitted to the medical ward during the intervention. This difference, which may have been influenced by seasonal variation, could have affected study outcome measures, which does reduce generalizability of the findings.

The reliability of the insulin and OHA error data is also a possible weakness of this study. The insulin and OHA medication error extraction charts from the first 20 participants were reviewed and analysed by two people. Reliability would have been increased further, if a 10-20% random sample of all the medication charts were reviewed and analysed by two people. Additionally, the medication charts (i.e. insulin chart, sliding scale chart and / or old medication chart) for sixteen patients were unavailable during data extraction making it difficult to identify errors. This may have affected the overall findings.

Participants in sample 2 were generally old and infirm and a number had also experienced some degree of amputation to their leg(s). Consequently, they found some questions on the self-efficacy scale difficult to answer, specifically those related to foot examination and going to parties (Qs 6, 11, 12). It is not known what, if any, effect this had on their responses or the self-efficacy results.
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The small size of sample 2 reduces the generalizability of the findings related to self-efficacy and patient's medicines information needs as it cannot be said to be truly representative of hospital in-patients with diabetes. Less confidence can therefore be put in the strength of the findings related to self-efficacy and patients' medicines information needs. It would be useful if a more representative sample of patients with diabetes were used in future studies exploring diabetes self-efficacy and patients' medicines information needs.

7.3.3 Critical evaluation of the research process

As a researcher it is important to review and critically evaluate the research process and to reflect on this process. Overall the study was successful in answering the research questions. The experimental approach that was adopted generated objective data on the outcome measures of interest.

Although concerns have been expressed by the nursing discipline over the fundamental issue regarding the suitability of scientific enquiry for investigating nursing interventions (Poole & Jones 1996), the researcher has demonstrated that the chosen methodology and methods were the appropriate choice to answer the research questions.

The study gives a clear and detailed account of each stage of the research process, from designing the intervention, developing the tools for data collection, ethical approval and data collection. At each stage the researcher kept detailed records of what helped or hindered the process.

For example, some minor difficulties were experienced by the researcher during the period of data collection. The hospital is located 150 miles from the University of Reading (the university where the researcher was registered as a student during data collection). Therefore it was not practical for the researcher to be on site all the time during data
collection. The DSN prescriber and Service Improvement Manager from the study hospital provided additional support recruiting patients.

Participants in sample 2 were generally old and infirm. It would be useful if a more representative sample of patients with diabetes were used in future studies. This would support the use of other research methods such as interviews, which would allow a more detailed exploration of the factors which appear to affect self-efficacy.

In questionnaires 2 and 3, participants were asked to indicate the extent to which their information needs were met. However, on reflection it is evident that several factors could have affected the information needs of this group of patients including time since diagnosis, presence of complications and co-morbidities etc. In future this question should be refined to make it more specific to patient information needs during the study period.

On reflection, it would have been useful if more clinical data had been collected e.g. blood glucose level, HbA1C and symptoms of hypo and hyperglycaemia. These well established physiological measures would have provided additional data and further evidence to support the findings. It may be useful to consider their inclusion in future studies that adopt the MMI.

During this project the researcher has achieved a steep learning curve. Undertaking research in a new practice setting, and working in an unfamiliar geographical area were both challenging aspects of this process. However, this study has allowed the researcher to appreciate the complexities of the research process, and experience the challenges of working in collaboration with members of an unfamiliar hospital trust. This vital experiential learning has since been applied to other research projects that the researcher has been involved with.
7.4 Part 3: Contribution to knowledge, methodology and theory

This section provides the contribution this study has made to knowledge, understanding, methodology and theory, each of which is explored below.

a) The contribution to knowledge and understanding

A quasi-experimental approach was adopted in order to evaluate the effect of the MMI from a DSN prescriber and generate objective data on measures related to diabetes in-patient outcomes and quality of care. The MMI, a new intervention which combined key elements from the established role of the DSN (i.e. medicines management, education, support and promotion of self-care) with the relatively new role as a prescriber, was successfully developed and implemented.

In this study, the prescribing role was specifically used to develop an intervention that addressed recognised shortfalls in the diabetes in-patient service. The study is the first to demonstrate that through practising autonomously a nurse prescriber was able to overcome previous inadequacies in the traditional healthcare system. These inadequacies include the need to discuss each patient with the medical team in order to deliver medicines to patients, and having limited access to a specialist prescriber. This concurs with several recent reviews of the literature (Ball 2009, Cooper et al. 2008, Drennan et al. 2009) that have described how the prescribing role increases autonomy, supports advanced nursing practice and allows nurse to develop new ways of working. This study adds an important new dimension to this body of evidence which, in addition to a dearth of literature on nurse prescribers who provide in-patient services, contains a lack evidence related to quality of care and patient outcome measures.
Several significant results across the intervention group of sample 1 and sample 2, such as the reduced number of in insulin and OHA medication errors, and reduced length of stay were identified. Additionally, in sample 2 the self-efficacy scores of participants were increased. These findings contribute to our knowledge and understanding about the benefits of the prescribing role. They are also the first study effects to be reported on patient outcome measures. This objective data confirms previous qualitative study reports that nurse prescribing can improve quality of care (Carey et al. 2009a, Latter et al. 2005) and improve patient safety (Bradley et al. 2007, Courtenay et al. 2009a, Stenner & Courtenay 2008).

Crucially, the findings demonstrate that care provided by a nurse prescriber is of a comparable high standard to traditional models of care, and this is important for two reasons. Firstly, as the NHS attempts to control costs, ensuring the quality and effectiveness of care is an increasingly essential requirement of service delivery (DH 2008c). Secondly, doctors and other health professionals have reported mixed views about nurse prescribers' level of clinical experience (Carey et al. 2009b, Rana et al. 2009) and the level of pharmacology training nurses receive (Bradley et al. 2006). No previous studies have reported on this aspect of nurse prescribing practice. The evidence generated in the current study demonstrates an important strength of the care nurse prescribers provide, which may also help alleviate the concerns expressed by other healthcare professionals.

This study demonstrated that significant cost savings could be made by a DSN prescriber delivering this intervention to the diabetes in-patient service. This adds to our knowledge and understanding about the financial implications associated with the prescribing role, and adds an important new facet to previously reported benefits. It is also an important
contribution to the body of knowledge for those who are involved with service improvement and quality assurance.

The introduction of nurse-led medication review was an important aspect of the care provided by the DSN prescriber. Although there are some recent qualitative reports (Carey et al. 2009a, Stenner & Courtenay 2008) that nurse prescribers are taking a more active role in medicines management, this is first study to formally evaluate this aspect of care on patient outcomes. The successful implementation of this new area of practice adds to our knowledge and understanding of how the prescribing role can be used to expand nurses’ roles and improve medication safety.

This is the first time the information needs of hospital in-patients have been explored. The results highlight the complexity of meeting the information needs of patients with diabetes. They also suggest that nurses need to pay greater attention to establishing the information needs of this group of patients.

The study additionally explored the different categories of medicines information that are important to in-patients with diabetes. The findings indicate that in-patients with diabetes are interested in different categories of information to those previously reported in the literature (Berry et al. 2006, Berry et al. 2008, Latter et al. 2005). They also indicate that the categories of information patients are interested in does change during the course of a disease. This improved understanding about information needs is important as patients with diabetes have repeatedly reported a lack of information during admission.

In both samples, the MMI had a more dramatic effect on reducing monitoring and administration errors. These findings are important as they suggest the MMI may need strengthening with respect to the prescribing stage of the medication process. They also
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contribute to our knowledge and understanding about the potential strengths and weaknesses of this model of care.

Other significant results that this study found were, in sample 1 a strong relationship between the total number of errors and length of stay i.e. as the total number of errors increased so did length of stay. The extent to which insulin and OHA errors were reduced was affected by admission category, with the most notable effects found in patients who tended to have unplanned and longer admissions. Admission category also affected the total number of errors and length of stay, with patients admitted to the two vascular wards experiencing the greatest number of errors and longest length of stay. These findings contribute to our knowledge and understanding, as they have not been reported in other studies exploring this area of practice.

Dissemination of the study findings has been achieved in several ways. At a local level this was achieved by presenting the results to ward staff and senior hospital managers across the hospital trust where the study was conducted. Further dissemination of the study findings within the field of nursing and healthcare practice has been achieved through national and international conferences presentations of the literature review and study findings relating to medication errors, length of stay and self-efficacy. A selection of these conference presentations are presented below:


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Carey, N, Courtenay, M (2007): *A Review of the Activity and Effects of Nurse-led Care in Diabetes; Evidence-Based Nursing Practice*, Hong Kong, China: (19-21st April)


Carey, N, Courtenay, M (2007): *A Review of the Activity and Effects of Nurse-led Care in Diabetes; Federation of European Nurses in Diabetes, 12th Annual Conference, Amsterdam, Netherlands: (14-15th September)*

Several articles have been published in peer reviewed journals (Carey & Courtenay 2007, Carey *et al.* 2008, Courtenay *et al.* 2007), and this has supported wider dissemination of the study findings within the field of nursing and healthcare practice. A copy of each article can be found in Appendix 12.

b) Contribution to research methodology

A lack of studies adopting an experimental approach or longitudinal design, as discussed in chapter 2.5, was highlighted in the literature reporting the effects of nurse-led interventions and patient outcomes on in-patients with diabetes.

The study offers an original contribution to methodology in this area as it is the first to use an experimental approach to explore the effects of an intervention provided by a DSN prescriber on in-patients with diabetes. The study, a quasi-experimental design, is associated with a high level of rigour and internal validity (Polit *et al.* 2001). This means a relatively high level of confidence can be inferred from the analysis of the data that the MMI was causally linked to the study outcomes.
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The longitudinal design is also original, and the study is both first to collect a series of data from in-patients with diabetes and report on outcome measures related to quality of care such as self-efficacy and patient information needs.

c) Contribution to theory

A need for studies to adopt a less medically orientated approach and more theoretical approach to this area of research was highlighted in the literature review chapter. The theory of medication errors (Leape 1994, Reason 1990), a general systems theory, was used as a framework to develop the medicines management intervention. This is the first study to use a theoretical framework in this area of research. The theoretical framework was used to guide the research process and ensured that the intervention adopted a structured and systematic approach to addressing some of the concerns in the diabetes in-patient service.

The error findings from both samples also provide further support for the theory of medication errors. As Reason (1990), Leape (1994) and the NPSA (2007) report, whatever system or approach to patient safety is adopted human error is inevitable and it is unlikely that while errors can be reduced they will ever be totally eliminated. A similar pattern of behaviour was evident in the findings of this study. Although errors were reduced by more than 50% across the intervention group of both samples 1 and 2, a high number of errors remained following the three month intervention period.
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7.5: Part 4: Recommendations

The findings from this study provided an insight into how the prescribing role can be used by a DSN to improve diabetes in-patient services. The results have confirmed and extended the body of knowledge in this area. In light of the findings, and the strengths and limitations of the study a number of recommendations have been made and are presented below.

7.5.1 Recommendations for future research

This study evaluated the effect of a MMI provided by a DSN prescriber on in-patient services in one district general hospital in the U.K. It is therefore important that further evaluation of the MMI is conducted using DSN prescribers in other hospital settings across the U.K.

Although beyond the scope of the current study, in future studies it would also be useful to evaluate the effect of the MMI on clinical measures used to monitor diabetes control e.g. blood glucose levels, and HbA1C. This additional data would provide further evidence to support the results found in this study.

A randomised controlled study could be conducted to explore the MMI further. This would ensure that the sample was more representative of patients with diabetes and reduce the risk of bias and erroneous findings. This would also increase the generalizability of the findings.

It is possible that nurse prescribers caring for other groups of patients who, similarly to patients with diabetes, are vulnerable to medication errors e.g. children and adults aged over 70 (NPSA 2007), may also be able to make a contribution to reducing medication errors. It would therefore be useful to explore the use of the MMI using nurses working in different clinical settings.
Chapter 7: Discussion

Given the complexity of meeting the information needs of patients with diabetes, further evaluation of the medicines information tool, using patients with varying disease duration and from a range of practice settings, including primary care is warranted. This would contribute to our understanding about the types of information patients are interested, and add to the validity of the tool.

In this study patients who tended to have unplanned and longer admissions, experienced the greatest reduction in insulin and OHA medication errors. In order to ensure the best use of resources and determine if there is a case for targeting the MMI to specific groups of patients, further evaluative research on patients who have unplanned and longer admissions is required.

The findings from this study are only applicable to the healthcare system in the U.K. In order to establish if the MMI is an effective model of care in other healthcare systems, it would be useful to conduct further studies in other countries that have a similar high prevalence of diabetes, and where nurses also have prescriptive authority i.e. U.S, Australia and Canada.

7.5.2 Recommendations

1) In order to overcome inadequacies in the traditional doctor-led model of care and improve the process by which in-patients with diabetes receive their medicines, it is recommended that other diabetes specialist nurses, who are involved with medicines management and working at advanced levels of practice, consider adopting the prescribing role.
2) In order to improve patient safety and the quality of diabetes in-patient services, it is recommended that other DSNs prescribers who care for this group of patients explore the adoption of the MMI.

3) In line with current government policy on improving patient safety (DH 2004, NPSA 2007), it is recommended that national policy makers encourage and support nurse prescribers who care for other patients, that are vulnerable to medication errors e.g. children, and adults aged over 70 (NPSA 2007), to explore the feasibility and effectiveness of the MMI in different practice settings.

4) The MMI provided by a DSN prescriber can produce as high quality care as traditional models of doctor-led care and achieve as good outcomes for patients. Given that the MMI has the potential to reduce the direct costs of care, managers and workforce planners should consider increasing the number of DSN prescribers who are employed to work for diabetes specialist in-patient teams.

5) The MMI provided by a DSN prescriber improved the process by which in-patients with diabetes received their medicines and as a result medication errors and length of stay reduced and diabetes self-efficacy increased. For these effects to be maintained managers need to ensure ongoing support and funding for the MMI is secured through local commissioning arrangements for workforce planning and service delivery.

6) In order that patients with diabetes are able to self-manage their condition they need to receive the right amount and type of information about their medicines. For this to be achieved, nurses need to be aware of the various factors that affect this aspect of care. It is therefore recommended that diabetes education and training for nurses is reviewed to ensure it is fit for purpose.
Chapter 7: Discussion

7.6 Conclusions

DSNs have an integral role to play in improving the services in-patients with diabetes receive and prescribing is an increasingly important part of the care they provide. The findings presented in this thesis demonstrate that the prescribing role can be successfully used by a DSN to develop a new model of care and overcome shortfalls in the diabetes in-patient service.

In addition to taking responsibility for prescribing decisions the study has shown that the increased autonomy provided through the prescribing role allowed the DSN to take a more active role in medication review. This in combination with the more consistent approach to care the MMI provided had a positive effect on patient safety and the quality of care in-patients with diabetes received. Crucially, the care provided was of a comparable high standard to traditional doctor-led models of care.

This model of care has important implications in terms of maximising resource use, the potential to reduce direct costs of care and, providing a more flexible and accessible model of service delivery. In order to understand this contribution more fully, further evaluation of the MMI using DSN prescribers in other UK hospital settings is required.

It is likely that nurse prescribing is having similar positive effects in other clinical areas. If the impact that nurse prescribing can have on healthcare provision is to be fully realised, further evaluative research must be conducted, using patients from different clinical settings.
References


References


References


DH (2003a) Liberating the Public Health Talents of Community Practitioners and Health Visitors, DH, London

References

DH (2003c) *Supplementary Prescribing for Nurses and Pharmacists within the NHS in England*, DH, London


DH (2008b) *Improving Emergency and In-patient Care for people with Diabetes*, National Diabetes Support Team


References


References


References


References


References


National Research Ethics Service (2006) Differentiating Audit, Service Evaluation and Research, DH,


Nursing and Midwifery Council (NMC) (2010) *Number of Independent Extended Nurse Prescribers*, Personal Communication with NMC.


Office of Public Sector Information (1998) *Data Protection Act*


References


References


References


Dear Dr Courtenay,

**Ethics and Research Committee**

**Project 05/14: Assessing the effects of a diabetes specialist nurse (and qualified nurse prescriber) on self efficacy, medication errors and utilisation of health services in individuals with diabetes**

Thank you for your recent letter. On behalf of the Ethics and Research Committee the Chairman has agreed that the above project be allowed to proceed but, in so doing, takes the view that it should additionally be considered by the relevant local NHS Research Ethics Committee. He recognises in so recommending that this remains a matter for negotiation between yourself and the Peterborough and Stamford NHS Foundation Trust.

Yours sincerely,

\[signature\]

| D.A. Stannard |
| Director of Quality Support |

13 July 2005
Dear

Self-efficacy (or confidence) questionnaire for people living with diabetes

I am a researcher at Reading University. I am undertaking a study (towards a PhD), evaluating the role of the Diabetic Specialist Nurse. You have been asked to participate in this research because you have diabetes and I would like you to give me your views about living with this condition.

The study compromises of three similar questionnaires. These questionnaires will be given out at the beginning of your hospital stay (questionnaire 1), at the end of your stay (questionnaire 2), and three months following your discharge (questionnaire 3). In order to complete the third questionnaire, you will be contacted by letter or telephone.

The questionnaire will take about 10 minutes to complete. A stamped addressed envelope (SAE) is enclosed for you to return it to me. If you feel, after reading this information, that you do not want to take part in this study, please return the questionnaire in the envelope provided. The research will be complete by June 2006, and the results will be made available to you via the Diabetic Specialist Nurse when you next attend the hospital out patient clinic. Your participation in this survey is entirely voluntary, and your responses will be confidential and anonymous.

If you have any questions, or require help completing the questionnaire, please do not hesitate to contact me. Thank you for reading this letter and I look forward to receiving your completed questionnaire.

Thank you for your participation

Yours Sincerely

Nicola Carey
Senior Research Fellow
CONSENT FORM

Title of Project: A study to evaluate the effect of the Diabetic Specialist Nurse Prescriber on self-efficacy for people with diabetes

Name of Researcher: Nicola Carey

1. I confirm that I have read and understand the information sheet dated ................. for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected.

3. I agree to take part in the above study.

Name of Patient Date Signature

Name of Researcher Date Signature

Please initial box
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<th>Patient ID</th>
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</thead>
<tbody>
<tr>
<td>Insulin doses not signed as given</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inappropriate dose of short acting insulin administered in response to hyperglycaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OHA medication not signed as given</td>
<td></td>
<td></td>
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<tr>
<td>Sliding scale doses not signed as given</td>
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<td></td>
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<tr>
<td>Omission of Insulin after hypoglycemia</td>
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<td>Charts Incomplete</td>
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<tr>
<td>Prescribing Errors</td>
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<tr>
<td>Insulin not written up</td>
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<td>Number of units of dose unclear</td>
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<td>Prescription chart not signed by prescriber</td>
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<tr>
<td>Insulin/Oral medication dose not adjusted with persistent BG &lt;4mmol</td>
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</table>

REVIEWER INITIALS

CHECKED BY INITIALS
Appendix 5

STUDY NUMBER

1. How long is it since you were diagnosed with diabetes?
   - Less than 1 year
   - 1-15 years
   - Over 15 years

2. Do you have any other illnesses or diseases?
   - No □
   - Yes □
   - Please specify:
     ........................................................................................................
     ........................................................................................................
     ........................................................................................................

3. Age: under 50 years □
   - 51-69 years □
   - Over 70 years □

4. Sex: Male □
   - Female □

5. Current marital status
   - Married/living with partner □
   - Divorced/separated □
   - Single (never married) □
   - Widowed □
Appendix 5

6. What type of accommodation do you live in?
   Detached/semi detached (including bungalow) □
   Terrace (including end terrace) □
   Purpose built flat/maisonette in block □
   Self contained flat in a converted house □
   Rooms in a converted house i.e.
   not self contained □
   Caravan/houseboat/mobile home □
   Nursing home □
   Other □

7. Are you currently employed?
   No □
   Yes □
   Please specify ..............................................................................

8. What is your ethnic group?
   White □
   Mixed □
   Asian/Asian British □
   Black/Black British □
   Chinese □
Appendix 6

The University of Reading
School of Health and Social Care

Self-Efficacy (or confidence) Questionnaire for People living with Diabetes

Study Number

Q1 173
• Thank you for agreeing to take part in this study. We are evaluating the role of the Diabetic Nurse Specialist

• The questionnaire will take about 10 minutes to complete

• The answers you give will be used in planning future service provision

• If you feel after reading this that you do not want to take part, or if you feel you want to withdraw at any point please return the questionnaire in the envelope provided.

• Please read every question carefully before you answer it and try to answer each one. Don’t worry if you make a mistake; simply cross out the mistake and put a mark in the appropriate place

• When you have completed the questionnaire please return it in the envelope provided

• The study is anonymous and the information you give will be treated in the strictest confidence
CONFIDENCE IN ACTIVITIES TO MANAGE DIABETES

Below is a list of activities you have to perform to manage your diabetes. Please read each one and then put a circle through the number which best describes how confident you usually are that you could carry out that activity.

For example, if you are completely confident that you are able to check your blood sugar levels when necessary, put a circle through 6. If you feel that most of the time you could not do it, put a line through 1 or 2.

For example

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>6</th>
</tr>
</thead>
</table>

I am confident that ...........

1. I am able to check my blood sugar if necessary

<table>
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<tr>
<th>Cannot do at all</th>
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</table>

2. I am able to correct my blood sugar when the sugar level is too high

<table>
<thead>
<tr>
<th>Cannot do at all</th>
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</table>

3. I am able to correct my blood sugar when the blood sugar level is too low

<table>
<thead>
<tr>
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</thead>
</table>

4. I am able to choose the correct foods

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<th>Cannot do at all</th>
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5. I am able to keep my weight under control

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<th>Cannot do at all</th>
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<th>Certain can do</th>
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6. I am able to examine my feet for cuts

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<th>Certain can do</th>
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7. I am able to adjust my eating plan when ill

<table>
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<th>Cannot do at all</th>
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<th>Certain can do</th>
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8. I am able to follow a healthy eating pattern most of the time

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<th>Certain can do</th>
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9. I am able to take exercise if the doctor advises me

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10. When taking more exercise I am able to adjust my eating plan

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<th>Cannot do at all</th>
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</table>

11. I am able to follow a healthy eating pattern when I am away from home/on holiday

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<th>Certain can do</th>
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</table>
12. I am able to follow a healthy eating pattern when I am out at a party

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<th>Certain can do</th>
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13. I am able to adjust my eating plan when I am feeling stressed or anxious

<table>
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<th>Cannot do at all</th>
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14. I am able to take my medication as prescribed

<table>
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15. I am able to adjust my medication when I am ill

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Thank you for taking the time to complete the questionnaire
Please check that you have filled in each question and return it in the envelope provided
At the end of your stay in hospital you will be asked to fill in a repeat of this questionnaire
This information is covered by the Data Protection Act
Self-Efficacy (or confidence) Questionnaire for People living with Diabetes
• Thank you for agreeing to take part in the next part of this study. We are evaluating the role of the Diabetic Nurse Specialist

• The questionnaire will take about 10 minutes to complete

• The answers you give will be used in planning future service provision

• If you feel after reading this that you do not want to take part, or if you feel you want to withdraw at any point please return the questionnaire in the envelope provided.

• Please read every question carefully before you answer it and try to answer each one. Don’t worry if you make a mistake; simply cross out the mistake and put a mark in the appropriate place

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For example

| Cannot do at all | 1 | 2 | 3 | 4 | 5 | Certain can do | 6 |

I am confident that .......

1. I am able to check my blood sugar if necessary

| Cannot do at all | 1 | 2 | 3 | 4 | 5 | Certain can do | 6 |

2. I am able to correct my blood sugar when the sugar level is too high

| Cannot do at all | 1 | 2 | 3 | 4 | 5 | Certain can do | 6 |

3. I am able to correct my blood sugar when the blood sugar level is too low

| Cannot do at all | 1 | 2 | 3 | 4 | 5 | Certain can do | 6 |

4. I am able to choose the correct foods

| Cannot do at all | 1 | 2 | 3 | 4 | 5 | Certain can do | 6 |
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11. I am able to follow a healthy eating pattern when I am away from home

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Q2 181
12. I am able to follow a healthy eating pattern when I am out at a party

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<td></td>
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</tbody>
</table>

15. I am able to adjust my medication when I am ill

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Certain can do</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The next question is about your information needs:

16. During your admission, to what extent have your information needs been met?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thank you for taking the time to complete the questionnaire
Please check that you have filled in all the sections and return it in the envelope provided
In 3 months time you will be asked to fill in a repeat of this questionnaire
This information is covered by the Data Protection Act
Appendix 8

The University of Reading
School of Health and Social Care

Self-Efficacy (or confidence) Questionnaire
for People living with Diabetes

Study number

Q3

183
• Thank you for agreeing to take part in final part of this study. We are evaluating the role of the Diabetic Nurse Specialist

• The questionnaire will take about 10 minutes to complete

• The answers you give will be used in planning future service provision

• If you feel after reading this that you do not want to take part, or if you feel you want to withdraw at any point please return the questionnaire in the envelope provided.

• Please read every question carefully before you answer it and try to answer each one. Don’t worry if you make a mistake; simply cross out the mistake and put a mark in the appropriate place

• When you have completed the questionnaire please return it in the envelope provided

• The study is anonymous and the information you give will be treated in the strictest confidence
CONFIDENCE IN ACTIVITIES TO MANAGE DIABETES

Below is a list of activities you have to perform to manage your diabetes. Please read each one and then put a circle through the number which best describes how confident you usually are that you could carry out that activity.

For example, if you are completely confident that you are able to check your blood sugar levels when necessary, put a circle through 6. If you feel that most of the time you could not do it, put a line through 1 or 2.

For example

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

I am confident that .......

1. I am able to check my blood sugar if necessary

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

2. I am able to correct my blood sugar when the sugar level is too high

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

3. I am able to correct my blood sugar when the blood sugar level is too low

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

4. I am able to choose the correct foods

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
5. I am able to keep my weight under control

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Certain can do</th>
</tr>
</thead>
</table>

6. I am able to examine my feet for cuts

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Certain can do</th>
</tr>
</thead>
</table>

7. I am able to adjust my eating plan when ill

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Certain can do</th>
</tr>
</thead>
</table>

8. I am able to follow a healthy eating pattern most of the time

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Certain can do</th>
</tr>
</thead>
</table>

9. I am able to take exercise if the doctor advises me

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Certain can do</th>
</tr>
</thead>
</table>

10. When taking more exercise I am able to adjust my eating plan

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Certain can do</th>
</tr>
</thead>
</table>

11. I am able to follow a healthy eating pattern when I am away from home

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Certain can do</th>
</tr>
</thead>
</table>
12. I am able to follow a healthy eating pattern when I am out at a party

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th></th>
<th></th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

13. I am able to adjust my eating plan when I am feeling stressed or anxious

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th></th>
<th></th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

14. I am able to take my medication as prescribed

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th></th>
<th></th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

15. I am able to adjust my medication when I am ill

<table>
<thead>
<tr>
<th>Cannot do at all</th>
<th></th>
<th></th>
<th>Certain can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

The next question is about your information needs:

16. Following your hospital discharge, to what extent have your information needs been met?

| | | | | | | |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Unmet | | | | | Totally met |
The last question is about the information you would like to receive about your medication.

17. What information is important to you in an explanation about your medicine?

Please rate each of the following types of information (from 1 not all important to 6 very important) for how important you feel it is to be included in an explanation about the medicine. (Please place a ☒ in the box of your choice)

<table>
<thead>
<tr>
<th>Information</th>
<th>Not at all important</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>What the medication is (drug type etc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What the medication does / how it works</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probability medicine will work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detailed questions about taking medicine (e.g. dosage)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possible side effects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interactions with other medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any alternatives to medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What to do if you forget to take it or take too much</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How will you know if medication is working</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risks of not taking medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to contact the nurse/doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Thank you for taking the time to complete the questionnaire
Please check that you have filled in each question and return it in the
envelope provided
This information is covered by the Data Protection Act
Appendix 9

The University of Reading
School of Health and Social Care
Bulmershe Court
Reading
RG6 1HY

Tel: 0118 3785840

Date as posted

Dear

Self-efficacy (or confidence) questionnaire for people living with diabetes

During your recent stay in hospital you completed part 1 and 2 of the above study. You were asked to participate in this research because you have diabetes and you have your medicines prescribed by a nurse and/or doctor. I am interested in your views about managing your diabetes and the medication you have been prescribed. The information we gain from you will be used to help inform the future development of prescribing in nursing.

The study comprises three similar questionnaires. This is the final part of the study. The questionnaire will take about 10 minutes to complete. A stamped addressed envelope (SAE) is enclosed for you to return it to me. If you feel, after reading this information, that you do not want to take part in this study, please return the questionnaire in the envelope provided. The research will be complete by June 2006, and the results will be made available to you via the Diabetic Specialist Nurse when you next attend the hospital out-patient clinic. Your participation in this survey is entirely voluntary, and your responses will be confidential and anonymous.

If you have any questions, or require help completing the questionnaire, please do not hesitate to contact me. Thank you for reading this letter and I look forward to receiving your completed questionnaire.

Thank you for your participation

Yours Sincerely

Nicola Carey
Senior Research Fellow
Dear

Self-efficacy (or confidence) questionnaire for people living with diabetes

During your recent stay in hospital you completed part 1 and 2 of the above study. You were asked to participate in this research because you have diabetes and you have your medicines prescribed by a nurse and/or doctor. I am interested in your views about managing your diabetes and the medication you have been prescribed. The information we gain from you will be used to help inform the future development of prescribing in nursing.

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If you have any questions, or require help completing the questionnaire, please do not hesitate to contact me. Thank you for reading this letter and I look forward to receiving your completed questionnaire.

If you have already completed the questionnaire please ignore this letter.

Thank you for your participation

Yours Sincerely

Nicola Carey
Senior Research Fellow
Dear

Self-efficacy (or confidence) questionnaire for people living with diabetes

I am writing to thank you for your participation in this study. I am very grateful for your cooperation and I hope that the questionnaires will provide important insight into the effect of the Diabetic Specialist Nurse Prescriber on self-efficacy (confidence) for people living with diabetes. The investigation will be complete by June 2006, and the results will be made available to you via the Diabetic Specialist Nurse when you next attend the hospital outpatient clinic.

Thank you for your participation

Yours Sincerely

Nicola Carey
Senior Research Fellow
MATERIAL REDACTED AT REQUEST OF UNIVERSITY