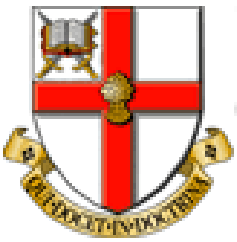


University of Chester

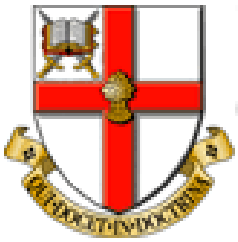
The Effectiveness of Telephone Consultation in the Management of Patients with Diabetes Mellitus

"Dissertation submitted in accordance with the requirements of University of Chester for the degree of Master of Science."

Philippa Joseph

(October 2013)

Student No.294612703



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Abstract

Background: Achieving optimal glycaemic control is a key clinical objective in diabetes management. The maintenance of near normal blood glucose levels is considered crucial in the prevention of the microvascular and macrovascular complications of diabetes mellitus (DM). Telephone support can be an integral part of good diabetes care and patients requiring such support are contacted by the Diabetes Specialist Nurse (DSN). These calls are time consuming and the effectiveness of this service had not been evaluated previously.

Research Question: Does telephone consultation with the DSN improve glycaemic control? - A review of telephone contacts over two months and subsequent follow up for six months.

Is there a relationship between the number and frequency of follow up consultations and improvement in glycaemic control?

Research Design and Method: A retrospective review of the local diabetes data base was performed to review patients who had received DSN telephone calls for poor glycaemic control. Patients were identified from weekly phone call lists in September and October 2012. The following data was collected and analysed: glycosylated haemoglobin A1c (Hba1c), weight, alterations to insulin dose and oral agents, number of calls per patient and the time period the calls were made over at baseline and six months following telephone contact.

Results: Data is reported as median with range, unless otherwise stated. 108 patients were called over the two month period. Of the 108 patients 56 (51.9%) were male and 52 (48.1%) were female. The mean age for males was 63.1±14.2 years and for females was 63.6±13.9years. 26 patients (24.1%) had type 1diabetes (T1DM) diabetes and 82 patients (75.9%) had type 2 diabetes (T2DM). Each patient had a median of five calls (range 1-27 calls) over a median of thirteen weeks (range 1-26 weeks). Nine patients were on oral hypoglycaemic agents (OHAs) only and 99 patients were on either insulin therapy alone or a combination of insulin and OHAs. HbA1c significantly improved from 78mmol/mol (43-140) to 72 mmol/mol (41-132) (9.3 [6.1-15] to 8.7 [5.9-14.2]%) at six months, p=0.0001, for those patients on insulin, (analysed using Wilcoxon test), however there was no significant improvement in HbA1c, p=0.400, for those patients on OHA's only.

Conclusion: DSN telephone support to patients approximately every eighteen days over thirteen weeks significantly improved HbA1c at six month follow up. Longer follow up is required to determine if this reduction is sustained.

Declaration of original work

"I hereby declare that work contained herewith is original and is entirely my own work. It has not been previously submitted in support of a Degree, qualification or other course."

Signature : Date: 10/10/2013

Presentation of work

A pilot study reviewing 39 patients on insulin therapy for treatment of their diabetes was presented as a poster in Manchester March 2013 at the Diabetes UK Professional Conference.

(see Appendix 1 for the poster).

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List of Abbreviations

BGM: blood glucose monitoring

CCG: Clinical Commissioning Group

CVA: Cerebrovascular Accident

CVD: Cardiovascular disease

DCCT: Diabetes Control and Complications Trial

DM: Diabetes Mellitus

DOH; Department of Health

DSN: Diabetes Specialist Nurse

FBG: Fasting Blood Glucose

GP: General Practitioner

HbA1c: Glycosylated haemoglobin

IFCC: International Federation of Clinical Chemistry

Kg: kilograms

mmol/mol: millimoles per mol

NHS: National Health Service

NICE: National Institute for Health and Clinical Excellence

OHA: Oral Hypoglycaemic Agent

QOF: Quality and Outcome Framework

PbR: Payment by Results

PCT: primary care trust

RCT: Randomised controlled trial

SD: Standard Deviation

SMBG: self- monitoring blood glucose

T1DM: Type 1 diabetes

T2DM: Type 2 diabetes

TDI: Total daily insulin dose

UKPDS: UK Prospective Diabetes Study

WHO: World Health Organisation

Chapter 1
Introduction

1. Introduction

1.1. What is Diabetes?

DM is defined as a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels (World Health Organisation [WHO], 2013). There are two main classification of DM. T1DM is an auto-immune disease resulting in the destruction of pancreatic β-cells, whereas T2DM is strongly associated with obesity and occurs as a result of failing pancreatic β-cell function, responsible for the production of insulin, often alongside insulin resistance (De Fronzo, 2009). DM in general causes a loss of the ability to maintain normoglycaemia through relative or absolute insulin deficiency.

Achieving optimal glycaemic control is a key clinical objective in diabetes management (Nathan, Kuenen, Borg, Zheng, Scoenfeld & Heine, 2009). The maintenance of near normal blood glucose levels is crucial to the prevention of the microvascular complications of diabetes (Williams & Pickup, 2004). Both the Diabetes Control and Complications Trial (DCCT, 1998) and the Stockholm Diabetes Intervention Study ([SDIS], Reichard, Berglund, Britz, Cars, Nilson, & Rosenqvist 1991) are in agreement with this and showed that intensive diabetes management

prevents and decreases the development and progression of the microvascular complications of T1DM. The ADVANCE study (Advanced Collaborative Group, 2008) randomised 11,140 participants with T2DM to either intensive glycaemic control, using gliclazide and additional medications to achieve a target HbA1c ≤ 6.5% or standard arm which used any medication except gliclazide with a target HbA1c according to local guidelines. The VA Diabetes Trial ([VADT] Duckworth et al, 2009) randomised 1,791 participants with T2DM uncontrolled on maximum OHAs or insulin therapy to either intensive glycaemic control HbA1c < 6.0% or standard glycaemic control HbA1c of at least 1.5% separation. Both studies used a treatment algorithm to titrate medications to achieve the desired outcomes. However in both studies there was no significant reduction in cardiovascular disease (CVD) in the intensively treated arm and infact the VADT study actually showed more CVD deaths in the intensive arm than in the standard arm, although this was not statistically significant. There was in an increase in the number of severe episodes of hypoglycaemia in both groups. The studies concluded that shorted duration of T2DM without established atherosclerosis may benefit from intensive glycaemic control, but treatment needs to be individualised in those patients with long duration of DM, history of severe hypoglycaemia, advanced atherosclerosis and advanced age, to reduce the risk of severe hypoglycaemia, protentially leading to increased risk of CVD mortality. DSN titration of OHA's allows for assessment of an individuals blood glucose monitoring (BGM) and reported hypoglycaemia more effectively than algorithm titration.

There are many barriers to optimising DM treatment, especially insulin therapy, include hypoglycemia, weight gain, and suboptimal initiation and dose titration.

Epidemiologic studies and randomised controlled trials (RCT) have shown that the risk for hypoglycaemia is proportional to the achieved level of glycaemic control, the closer the mean glucose or HbA1c level is to normal, the greater the risk (Cryer, 2002). In patients with T2DM, those using insulin have the highest risk for hypoglycaemia (Leese, Wang, Broomhall, Kelly, Marsden, Morrison et al, 2003).

1.2. **Diabetes Epidemiology**

DM is a condition of epidemic proportions with an estimated worldwide prevalence, in 2011, of 366 million, and a United Kingdom (UK) prevalence of 2.9 million people (Quality and Outcome Framework [QOF], 2011). This figure is expected to rise to five million people in the UK by 2025 and 552 million people worldwide by 2030 (Diabetes UK, 2012). Of the people diagnosed with DM in the UK it is estimated that 90% are diagnosed with T2DM and 10% with T1DM.

The 2011 Census data states that Wirral, where the study was conducted, has a population of 319,800 (Office for National Statistics, 2011), of whom 15,353 people are diagnosed with DM (Health and Social Care Information Centre, 2012). Patients with DM living in the most disadvantaged areas need further support to ensure they are able to improve their diabetic control (Wirral Primary Care Trust, 2007). T2DM is also more prevalent amongst certain social groups. The most disadvantaged in the UK population are two-and-a-half times more likely to have DM at any given age whilst complications of DM, such as CVD, cerebrovascular disease and nephropathy have been estimated as three and a half times higher in the lower socio economic groups (Weng, Coppin & Sonksen, 2002). There are persistently high levels of deprivation in the Northwest. The Index of Deprivation combines a range of economic, social and

housing indicators to provide the most comprehensive picture of deprivation. The Wirral remains 60th out of 326 on the Index of Multiple Deprivation 2010, with Liverpool being at position one as the most multiple deprived localities nationally (Department for Communities and Local Government, 2011). In February 2011 Wirral had 18,335 people claiming out of work benefits in its most deprived areas, this is 35.7% of the working age population in this area which is over double the national average (Appendix 2 shows a map of the Wirral and its most deprived areas).

The overall aim of DM care is to enable people to achieve a quality of life and life expectancy similar to that of the general population. In essence it is important to reduce the risk of complications associated with DM which can lead to increase morbidity and mortality. A good services providing DM prevention and management includes ensuring equitable access for vulnerable groups, such as those living in institutional care and those experiencing social deprivation, as well as for black and minority ethnic groups (Diabetes UK, 2005). Provision of resources need to ensure that individuals with the most need have access to appropriate, accessible health care.

1.3. Cost of Diabetes

The costs of dealing with the complications of DM, e.g. CVD including heart disease, cerebrovascular accidents (CVA), retinopathy which can lead to blindness, nephropathy which can lead to renal failure and amputations, vastly outweigh the costs of early intensive therapy. Early treatment results in better outcomes and lower costs for the National Health Service (NHS). Approximately £23.7 billion was spent on DM in the 2010/2011 financial year, which equates to approximately 10% of NHS resources, with the ratio of the cost of complications to the cost of treatment

exceeding three to one (Hex, Bartlett, Wright, Taylor & Varley, 2012). The figure is expected to rise to 17% of NHS resources by 2035/6 (Hex, Bartlett, Wright, Taylor & Varley, 2012). Using national data from the 2001 census and Wirral General Practitionner (GP) registered population data, it can be estimated that the cost of DM to the NHS in Wirral is over £7.4 million annually (Wirral Primary Care Trust, 2007).

1.4. **Provision of Services**

Traditionally DM services have been provided in both primary and secondary care settings, with GPs referring the most complex patients with DM into the hospital clinic. On April 1st 2013, Primary care trusts (PCTs), who used to commission most NHS services and controlled 80% of the NHS budget were abolished and replaced with clinical commissioning groups (CCGs). CCGs have taken on many of the functions of PCTs and in addition some functions previously undertaken by the Department of Health (DOH). CCGs commission most services, including planned hospital care and they can services from any provider that meets NHS standards and costs, which can be NHS hospitals, social enterprises, charities, or private sector providers.

The provision of diabetes services is complex as care is provided by a wide range of professionals, including general practitioners (GPs) and other primary healthcare professionals and specialist diabetes teams, as well as people with diabetes and their carers. The achievement of good outcomes for people with diabetes is dependent on the provision of well-organised and coordinated diabetes services that draw on the knowledge and skills of health and social care professionals working across primary and secondary care (Diabetes UK, 2005).

According to Haddad and Chetty (2012), most diabetes management occurs outside the clinics yet patients look for healthcare providers for support and counselling. Unfortunately due to limitations in staffing and contracting arrangements counselling patients on diet, exercise and other important self-management behaviours is not accomplished as part of routine care.

1.5. Telephone Support

Patients require a great deal of support if they are to maintain good control. Finding systems to provide ongoing support and follow-up for patients remains a challenge. Telephone contact is possibly the most versatile, accessible and cheapest medium. Car and Sheikh (2003) suggest that telephone follow-up extends the support provided through the reinforcement of behaviors and by allowing further adjustments in therapy without the need for another clinic visit.

1.6. Defining Variables

The study involved patients who were all under the care of the local hospital DM clinic and needed contacted by a DSN, who was based in the hospital outpatients department. Contact was made via the telephone. Assessment of DM was made during the consultation using patients' home BGM levels with overall glycaemic control being assessed prior to contact and six months after by measuring HbA1c. HbA1c was analysed using International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) values. The DCCT aligned values for HbA1c will also be reported in the results. Weight was recorded in kilograms, using SECA seat scales, which are calibrated on a yearly basis.

1.7. The Research Project

The following retrospective study was designed to assess the effect of telephone contact by the DSN to improve HbA1c in patients requiring follow up from self - referral or following a clinic referral. This report explores the reason for the telephone contact and the impact of the DSN in more detail and assesses the evidence for and against telephone follow up for improving glycaemic control. The report describes the methodology and presents results for the study with reference to the effect on glycaemic control, weight, alterations in treatment and the number and frequency of phone contacts.

Chapter 2

Literature Review

The following literature review investigates in more depth the impact DSNs have in improving glycaemic control in patient with DM and the issues surrounding managing patients with DM. Current developments in technology to assist management and facilitate access to BGM results will also be discussed.

2.1. Glycaemic Targets in Diabetes

The National Institute for Clinical Excellence ([NICE], 2009) recommend a target HbA1c of between 48mmol/mol (6.5%) and 58mmol/mol (7.5%) for individuals with DM. The results of the latest National Diabetes Audit 2010-2011 indicates that there is much need for improvement as only 6.9% of individuals with T1DM achieved HbA1c <48mmol/mol (6.5%), and only 28.3% achieved HbA1c ≤58mmol/mol (7.5%). The results were only slightly improved in patients with T2DM with 26.4% of individuals achieving a HbA1c <48mmol/mol (6.5%), and only 66.5% achieving a HbA1c ≤58mmol/mol (7.5%) (Health and Social Care Information Centre, 2012). DeVries, Snoek and Heine (2004) concur with this and suggest that around 25% of the adult T1DM population have persistently poor glycaemic control.

Teoh, Home and Leiter (2011) suggest that targets must be individualised to maintain an appropriate balance between the benefits and risks associated with good glycaemic control. The Action to Control Cardiovascular Risk in Diabetes ([ACCORD], 2008) Trial are in agreement with this and recommended that although an appropriate HbA1c target is generally 53mmol/mol (7.0%) individualized glycemic targets may

be appropriate for some patients for instance those who are older, have longer duration of DM, have a history of severe hypoglycemia, exhibit advanced microvascular or macrovascular complications, or present with extensive comorbidities. It is therefore essential to discuss with the patient appropriate HbA1c targets, which are also achievable.

Several studies have shown that good glucose control is associated with a decreased risk of microvascular and macrovascular complications (DCCT, 1993; Reichard, Nilsson & Rosenqvist, 1993; Malmberg, 1997 & The UK Prospective Diabetes Study [UKPDS], 1998). However many studies show that good glycaemic control is often difficult to achieve. In a review of 1641 patients records, in a primary care setting, Goudswaard, Stolk, Zuithoff and Rutten (2003) suggest that the worse metabolic control in those treated with either OHA or insulin indicates that current treatment regimens might be not sufficiently applied to reach the targets of care. The study found that fasting blood glucose (FBG) appeared to be a strong predictor of HbA_{1c}, which underlines the usefulness of this simple test in daily DM care.

The challenge remains to find systems to provide follow up and support for patients, which can facilitate titration of treatment. One of the most versatile, accessible and cheapest medium to maintain patient support and contact is the telephone. This allows for reinforcement of behaviours and adjustment of therapy, without the need for a further clinic appointment (Car & Sheikh, 2003). Wu, Forbes, Griffiths, Milligan and While (2010) acknowledge that there is evidence to suggest that patients are achieving better diabetes control, however patients require a great deal of support if they are to maintain good control. In a meta-analysis of controlled trials they concluded that

telephone follow up targeting patients with the poorest control can have significant clinical benefit and that varying the intensity of the follow-up based on patient need appeared to deliver better outcomes.

According to Thompson, Kozak and Sheps (1999) a common approach for the intervention arm of several studies is to provide regular telephone contact with diabetes nurse educators for advice about insulin adjustment. As part of a chronic disease management strategy, telephone services can improve outcomes (Weinberger, Tierney, Booher & Katz, 1989; Debusk et al, 1994), which leads to a decrease in treatment costs (Wasson, Gaudette, Whaley, Sauvigne, Baribeau & Welch, 1992).

2.2. Guidelines in Diabetes

NICE (2004) recommend that patients with T1DM should be provided with open-access services on a walk-in and telephone-request basis during working hours and a helpline staffed by people with specific diabetes expertise should be provided on a 24-hour basis. Diabetes UK, (2009) acknowledge that being able to discuss thoughts or ideas, or to ask for advice in times of doubt or difficulty was reported as contributing directly to the success of patients' self-management. NICE (2008) produced guidelines for the management of T2DM suggesting that when starting insulin therapy a structured programme employing active insulin dose titration should be used. This should encompass, structured education, continuing telephone support, frequent self-monitoring, dose titration to target, dietary understanding, management of hypoglycaemia, management of acute changes in plasma glucose control and support

from an appropriately trained and experienced healthcare professional. Patients often find it difficult to attend the clinic setting and although some of these activities require face to face contact, many can be achieve through none face to face contact. It is essential that access to information and healthcare professionals is provided for patients in a way that is convenient to the patient, whether that be phone contact, email or websites.

Regular assessments of blood glucose levels and effective self-care may improve glycaemic control, thereby reducing the risk of complications from DM (DCCT, 1993; UKPDS, 1998). Unfortunately, many patients fall short of targeted glucose levels because of problems obtaining treatment or inadequate self-care (Kurtz, 1990). In particular, low income patients with DM use fewer outpatient services and have more hospitalizations than those with higher incomes (Bindman et al., 1995). Since telephones are almost universally available (Anderson, Nelson & Wilson, 1998), clinicians and associated professionals can use them to conduct health status assessments and provide self-care education for patients who have difficulty attending outpatient care.

2.3. Effectiveness of Diabetes Specialist Nurses

Specialist nurses are defined as 'a registered nurse, who, after a significant period of experience in a specialised field and with additional nursing education, is authorised to practice as a specialist and be involved in clinical practice, consultation, teaching and research (Tang, 1993). DSNs were introduced approximately sixty years ago to support people with DM and their carers' in the management on their condition (Gosden et al., 2009). The DSN is also trained to make adjustments to a patient's

treatment regimen, for example insulin dosage. DSNs may also advise patients on the management of inter-current illnesses, in particular advising on diabetic treatments during other illnesses. This enables a broader approach to patient management.DSNs provide education and support services to people with DM in many health care systems. A key goal is helping enable people to self-manage their DM. However, in a meta-analysis of six trials Loveman, Royle and Waugh (2003) found no strong evidence of benefit of care from DSNs for adolescents and adults with DM. Although short-term benefits may be possible, this has not been shown to result in long-term improvements. People receiving care from DSNs do not appear to have improved health when compared with usual care in hospital clinics or primary care with no specialist nursing input. There were limitations with the meta-analysis as all the trials included in the analysis had different interventions. The authors recommended the need for RCTs. Although there was no improvement in glycaemic control, data for quality of life measures were not collected (Loveman, Royle & Waugh, 2009).

Yong, Power and Gill (2002) studied forty three insulin-treated patients with HbA_{1c} levels > 7.5% who were given dietary advice and insulin dose adjustment. Almost two-thirds (63%) of patients achieved improvement, however the 'non-improver' group (37%) showed a mean deterioration in HbA_{1c}. They concluded that DSN intervention for poorly controlled insulin-treated diabetic patients is generally effective, but intervention may be best targeted to responsive patients.

2.4. Shifting Diabetes Services

Since the emergence of the Quality and Outcomes Framework ([QOF], 2004) there has been a trend to shift services for long-term conditions like DM out of hospitals

into primary care. This shift was also recommended by the White papers, Shifting the Balance of Power: The Next Steps (DOH, 2002) and Our health, our care, our say: a new direction for community services (DOH, 2006). The aim is to benefit people with long term conditions like DM by providing easily accessible services closer to home.

According to Hill (2007) the effects of payment-by-results (PbR) will support this by encouraging the commissioning of cost effective services that meet the needs of the local population. However the Association of British Clinical Diabetologists ([ABCD], 2012) are concerned and suggest that the PbR tariff, which placed a set cost for each clinical encounter, has created a perverse disincentive to seek a specialist assessment. As a result many people with DM are deprived of access to the specialist team. PbR is not an appropriate funding model for long term conditions such as DM, as it disrupts the seamless cross boundary care pathway which is the essence of success in a long term condition (ABCD, 2012). With such a large population of people with DM it is now increasingly accepted that primary care will provide the majority of routine clinical care for this group (Diabetes UK, 2005). In the long term, telemedicine could dramatically reduce the overall costs of health services because of its potential to allow a fundamental restructuring of the way health care is delivered. This would principally result from redistributing resources from the hospital environment into primary care. Providing more services in primary care and ultimately in patients' homes could be considered to be the ultimate goal for health-care delivery and in part this could be facilitated by telemedicine (Hjelm, 2005). There is good evidence that the use of telehealth improves the quality of DM home care, including improved self-monitoring and self-care, and better physiological control (Biermann, Dietrich & Standl, 2000).

2.5. Telemedicine in Health Care

Telemedicine is a vast subject, but as yet there is limited data on the clinical effectiveness and cost-effectiveness of most telemedicine applications. For many years, the telephone has been extensively used by health professionals and patients for keeping in touch. This is widely viewed as an effective form of telemedicine (Hjelm, 2005). According to a study by King et al, (2012) evidence suggests that what patients want from technology is real-time assistance with daily behavioural decision-making, ability to share information with their healthcare team, connections with others for support and choice.

DM telecare involves patient transmission of self-monitored blood glucose and feedback (including support and advice) from a DM health professional (Montori et al., 2004). Although the use of older approaches (telephone, fax) is commonplace, telemedicine applications increasingly use the latest innovations in computer and network technologies and other equipment (Roine, Ohinmaa & Hailey, 2001). Advances in communications technology have increased the potential methods and speed by which health-care professionals and patients can communicate. These have led to improvements in communication through faster access to the health professional. This is more convenience for patients as it saves time from attending the health care setting and the cost of travel and parking. It also improves equity of access to care previously denied because of such factors as socioeconomic constraints, especially in countries in the developing world.

2.6. Studies using Direct Telephone Contact

There have been many studies investigating the effect of direct phone contact between patients and the DSN. Thompson, Kozak & Sheps, (1999) studied forty six patients who were randomised to receive either standard care or to have regular telephone contact with a DM nurse educator for advice about adjustment of insulin therapy. Twenty three patients in the intervention group received individualised telephone contact on an average of three per week, lasting fifteen minutes over six months. Insulin adjustments were recommended during most calls. Twenty patients experienced 10% drop in HbA1c.

Kim and Oh, (2003) performed a similar study using thirty six patients, twenty who were in the intervention group. The intervention, which consisted of continued education and reinforcement of diet, exercise, medication adjustment recommendations, as well as frequent self-monitoring of blood glucose levels, was administered through twice weekly phone contact for the first month and weekly contact for the next two months. Both studies showed a reduction in HbA1c in the intervention arm after six months and twelve respectively. However both studies acknowledge the limitations of the studies including the time issue of the telephone contact and the expense of using the DM nurse educator for the intervention. The cost of poor glycaemic control and the complications associated with poor control outweigh the limitations identified in the study.

A study by Piette et al, (2000a) identified a cohort of 280 patients who were randomly assigned to usual care or to receive an intervention that consisted of usual care plus biweekly automated assessment and self-care education calls with telephone follow-

up by a nurse educator. Outcomes measured at twelve months included survey-reported self-care, perceived glycemic control, and symptoms, as well as HbA1c and serum glucose levels. The intervention group showed increased rate of glucose monitoring, foot inspections and weight monitoring and an improvement in HbA1c which was 0.3% lower than the control group. The intervention group also reported fewer incidences of acute complications, including hyperglycaemia and hypoglycaemia. These improvements were achieved with an average of less than six minutes per month of nurse-patient contact. The nurse was able to use time more judiciously, focusing on the patients who most needed assistance.

In contrast a meta-analysis of RCTs on patients with T2DM conducted by Wu, Forbes, Griffiths, Milligan and While, (2010) contradicts the above studies suggesting that overall, telephone contact has a limited impact on glycaemic control. From a total of 8389 studies screened, thirty sixwere selected for full assessment, which were reduced to just seven studies for the analysis. The other studies were excluded for a number of reasons insluding not being RCT design, multiple interventions not just telephone contact, T1DM patients included in the studies or telephone follow up was not the intervention component. From the studies analysed three studies showed that patients with the poorest control appeared to benefit the most from telephone follow-up (Young et al, 2005; Piette et al 2000b; Piette, Weinberger, Kraemer & McPhee, 2001). However it was acknowledged that telephone interventions may need to be more flexible in their design, so that they target patients with particular characteristics who may benefit from either a general regular contact or reminder to those who need more specialist support and intervention (Wu, Forbes, Griffiths, Milligan & While, 2010). It is essential that patients who are motivated and willing to make alterations to their

treatment are targeted for telephone contact so that the DSN / educator's utilise their time in the most effective way.

The landmark DCCT (1993) clearly proved the benefits of achieving and maintaining near-euglycemia in patients with T1DM. However, to achieve good control, follow-up was frequent, weekly phone contact and monthly visits. To applies these techniques to large populations would be both time consuming and expensive.

2.7. Studies Using Indirect Telephone Contact

2.7.1. Modem Transfer

As well as studies using direct telephone contact many studies have looked at automated telephone contact modem transfer and helplines. In a RCT of thiery one patients examining telecare versus modem transmission in patients with T1DM on an intensive insulin regimen, but failing to achieve glycaemic control Montori et al, (2004) found telecare to have a small impact on glycemic control after six months. Intervention was in the form of glucometer transmission with feedback. There was a trend in enhanced adherence to self-monitoring, which was greater in the telecare group, and better glycemic control in both groups. The main difference in care delivery between the two groups was in the health professional's time. The greater nurse feedback was associated with more insulin dose changes.

2.7.2. Diabetes Helplines in Diabetes Management

As well as contact with the DSN to facilitate diabetes management there are many other valuable resources to assist patients in self-management. Barnett, Chumbler,

Vogel, Beyth, Quinn and Kobb (2006) studied 800 veterans with DM to assess healthcare use in those enrolled in a Department of Veterans Affairs (VA) Care Coordination Home Telehealth programme, compare o those who were not. Patients in the intervention group used this messaging device daily to answer scripted questions about their DM symptoms and health status. The program consisted of nurse care coordinators (registered nurses or advanced registered nurse practitioners) who used disease management protocols to manage treatment and to educate the veterans about their disease to prevent more costly interventions. Barnett et al (2006) observed lower HbA1c levels and fewer "work-in" primary care visits in their two-year follow-up. In a separate study using a multi-pronged approach that included toll-free help lines for patient questions and glucose reporting with telephone follow-up and intervention, Malone, Shilliday, Ives and Pignone (2007) reported significant improvements in HbA1c level, diabetes-related knowledge, and satisfaction among the intervention group. Algorithms were developed for the intervention and there was formalization of flow or follow-up with the addition of a trained, non-health care provider staff member to provide education and facilitate therapeutic intervention. The algorithms allowed for more aggressive treatment for patients. Structured programs allow for DM to be managed in any setting by members of the multi-disciplinary team, not necessarily the doctor or the nurse.

2.7.3. Automated Systems

Telephone-supported DM care improves glycaemic control. However, such programs can be labour intensive and costly. Automated calling systems represent a pragmatic and inexpensive way to improve telephone care. Automated telephone disease management (ATDM) systems use specialised computer technology to deliver

messages and collect information from patients using their touch-tone keypad or voice-response technology.

According to Piette, Weinberger, Kraemer and McPhee (2001) ATDM systems can augment telephone care by providing frequent monitoring and health education to large patient panels while allowing clinicians to focus attention on individuals who need it most. In a RCT of 272 individuals with DMs on OHAs patients in the intervention group, receiving ATDM showed a greater improvement in HbA1c compared to the control patients, receiving usual care, 72mmol/mol (8.7%) and 77mmol/mol (9.2%), respectively. The ATDM patients used their touch-tone keypad to report information about their self-monitored blood glucose (SMBG) readings, other self-care activities, perceived glycemic control, symptoms, and use of guideline-recommended medical care. The trial shows that ATDM can be used to successfully manage DM care as long as the messages and responses are reviewed to ensure any patients requiring further intervention are identified.

2.8. Issues with Telemedicine

Although telemedicine clearly has a wide range of potential benefits, it also has some disadvantages. Heinzelmann, Lugn and Kvedar (2005) identified several problems encountered by healthcare professionals while using telemedicine. These range from staff discomfort with new technology to those who are concerned that telemedicine threatens healthcare practice. The main drawbacks of telemedicine that can be envisaged are a breakdown in the relationship between health professional and patient, issues concerning the quality of health information and organizational and bureaucratic difficulties (Hjelm, 2005). According to Goold and Lipkin (1999) the

doctor/healthcare professional–patient relationship has been and remains a keystone of care. This relationship is often lost through the use of telemedicine as it often involves patient contacting helplines or automated systems for management of their DM, which might alter the fundamental relationships between patients and their health care professionals.

Other issues that need to be addressed include legal and ethical concerns, human and cultural factors, such as resistance to change, lack of infrastructure, linguistic differences and illiteracy technical and organisational factors (Craig and Patterson, 2006). Issues with colloquial terms and regional accents can often lead to misunderstanding of information given to patients. Layman (2003) and Briggs (2001) used the concept of non-maleficence to emphasize professional responsibility, for confidentiality, since the legal aspect of confidentiality focuses on the relationships between individuals involved in delivering care rather than on systems used. When telemedicine involves transmission of data for management of care it is essential to ensure that secure networks are used to protect confidentiality and privacy.

2.9. The research questions

2.9.1. Aim of project

The aim of the research was to evaluate the effectiveness of telephone consultation by the DSN in the management of patients with DM.

2.9.2. Primary research question

Is there an improvement in glycaemic control and weight following telephone follow up, in patients with DM, over a six month period?

Is there a relationship between the number and frequency of follow up consultations and improvement in glycaemic control?

Primary outcomes: HbA1c and Weight, Dose Adjustment of Insulin

Chapter 3

Methods

3.1. Study design

The study design is a retrospective review of the local DM data base. The review aimed to examine whether telephone contact with patients from the DSNs affected biometric parameters. Information was collected using the hospital computer system Cerner. A contact list prints weekly to inform the DSNs which patients they need to contact. The lists were collected for a period of two months, which were the months of September and October 2012 inclusively. The patients' demographics, blood results and vital signs are collected routinely at every clinic visits. Information regarding HbA1c, weight and total daily insulin dose (TDI) were recorded at baseline and the number of phone contacts, frequency of contacts, alteration to treatment and HbA1c and weight were recorded six months after the initial phone contact. Due to the complexity of DM a number of patients had previous contacts with the DSN prior to the data collection period, but the data was only recorded for the study period.

3.2. Ethical approval

Ethical approval was sought through the University of Chester, Faculty of Applied Sciences Ethics Committee and was granted 5th April 2013. (Appendix 3 show the Ethics Submission Form, and Appendix 4 shows the approval letter). Ethical approval was not required from the Wirral University NHS Foundation TrustResearch and Development Department as the study was a retrospective study of the current DM service (Appendix 5). Permission to undertake the study and use the patients recorded data was granted by the two DM Consultants (Appendix 6).

3.3. Dependent variables

The dependant variable was HbA1c measured using the local phlebotomy service and the hospital laboratory. Results were reported using IFCC (International Federation of Clinical Chemistry) units, although DCTT results will also be included in the results section. For several years, most laboratories in the UK reported HbA1c levels in DCCT aligned percentages, which allowed us to directly compare HbA1c values in our patients with those of the participants in studies such as the DCCT (1993) and the UKPDS (1998). The IFCC has established the "true" HbA1c concentrations in samples, and so this new IFCC standard has been recommended as the basis for standardising HbA1c values across the globe (Consensus Committee, 2007). Patients were weighed using SECA seat scales, which are calibrated on a yearly basis. Weight was recorded in kilograms (kg).

3.4. Independent Variable

The independent variable was number and frequency of telephone contact with the DSN. The phone contacts involved the DSN assessing SMBG and discussing treatment regimes. If patients reported elevated BGM the DSN would titrate OHAs or insulin doses, provided no risk of hypoglycaemia was evident. Education was also provided on issues such as diet, carbohydrate counting, weight management, treatment in illness and any issues surrounding injection technique or injection sites.

3.5. Population and subjects

3.5.1. Sample size

The target size was 100 patients, as it was estimated that this represented the number of patients telephoned over the two month period. A total of 113 patients were actually contacted over the two month period, however only 108 were included in the analysis as follow up data was not available for five of the patients, as three had died and two were lost to follow up having been discharged from the clinic.

3.5.2. Population and recruitment

The population consisted of T1DM andT2DM patients who were under the care of the Clatterbridge Diabetes Department, based at Wirral University NHS Foundation Trust. All subjects required further input from the DSN for a number of reasons. Patients either self-referred or were referred to the DSNs by the medical team following a clinic appointment or an inpatient stay. The sample included all the patients contacted within the two month time period. This is a representative sample as it reflects characteristics of the total population (Aparasu, 2011).

3.6. Eligibility criteria

3.6.1. Inclusion criteria

Patients were all over the age of 16, with no upper age limit.

3.6.2. Exclusion criteria

Patients were excluded from the study if they had no six month follow up data.

3.7. Consent

Individual patient consent was not sought for this retrospective study as it was a review of the current DM service. Participants' data was collected for the study, in the form of HbA1c, weight, treatment regimens, however none of the information in the study is patient identifiable. By virtue of the fact that patients' attend the hospital setting and have blood samples taken for the clinic visit they are giving implied consent to having their information on the hospital data base and for this information to be used for audit purposes.

3.8. Procedures

Patients were entered into the study if they were contacted by the DSNs via the telephone within the two month recruitment period of September 2012 and October 2012. Patients HbA1c and weight prior to the recruitment period was recorded. Patients then had their HbA1c and weight recorded six months after the recruitment period as part of their clinic visit. As well as these parameters the frequency of phone contacts, the number of weeks the calls were made over and the number of failed phone contacts were also recorded. Failed contacts were when the DSN attempted to contact the patient but was unable to directly speak to the patient, i.e. leaving an answer machine message or unable to leave a message or speaking to a relative who was unable to provide information to the nurse about glycaemic levels. In the original proposal for the research the duration of the phone contact was intended to be included, however a change in the computer system meant that this data is no longer recorded on the patients contact form so this was excluded in the data collection. Figure 1 shows a Flow Chart of the study procedures.

3.9. Statistical analyses

Analysis of the data was performed using IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp. The Test for Normality was performed on all the data. Normality is tested to establish whether a set of observations are from a completely-specified continuous distribution (Coakes & Steed, 2004). For sample sizes over 100 Kolmogorov-Smirnov test of normality was used and for sample sizes less than 100 Shapiro-Wilk was used (Coakes & Steed, 2007).

Analysis of the data was performed on the total study population. The data was then split into two groups for further analysis. Group 1 was defined as patients on insulin alone or in combination with OHAs for their DM treatment and Group 2 was defined as patients on OHAs only. Normality was tested for the whole population group of 108 patients, and then for Group 1 and Group 2.

Parametric tests were used for some analysis when the sample was normally distributed. This included comparing alterations in individual's weight at baseline and six months where the Paired Samples t-test was used (Williams & Wagg, 2004). Data was reported as mean and standard deviation (SD) when sample was normally distributed. For the analysis of HbA1c and insulin doses at baseline and six months assumption of normality was violated so the non-parametric test Wilcoxon Signed Ranks Test was used, with median and range being reported (Williams and Wragg, 2004).

To examine if there was a relationship between the number and frequency of calls and analterations inHbA1c and weight the test of correlation was performed. Assumption

of normality was violated so Spearmans Rho was used to analyse the correlations (Williams & Wragg, 2004).

The level of statistical significance (p-value) was set to <0.05. For all tests an α-level of 0.05 (two-tailed) was considered statistically significant and confidence intervals of 95% were used to interpret findings. Medians and interquartile ranges were calculated as these measures of central tendency and spread are less sensitive to the presence of outliers (Carling, 2000).

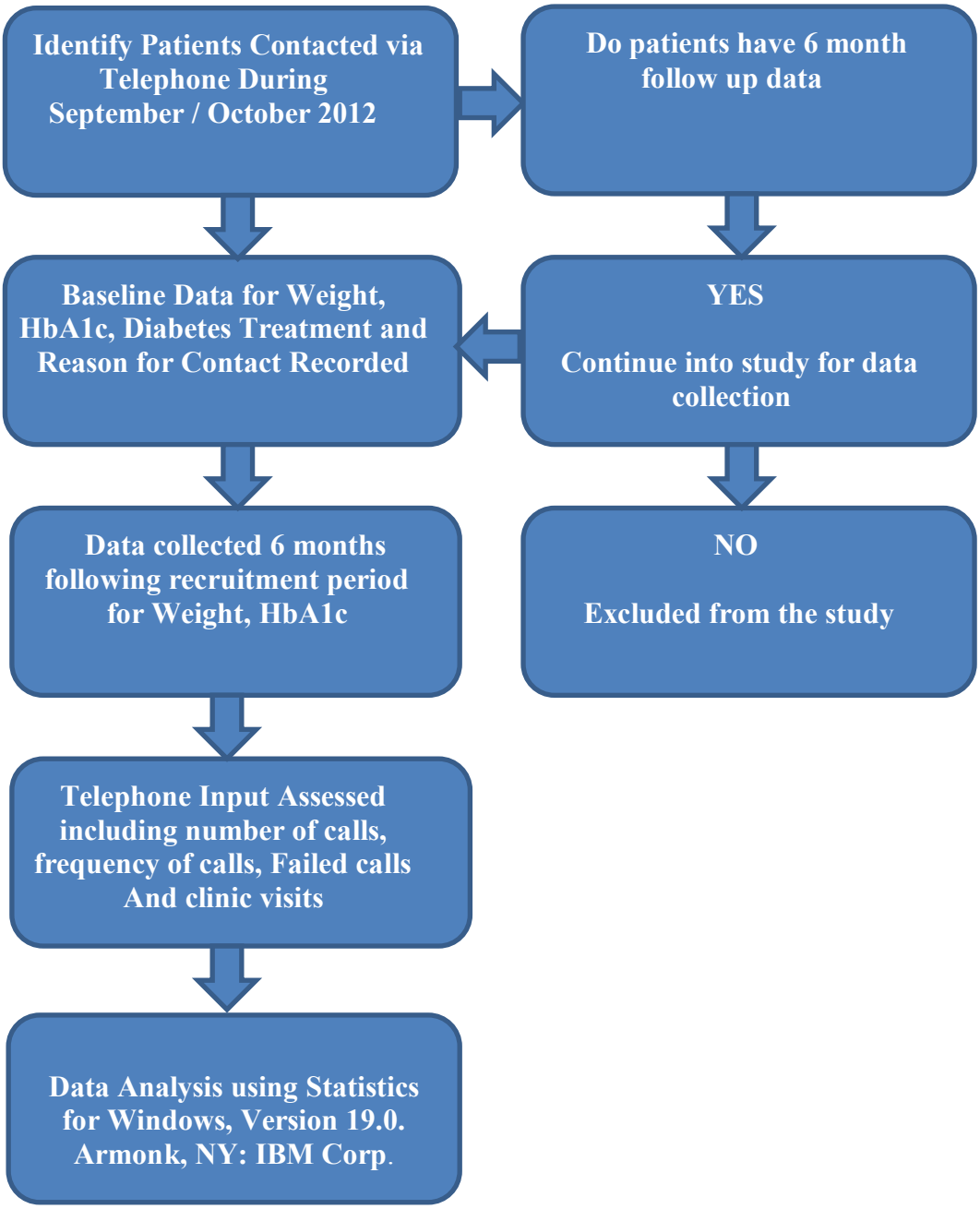

Figure 1 Flowchart of Study Procedures

Chapter 4

Results

4.1. Subject Characteristics

For the purpose of statistical analysis the patients who were taking insulin will be analysed separately from those on OHAs alone. The patients on insulin therapy or insulin therapy plus OHAs for their DM management will be referred to as Group 1 and the patients on OHAs only will be referred to as Group 2.

4.1.1. Characteristics for All Patients

A total of 113 patients were contacted during the two month time of September and October 2012, of whom 108 patients were eligible to be included in the study and have their data analysed. Of the 108 patients 56 (51.9%) were male and 52 (48.1%) were female. The mean age for males was 63.1±14.2 years and for females was 63.6±13.9years. Out of the 108 patients 26 (24.1%) had T1DM and 82 (75.9%) had T2DM. Table 1 shows the Baseline demographic and biomedical characteristics for Total Study Population, Group 1 and Group 2. Weight results were missing for three of the patients in Group 1 as they were wheelchair bound and unable to get onto the scales.

Table 1 Baseline demographic and biomedical characteristics for Total Study Population, Group 1 and Group 2. (Values are median unless otherwise stated).

Variable	Total Group	Group I	Group 2
Number of patients	108	99	9
Number of females	49 (45%)	46 (46.5%)	3 (33.3%)
Age (years)	64 (22-85)	64 (22-85)	74 (63-81)
HbA1c (mmol/mol)	74±18*	78 (43-140)	67 (39-107)
HbA1c (%)	8.9	9.3 (6.1-15)	8.3 (5.7-11.9)
Total daily insulin dose (units)	44 (0-190)	48 (4-190)	N/A
Weight (kg)	87.9 (44.5-143.3)	89.7±18.1*	97.0±24.3*

*Mean and SD reported

4.2. Descriptive Results

Patients were contacted by the DSNs for a number of reasons. Table 2 shows a break down of the reason for phone contact. Patients were contact for follow up as a result of a clinic visit or self-referral in the form of patients phoning or dropping into the DSNs office for education, advice and titration of medication. Of the nine patients in Group 2, one patient was contacted after being given a new meter, three for poor glycaemic control, one for support follow a clinic visit, two after commencing exenatide and two to assess their blood glucose monitoring results following a clinic visit. Although the DSN was asked to contact the patients in Group 1 for a variety of reasons they all needed their insulin titrated to improve control or reducing to prevent hypoglycaemia.

Table 2 Reason for Phone Contact

		Type of Diabetes	
Reason for contact	Insulin Titration	7	33
	Hypoglycaemia	6	9
	Illness	0	1
	Meter	1	1
	Poor Control	12	27
	Support and Contact	1	4
	Exenatide	0	3
	Blood Glucose Monitoring	0	2
	Hyperglycaemia	0	1

4.3. Analysis

4.3.1. HbA1c

HbA1c was analysed pre and post for all 108 patients. Normality was tested using the Kolmogorov-Smirnov (Coakes and Steed 2007). As the assumption of normality was violated, Wilcoxon's signed rank test (Williams and Wragg, 2004). Analysis was then performed on Group 1 and Group 2. As the total numbers in both groups was less than 100 normality was tested using Shapiro-Wilk and again the assumption of normality was violated, so the Wilcoxon's signed rank test was used to analyse the data for both groups (Coakes and Steed, 2007). Median and range was reported for all the results. The results for HbA1c levels are reported using IFCC and DCCT values (see Table 3).

4.3.2. Weight

Weight was analysed pre and post for all 108 patients. Normality was test using Kolmogorov-Smirnov and assumption of normality was violated (Coakes and Steed,

2007), so the Wilcoxon Test was performed (Williams and Wragg, 2004). Analysis was then performed on Group 1 and Group 2. Normality was tested using Shapiro-Wilk for both groups and which indicated the sample was normally distributed (Coakes and Steed, 2007). The Paired T Test was then used to analyse the data (Williams and Wragg, 2004). Mean and SD were reported for the Paired t-test results for Group 1 and Group 2 (see Table 3).

4.3.3. Insulin Dose

Insulin dose was analysed pre and post for Group 1 as none of the patients in Group 2 were on insulin therapy for their diabetes. Normality was tested using Shapiro-Wilk and assumption of normality was violated (Coakes and Steed, 2007) therefore the Wilcoxon Ranks Sign test was used to analyse the data (Williams and Wragg, 2004). Descriptive statistics were reported as median and range. (See Table 3).

Table 3 Primary outcomes baseline through six months (**Values are median)**

Variable		Baseline	6 Months	Difference within groups baseline to 6 months
HbA1c (mmol/mol)	Total Group N=108	76 (39-140)	72 (39-132)	z=3.880 p=0.0001**
	Group 1 N=99	78 (43-140)	72 (41-132)	z=3.801 p=0.001**
	Group 2 N=9	67 (39-107)	64 (39-120)	z=0.841 p=0.400
HbA1c (%)	Total Group	9.1 (5.7-15)	8.7 (5.7-14.2)	z=3.880 p=0.0001**
	Group 1	9.3 (6.1-15)	8.7 (5.9-14.2)	z=3.801 p=0.001**
	Group 2	8.3 (5.7-11.9)	8.0 (5.7-13.1)	z=0.841 p=0.400
Weight kg	Total Group	87.9 (44.5-143.3)	88.3 (46.2-141.1)	z=1.492 p=0.136
	Group 1	89.7±18.1*	90.3±18.4*	p=0.131
	Group 2	97.0±24.3*	94.7±23.7*	p=0.02**
Dose of Insulin (units)	Total Group	N/A	N/A	
	Group 1	48 (4-190)	54 (0-220)	z=3.258 p=0.001**
	Group 2	N/A	N/A	

*denotes normality meets so mean and standard deviation reported
** denotes statistically significant result at α-level of 0.05

4.4. Correlation between HbA1c and Number and Frequency of Calls

4.4.1. Correlation HbA1c and Number of Calls

The median number of phone calls was 5 with a range of 1-27 calls within thesix month time period. Figure 2 shows the number of telephone calls over the six months.

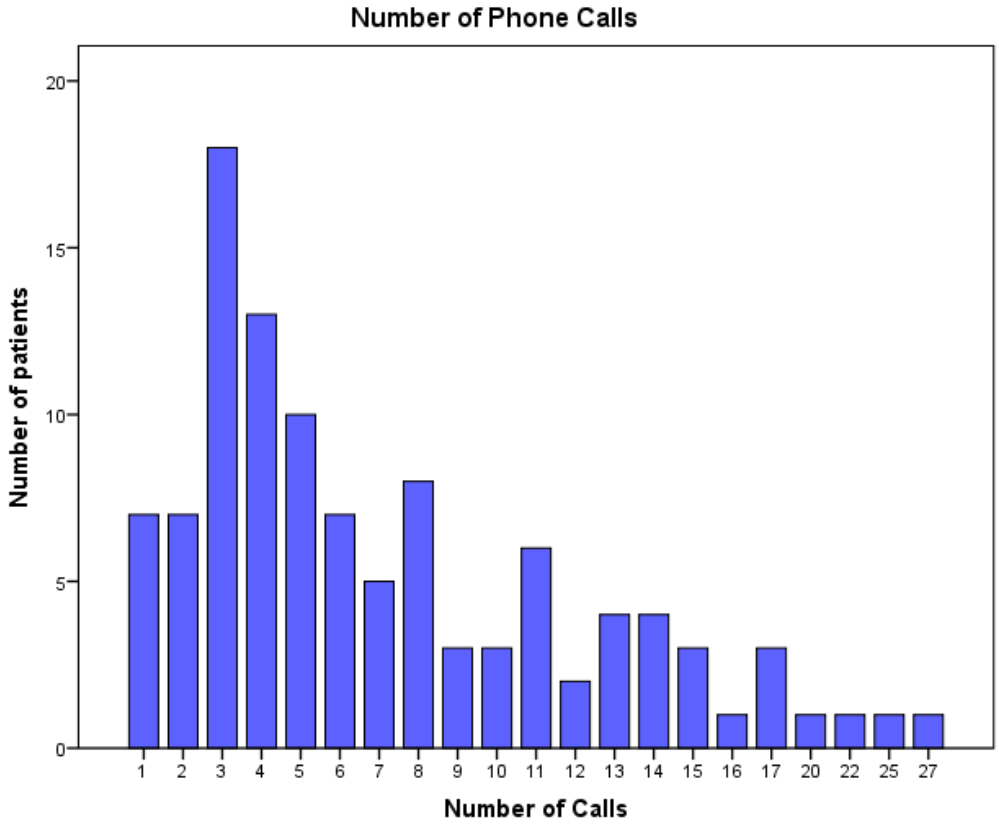

Figure 2 Graph of Number of Phone Calls over the Six Month Period

Spearman's Rho test was performed to see if there was any correlation between the number of phone calls and an alteration in HbA1c levels. The non-parametric test had to be used as the assumption of normality was violated. Table 4 shows the results of Spearman's Rho test indicating that there was a correlation between improvement in HbA1c and the number of phone contacts made p=0.022. However when the r value is examined it can be seen that r=-.220, indicating that there is a low negative correlation between HbA1c and number of phone calls. The coefficient of

determination was calculated and this gave a result of 4.84% (Cohen and Holliday, 1996). The correlation coefficient (r value) indicates to what degree correlation exsists. A level of zero indiscates there is no correlation and a level of -1 or +1 indicates there is perfect correlation. Levels inbetween indicate that there is some degree of correlation but not perfect correlation (Sapsord & Jupp 2006)

Table 4 Spearman's Rho Correlation Results

Correlation	Sig (2-tailed)	Correlation Coefficient	Coefficient of Determination
Number of Calls Vs HbA1c	**0.022***	**-.220**	**4.8%**
Frequency of Calls (weeks) Vs HbA1c	**0.020***	**-.224**	**5.0%**
Dose Adjustment Vs HbA1c	**0.032***	**-.216**	**4.7%**
Dose Adjustment Vs Weight Change	**0.292**	**.107**	**1.1%**
Failed Contacts Vs Number of Contacts	**0.0001****	**.346**	**12%**

***Correlation is significant at the 0.05 level (2-tailed)**
****** **Correlation is significant at the 0.01 level (2-tailed)**

4.4.2. Correlation HbA1c and Frequency of Calls

The median number of weeks the telephone calls were made over was thirteenweekswith a range of 1-26 weeks within the six month time period. Figure 4 shows the frequency of calls in weeks over the six months.

Spearman's Rho test was performed to see if there was any correlation between the frequency of phone calls and an alteration in HbA1c levels. The non-parametric test had to be used as normality was not achieved. Figure 5 shows the results of Spearman's Rho test indicating that there was a correlation between improvement in HbA1c and the frequency of phone contacts made p=0.02. However when the r value is examined it can be seen that r=-.224, indicating that there is a low negative correlation between HbA1c and number of phone calls. The coefficient of determination was calculated and this gave a result of 5.02% (Cohen & Holliday, 1996)

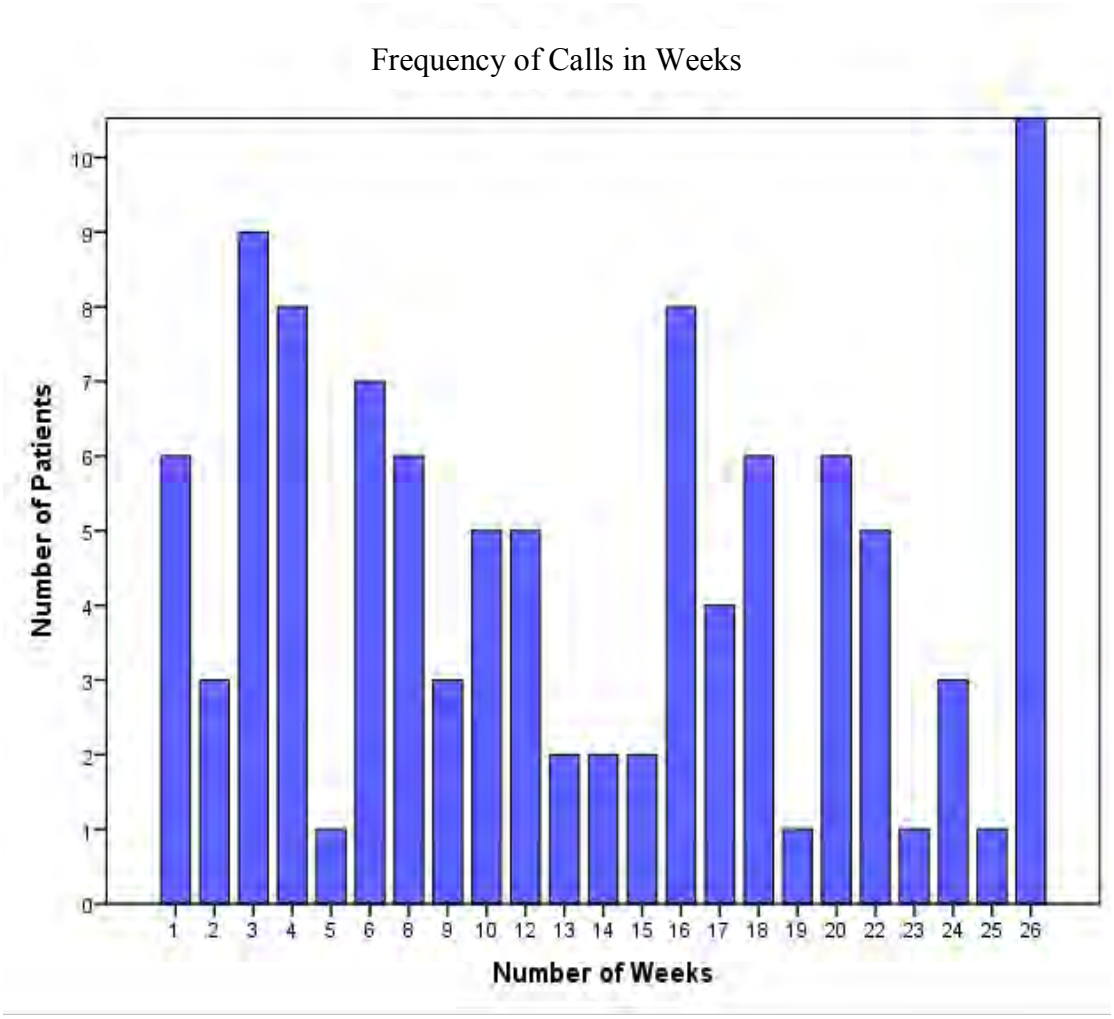

Figure 3 Graph of Frequency of Calls in Weeks over the six month period

4.4.3. Correlation between HbA1c and Dose Adjustment

A Spearman's Rho test for correlation was performed to see if there was any correlation between alterations in HbA1c and insulin dose adjustment. This was just performed for the patients in Group 1. The results (see Table 4) showed there was a correlation between HbA1c and dose adjustment p=0.032, however the r=-.216 value again indicated that there is a low negative correlation between HbA1c and insulin dose adjustment. The coefficient of determination was calculated and this gave a result of 4.67% (Cohen and Holliday, 1996).

4.5. Failure to Contact

During the six month study period the DSNs made many phone calls which resulted in no contact with the patient. This included speaking to relatives as patient unavailable, messages left on answer machines and the DSN being unable to leave any message to inform the patient they had been trying to contact the patient. The median number of fail to contact was one phone contact with a range of 0-7. The data was examined to see if there was any correlation between the number of phone contacts and the number of failed contacts. The assumption of normality was violated so Spearman's Rho test of correlation was performed. The results (see Table 4) showed there was a correlation between number of phone contacts and number of failed contacts p=0.0001. However the r=-.346 value indicated that there is a low negative correlation between the number of contacts and the number of failed contacts.The coefficient of determination was calculated and this gave a result of 11.97% (Cohen and Holliday, 1996).

Chapter 5

Discussion

5.1. Summary of Main Results

The review was undertaken to determine the effectiveness of telephone consultation in the management of patients with DM. The data was collected from a total of 108 patients. Although the majority of patients were contacted for insulin titration (n=99) patients were contacted for numerous other reasons (see Table 2).

5.1.1. Insulin Treated Patients

5.1.1.1. HbA1c Results

The results of the study indicate that after six month telephone contact with the DSN HbA1C significantly improved from 78mmol/mol (range 41-132 [9.3%, range 6.1-15%]) to 72mmol/mol (range 41-132 [8.7%, range 5.9-14.2%]), p=0.001 in those patients requiring contact for poor control and insulin titration. Despite the significant improvement, in participants treated with insulin, HbA1c levels were still above the recommended target of 48mmol/mol (6.5%) to 58mmol/mol (7.5%), (NICE, 2009).

In a RCT by Thompson, Kozak and Sheps (1999) forty six patients with HbA1c ≥ 69mmol/mol (8.5%) were randomised to either regular telephone contact with a diabetes nurse educator for advice about adjustment of insulin therapy or to continue regular clinic visits. The telephone intervention group received approximately three calls weekly, lasting on average fifteen minutes. At six months mean HbA1c in the intervention group was 62mmol/mol (7.8%), compared with 74mmol/mol (8.9%) in

the standard care group, ($p < 0.01$). The telephone advice for the 23 patients in the intervention group took approximately seventeen hours per week of nursing time. This amount of input is not transferrable to large cohorts of patients. In the study the DSN only worked fifteen hours and had other responsibilities such as ward inpatients and DSN led clinics so frequency of calls were limited.

According to Kennedy, Herman, Strange and Harris, (2006) the frequency of communicating insulin titration via clinical contact, telephone, e-mail, or fax is highly correlated with improvement of HbA1c levels. The GOAL A1C trial randomised 7,893 patients with T2DM requiring insulin therapy to usual care, algorithm titration or active weekly titration. All groups showed an improvement in HbA1c. Patients in the usual titration groups had mean HbA1c reductions of 14mmol/mol (1.3%) from baseline to end point of twenty four weeks, whereas patients in the active titration groups achieved a mean reduction of 16mmol/mol (1.5%) (Kennedy, Herman, Strange & Harris, 2006). This is a greater reduction than seen in the study where the reduction in HbA1c was 6mmol/mol (0.6%). In addition to the phone contacts the GOAL A1c trial used a treatment algorithm in all groups to encourage insulin titration, which are a useful resource when DSN resources are limited. There are advantages to algorithms, however it is important that education is given in addition to ensure patients titrate safely and are aware when not to adjust their insulin. Less frequent contacts would be required if a treatment algorithm could be incorporated in conjunction with telephone contact follow up.

5.1.1.2. Weight Results

Weight gain is a major concern for patients on insulin therapy. The results of the study showed that in the patients treated with insulin the weight increased from 89.7±18.1kg to 90.3±18.4kg but this increase was not significant (p=0.131). In T1DM, weight gain is often perceived as desirable as weight gain on commencing insulin is viewed as normalisation to previous weight (Russell-Jones & Khan, 2007). In the DCCT (1993) the intensive therapy arm gained an average of 5.1 kg, whereas the conventional arm gained 2.4 kg, after an average follow-up of 6.5 years. Approximately half the study population of the DCCT were recruited within the first five years of diagnosis, however the rest were recruited within fifteen years of diagnosis. This shows that the weight gain observed in the trial was not solely as a result of normalisation of body weight on initiation of insulin.

The results of the study showed that in T1DM patients (n=26) in group 1 weight increased from a median of 84.1kg to 87kg, an increase of 2.9kg, however the T2DM patients (n=73) in group 1 showed a decrease in median weight from 89.7kg-88.7kg (-1kg), after six months. The weight loss in the T2DM patients in Group 1 could have been as a result of the initiation of other agents. Three patients had metformin added to their insulin therapy and four patients had a Glucagon-like peptide-1 analogue (GLP analogue [see Appendix 7 for information]) added (n=1 Byetta and n=3 Bydureon). All clinical studies examining the addition of a GLP-1 to insulin therapy in patients with T2DM have reported weight losses from baseline from -1.8 to -12.8 kg (Holst & Vilsbøll, 2012).

The UKPDS (1998) of T2DM individuals showed that insulin associated weight gain was greater in patients receiving intensified intervention than that of conventional intervention, 5.1 vs. 3.7 kg, ($p < 0.0001$) during the first twelve months of therapy, but the mean weight of both groups increased to values beyond ideal. In a study of fourteen patients using MDI therapy, titration using an algorithm produced a lowering mean plasma glucose levels from 17.5 to 7.7 mmol/l ($p < 0.001$), but in just six months, mean weight gain was nearly nine kg (Henry, Gumbiner, Ditzler, Wallace, Lyon, & Glauber, 1993). Weight gain correlated directly with mean serum insulin level demonstrating that insulin therapy can be used to bring about dramatic improvements in glycaemic control, but with the penalty of significant, dose-related weight gain.

A study by Ryan, Livingstone, Ducluzeau, Salle, Genaitay and Ritz, (2008) found that the mean weight gain of 1.8 kg in twent three T2DM patients during the first six months of insulin therapy was not accompanied by a change in glucosuria, resting energy expenditure, or physical activity. It was concluded that increased energy intake was the only plausible explanation for the observed weight increments. Weight gain is also thought to be proportional to the number of insulin injections, or the TDI dose (Yki-Järvinen, 2001; Yki-Järvinen & Ryysy, 1999). The results of the study showed there was no correlation between TDI dose and alteration in weight ($p=0.92$).

5.1.1.3. Insulin Dose Change

Results indicate that one of the participants' insulin stopped during the six month follow up period. This patient had poor glycaemic control and stopped insulin themselves. As a result of this, their OHAs were titrated to try and improve control.

The results show there was a significant change in TDI dose from 48 units (range 4-190) to 54 units (range 0-220), p=0.001. However despite the change in TDI it did not result in achieving a target HbA1c level. Insulin titration needs to be more aggressive to achieve target HbA1c levels. There are many reasons why this is not always feasible including hypoglycaemia and weight gain.

Cryer (2002) found that iatrogenic hypoglycemia hampers tight glycemic control and is considered the limiting factor in DM management. In the ACCORD study, (2008) there was an increase rate of severe hypoglycaemia, requiring third party intervention, in the intensive group compared to standard care of 3.1% and 1% respectively. This is in agreement with the DCCT (1993), where based on the first 817 subjects who were enrolled, 216 subjects reported 714 episodes of severe hypoglycaemia of which 549 (77%) occurred in intensively treated subjects. Severe hypoglycaemia occurred more often during sleep (55%) (DCCT Research Group, 1991). The DCCT (1993) occurred prior to the introduction of analogue basal insulins. A meta-analysis by Rosenstock, Dailey, Massi-Benedetti, Fritsche, Lin and Salzman, (2005) of 2,304 T2DM patients showed that the risk of severe hypoglycemia and severe nocturnal hypoglycemia were reduced with insulin glargine by 46% (P=0.0442) and 59% (P=0.0231), respectively. The risk reduction of hypoglycaemia is similar in T1DM patients as shown in a RCT by Vague, et al (2003) who reported the risk of hypoglycemia was 22% lower with insulin detemir than with NPH insulin ($P < 0.05$) and 34% lower for nocturnal hypoglycemia ($P < 0.005$), in a sample of 448 individuals. Insulin can therefore be more aggressively titrated when using the newer analogue insulins, to achieve target HbA1c.

In the study there was a significant correlation between improvement in HbA1c and dose adjustment of insulin (p=0.032). However this was a low negative correlation, r= 0.216 which indicates that as the insulin dose increases the HbA1c decreases, but there is weak link between the correlation meaning that it might not be the dose increase which is causing the HbA1c to decrease. The co-efficient of determination was 4.7%, suggesting that there is only a 4.7% chance that the improvement in HbA1c was as a result of dose titration...

5.1.2. OHA Treated Patients

5.1.2.1. HbA1c Results

There was an improvement in HbA1c in group 2 which contained the patients on OHAs only, but this improvement was not significant (p=0.400), with HbA1c altering from 67mmol/mol (range 39-107mmol/mol [8.3%, range 5.7-11.9%]) at baseline to 64mmol/mol (range 39-120mmol/mol [8.0%, range 5.7-13.1]) at six months. The numbers of individuals in this group was limited to just nine patients as patients on OHAs treatment alone tend to be managed in the Primary Care setting. The patients in this group were contacted for a number of reasons including assessment of BGM after being giving a replacement meter, for poor glycaemic control, to assess control and for support, for assessment of exenatide treatment and to assess BGM results. The majority of these patients needed to commence insulin due to their poor glycaemic control, however this did not occur during the six month follow up period as the patients wanted to be given the opportunity to improve their glycaemic control through lifestyle modification.

A RCT of 473 individuals with T2DM showed no significant change in HbA1c in the intervention group 64mmol/mol to 63mmol/mol (8.0% to 7.9%) compared to control 65mmol/mol to 63mmol/mol (8.1% to 7.9%) at eighteen months (Blackberry et al, 2013). The intervention was structured telephone coaching to prime patients with the aim of self managing their DM including lifestyle issues, medication adherence and dosing, self monitoring of their disease, and how to take greater initiative in the therapeutic alliance with the treating doctor, facilitating appropriate intensification of medications to achieve treatment goals. At baseline 74% of participants were taking oral medications only in the intervention group and 70% in the control group which decreased to 58% and 61% retrospectively at eighteen months. The RCT showed there was no improvement in HbA1c or intensification of insulin or other treatment methods. The intervention used practice nurse in the Primary care setting, who received a two day training session to deliver the telephone coaching sessions, whereas this study used DSNs who had ten years of experience adjusting insulin and other treatments and coaching patients on lifestyle issues. Both studies showed it is difficult to improve HbA1c in those patients on OHAs through telephone consultant and other methods such as education courses may be more beneficial.

The ADVANCE study (2008) involved a protocol driven titration of OHAs and then insulin therapy if target HbA1c level was not achieved at each study visit. Mean HbA1c at the start of the study was 58mmol/mol (7.5%) which reduced to a mean level of 48mmol/mol (6.5%) and 56mmol/mol (7.3%) in the intervention group and standard care group respectively. The median follow up in the ADVANCE study was five years compared to six month in this study.

The time frame of this study was limited which did not enable titration of medication to achieve a significant improvement in HbA1c. Patients on OHA's alone are often reluctant to titrate their medication or to commence insulin therapy so it often takes time for the DSN to develop a trusting relationship to facilitate this. Patients often delay the decision to commence insulin and opt for lifestyle modification before the inevitable happens and they require insulin therapy.

A RCT by Young et al, (2005) showed a decrease in HbA1c, in patients with T2DM, following twelve months follow up in the intervention group of 0.3% from baseline. Intervention included telephone contact every one-three months for twenty minutes, to assess gaps in knowledge, patients readiness to change, medication adherence and BGM, The trial include 591 patients over 25 practices. The number of practices involve in the trial allowed the phone contact duration to be twenty minutes.

In this study the telephone contact were made by two DSNs who work a total of twenty nine hours a week. Telephone contacts are just one aspect of their job description, in addition to inpatients, nurse led clinics, T1DM education class and patient drop in visits. This meant that the duration of telephone contact time and the frequency of phone contacts are limited due to time constraints in the DSNs working day. Longer duration of phone contact would have allowed for more education and advice regarding lifestyle issues, such as exercise, dietary intake and weight management.

5.1.2.2. Weight Results

Patients weight decreased significantly from 97.0±24.3kg to 94.7±23.7kg, ($p=0.02$). Except for two patients who required contact for assessment of BGM, all patients had

a weight loss of between 0.7kg-5.9kg. NICE guidelines, (2008) suggest that individuals with DM, who are overweight, should aim for an initial body weight loss of 5–10%, while remembering that lesser degrees of weight loss may still be of benefit and that larger degrees of weight loss in the longer term will have advantageous metabolic impact.

Atherosclerotic cardiovascular disease is increased several fold in most patients with T2DM, particularly patients who are older and have other risk factors, including hypertension, obesity and dyslipidaemia (Stamler, Vaccaro, Neaton & Wentworth, 1993). Weight loss can improve glucose control, as it has been associated with reduction in HbA1c, improvements in dyslipidemia and hypertension, and reduced mortality. Williamson, Thompson, Thun, Flanders, Pamuk and Byers (2000) found that in prospective analysis, with a twelve-year mortality follow-up of 4,970 overweight individuals with T2DM intentional weight loss was associated with a 25% reduction in total mortality, and a 28% reduction in CVD and diabetes mortality. Intentional weight loss of 20-29 lb was associated with the largest reductions in mortality by approximately 33%.

In contrast The Look AHEAD study, (2013) randomly assigned 5,145 participants with T2DM to either Intensive Lifestyle Management, (including enrolment in a weight management program providing individual and group support for changing eating behaviour and engaging in physical activity) or to the Support and Education group (receiving infrequent support on general health topics). It was stopped early after eleven years as it was concluded there was no difference in cardiovascular disease rate between the two groups, but other health benefits were achieved. The

intervention group had weight loss of 6% of their initial weight, 8.7 ± 7.6 kg versus 3.5% for the control group, 0.8 ± 5.0 kg, at the study's conclusion (Look AHEAD Research Group, 2013). It appears that weight loss can reduce CVD and mortality, however weight loss needs to be significant, at least 20 pounds (lb).

5.2. Frequency and Number of Contacts

The median number of calls over the six month period was five calls (range 1-27 calls) over thirteen weeks (range 1-26 weeks), which equates to a phone contact approximately every eighteen days. The frequency of contacts corresponds to studies by Glasgow and Toobert (2000); Piette et al (2000a) and Kirkman et al (1994), who contact particpiants biweekly or at least monthly. Kennedy, Herman, Strange, Harris and GOAL AIC Team, (2006) showed that active titration of insulin over a weekly period compared to 'usual care' or algorithm titration resulted in greater number of patients reaching target HbA1c <7.0%. Swinnen and DeVries (2009) found following a medline search that the frequency of both clinical and telephone contacts were independent predictors of HbA_{1c} improvement and that the frequency of contact with the study team is highly correlated with the improvement in glycaemic control achieved after basal insulin initiation in T2DM.

It is useful to know if there is any correlation between improvement in HbA1c and number of telephone calls or frequency of telephone contacts. The results showed there is a significant correlation between the number of calls and reduction in HbA1c ($p=0.022$), however this is a low negative correlation, meaning that the more phone contacts the patient received the greater the improvement in HbA1c. However it is impossible to report conclusively that this is the reason for the improvement in

HbA1c. The coefficient of determination was 4.8%, indicating that there is a 4.8% probability that HbA1c improvement is as a result of the number of phone contacts. The results show that there was also a significant correlation between frequency of phone contacts and improvement in HbA1c, (p=0.020). Again this was a low negative correlation, r=-.224, which indicates that although there was a correlation, it is a low correlation meaning that it can not be reported conclusively that improvement in HbA1c was as a result of frequency of telephone contacts. The co-efficient of determination was 5%, suggesting that there is only a 5% chance of the improvement in HbA1c being as a result of the frequency of telephone contact.

5.3. Failed to Contact

The main problem with telephone contact is the number of failed to contact. The study showed a median of one fail to contact (range 0-7 fail to contact). Failed to contact included the DSN left messages on answer machines or with relatives but often were unable to leave any contact message for the participants, meaning time is often spent contact patients with no outcome. A total of 779 telephone contacts were made over the two month study period and out of these there was a total of 169 failed contacts (21.7%). Each attempted contact takes approximately five minutes, which means over the six month study period the DSN used approximately fourteen hours contacting patients with no clinical benefit. More efficient ways of working need to be introduced to reduce the wasted time. For instance those patients who are unable to return calls, due to working hours, or no answer machine service may need to use email contact or fax through BGM results. Protocol or algorithm titration guidelines may need to be developed to give patients, following their clinic visit, with phone contact on a monthly basis from the DSN to assess control. Patients are always

provided with contact details to enable them to access the DSN if required in-between planned contacts.

5.4. Development of the Service

Currently the DM service involves both clinic visits and telephone contact in both primary and secondary care. Telephone contact is one method of contacting patients, between clinic visits, to assess glycaemic control and titrate medication, however alternative methods of contact need to be assessed. Clinic visits to the secondary care outpatient service are an expensive resource with a clinic visit currently costing £225 and £227 for an initial outpatient consultant led clinic appointment for a single professional and a multi professional contact respectively (Department of Health, 2013). This cost is reduced to £101 for follow up attendance irrespective of whether it is a single or multi professional clinic. There is a recommendation of a £23 charge for non face-to-face outpatient contact but this is non mandatory tariff. The effectiveness of telephone contact in improvement HbA1c needs to be used to commission payments for the DSN telephone service as currently there is no payment attached to this service. Telephone contact is not only a more cost-effective resource compared to clinic visits it is also more convenient for the patients.

Wirral is a borough of contrast and diversity in both its physical characteristics and social demographics. There are both rural areas and townships and urban and industrialised areas in a compact peninsula of 60 square miles. People with DM living in the most deprived areas of Wirral are significantly more likely to be admitted to hospital as an emergency case (Wirral NHS, 2012). Out of the 108 participants in the study 54 lived in the most deprived areas of the borough. Figure 4 shows a graph of

patient distribution by postcode within the Wirral area and Appendix 2 shows a map of the Wirral with a breakdown of the postcode areas and the areas of deprivation corresponding to these postcodes. Clatterbridge Hospital is set in a rural area and has a limited public transport link. Patients often find difficulty getting to the hospital and if using public transport they often have to use more than one bus and if they drive to the hospital there is an additional charge for car parking. This is an expense which can be avoided through providing a DSN phone service.

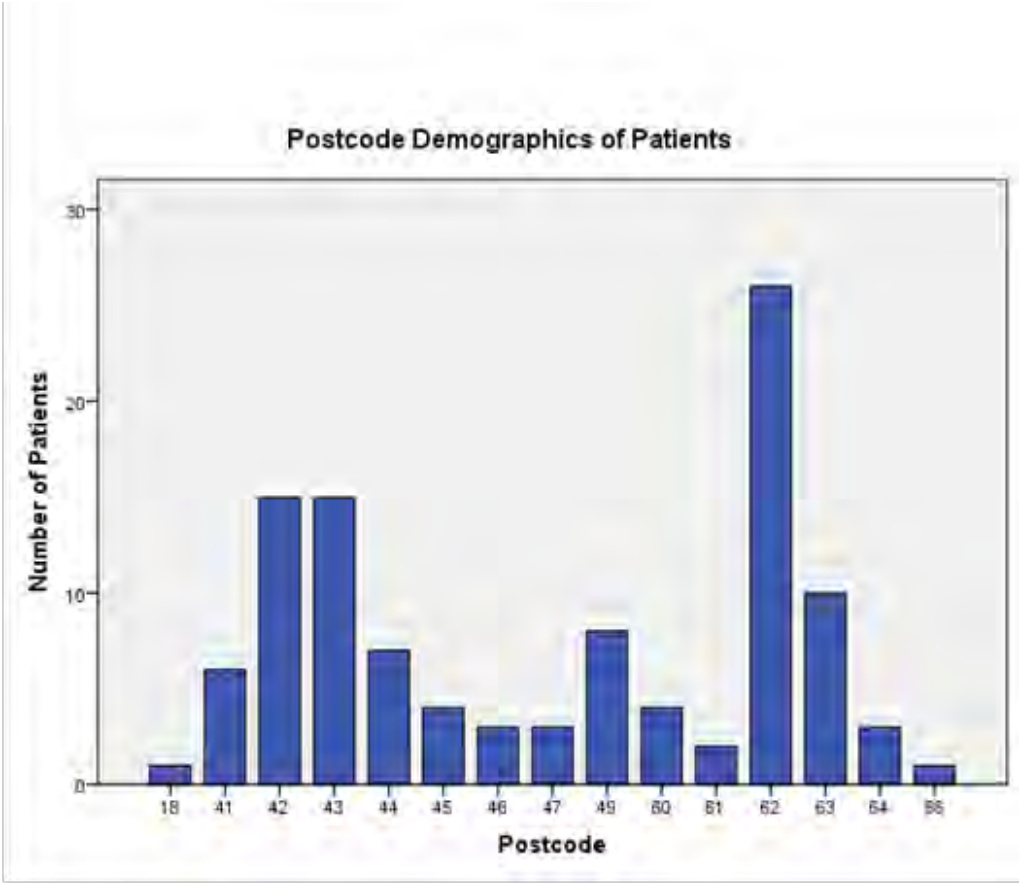

Figure 4 Patient Distribution by Postcode on the Wirral

5.5. Strengths of the Study

The study was a retrospective review of the current DM service. This allowed for a review of the current service without any investigator bias. If the study design had

been a prospective review the investigator may have been more inclined to titrated treatment more aggressively. Data were handled sensitively taking sample size, skewed variables and outliers into consideration through the use of non-parametric tests, and medians and interquartile ranges as measures of centrality and dispersion.

As the study design was a retrospective review of the data base participants were unaware they were part of a review. Many studies have shown an improvement in HbA1c whilst the patient are in contact with the study nurse however this often disappears when the contact has finished. This is referred to as the "Hawthorne Effect". This stems from the observation that people alter their behavior when they know that this is being studied, in ways that may influence study outcomes. This has implications for the conduct of clinical trials, which should allow for the likelihood that HbA1c will already be falling in most participants by the time any other intervention is introduced (Gale, Beattie, Hu, Koivisto & Tan, 2007).

5.6. Limitations of the Study

There weresome limitation to the study design. The sample size was limited due to the time constraints to allow for the six month follow up and to manage the time frame of the Master Programme. The results showed an improvement after six months, but it would be beneficial to see if this improvement continues after twelve months and then two years.

There was no data collected for psychological well-being and satisfaction scores associated with contact with the DSN. Although it is important to improve patients glycaemic control, often it is necessary to improve patients psychological wellbeing through DSN support before you can begin to titrate their treatment.

As well as the patients satisfaction questionnaires other data was not collected including the length of diagnosis of DM and insulin regime, whether it was basal insulin, twice daily insulin or a basal bolus regime, as this may have made a difference to the aggrresiveness of insulin titration.

5.7. Future Research

The study has given an overview of the current DM telephone service being provided by the DSNs. The study design was a retrospective review which meant thst the DSN was unable to record some of the data as it was missing. A RCT would provide more robust data and enable the essential data to be collected. Information on patients' satisfaction of the DSN contact service and patients well-being scores would be useful to collect.

There was no structure to the telephone consultation in this study so further studies would benefit from a protocol drive telephone consultation to ensure all aspects of diabetes care are covered. Treat to target algorithms should be incorporated into future studies to ensure treatment is titrated aggressively.

Chapter 6

Conclusion

The research question asked whether telephone consultation with the DSN improves glycaemic control, and whether there was a relationship between the number and frequency of follow up consultations and improvement in glycaemic control?

The study showed that there was an improvement in HbA1c, following contact by the DSN over a duration of six months, however target HbA1c was not achieved. Improvement in HbA1c is often dependant on patients' willingness to make changes to their treatment. Patients build a relationship of trust with their DSN which enable treatment titration, however issues with acute complications associated with diabetes such as hypoglycaemia often prevent patients achieving glycaemic control.

Despite there being a significant correlation between improvement in HbA1c and telephone contacts, the correlation was weak so it can not be inferred that the improvement was a result of number of calls or the frequency of calls.

DSNs use telephone contacts to manage patients' diabetes on a daily basis, unfortunately message are left which aren't always returned or no contact is achieved. More efficient methods of contact need to be developed to enable assessment and alterations of patients' treatment

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Yki-Järvinen, H. (2001) Combination therapies with insulin in type 2 diabetes. *Diabetes Care*, 24, 758– 767.

Yong, A., Power, E., & Gill, G. (2002) Improving glycaemic control of insulin-treated diabetic patients – a structured audit of specialist nurse intervention. *Journal of Clinical Nursing*, 11(6), 773–776.

Young, R.J., Taylor, J., Friede, T., Hollis, S., Mason, J.M., Lee, P., et al (2005) Pro-active call centre treatment support (PACCTS) to control glucose control in Type 2 diabetes. *Diabetes Care*, 28, 278-282.

Appendix 1 Poster Presentation Diabetes UK 2013

Diabetes Specialist Nurse Telephone Support Improves HbA1c at 6 months

P Joseph, K Leong, KS Leong
Clatterbridge Diabetes Centre, Bebington, Wirral, CH63 4JY

Introduction

- Glycaemic control is a key clinical objective in diabetes management
- Patients require a great deal of support if they are to maintain good control
- Telephone contact is possibly the most versatile, accessible and cheapest medium
- Insulin adjustment from a diabetes nurse educator can be an effective method of improving glucose control in insulin-requiring diabetic patients
- Nurse telephone intervention can improve HbA1c, and diet and blood glucose testing adherence.

Aim

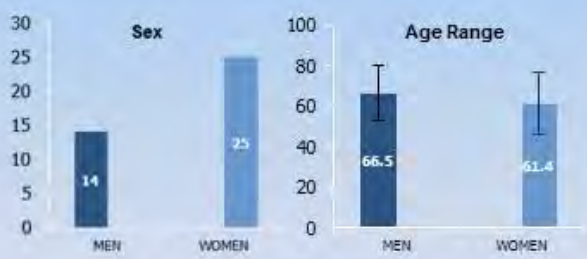
Telephone support is an integral part of good diabetes care and patients requiring such support are contacted by the Diabetes Specialist Nurse (DSN). These calls are time consuming and the effectiveness of this service had not been evaluated previously. The aim was to evaluate the impact of the DSN telephone support service on patients with suboptimal glycaemic control (HbA1c >58 mmol/mol).

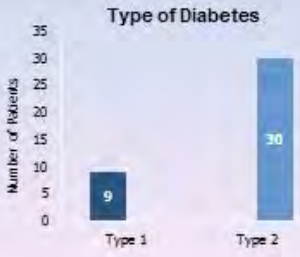
Method

Patients who had received DSN telephone calls for poor glycaemic control were identified from weekly phone call lists in Dec 2011 and Jan 2012. The following data were collected and analysed: number of calls per patient, the time period the calls were made over, Hba1c before the calls and 6 months after.

Patient Demographics

107 patients were called over this period
39 (36% of calls) patients were contacted to improve glycaemic control (all were on insulin)
There were 14 male and 25 female, mean age 63 ± 15 years





Results

Each patient had an average of 6.6± 4.2 calls (range 1-17), the median number of calls was 5.
Therefore, on average, patients had a call approximately every 2.1 weeks (Figure 1).

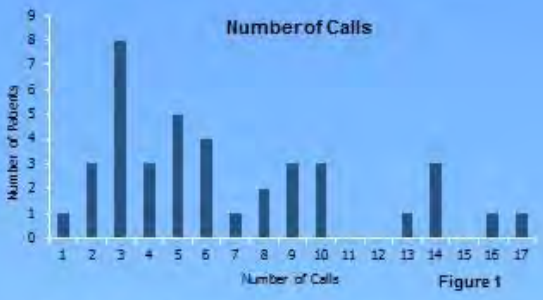
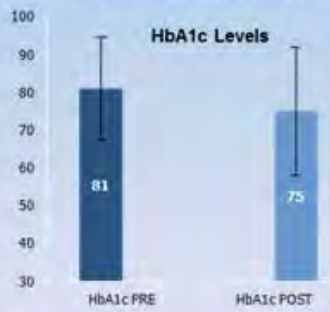


Figure 1

The patients were contacted over 14.4± 8.8 weeks (range 1-26) to improve glycaemic control (Fig 2). Not all patients required telephone support over the 6/12 period, for example only 5 patients required intervention over the whole 6/12.

Figure 2



HbA1c in these patients had significantly improved from **80.5 ± 13.7** (9..6%) to **74.7 ± 16.9** (9.0%) mmol/mol at 6 months (p=0.004, analysed using Wilcoxon test).

Conclusion

DSN telephone support to patients approximately once every 2 weeks over 14 weeks significantly improved HbA1c in the short term. Longer follow up is required to determine if this reduction is sustained.

Ordnance Survey. (2012). Map of CH Postcode Area. London, United Kingdom: Author **Ordnance Survey, (2009) Map of Areas of Deprivation Wirral, London, United Kingdom: Author**

Appendix 2 Maps of Wirral with Postcode Breakdown and Indication of Areas of Deprivation

Appendix 3 Ethics Application Form

University of Chester

For office use: FREC reference number _____

Lead reviewer _____

Faculty of Applied Sciences
Research Ethics Committee

Application for Ethical Approval of a Retrospective Research Study

Applicant name:	Philippa Louise Joseph
Department/Centre:	Clinical Science
Programme of study:	MSc Diabetes Management
New application:	[X] **or** **Resubmission:** [ ] (Please X in appropriate box)
Title of study:	The Effectiveness of Telephone Consultation in the Management of Patients with Diabetes
Application version:	Version 1
Date of application:	20th February 2013
Date of FREC meeting to which application is being submitted:	20th March 2013
Please tick this box if you would like to attend the meeting:	[X]

- Students are advised to discuss their proposal with their supervisor before submitting an application for ethical review. All applicants are advised to read the accompanying guidance notes before completing this application form; these can be found on IBIS.
- Once you have completed your application form, and it has been signed by you and your supervisor/line manager, please submit **ONE** paper copy of your application (including a complete reference list and **all** appendices) to: FREC Secretary, Dean's Office, Faculty of Applied Sciences, Molloy 106, University of Chester, Parkgate Road, Chester, Cheshire, CH1 4BJ, United Kingdom.
- In addition, an electronic copy of the application (including a complete reference list and **all** appendices) should be emailed to frec@chester.ac.uk by the submission deadline.

University of Chester

Approval from Academic Supervisor

I confirm that the applicant has discussed their research proposal with me, and that I have read and agree to support this application.

Name: **Duane Mellor**

Signed: _____

Date:

OR

Approval from Line Manager

I confirm that the applicant has discussed their research proposal with me. I understand the purpose of the research and am aware of all the implications (including time) that conducting this research may have. I am in agreement with the research and support this application.

Name: **N/A**

Signed: _____

Date:

Student No.294612703

University of Chester

Faculty of Applied Sciences
Research Ethics Committee

Signatures

Applicant's signature

I confirm that:

- The information in this application is, to the best of my knowledge, accurate and I take full responsibility for it;
- I undertake to abide by the ethical principles embodied in the good practice guidelines identified in this application;
- If the research is approved, I undertake to adhere, without deviation, to the study as outlined in the application;
- I am aware of my responsibility to be up-to-date and compliant with the requirements of the law and relevant guidelines relating to data security; and
- I understand that personal data about me as a researcher and this application will be held by the Faculty Research Ethics Committee and that this will be managed according to the principles established in the Data Protection Act.

Name: **Philippa Louise Joseph**

Signed:

Date:

- Please ensure that your academic supervisor/line manager has seen and agreed to support this proposal; they must sign this form to indicate they are happy for the proposal to be submitted.

- All relevant signatures must be obtained **before** submitting this application. **Failure to have all the required signatures will result in your application being returned to you**, which may delay your review.

- Applicants should note that it is their responsibility to submit their proposal in sufficient time, particularly when working to tight/strict deadlines. This includes allowing adequate time prior to submission for the supervisor/line manager to read the proposal, provide feedback, and review any amendments before agreeing to support the proposal and signing the application form overleaf.

University of Chester

Faculty of Applied Sciences
Research Ethics Committee

Applicant's Checklist

Title of Study:	The Effectiveness of Telephone Consultation in the Management of Patients with Diabetes
Lead researcher:	Philippa Louise Joseph

- **This document MUST be completed and submitted as part of the application form. Please ensure ONE copy of each document, as detailed below, is attached as an appendix to this application form. ALL appendices MUST have dates and version numbers clearly marked.**
- **Indicate 'yes/no' as applicable, and continue your document list on a continuation sheet if necessary.**

Document	Enclosed?	Appendix №	Version №	Date
FREC application form	**Mandatory**		1	February 13
List of references	**Mandatory**	1	1	February 13
Summary C.V. for lead researcher	**Mandatory**	2		
Written permission(s) from the relevant organisations to undertake the research (eg. to use collected data for research purposes)	Y ☒ / N ☐	3	1	13/04/2011
Written confirmation that participants have agreed for their data to be used for the purpose(s) outlined in this proposal	Y ☐ / N ☒			
Other documents *(Please specify below, as necessary)*	Y ☒ / N ☐			
Letter from local R+D Department	Y ☒ / N ☐	4	1	15/03/2011
Diabetes UK Poster	Y ☒ / N ☐	5	1	February 2013
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			
	Y ☐ / N ☐			

University of Chester

Faculty of Applied Sciences
Research Ethics Committee

Application Form

Part 1: Introduction

1. Title of research project
The Effectiveness of Telephone Consultation in the Management of Patients with Diabetes

2. Lead researcher (the applicant)
NB. The lead researcher must submit a copy of their current CV (max. 2 sides of A4) with this application.

Name of applicant	Philippa Louise Joseph
Status (eg. MSc student; PhD student; staff researcher; other – please specify)	MSc Student
Address for correspondence	
Contact telephone number	
Contact email address	
Qualifications	

3. Other individuals who may work on the research project
NB. If there are more than two additional researchers, please note their details on a separate sheet and append to this application. A summary CV (max. 2 sides of A4) for each additional person must accompany this application.

Name	
Status (eg.student; tutor / supervisor; researcher; statistician)	
Institution	
Contact telephone number	
Contact email address	

Name	
Status (eg.student; tutor / supervisor; researcher; statistician)	
Institution	
Contact telephone number	
Contact email address	

University of Chester

4. Academic supervision

Postgraduate students (taught or research) of the University of Chester must state who will act as academic supervisor(s) for their project. Some projects may also be supervised by experts external to the University of Chester. External supervisors should also be listed, and a brief summary CV of their **relevant** qualifications, training and experience should be appended to this application. You do not need to submit a CV for your University of Chester supervisor(s).

Primary supervisor (University of Chester): Duane Mellor

Additional supervisor(s) (University of Chester and/or External):

5. Good research practice

Please confirm that the research will be carried out in accordance with the University of Chester's guidelines as outlined in the Research Governance Handbook.

☒ *Check here if you agree to undertake the research in accordance with the University of Chester guidelines.*

Please state which other professional codes of conduct you will abide by (if applicable):

NMC Code of Professional Practice
GCP

6. Confirmation of exclusivity

I confirm that this application has NOT been submitted for ethical review by any OTHER Research Ethics Committee.

☒ *Check here.*

If this is a resubmitted application to FREC, please indicate your FREC reference number and the date at which your original (1st submission) application was first reviewed:

FREC reference number: 000/00/AA/AAAA

Date of 1st review:

University of Chester

Part 2: The research

1. Type of research proposed

Please indicate whether the proposed research is:

☒ Quantitative ☐ Qualitative ☐ Both

2. Outline of the research

Please provide a brief outline of the proposed research under the sub-headings provided below.

i. Aims and objectives

To determine if telephone follow up leads to an improvement in glycaemic control in patients with diabetes

ii. Hypotheses and/or research question(s) to be addressed

There will be an improvement in glycaemic control following telephone follow up, in patients with diabetes, over a 6 month period

There will be a relationship between the number and frequency of follow up consultations and improvement in glycaemic control

iii. Rationale, to include a brief synopsis of the background to the research

(NB. maximum of 500 words)

Achieving optimal glycaemic control is a key clinical objective in diabetes management (Nathan et al 2009). Patients require a great deal of support if they are to maintain good control. Finding systems to provide ongoing support and follow-up for patients remains a challenge. Telephone contact is possibly the most versatile, accessible and cheapest medium. Car and Sheikh (2003) suggest that telephone follow-up extends the support provided through the reinforcement of behaviors and by allowing further adjustments in therapy without the need for another clinic visit.

Thompson, Kozak and Sheps (1999) and Kim and Oh (2003) performed similar studies where patients were randomized to receive standard care or to have regular telephone contact with a diabetes nurse educator. Insulin adjustment from a diabetes nurse educator can be an effective method of improving glucose control in insulin-requiring diabetic patients. Both studies found that nurse telephone intervention can improve HbA1c, and diet and blood glucose testing adherence.

Wu, Forbes, Griffiths, Milligan and While (2010) conducted a meta-analysis of randomised controlled trials which suggests that overall, telephone contact has a limited impact on glycaemic control. Three studies showed that patients with the poorest control appear to benefit the most from telephone follow-up (Young et al 2005, Piette et al 2000, Piette, Weinberger, Kraemer and McPhee 2001).

Since there is differing opinion on the effectiveness of telephone contact in the management of patients with diabetes it is important to audit and evaluate the service. A pilot audit was performed as part of an abstract for Diabetes UK 2013, see Appendix 5, but this work needs to be developed to assess the value of the service. Currently telephone consultations are not included in Payment by Results, however a block contract is in place which pays for 2.7 whole time equivalent Diabetes Specialist Nurse time. To ensure the value of the telephone serivce, compared to clinic visits the value needs to be realised. Clinic visits are time consuming for staff and patients and have a financial aspect with parking fees and time off work. Undertaking review using phone contact increase the number of patients reviewed and is more convenient for the patients.

Telephone support is an integral part of good diabetes care and patients requiring such support are contacted by the Diabetes Specialist Nurse (DSN). These calls are time consuming due to

University of Chester

the number of patients contacted so the effectiveness of this serviceneeds to be evaluated.

iv. Study design, to include who will be providing the data (as well as why the data was originally collected and in what circumstances), inclusion/exclusion criteria, sample size and justification

The information will be collected from the hospital computer system Cerner. Each week a list of patients to be contacted by the Diabetes Specialist nurses is printed out. The patients demographics, blood results and vital signs are collected routinely at clinic visits. The study design is a retrospective review of the local diabetes data base.

- The sample is comprised of patients with type 1 and type 2 diabetes who required follow up after attending the outpatient clinic.
- Patients were identified from a telephone contact list over a two month period who required review following initiation of new treatment or titration of current treatment to intensify control.
- The estimated average size of the sample is 100 participants. The inclusion criteria will be:
- Males and Females
- Aged above 16
- Type 1 or type 2 diabetes, requiring additional support or intervention

The following data will be extracted from routinely collected clinical data stored on the diabetes database.

- Baseline data and six month data will be recorded.
- Data will be recorded for the following factors
- Reason for telephone contact
- HbA1c
- Weight
- Number of telephone contacts
- Frequency of phone contacts
- Duration of telephone contact
- Insulin doses
- Alterations in oral hypoglycaemic agents

v. Proposed method(s) of data analysis

- The data will be analyzed using SPSS. The analyses used will be descriptive statistics, followed by t-test for related samples (Paired t-test) (Coakes & Steed, 2007).

3. Informed consent

Has informed consent been obtained from participants which allows the organisation that holds the data to share it, or allow it to be used for research purposes?

☒ **Yes** ☐ **No**

If 'No', please explain:

Although individual patient consent was not taken, patients give implied consent by virtue of the fact they attend the hospital clinic and have their bloods taken for their clinic visits.

This is a retrospective audit so the data is already collected and the participants are anonymous. I have written permission from Wirral Hospital University Trust to say that I do not need hospital ethical approval and permission from the Trust to use the data. Letters of approval attached in the Appendix 3 and Appendix 4.

University of Chester

*A copy of the consent form(s) used, or a letter of confirmation from the organisation which holds the data, **must** be appended to this application.*

4. Ethical issues

Please summarise what you think are the ethical issues inherent in this study. The questions that follow will give you the opportunity to demonstrate how you will manage these issues in the conduct of your research.

This is a service evaluation of routinely collected information, thus removing these issues, no linked data will be removed from site

What measures will be taken to protect the confidentiality of participants' data?

You should consider data in hard copy, electronic and audio/audio/visual form. You should explain how the anonymity of participants is protected during the data collection process, during data analysis and at the end of the research project. (Applicants are advised to consult the University of Chester's Research Governance Handbook for further information).

A list of patients case sheet numbers will be created which will be kept on the hospital computer data base. These computers are protected with Anti-Virus and Spyware and each member of staff has a unique log on and password. The files on the computer can only be accessed by myself using my unique log in and password. When using the flash drive non-identifiable patient numbers will be assigned to each participant which will correspond to the numbers on the hospital computer, ensuring anonymity. Encrypted flash drive will be used to collect the information. The flashed drive will be locked in a filing cabinet when it is not being used to collect or analyse the data. This is to ensure the safety of the data.

Who will have control and act as custodian of the data used in / generated by the research?

Philippa Joseph

Can you confirm that the data will be retained in accordance with the University of Chester's Research Governance Handbook, which states that "data generated in the course of research should be kept securely in paper or electronic format, as appropriate, for a minimum of ten years from the date of final publication"?

☒ Yes, I confirm that data will be stored securely and confidentially for a minimum of 10 years.

5. Potential benefits

Are there any potential benefits to participants and/or wider society as a result of this research study?

Benefits of the study will include service development, if issues are raised, to improve the current diabetes service delivered to patients. Phone contacts are a routine part of the Diabetes Nurses role it is improtant to ensure we are using these opportunities to not only try and improve glycaemic control but provide health promotion messages as well.

Other potential benefits could be for commissioning as currently no payment is made for non face-to-face contacts, and if these are found to be of benefit then a business plan could be developed to access some payments. Commissioners could save money by reducing clinic visits which are costly to both the commissioners and the patients and use telephone contact as an alternative if this is found to be as effective.

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Part 3: Financial and other arrangements

1. **Please state any financial or other interests (including any conflicts of interest) that the Applicant, their Department/Centre, supervisor(s) or employer has in relation to the conduct of this research.**

   None

2. **Please state the amount of payment, if any, that will be paid to the researcher(s) *[over and above their normal salary]*.**

   None

3. **What additional costs will be incurred by the University of Chester through the conduct of the research, and how are these to be met? Please state whether funding for the research has been secured.**

   None

4. **Please confirm that the necessary arrangements have been, or will be made to comply with the requirements of the UK Data Protection Act (DPA) 1998 with regard to computer storage and processing of participants' personal information, and that generally the data supplied and generated during the course of the study will remain confidential.**

   ☒ Yes, provisions will be / have been made to comply with the DPA.

5. **What arrangements are in place for monitoring the conduct of the research, and dealing with any issues, complaints or adverse effects which may arise from the research?**
   [Note that, in the first instance, complaints should be addressed to the Dean of the Faculty of Applied Sciences, Professor Sarah Andrew.]

   The research will be governed via Clinical Audit

Student No.[redacted]

Appendix 4 Ethics Approval Letter

University of Chester

Faculty of Applied Sciences
Research Ethics Committee

frec@chester.ac.uk

5th April 2013

Dear Philippa,

Study title: **The Effectiveness of Telephone Consultation in the Management of Patients with Diabetes.**
FREC reference: **772/13/PJ/CSN**
Version number: **1**

Thank you for sending your application to the Faculty of Applied Sciences Research Ethics Committee for review.

I am pleased to confirm ethical approval for the above research, provided that you comply with the conditions set out in the attached document, and adhere to the processes described in your application form and supporting documentation. The Committee would however, like to make the following recommendations:-

- In Part 2, Section 3, Informed Consent – Change the tick box to state 'yes'.
- In Section 4, Ethical Issues - Write about confidentiality in addition to where the data will be stored.
- Section 5, Potential Benefits – This section requires completion.
- Clarify where the flash drive will be stored when not in use.

FREC B
Approval letter – 2012/13

Student No: [redacted]

Please forward a copy of the revised documentation together with the response to FREC template to FREC Secretary, Dean's Office, Faculty of Applied Sciences, Molloy 106 with an electronic copy to frec@chester.ac.uk

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Application Form	1	February 2013
Appendix 1 – List of References	1	February 2013
Appendix 2 – C.V. for Lead Researcher	1	February 2013
Appendix 3 – Written Permission – Wirral University Teaching Hospital	1	April 2011
Appendix 4 – Confirmation of Service Evaluation – Wirral University Teaching Hospital, Clinical Trials Unit	1	March 2011
Appendix 5 – Diabetes UK Poster	1	February 2013

With the Committee's best wishes for the success of this project.

Yours sincerely,

Prof. Cynthia Burek
Acting Chair, Faculty Research Ethics Committee

Enclosures: Standard conditions of approval.

Cc. Supervisor/FREC Representative

Student No.[redacted]

Appendix 5

Wirral University Teaching Hospital NHS
NHS Foundation Trust

Clinical Trials Unit
C Block North
Arrowe Park Hospital
Arrowe Park Road
Upton. Wirral
CH49 5PE

Tel: 0151-604-7311
Website: http://www.whnt.nhs.uk

15th March 2011

Philippa Joseph
Diabetes Specialist nurse
OPD Clatterbridge Hospital

Re: Diabetes audit (Effectiveness of Telephone Contact in Diabetes Management)

Dear Pippa

I have discussed your proposal with the Caldicott Guardian, Dr Melanie Maxwell, and we are of the opinion that the project is a service evaluation, and therefore that it does not require approval by an NHS Research Ethics Committee.

Furthermore, the R&D Department at Wirral University Teaching Hospital Trust does not undertake formal Research Governance reviews of audits or service evaluations; accordingly, The Trust will accept the University's ethical review as being sufficient and proper for the purpose of approval.

Kind regards

[redacted]

Professor Rod Owen
Manager, Clinical Trials Unit

Student No.[redacted]

Appendix 6

Wirral University Teaching Hospital NHS
NHS Foundation Trust

Clatterbridge Hospital
Clatterbridge Road
Bebington
Wirral
Merseyside
CH63 4JY

Tel: 0151 334 4000

13th April 2011

TO WHOM IT MAY CONCERN

I am writing to confirm that I give permission for Phillipa Joseph to have access to and use information from the diabetes database for her MSc Course.

The data will be anonymised.

Dr K S Leong Consultant Diabetologist

Dr J W Lorains Consultant Physician

Appendix 7 – Information on GLP-1 Mimetics

This class of drug includes:-

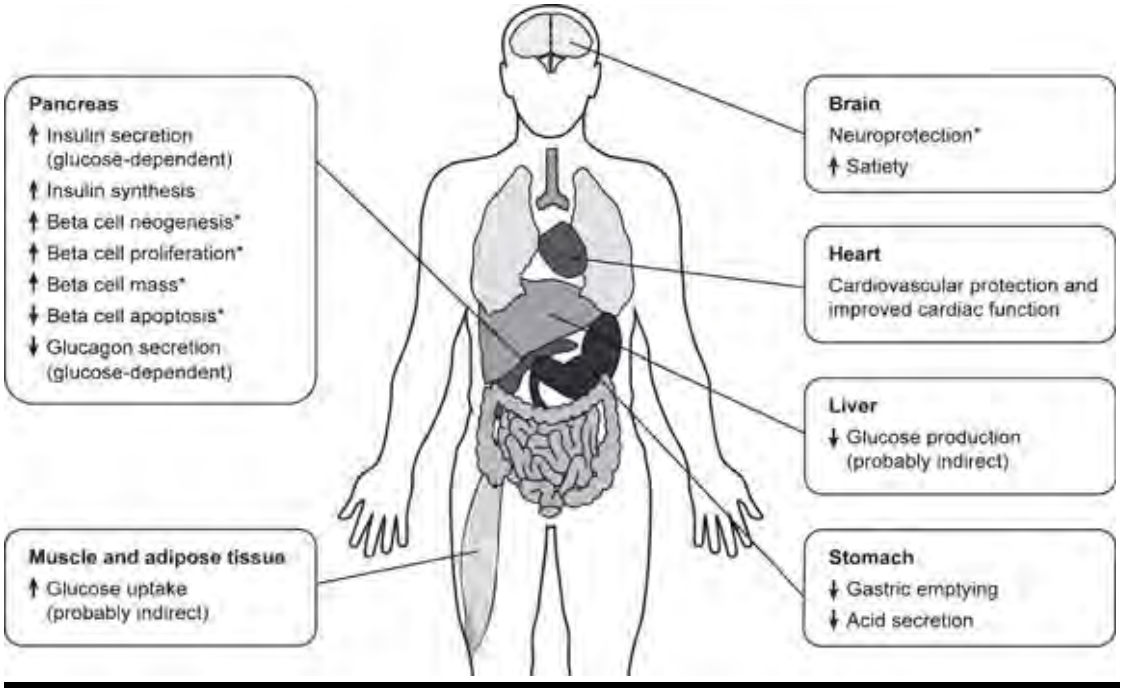
Byetta

Bydureon

Liraglutide

Lixisenatide

Endogenous GLP-1 is secreted in anticipation of a meal and in response to ingested glucose in order to potentiate endogenous glucose-stimulated insulin secretion. In terms of diabetes management, native GLP-1 has been considered for the treatment of T2DM (Gutniak, Linde, Holst, Efendic, 1994). However, its half-life after subcutaneous injection is only 1.5–3 min in humans (Vilsboll, Agerso, Krarup & Holst, 2003). Several long-acting GLP-1 mimetics have been developed to overcome this limitation, including exenatide and liraglutide as well as others currently under development. GLP-1 mimetics, which target postprandial glucose, should complement the activity of basal insulins, which are typically titrated based on fasting glucose levels. The GLP-1 mimetics that are either approved or in development have varying abilities to replicate the strong prandial effect of endogenous GLP-1.



Mode of Action of GLP-Mimetic