The failing diabetic patient in primary care

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The Failing Diabetic Patient in Primary Care

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Abstract

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Diabetes is a progressive disorder. The majority of people with Type 2 diabetes are likely to require more intensive treatment regimes over time and a substantial proportion have sub-optimal glycaemic control as measured by glycated haemoglobin (HbA1c). For these people a change to insulin is a possible option. However, this requires a major step for most people and their clinicians. The aim of this research was to ascertain the size of the problem, to obtain the views and perceptions about diabetes management of people with Type 2 diabetes and their carers' (including diabetic nurses and general practitioners), to establish a consensus based management regime, and to ascertain the possible impact on diabetes specific quality of life of the commencement of insulin.

This thesis used four methodologies. An existing primary care database was analysed to assess the scale of the problem of the poorly controlled Type 2 diabetic population in primary care. Qualitative research using focus groups was used to explore the beliefs of patients and clinicians towards diabetes and in particular the commencement of insulin in those failing on oral treatment. A mixed

consensus group was used to describe a care pathway for these patients. Finally, in a cohort of people with Type 2 diabetes failing on oral therapy, a disease specific questionnaire was used to ascertain quality of life issues around the initiation of insulin.

Main findings:

1) Over half of people with Type 2 diabetes were in poor glycaemic control, defined as an HbA1c >8%.
2) People with Type 2 diabetes viewed diabetes as a "mild disease", using their experience and the social effects of living with their diabetes to monitor progress. They saw insulin as a last resort to be delayed as long as possible.
3) Clinicians felt the majority of diabetes care could and should be provided in the community with an active management approach. Non-compliance with treatment was seen as an issue. Insulin was viewed positively while, at the same time, seen as being actively resisted by patients. The increase in resource and workload around insulin initiation was a major concern.
4) Much uncertainty remained regarding the management of the failing diabetic patient. The value of early insulin treatment was questioned for the asymptomatic patient. Shared decision-making was advocated but problems around risk/benefit information and lack of resources in both primary and secondary care were highlighted.

5) Insulin treatment in a cohort of people with Type 2 diabetes in poor glycaemic control on oral hypoglycaemic agents resulted in a modest but significant improvement in glycaemic control in routine care. Insulin initiation did not result in a change in quality of life. Patients' satisfaction with their tablet treatment was high but increased significantly on starting insulin therapy. However, these conclusions were limited by low study numbers from poor study recruitment.

Conclusions

Improving the care of people with poorly controlled Type 2 diabetes who are on maximal oral treatment is not straightforward and represents large resource and workload issues. Patient and clinician beliefs affect management and are not always currently sought and addressed. The benefits of early, more aggressive treatment with insulin need to be better quantified and information better presented to allow patient participation in decision making: glycaemic control is not the only factor that needs to be considered. A large gap in resources to achieve this was identified. The effect of insulin treatment on quality of life unfortunately has not been adequately answered in this research due to low participant numbers.

For Elaine, Mark and Sarah

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Authorship note

The contribution of a number of individuals to this thesis is formally acknowledged.

Professor Pali Hungin contributed to study design and participated in analysis of the focus group and consensus group studies and contributed to study design of the insulin quality of life study. Diabetic specialist nurses, Dianna Nayman and Shirley Pearson collected data and administered questionnaires for the insulin quality of life study.

I confirm that no part of the material offered has previously been submitted by me for a degree in this or any other university. If material has been generated through joint work, my independent contribution has been clearly indicated. In all other cases, material from the work of others has been acknowledged and quotations and paraphrases suitably indicated.

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Chapter 1

1. Introduction

Globally, diabetes is one of the commonest chronic diseases affecting 5% of the world's population[1] and doubling every generation[2]. Type 2 diabetes accounts for up to 95% of this total. In the UK it affects 1.8 million people with an estimated 1 million currently undiagnosed[3].

The costs to the NHS are high, with diabetes accounting for 5% of total costs and 10% of hospital inpatient costs. The indirect costs are less well documented but probably equally high. The cost to the individual in terms of loss of earnings and decreased quality of life are also considerable and often forgotten. Life expectancy is decreased on average by up to 10yrs.

Type 2 diabetes gives rise to metabolic disturbance by two main factors: a reduced capacity for the pancreatic islet cells to produce sufficient insulin and a reduced ability of the body's tissues to utilise insulin effectively, so called 'insulin resistance.' This results in poor diabetic control with hyperglycaemia leading to diabetic complications. The increasing trends towards reduced physical activity, convenience foods, and obesity are major factors in fuelling the diabetes epidemic.

Treatment of Type 2 diabetes has so far yielded only partial success. Over time diet and oral hypoglycaemic drugs fail to adequately control blood glucose levels at which point insulin treatment is usually required. In the primary care setting the use of insulin has always been regarded as problematic. This has been in part because of the perceived logistical difficulties in initiating insulin

therapy in primary care, but also because of the attitudes of both clinicians and patients towards the use of insulin, especially concerns around the areas of needles, injections, and the risk of hypoglycaemia.

As a practicing clinician I am well aware of patients who have had poor diabetic control despite oral therapy but in whom a switch to insulin represented a step too far. Understanding the attitudes of both care providers as well as patients is key towards helping facilitate the decision to use insulin therapy. In addition it is important to have an estimate of the improvement that can be expected from such a switch and the impact on quality of life and diabetic control produced.

This thesis is thus rooted in pragmatic care. From a general practitioner's viewpoint the use of routine insulin would need to be justified and in many cases it may be necessary to alter the mind set of carers so that they have a lower threshold for the use of insulin in people with Type 2 diabetes. In this thesis I have explored the following:

- The extent of the problem of diabetes
- The attitudes of patients towards diabetes and insulin treatment
- The attitudes and perceptions of primary care clinicians towards diabetes and insulin treatment
- Can a consensus be reached on the management of the person with poorly controlled diabetes?
- What is the impact of the introduction of insulin therapy on quality of life and diabetic control?

As a result of this research it was possible to better understand the dynamics surrounding the management of poor diabetic control in primary care and assess the true impact of introducing insulin therapy for the person with poorly controlled Type 2 diabetes. These factors need to be taken into account in planning local community based diabetes services.

The thesis has represented a journey in terms of my own awareness of the topic, the methodologies used and also in understanding the difficulties in conducting research within the pragmatic setting of clinical care.

Chapter 2

2. Literature Review

Diabetes is a condition characterised by chronically raised blood glucose levels. It is caused by a reduced effect of the pancreatic hormone insulin, due to an absolute or relative lack of insulin production and/or reduced insulin action (insulin resistance).

Early clinical descriptions of diabetes are to be found in ancient Egyptian writings (e.g., Ebers Papyrus, 1500 BC). Polyuria and wasting were recognised as cardinal symptoms and it was initially thought to be due to a disease of the kidney. The word 'diabetes' was coined in the 2nd century AD by Aretaeus of Cappadocia, deriving from the Greek for 'a passer through, a syphon'. John Rollo (d.1809) applied the adjective 'mellitus' to diabetes (Greek and Latin for 'honey'). The causes of diabetes have been explored particularly over the last three centuries, from the discovery of sweetness of the urine by Thomas Willis in the 17th Century, through to the discovery of insulin by Banting and Best in 1921, and subsequently the unravelling of its structure by Sanger in 1955 and Hodgkin in 1969.

There are two main types of diabetes. Type 1 (previously termed Insulin Dependent Diabetes Mellitus) presents in childhood or early adulthood, and accounts for approximately 15% of all diabetes in Europe. It is caused by an autoimmune destruction of the pancreatic beta cells responsible for insulin production. Insulin treatment is required to maintain life. Type 2 (previously termed Non-Insulin Dependent Diabetes Mellitus) accounts for around 85% of diabetes in Western countries, typically presenting over the age of 40yrs. It is caused by a relative lack of insulin production in association with a variable

degree of 'insulin resistance': available insulin having a reduced effect on target tissues.

Diabetes is diagnosed in one of three ways[4]: a random plasma glucose of >11.1 mmol/l accompanied by symptoms of diabetes; by a fasting plasma glucose =/>7.0mmol/l; or by a random plasma glucose =/>11.1mmol/l, 2hrs after an oral 75g glucose load (the oral glucose tolerance test).

This thesis is concerned with Type 2 diabetes and further discussion will concentrate on this.

2.1. Aetiology

Type 2 diabetes is caused by a combination of reduced insulin secretion from pancreatic beta cell dysfunction and decreased insulin action (insulin resistance) at a cellular level[4, 5]. Genetic and environmental factors are involved. A genetic component is suggested by a reported lifetime concordance of between 33-90% for identical twins. Having a single parent with diabetes imparts a 15% lifetime risk of diabetes, rising to 75% if both parents are affected[3]. Despite family aggregations, inheritance is not straightforward and appears to be multigenic and is as yet, incompletely understood. Environmental factors implicated include particularly, obesity and a sedentary lifestyle[6, 7].

Insulin resistance is present in 90% of people with Type 2 diabetes[8] and present in most people in the pre-diabetic state[5, 9]. It occurs when the body has a reduced response to circulating insulin in its target tissues: skeletal muscle, adipose tissue and liver[10]. Decreased insulin sensitivity leads to a compensatory hyperinsulinaemia[9]. This cannot be sustained due to

pancreatic beta cell dysfunction, resulting in increasing hyperglycaemia and the development of impaired glucose tolerance and diabetes[11, 12]. Insulin resistance is associated with a cluster of atherogenic risk factors in the insulin resistance (or metabolic) syndrome, first described by Reaven[13]. Features include insulin resistance, hyperinsulinaemia, glucose intolerance or diabetes, dyslipidaemia (high triglycerides, low hdl cholesterol), and hypertension. Visceral obesity and a pro-coagulant state were other associations noted later and now included in the syndrome.

2.2. Epidemiology

Type 2 diabetes is one of the most common chronic diseases in the UK[14] affecting 1.8 million people with an estimated further 1million undiagnosed[3].

The number of adults with diabetes has been estimated worldwide to be 135 million in 1995, rising to 300 million by 2025[15]. Most of this increase is expected to occur in developing countries where a 170% increase is expected, from 84 to 228 million. Developed countries, however, do not escape this trend with an expected 42% increase, from 51 to 72 million.

Prevalence has increased dramatically, predominantly because of changes towards a more sedentary lifestyle, increasing obesity and ageing [16]. Large geographical variations are seen with a ten-fold variation in prevalence between the highest and lowest risk populations. Rates are highest in the Pima Indians of Arizona, USA (50%), and on the South Pacific island of Nauru (40%). These communities have experienced radical change from a traditional to Westernised lifestyle. Low rates are seen in undeveloped rural areas such as parts of Africa and China.

Diabetes is a major cause of mortality and morbidity - the most common cause of blindness in people of working age[17], a major cause of kidney failure and of lower limb amputations[14]. Mortality for patients with Type 2 diabetes is twice that of the non-diabetic population even after adjusting for age, blood pressure, cholesterol, body mass index and smoking[18]. In the UK, cardiovascular disease accounted for around 75% of deaths in people with diabetes[14].

2.3. Economic costs

The overall economic burden is great. The NHS spends 5% of its budget (£3.5 billion) on diabetes care and this is expected to rise to 10% by 2011[19]. In Europe, the cost of treating diabetes and its complications has been estimated to be 5.8% of the total healthcare budget[20]. Diabetic patients used up to 9.4% of all inpatient bed days[21] and have 4 times the probability of being admitted to hospital compared to non-diabetic populations (x12 the rate of admission for heart disease and stroke) [21]. Up to 10% of the UK hospital budget is spent on treating diabetes and its complications[22].

The indirect costs of diabetes may amount to as much as one and a half times those of the direct costs[23]. Indirect costs may be categorised, in rank order, as lost productivity due to short-term illness, permanent disability and premature death. It is estimated that people with diabetes spend £500 million of their own money coping with their diabetes and social services costs amount to £230 million[24].Type 2 diabetes has a negative effect on employment status and work productivity, even when there are no major complications. In an international randomised controlled trial[25] 26% less people with Type 2

diabetes were employed when compared to the general population, after allowing for age, gender and nationality. It is estimated that people with Type 2 diabetes lose twice as much time from work as the general population[14, 26].

2.4. Management of Type 2 diabetes

Type 2 diabetes is initially managed by dietary change, limiting the consumption of saturated fats and replacing them with monounsaturated or polyunsaturated fats. Complex carbohydrates are substituted for simple carbohydrates and a high fibre intake encouraged. Dietary advice has been significantly modified in recent years with greater flexibility in the proportions of energy derived from carbohydrate and monounsaturated fats[27]. It is suggested that fats are limited to <35% of total energy intake: saturated fats <10%, n6 polyunsaturates <10%, n3 polyunsaturates at least two portions per week of oily fish, and monounsaturates increased to 10-20% of energy intake. Carbohydrates should be limited to 45-60% but sucrose can be taken up to 10% of energy intake, provided it is taken in the context of a healthy diet.

Weight reduction and an increase in exercise are advocated but in practice are difficult to achieve for the majority of patients. Only 10-20% achieve good glycaemic control on diet alone. The majority require the addition of oral hypoglycaemic drugs or insulin. Insulin will be required by almost 50% of patients within 6yrs of diagnosis[28].

2.4.1. Oral Hypoglycaemic Agents (OHA)

There are four main groups of oral agents used to control hyperglycaemia: the biguanides, insulin secretagogues, thiazolidinediones, and alpha-glucosidase inhibitors.

2.4.1.1. Biguanides

Metformin is the only biguanide used in the UK. It increases insulin action, although the exact mechanism is not fully understood. It decreases hepatic gluconeogenesis thus reducing glucose production. It does not cause weight gain or hypoglycaemia and in the obese is associated with a significant reduction in diabetes related events, all cause mortality, and stroke[29].

2.4.1.2. Insulin secretagogues

Two drug groups increase pancreatic insulin secretion: the sulphonylureas (SUA) and the meglitinide analogues. SUA stimulate insulin secretion by binding to sulphonylurea receptors (SUR) on the pancreatic beta-cell plasma membrane, causing membrane depolarisation and exocytosis of insulin granules. They are associated with weight gain. The meglitinides, repaglinide and nateglinide, bind to the SUR by a different mechanism to the SUA resulting in a shorter duration of action, and are therefore used to control postprandial hyperglycaemia. Insulin secretagogues can be used alone or in conjunction with metformin.

2.4.1.3. Thiazolidinediones

Otherwise known as the 'glitazones', this group of drugs are insulin sensitizers. They enter the cell and bind to the peroxidase proliferator-activated receptor (PPARγ). This is a nuclear receptor found mainly in adipocytes, and to a lesser extent in muscle and the liver. The glitazone forms a complex in the cell that stimulates expression of insulin-sensitive genes. These increase glucose uptake, increase adipocyte lipogenesis and decrease circulating fatty acid levels. Glitazones are associated with weight gain and fluid retention. They can be used as monotherapy or added to metformin or SUA.

2.4.1.4. Alpha-glucosidase inhibitors

Alpha-glucosidase inhibitors delay carbohydrate absorption thereby lowering postprandial blood glucose levels. They inhibit disaccharidase enzymes and this gives a high incidence of gastrointestinal side effects. They are only effective in patients with adequate beta-cell function.

2.4.2. Oral Hypoglycaemic Agent (OHA) Failure

The natural history of Type 2 diabetes whether initially controlled with diet alone, diet and oral drug treatment, or diet and insulin, in the absence of any precipitating event, is towards loss of glycaemic control [28, 30, 31]. Poor glycaemic control is defined as an HbA1c level >7.5% [24]. In the UKPDS study[28] oral treatment failure was more likely to occur in patients with younger age at onset of diabetes (<54yrs mean), in the lean, and in those with high fasting plasma glucose (FPG) at onset. The failure rate was proportional to the FPG at randomisation (61% for FPG >10 mmol/l, 23% for those with initial FPG <7.8 mmol/l). The annual failure rate was 7% and linear, 44% over six years. Pontiroli found a similar rate of 6.2% pa for oral treatment failure in the lean and 1.2% pa and 2.5% pa in the obese and overweight respectively[32].

2.4.2.1. Immunogenic factors

The presence of autoimmune antibodies in a small number of late onset diabetes suggests a slowly evolving autoimmune insulitis of the insulin dependant type. It suggests that these patients are in fact a discrete subgroup of type 1 diabetes. Antibodies to Glutamic Acid Decarboxylase (GAD) were found in 76% of insulin deficient Type 2 diabetic patients, but in only 12% of non-insulin deficient patients[33]. A minority, 10-15%, of people with Type 2 diabetes have Islet Cell Antibodies (ICA's)[34]. Marked impairment of beta-cell

function was seen when ICA's were associated with phenotype HLA-DR3/DR4[35]. The presence of these antibodies was associated with impaired beta cell function, lower body weight, and with a higher frequency of other organ-specific antibodies and autoimmune disease[33, 34]. This group can be differentiated from Type 2 diabetes by defining the period of good glycaemic control prior to oral treatment failure. A prolonged period of 3-5 years would avoid misclassification[36].

2.4.2.2. Insensitivity to OHA

Patients failing on one oral agent do no better with substitution of another[37, 38]. Withdrawal of chronic sulphonylurea or metformin therapy has generally shown deterioration in glycaemic control[39, 40]. These findings suggest that oral treatment failure is not a drug related problem but rather a patient-related or disease-related problem.

2.4.2.3. Insulin release and Insulin resistance

Reduced insulin secretion and increased insulin resistance are the hallmarks of Type 2 diabetes[41]. In two studies of non-obese patients with oral treatment failure an increased insulin resistance and decreased beta cell function was noted compared to those patients still responsive [42, 43]. Insulin resistance is related to obesity in Type 2 diabetes [44, 45]. Weight loss can reduce insulin resistance but does not appear to influence insulin secretion [46, 47].

2.4.3. Treatment options for OHA failure

Treatment options advocated have included very low calorie diet, temporary intensive insulin therapy, combined therapy with insulin and oral hypoglycaemic agents, and standard or intensive insulin therapy.

2.4.3.1. Very low calorie diets (VLCD)

VLCD supplying 400-600 calories per day (protein, with vitamin, potassium and magnesium supplements) over 3-4 weeks has shown better initial improvement in blood glucose control than conventional diets [48, 49]. Weight loss is commonly regained off the diet but improvement in blood glucose levels may persist for up to 1 year. VLCD therapy has also been used on an outpatient basis with success[50]. This type of dietary treatment may be helpful in patients with severe obesity and poor dietary compliance but long-term results are not sustained. The American Diabetic Association suggests that they should be considered only in conjunction with a structured weight management programme [49] while the European Association for the Study of Diabetes (EASD) suggest their use should be restricted to patients with a BMI of 35 kg/m or over, who are supervised in experimental medical centres[16].

2.4.3.2. Temporary intensive insulin therapy

Intensive insulin therapy requires the patient's admission to hospital for treatment. Normoglycaemia is obtained using continuous subcutaneous insulin infusion and maintained over 2-3 weeks [51, 52]. This can improve insulin resistance and endogenous insulin secretion, allowing control to be maintained by oral hypoglycaemic agents and diet. The authors of the cited studies restricted treatment to those patients with relatively unimpaired endogenous insulin secretion (as implied by C-peptide levels) and achieved good control over periods of over 2 years in 50% of cases.

2.4.3.3. Combination therapy

Secondary failure occurs over time with all forms of monotherapy. This was demonstrated to diet by Hadden et al.[30] and to diet, sulphonylurea, metformin

and insulin in the UKPDS study[28]. Combination therapy was initially studied as an adjunct to failed insulin therapy. Meta-analyses had shown typically a reduction in glycated haemoglobin of 1% [53-55]. This was regarded as a disappointing result and many advised against its use[53, 56, 57]. Adding insulin to sulphonylurea treatment at the time of sulphonylurea failure has been shown to be effective provided some residual endogenous insulin secretion remains, as is usually the case. Evening intermediate or long-acting insulin suppresses overnight hepatic glucose production (HGP) improving fasting plasma glucose (FPG). This effect on HGP may be due to insulin's suppressant effect on free fatty acid concentrations[58]. The daytime sulphonylurea deals with post-prandial glucose peaks by stimulating remaining endogenous insulin secretion. Medium or long acting insulin preparations at bedtime have been shown to control FPG with little risk of nocturnal hypoglycaemia[58-60] and to be less likely than a morning insulin dose to cause daytime hypoglycaemia[60]. This is particularly relevant to the elderly diabetic. Controlled studies have shown the effectiveness of a combination of bed-time insulin with day-time sulphonylurea (BIDS) in patients with recent OHA failure [61-63]. Combination therapy gave better FPG and glycated haemoglobin levels than a single insulin injection alone. Yki-Jarvinen et al. compared bedtime insulin combined with sulphonylurea, metformin, or a second insulin injection [64]. Weight remained unchanged in the insulin with metformin group, compared to significant weight gain (3.6-4.6kg) with the other combinations. This was achieved with slightly better glycaemic control and less hypoglycaemia. Combination therapy gives levels of control similar to multiple injection insulin regimes with less inconvenience, less weight gain and reduced hyperinsulinaemia. Compared to

single injection insulin therapy it gives better control. Superficially, combination treatment is some 30-50% more costly. However, if factors such as extra supplies of syringes / pens, needles, greater use of SMBG readings, more frequent out-patient attendance, and possibly more emergency treatment are considered, it may well be cost-effective. Moreover, multiple injections, particularly in the elderly, may require greater supervision from relatives or district nurses.

2.4.3.4. Insulin therapy

Indications for insulin treatment include ketosis, significant weight loss regardless of initial weight and severe symptoms of hyperglycaemia[56]. Insulin treatment is associated with improvement in general well being[65, 66]. Use in the obese patient, particularly if gaining weight, is problematical. Often all that is achieved is excess weight gain with no improvement in glycaemia. Intensive insulin regimes can achieve near normoglycaemia in experimental conditions at the expense of significant weight gain[67]. More rigid outpatient regimes have given similar results to standard regimes[65, 68]. However, in an attempt to improve community care in Michigan, USA, insulin use increased but without improvement in glycaemic control[69].

Long acting insulins have been used alone or in combination with oral agents as the initial treatment for oral treatment failure. The advent of genetically engineered long acting insulins (insulin glargine and detemir) has refined treatment, providing a more stable baseline insulin level over a 24hr period. Some patients will require a full insulin regime, usually with twice daily premixed insulin.

2.4.4. Behavioural Aspects

Diabetes is one of the most psychologically and behaviourally demanding of the chronic medical illnesses and psychological factors are relevant to nearly every aspect of diabetes and its treatment[70]. Patients are required to take over the management of processes that the body normally self regulates. This involves life-long behavioural change. Diet, exercise and blood glucose levels need to be monitored on a daily basis. Advances in treatment require the patient to undertake ongoing education and display adaptability to cope with changes in management that these advances bring about. A longitudinal study by Davis showed psychological impact was one of the top five predictors of mortality in diabetes[71].

2.4.4.1. Adherence

Diabetes is a complex, demanding, chronic illness that requires high levels of responsibility from the patient. It is therefore not surprising that adherence can be low in diabetes. Haynes defined it as

> *"The extent to which a patient's behaviour coincides with medical advice."[72]*

Adherence is less value laden than compliance and better conveys the self-regulatory nature of the diabetic regime[73, 74]. The term concordance is also currently used, being thought to indicate a more active role played by the patient in agreeing a course of action. To comply, patients must have been given explicit instruction on exactly what is expected of them. Vague generalisations such as 'lose weight' or 'increase your exercise' are not sufficient. It must be specific and based on the individual patient's situation. The

patient must have understood what is being asked of them. Very little is remembered from face to face consultations. Key points need reinforcing with written literature.

The medical model typically sees the doctor as the 'expert' who 'knows best' and the ideal patient as the passive, obedient recipient of instructions. Patients not conforming are characterised as 'deviant' and attempts have been made to identify the characteristics of the 'non-compliant patient'. This is not the model that the patient necessarily uses[75]. The patient approaches the consultation with ideas and views on illness and the use of medicines and has expectations both of the doctor and of advice or treatment offered. Advice will be discussed with family and friends before being evaluated. Various theories have been put forward to explain patient behaviour and these will be expanded further.

In a study of behavioural influences on patient self-care Hunt found the key factors influencing treatment choices were 1) belief in the power of modern medicine; 2) the desire to act and feel "normal"; 3) the desire to avoid physical symptoms; and 4) limited economic resources[76]. All patients were trying to control their diabetes but none of them followed all recommendations all of the time. Advice was modified in light of everyday circumstances. Self-care behaviour is reasoned behaviour[77, 78]. Similarly, in patients attending a Rheumatology clinic, Donovan found patients were active in their non-compliance. They drew on their lay beliefs and experiences, together with information gleaned from other sources such as friends, the media and pharmacy staff[79].

Adherence is not a one-dimensional construct. Adherence to one aspect is not necessarily related to adherence to other aspects of self-management[80]. It may be high for one aspect such as tablet taking, but be low for other aspects such as exercise or diet. It also varies between individuals and within individual patients over time[80]. It has been suggested that different health beliefs influence specific self-care tasks[81].

Adherence is a difficult concept to measure. Health status measurements, such as glycosylated haemoglobin (HbA1c), have often been used as surrogate measures, despite the literature finding no direct relationship between adherence and diabetes control[80, 82, 83]. The adequacy of the prescribed regime and the progressive nature of the disease process itself affect glycaemic control. Provider ratings have proved similarly inaccurate and open to bias[84]. Behavioural assessment is highly specific and useful for detecting technical skills deficits, such as insulin administration or blood glucose testing, but is labour intensive and requires observer training[85]. Counting permanent products, such as pill counts, can at times be helpful, but is little used outside of research studies. Home blood glucose monitoring can now be better assessed when using meters with large memories that can be downloaded. Self reporting has been successfully used to assess concordance with multiple behavioural components, using diaries[80], and 24hr recall interviews[86]. These have proved reliable, may be conducted by telephone, but do require trained interviewers.

Non-adherence varies across the different components of the diabetes regime. It is dynamic, varying during the course of the disease and at different times in

a person's life. It is not surprising therefore that global measures of concordance are unreliable[84]. Instruments that measure specific components are more useful, but more work needs to be done to assess validity and reliability over differing populations (children, adolescents, adults, and the elderly).

As Cox states[87], the initial question may have been "what affects compliance?" The final question however needs phrasing as "what individual, social and environmental factors affect specific self-care behaviours?"

2.4.4.2. Patient Characteristics

Poor coping skills, both for diabetes specific problem solving skills and management of general stress, have been shown to influence self-care and treatment outcomes[88].

Diabetic patients are twice as likely to be depressed as non-diabetic patients[89]. people with diabetes with complications have five times the frequency of depression compared to the non-diabetic population[90].

2.4.4.3. Health Beliefs

Behavioural adherence to the complicated diabetic regime is understandably difficult to constantly achieve. Health beliefs have been associated with regime adherence and metabolic control. Here again there is no straightforward relationship. Improved control relates to beliefs on specific regime tasks.

Health beliefs have been suggested as a promising alternative to traditional personality variables in predicting adherence[91]. Becker developed the Health Belief Model for predicting medical regime compliance from the original work of Rosenstock[92, 93]. Support for this model has been found in a variety of

medical conditions[94]. This model postulates that the likelihood of a patient adhering to a medical regime is determined by five psychological readiness variables: a) the perceived susceptibility to the disease process; b) the perceived severity of the condition; c) the perceived benefits of taking action, d) the perceived costs of taking action and e) the degree to which internal or external cues to action are present to activate the other factors.

Partial associations of specific variables of the model have been shown. In diabetic populations, perceived illness severity was associated with adherence to diet and weight loss[95]. Global response to the health belief model has been found[95]. Harris[96] examined the health beliefs of 93 male diabetic patients. Belief in severity of the illness was associated with compliance, but overall, health beliefs were better predictors of metabolic control than of compliance itself. Brownlee-Duffeck et al.[73], looking at the health beliefs of 193 type 1 diabetic patients, found older patients' belief in the perceived benefit of regime adherence was associated with both adherence and metabolic control. In younger patients, perceived costs figured most prominently in relation to adherence, but perceived severity and susceptibility were the most important beliefs associated with metabolic control.

Ajzen's theory of reasoned action suggests that behaviour is strongly correlated with intention to perform that behaviour[77]. This in turn is modified by a person's attitude toward the behaviour and the subjective norm (the influence of family, friends and experts). Wolfenbuttel, using Ajzen's attitude-behaviour model to study insulin injecting in elderly people with Type 2 diabetes, found a high correlation between intention to and actually starting insulin treatment. The

main factor influencing intention was the subjective norm, especially health care professionals[97].

Explanatory or commonsense models of illness seek to link disease and symptom labelling with patient perspectives on the aetiology, course and treatment of illness[98]. The common sense model posits that individuals' understanding of illness is based upon somatic symptoms and life experiences and thus may differ significantly from the biomedical view of illness[99, 100]. Cowen suggests that variation in patient-practitioner perspectives in Type 2 diabetes affects patients' disease orientation[101]. Hunt, in an ethnographic study of Mexican American people with Type 2 diabetes, found patients attempted to connect biomedical causes and treatment success or failure through personal histories[102]. A further ethnographic interview study of older women with Type 2 diabetes showed lay aetiological perspectives were associated with dietary adherence more so than socio-demographic factors including ethnicity, education and income[103]. Those who implicated previously poor dietary practices, currently being overweight, or having 'improper bodily functions' were all more likely to follow dietary advice. Glasgow related personal belief models and socio-environmental barriers to self reported diabetes self-management[104]. Regime specific measures were found to be stronger predictors than were more general measures. Looking at the construction of illness beliefs Hunt et al. described an iterative process of initial beliefs modified by ongoing experiences and social circumstances. They concluded that illness explanations are dynamic entities determined by their usefulness in the individual person's social environment[105]. "Consideration of

the causal reasoning of patients opens up a window onto the understanding and interpretations of their illness"[102].

A patient's Health Locus of Control (HLOC) has been suggested as having an influence on health behaviour and outcome. HLOC has been described as the degree to which individuals feel able to influence their own health behaviour[106]. People with an internal HLOC believe they have control over health behaviours and hence can influence outcomes. Those with an external HLOC feel powerless to control their health and therefore feel unable to affect their health outcomes[107]. Peyrot examined diabetes-specific locus of control (DLC)[108]. They found that the internal DLC could be further subdivided into autonomy and self-blame components. Autonomy was generally associated with positive outcomes whereas self-blame was associated with negative outcomes. This is consistent with other work[109]. Externality associated with chance had negative outcomes. The other dimension of external DLC, powerful others, could also be usefully split into two components. Negative outcomes were associated with strong health professional influence whereas positive outcomes were found with non-medical significant others.

2.4.4.4. Coping strategies

Kelleher[110] sees the patient's attempt to incorporate diabetes into their lives as one more role to fulfil. People have multiple different life roles or identities[111] (parent, mother, husband) that have to be balanced. The diabetic role is but one more to be accommodated. Issues and problems have to be faced in developing all these identities. In his qualitative study of 30 diabetic patients he found three main themes. The theme of being 'normal', the theme of control (whether feeling in control, or daily life being dominated by the

diabetes), and loss of spontaneity (how much life had to be altered to fit around diabetes). Tying in with these themes, he found three overall coping strategies. Being in control – 'copers' were willing to alter treatment regime rather than reduce their social roles and saw themselves as healthy. Adapting to diabetes – 'normalisers' accept they have diabetes but alter social relationships to fit around it. They still regarded themselves as healthy. 'Worriers and agonisers,' in whom diabetes maintains dominant, find diabetes interferes with other life roles, causing anxiety and a perception of ilhealth.

Maclean[112] examined the meaning patients attach to self-care actions in relation to diet. Many individuals sought a balance between health and well-being. When health did not compromise well-being adherence to diet was not a problem but if there was a conflict patients took liberties with their diet. Murphy and Kinmonth[113] found, in people with Type 2 diabetes, two broad groups. Firstly, those who avoided short term symptoms by adjusting diet etc, or adjusted their lives around avoiding symptoms. They tended to feel diabetes was serious but not for them. The second group were avoiding long-term complications and felt they had a controlling role over their diabetes, and were more likely to feel diabetes was serious for them.

2.4.4.5. Psychosocial Factors

Davis, looking at correlates of survival in a longitudinal study of Type 2 diabetic patients, found that social impact of diabetes (measured by the Diabetic Educational Profile) was in the top five correlates of mortality (age, social impact, renal function, complexity of dietary regime, and history of smoking) above diabetic control as measured by glycated haemoglobin and other physiological parameters[71].

Family support has been shown to have both positive and negative effects. Regime-specific measures of family support differentiated high or low adherence better than global family support measures[114]. Non-family support has not been extensively researched.

2.4.4.6. Physician attitudes

It has been assumed that doctors' management of diabetes is based firmly on their knowledge of medical science and variation in performance is due to ignorance, forgetfulness or conscious disregard[115, 116]. Increasing knowledge alone is not sufficient to improve doctor performance[117, 118]. However, doctors' beliefs have been shown to be equally or more important. Kinmonth and Marteau, in a questionnaire study, showed GP teachers to have a more pessimistic outlook on type 1 diabetes, to perceiving the disease to have more risks, and to have a lower belief in the efficacy of treatment compared to a previous sample of secondary care doctors[119]. Marteau showed differences in beliefs when comparing paediatricians and general physicians. Paediatricians attributed less risk of diabetes complications, believed less in the efficacy of tight blood glucose control and tolerated a wider variation in blood glucose levels in their patients[120]. Weinberger found doctor beliefs, rather than their knowledge of effective diabetes management, to predict good blood glucose control[121]. He compared two groups of medical internists (12 in each group), dividing them into successful (those whose patients' blood glucose levels were below the clinic mean) and those who were unsuccessful (above the mean). The successful group was distinguished by their belief in strict blood sugar control, the early use of oral hypoglycaemic agents, and their perception that they were doing less well compared to their

peers. Pendleton found physicians rated the difficulty in complying with aspects of diabetic regime higher than did their patients[122]. This was felt to be due to either the physicians overestimating the difficulty or patients underestimation (or underreporting) of the difficulty. Discrepancies have been shown between patient and physician perceptions of treatment goals. In a study of obese Type 2 patients there was a 53% discrepancy in overall goals, a 57% discrepancy in specific weight loss goals and a 43% discrepancy in blood glucose goals[123]. Clinicians tend to frame their explanatory models of diabetes in patho-physiological terms, whereas patients emphasised the social domain and the impact diabetes had on their lives[101].

Doctors need to be aware of their patients' perceptions of compliance and of their readiness to change lifestyle behaviour. Verheijden, in a study of Dutch primary care physicians, found relatively low agreement between perceptions of physicians and those of patients regarding patients' readiness to change behaviour, adding another potential barrier[124]. Cowen highlighted the differences in patient and doctor perspectives that can have significant effects on how standard biomedical advice is received[101]. Hulka suggested that compliance is a function of the doctor-patient relationship[125]. A study of 93 diabetic men showed belief in severity of illness to be related to compliance. Health beliefs were stronger predictors of metabolic control than of compliance itself[96]. Educating health care professionals on the specific problems of compliance may be more effective than educating patients[126]. In a study of nurse / patient communication Street et al found improved glycaemic control was associated with nurses being less controlling and directive[127].

2.4.4.7. Barriers to adherence

Barriers to adherence may involve factors such as costs, time involved, availability of resources locally, and competing demands. Patient beliefs and health care provider attitudes, as well as social norms and pressures, can at times act as barriers to improved glycaemic control.

Intensive treatment is associated with an increase in hypoglycaemic episodes and weight gain[128]. Lorenz has argued that use of the word 'intensive' in regard to insulin therapy is, in itself, a barrier to patients receiving best treatment, both from the physicians' and the patients' perspective[129].

Larme and Pugh, using in-depth interviews and rating scales, found primary care providers in Texas perceived diabetes as difficult to treat and were wary of hypoglycaemia when considering insulin. They felt inadequate in their ability to control the disease and lacked time to deal with the patient education and instruction necessary to instruct patients in insulin use. Korytkowski[130], similarly identified physicians' perception of their inadequacy in controlling the disease with treatments other than insulin, and concerns over hypoglycaemia and weight gain as key barriers to insulin therapy.

Polonsky and Jackson coined the term 'psychological insulin resistance'[131] to describe patients' resistance to starting insulin. They identified perceived loss of control over one's life (insulin restricting life), poor self-efficacy (doubts about ability to cope with an insulin regime}, personal failure (guilt at not controlling diabetes with earlier strategies), perceived disease severity (insulin indicating their disease is entering a more serious phase), injection-related anxiety, and a perceived lack of positive gain from insulin (will not improve glycaemic control)

as key factors inhibiting patients from initiating insulin. In a study of insulin naïve Type 2 diabetic patients 57% expressed insulin related anxiety[132].

Monitoring of blood glucose levels with frequent finger prick testing may be perceived by the patient as painful, time consuming, and often producing poor results: in effect a punishment. Because adherence does not guarantee good glycaemic control again it may be viewed negatively. Behaviourally, improved self-care leading to failure to improve control, inevitably leads to reduced further efforts.

Social stigma has been identified as a barrier to effective diabetes self-management[133]. Patients avoid injecting themselves in public and may therefore inject at inappropriate times or places. They fear discrimination in the workplace, many trying to keep their diabetes a secret.

Thus, Type 2 diabetes is a complex chronic progressive illness requiring a high level of self-care behaviours from patients. Diet and oral treatments eventually fail to control blood glucose levels and insulin therapy is often then required. However, there are many influences affecting whether patients start insulin therapy, from both patient and clinician perspectives. These will be further explored in this thesis.

Chapter 3

3. Type 2 diabetes: the size of the problem

3.1. Introduction

With the increase in obesity and a sedentary lifestyle, Type 2 diabetes is increasing at an alarming rate. It is estimated to affect 110 million people worldwide and this figure is likely to double by the year 2010[134]. In the UK it affects 1.8 million people with an estimated 1 million currently undiagnosed[3]. The costs of diabetes care come mainly from dealing with the complications of diabetes, particularly by secondary care. It is estimated that 15% of the United States total healthcare budget is taken up with diabetic care[135]. In the UK diabetes care consumes up to 10% of the NHS acute sector budget[136]. This accounts for direct costs only; the indirect costs (lost productivity, permanent disability and premature death) may be even greater[23].

To investigate the scale of the problem in more detail, particularly in relation to people with poor glycaemic control, a representative single district with a comprehensive diabetic register was chosen as the basis of a demographic and clinical database. This project, the first in this thesis, was undertaken in 1999 and was based on the latest available complete year's data, 1998.

3.2. The North Tees diabetic register

A comprehensive, community based register of people with diabetes was started in the North Tees district of Northern England in 1992 and has been previously described and found similar to other published UK data[137]. All general practices in the area participated in the register together with the North Tees district hospital. The Cleveland Multidisciplinary Audit Advisory Group supported the register project and a working group consisting of the local diabetologist, two general

practitioners, three nurses and audit support staff oversaw the running of the project. Data were collected directly from general practice records by a single diabetes facilitator visiting individual practices on an annual basis. The 100% participation of practices and the one person responsible for data collection ensured a high level of data completeness. Data were fed back to practices on an annual basis comparing individual practice data to the anonymised district data.

Consent was obtained from the individual general practices for access to their data held on the register.

The register served the population of Stockton local authority district of the Tees Health Authority, with an estimated population of 178,920 in 1999[138].

In 1998 there were 3549 people with diabetes on the register giving prevalence for diabetes of 1.98%. Fourteen percent had Type 1 diabetes and 86% had Type 2l diabetes.

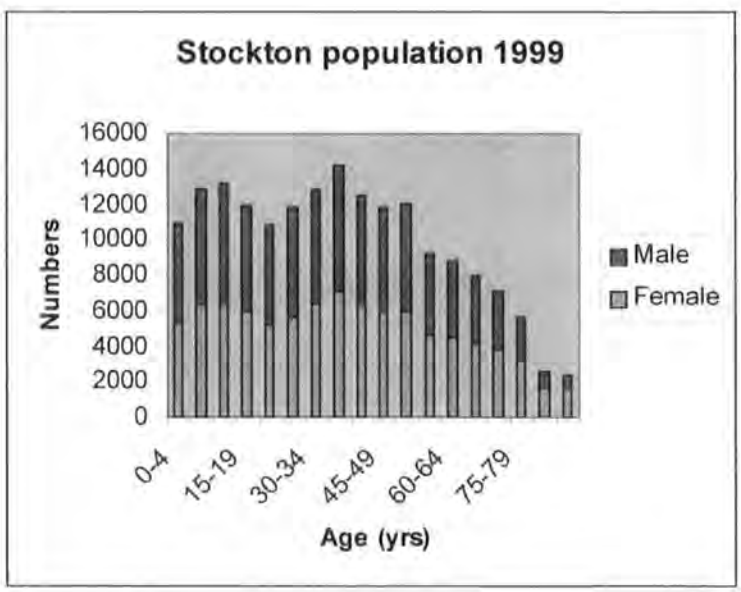


Figure 1 Estimated population of Stockton on Tees for 1999[138]

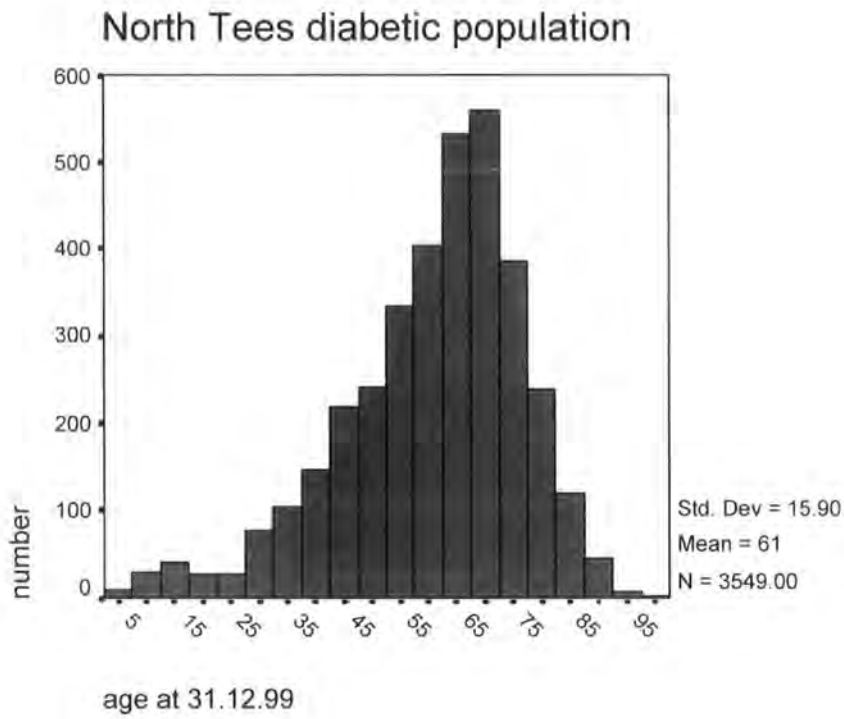


Figure 2 Total North Tees diabetic population 1999

Type 2 diabetes had been defined here, arbitrarily, as age at onset of diabetes 35 years or older. It is unusual for Type 1 diabetes to present above this age but there are signs of Type 2 diabetes presenting at an earlier age particularly in people of Asian extraction. However, Type 2 diabetes remained, in the main, a disease of the middle-aged and elderly.

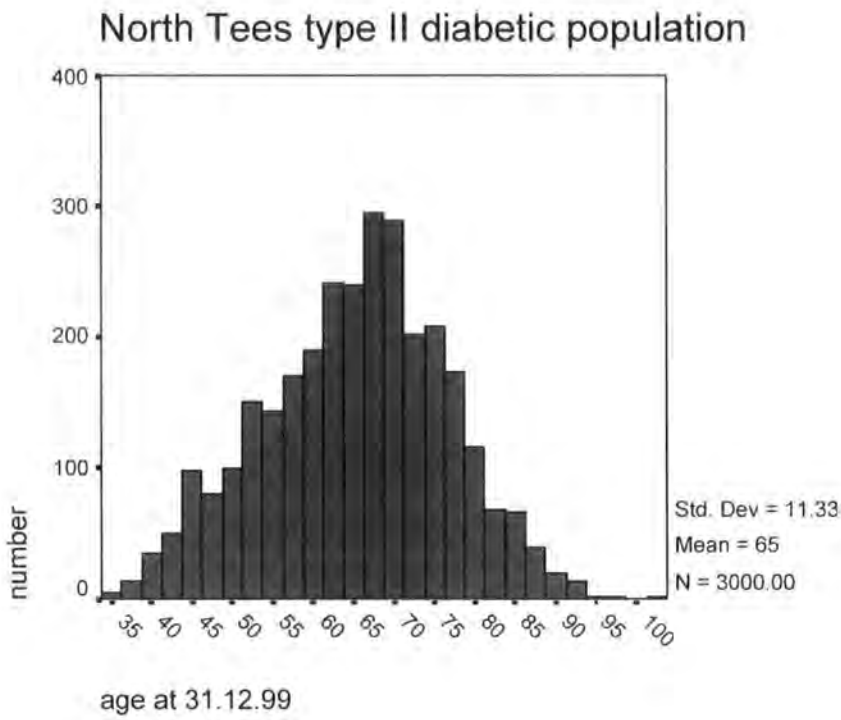


Figure 3 North Tees type II diabetic population

Looking at the Type 2 diabetic population, the average patient has had their diabetes for five years and to be in relatively poor glycaemic control with a glycosylated haemoglobin (HbA1c) of 8.2%. It is of note that general practice provided total care for over 80% of the population.

Table 1 Characteristics of the North Tees Type 2 diabetic population

Number (n)	3000
Age in yrs (SD)	65.2 (11.33)
Female (%)	1372 (46%)
Median duration of diabetes in yrs (IQR)	5.0 (1.5-8.5)
Mean HbA1c % (SD)	8.2 (1.4)
Diet only (%)	739 (25%)
Tablet treated (%)	1740 (58%)
Insulin treated (%)	521 (17%)
Systolic blood pressure in mmHg (SD)	145 (19.9)
Diastolic blood pressure in mmHg (SD)	81 (9.9)
Cholesterol (SD)	5.6 (1.16)
Creatinine (SD)	95 (28.6)`
GP care	81%
Hospital care (total and shared)	19%

3.3. The 'stable' Type 2 diabetic population

To avoid patients with poor control who were in the initial stages of having their therapy adjusted, I used a duration of diabetes of >3 years to define a group of patients who should be on optimized, possibly maximal, therapy. 1743 patients meet these criteria, of which 1467 (84%) had a current HbA1c reading. Of these, 873 (58.7%) patients were in poor control, as defined by an HbA1c >=8%.

Table 2 Characteristics of the stable Type 2 diabetic population (means (SD) unless otherwise stated).

	Patients with data	
Age at diagnosis in years	1743	57.0(10.96)
Median duration of diabetes, years (IQR)	1743	8.0(4.5-11.5)
Female %	766	44%
Diet only	240	14%
Tablet treated	1065	61%
Sulphonylurea (SU) only		45%
Biguanide (MF) only		12%
SU+MF		43%
Insulin treated	438	25%
HbA1c %	1487	8.5(1.43)
BMI	1293	28.9(5.52)
Systolic blood pressure mmHg	1558	146(20.6)
Diastolic blood pressure mmHg	1562	80(10.1)
Serum cholesterol	1200	5.5(1.09)
Serum creatinine	1413	97(29.6)
Current smoker	260	15%
Hypertensive	771	44%
Previous myocardial infarction	234	13%
Stroke incidence in 1999	35	2%
Retinopathy	360	21%
Laser treatment in 1999	52	3%
Admission for hypoglycaemia in 1999	12	0.7%
GP care	1363	78%
Hospital care (total and shared)	418	24%

Interestingly, the characteristics of this group were similar to the total Type 2 population except for their longer duration of diabetes as would be expected. There were fewer people on diet only and slightly more on insulin treatment.

Table 3 examines the effectiveness of the different treatment modalities in achieving good glycaemic control. The insulin treated group developed diabetes at an earlier age and had had their diabetes for longer than the other two groups. Glycaemic control had deteriorated across the groups despite intensifying treatment. Complication rates were similar for hypertension and macrovascular disease but with higher rates of retinopathy and photocoagulation in the insulin treated group. Weight as expressed by BMI was not significantly higher in the insulin group but they did have a higher rate of severe hypoglycaemia needing hospital admission. Secondary care was involved in a small proportion of the care of diet and tablet treated patients but was involved in almost two thirds of the insulin group. Again, no differences were seen in blood pressure, cholesterol, creatinine, gender, smoking status or BMI.

Table 3 Stable Type 2 diabetes: characteristics of treatment groups of (means (SD) unless otherwise stated)

	Treatment		
	Diet	Tablet +diet	Insulin + diet
Age at diagnosis in years	60.5(11.76)	58.6(10.25)	51.3 (10.11)
Median duration of diabetes, years (IQR)	6.0(4.0-8.0)	7.0(4.0-10.0)	11.0(6.0-16)
Female %	37%	42%	52%
HbA1c %	7.1 (0.87)	8.5 (1.39)	9.1 (1.32)
BMI	27.6 (5.00)	28.9 (4.95)	29.5 (5.80)
Systolic blood pressure mmHg	145 (20.4)	147 (20.3)	143 (21.0)
Diastolic blood pressure mmHg	80 (9.3)	81 (9.9)	78 (10.7)
Serum cholesterol	5.5 (1.03)	5.5 (1.09)	5.4 (1.12)
Serum creatinine	97 (20.2)	85 (30.5)	100 (31.0)
Current smoker	16%	14%	17%
Hypertensive	43%	46%	40%
Previous myocardial infarction	15%	12%	16%
Stroke incidence in 1999	1.3%	2.3%	1.8%
Retinopathy	8.3%	18%	34%
Laser treatment in 1999	0%	2.1%	6.8%
Admission for hypoglycaemia in 1999	0.4%	0.4%	1.6%
GP care	77%	84%	64%
Hospital care (total and shared)	4%	11%	66%

What were the differences between people whose diabetes was in good or in poor control? The poorly controlled group was characterized by an earlier age of onset and a longer duration of diabetes. As would be expected from the natural history of Type 2 diabetes as a progressive disease, very few poorly controlled patients were on diet alone and a higher proportion were on insulin. The proportion on tablet treatment was similar in both groups. There were no significant differences in blood pressure, serum cholesterol or serum creatinine between the two groups. The vast majority of patients (84-90%) received their care in general practice. However, more poorly controlled patients were seen in secondary care (36%), whether for total care or in a shared-care arrangement with general practice.

Table 4 Stable Type 2 diabetic patients: comparison of those in good as opposed to poor glycaemic control

Variable	Good control (HbA1c <8%)	Poor control (HbA1c >=8%)
Number (%)	614 (41.3)	873 (58.7)
Age in yrs (SD)	68.6 (10.04)	65.3 (10.04)
Female (%)	241 (39)	400 (46)
Median duration of diabetes in yrs (IQR)	7.0(4.0-10.0)	9.0 (5.0-13.0)
Mean HbA1c % (SD)	7.2 (0.54)	9.4 (1.14)
Diet only (%)	148 (24)	27 (3)
Tablet treated (%)	397 (65)	536 (61)
Insulin treated (%)	69 (11)	310 (36)
GP care	90%	84%
Hospital care (total + shared)	15%	36%

Table 5 Glycaemic control achieved by different treatments in patients with stable Type 2 diabetes

Treatment	Good control (HbA1c <8%)	Poor control (HbA1c >=8%)
Diet only	89%	11%
Tablet + diet	50%	50%
Insulin + diet	29%	71%

As would be expected, most people on diet only were relatively well controlled; otherwise they would have been offered more intensified treatment. The

exceptions would be those with significant co-morbidity and limited life expectancy. Only half of the tablet treated group achieved good control leaving the same number in poor control, which should potentially have been offered insulin treatment. However, insulin treatment was even less successful at achieving good control with less than a third below the target level.

Patients remaining in poor control on oral hypoglycaemic drugs (OHA) are of particular concern. Two questions required answering. Were these patients receiving maximal oral treatment and if so should they have received a trial of insulin therapy? Table 6 looks at this group in more detail.

Table 6 Characteristics of stable Type 2 diabetic patients on oral treatment who remain in poor glycaemic control (means(SD) unless otherwise stated)

OHA	N (%)	Female	Age in yrs	HbA1c %	BMI	Duration of diabetes*
Sulphonylurea (SU)	194(36)	42%	68(9.9)	9.2(1.14)	27.6(4.21)	7.5(4.0-11.0)
Metformin (MF)	56(11)	41%	62(10.4)	9.1(0.99)	31.2(5.21)	6.0(3.1-8.9)
SU+MF	286(53)	46%	66(9.7)	9.5(1.17)	29.4(5.28)	8.0(5.5-10.5)

* median (IQR)

With 47% of patients on monotherapy, (36% on sulphonylurea monotherapy) there was a strong suggestion that oral treatment had not been maximized. Gastrointestinal side effects do occur in 20-30% of patients on metformin[139, 140]. However, only 4-5% of patients cannot tolerate metformin therapy with a gradual titration of dose[139]. This would suggest that there was room for further optimization of oral therapy for a substantial number of patients.

3.3.1. Glycaemic control and duration of diabetes.

Figure 4 shows the duration of diabetes for the whole Type 2 diabetic population with a median duration (interquartile range,IQR) of 5.0(1.5-8.5) yrs.

Glycaemic control is known to deteriorate over time[128]. This is clearly shown, for the total Type 2 diabetic population (figure 5), when comparing mean glycaemic control (HbA1c) over time.

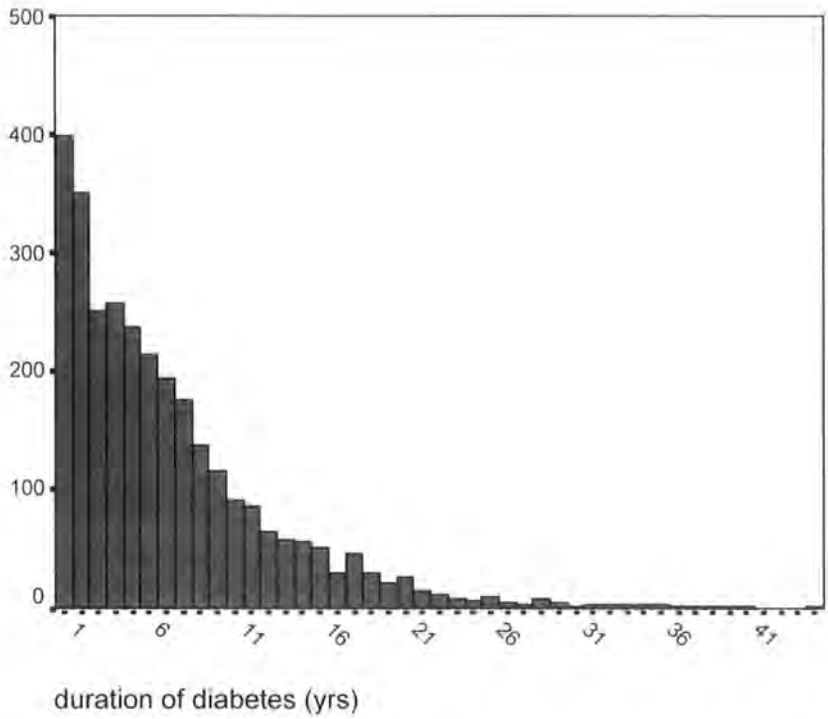


Figure 4 Type 2 diabetic population: duration of diabetes (n=3000)

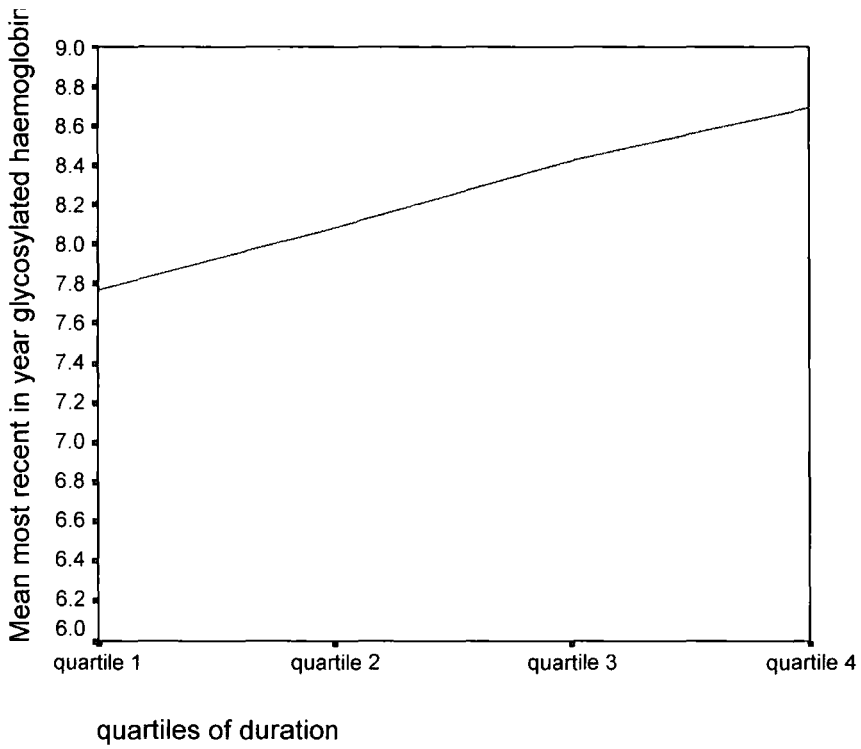


Figure 5 Total Type 2 diabetic population: glycaemic control over time expressed as mean HbA1c over quartiles of duration of diabetes

Looking at this in detail (figure 6), there is a small initial improvement in control over the first year followed by a steady rise in HbA1c over time.

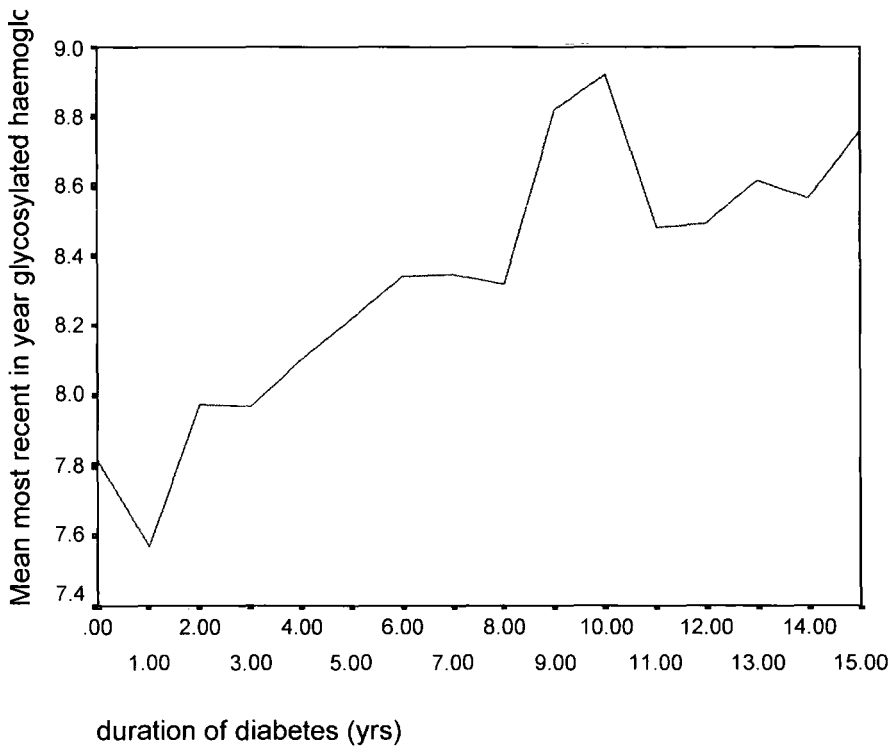


Figure 6 Total Type 2 diabetic population: mean change in glycaemic control (HbA1c) over a 15yr period

This was similar to the findings in the conventionally treated group of the UKPDS study[128]. However, the UKPDS patients had a significantly lower HbA1c at onset (HbA1c 7% v 7.8%) suggesting that patients were diagnosed at an earlier stage in their disease in the research study compared to routine care.

3.4. Conclusion

When studying a 'stable' diabetic population who had had their diabetes for three or more years and therefore should have been on optimal treatment, 59% remained in poor glycaemic control (HbA1c >=8%). Of those, 50% of tablet treated and 71% of insulin treated patients were poorly controlled. In the tablet treated group 46% were on monotherapy suggesting that oral treatment may not have been maximized.

In most regards the poorly controlled group differed little from those patients who achieve good control. However, they were slightly younger (65.3yr v 68.6yr), had their diabetes for longer (9.0yr v 7.0yr) and a higher proportion were on insulin (36% v 11%).

Regardless of level of glycaemic control the majority of patients remained under review by their general practitioners (good control 90%, 84% poor control). However, an increased proportion of poorly controlled patients were seen in secondary care (35% v 15%) under total hospital supervision or with some form of shared care.

This situation presented a challenge to future improvements in care. There were issues around maximizing oral treatment and how intensive treatment should have been from the outset. Also the question of earlier use of insulin treatment needed to be addressed. There were major workload and resource implications if all people with poorly controlled Type 2 diabetes were to be offered optimal treatment.

Chapter 4

4. Beliefs and attitudes of people with poorly controlled Type 2 diabetes

4.1. Introduction

Type 2 Diabetes is a chronic progressive disease causing significant morbidity and mortality. With the Western tendency to follow an increasingly sedentary lifestyle and the associated increase in obesity, diabetes is projected to double in prevalence by the year 2010[134].

Patients are initially treated by dietary modification but most require the addition of oral diabetic drugs to maintain control. Up to ten percent of patients per annum fail to maintain glucose control despite oral diabetic drugs[28]. It is well recognized that prolonged hyperglycaemia increases the morbidity and mortality of people with diabetes[141, 142]. This has personal costs but also puts a significant strain on NHS resources with almost 5% of total NHS expenditure relating to diabetes care[143].

Most patients in poor glycaemic control on oral treatment will require insulin. However, many patients remain in poor control for prolonged periods of time, there often appearing to be collusion between patient and physician to avoid insulin treatment[144]. Why is this? Clinicians' concerns have centred on patient compliance as a major issue. Adopting the traditional biomedical model, clinicians have regarded non-compliance as a patient failure to follow advice with the sort of moral judgment that this entails. Attempts to improve compliance by improving patient education have been largely unsuccessful. However, physicians' perspectives have been shown to differ from those of patients. A study of thirty Type 2 diabetic patients and their physicians showed that the doctors overestimated the difficulties patients had in coping with both diet and

treatment[122]. Similar findings came out in the subsequent study on health care professionals' beliefs where clinicians overestimated the difficulties patients experienced converting to insulin therapy. To bridge this gap it is important to understand how patients view the experience of living with diabetes. This study sought to investigate the influence of patients' beliefs and attitudes on their management of their diabetes.

4.2. Aims

To explore the experiences of people with poorly controlled Type 2 diabetes seeking to identify and understand their beliefs and attitudes to their disease and insulin treatment in the context of family practice.

4.3. Subjects and Methods

4.3.1. Subjects

After local research ethics committee approval I identified Type 2 diabetic patients in poor glycaemic control from a local district diabetes register representing a single Primary Care Group (PCG). I contacted general practices, one from each of the four main areas covered by the PCG. I invited them to participate in the study and supplied them with a list of patients in poor diabetic control in their practice from the district diabetes register. They were asked to identify suitable candidates from the list or from their own knowledge of patients. General practitioners made initial contact with their patients and after provisional agreement I contacted the patients by telephone outlining the study and supplying written information by post. I had no previous knowledge of patients. All patients contacted consented to participate.

4.3.2. Setting

The study population was drawn from a single PCG area in the North of England. The four general practices were broadly representative of the different areas comprising the PCG area: three urban practices and one suburban practice.

4.3.3. Focus group interviews

This study was exploratory and a qualitative approach was felt to be appropriate. Focus groups have been widely used in health care to assess understandings of illness and illness behaviour[145]. They were chosen for their ability to examine not only what people think but also how they think and why they think that way[146], using their unique feature of participant interaction to allow refining and clarifying of individual's views. The focus groups were held in the teaching centre of the local district general hospital in a small quiet discussion room. I conducted four groups over a period of four months with a total of 27 participants. This was a purposive sample of people with poorly controlled Type 2 diabetes, stratified by age (under and over 65yrs of age) and by treatment (tablet treatment or insulin injections).

4.3.4. Group process

After refreshments were served I introduced myself as a local general practitioner with a particular interest in diabetes. The object of the discussion was stated as the need to understand how people felt about their diabetes and its treatment with the aim of improving diabetes care. I made clear that the discussion was confidential and that no one would be identifiable in the final report. The discussion was directed by a set of semi-structured open questions (appendix 1 and 2). Initial questions were designed to put people at ease and

establish group cohesion. These were followed by general questions leading in to more specific issues. Groups consisted of six to eight members and lasted 75-90 minutes. Four groups were held at which point saturation was achieved with no new ideas coming forward. Audio recordings of the meetings were made for later transcription.

4.3.5. Data analysis

The audio recordings were transcribed in full and entered into the qualitative computer software programme QSR NUD.IST vivo (non-numerical unstructured data-indexing search and theory building) for analysis. Each group was initially analysed independently and then comparisons made across groups. Coding was performed using the editing organizing style described by Miller and Crabtree[147]. "Using the editing style, the analyst identifies new categories through direct interaction with and sifting and coding of the text." Codes were developed directly from the text by identifying relevant categories and themes in an iterative process between the text and the organizing process, bearing many similarities to grounded theory[148].

4.3.6. Validity and reliability

Full transcripts of the focus groups were used for analysis with the use of computer software to encourage coding rigour. Stratified purposive sampling was used to maximize variation and to ensure representative groups were studied. It was felt on theoretical grounds that views might differ between the younger and older age groups and that participants already on insulin treatment might have a different perspective from those considering it. Two independent analyses of the text were made by the researcher (DAJ) and an experienced primary care researcher (APSH).

Reliability was also assessed by comparing statements within and across groups[149].

Confirming and disconfirming cases were sought (deviant case analysis)[150] where views contrary to the researchers' explanatory scheme were given fair account, examined, and why they might vary was discussed[151]. Respondent validation was used to feed back the findings to participants to confirm that they represented a reasonable account of their experience[152]. All participants were posted a summary of the results. They were asked to indicate their overall agreement with the summary on a five point Likert scale from strongly disagree to strongly agree. Other comments were encouraged and space left for these on the reply sheet.

4.4. Results

Four focus groups were held involving a total of 27 participants. The groups were stratified by age and treatment type each with six to eight members in each group.

4.4.1. Demographics

Participants were fairly evenly distributed across the groups.

Table 7 Participant distribution by age, sex and treatment

	Age		Treatment		Sex	
	<65yr	>65yr	Oral	Insulin	Male	Female
n=	14	13	14	13	15	12

Table 8 Participant demographics

Age group (yrs)	Treatment	Age (yrs) mean (range) n=27	Duration of Diabetes (yrs) n=27	HbA1c (%) n=24	BMI n=24
65 & over	Oral	69 (65-67)	13.6 (8-19)	9.5 (8.4-10)	29.2 (28-32)
	Insulin	70 (65-75)	14.3 (9-25)	10.4 (8.7-12)	25.6 (18-31)
Under 65	Oral	59.5 (48-64)	5.9 (5.4-10)	9.5 (8.1-11.5)	32.7 (26-46)
	Insulin	55.5 (45-64)	11.5 (5.4-22)	9.6 (8.3-11)	33.6 (29-36)

Table 9 Demographics of the poorly controlled district diabetic population (HbA1c >8%)

Age group (yrs)	Treatment	Age Mean (yrs)	Duration of Diabetes (yrs)	HbA1c (%)	BMI	Sex (% female)
65 & over	Oral	73	10	9.3	28.1	52
	Insulin	72	15.8	9.5	28.9	53
Under 65	Oral	57	7.5	9.5	30.2	35
	Insulin	57	11	9.5	30.6	49

A number of concepts were identified relating to how participants perceived diabetes and how they evaluated information on management.

4.4.2. Themes identified

4.4.2.1. The nature of Type 2 diabetes

Type 2 diabetes has previously been regarded as a mild disease by both the medical profession and public alike due in part to its insidious onset and mild or even no initial symptoms. However, it is now recognized that Type 2 diabetes carries a heavy toll in terms of morbidity and mortality especially from cardiovascular disease. Indeed it has been termed *'the silent killer'[153].* Participants still viewed diabetes as mild disease.

> *P07G1: As an illness its nothing. ... I can eat almost anything so to me it's not a disease it's an inconvenience.*

> *P10G2: I can't say it really bothered me being a diabetic.*

> *P14G3: If the doctor hadn't have told me I wouldn't have known any difference. I still don't feel as if I've got diabetes. It doesn't seem to affect me much really.*

However, a minority expressed an alternative view.

> *P13G2: It is a serious problem. I think if you don't take your medication, like my sister who died a fortnight ago it starts affecting the rest of your body like your heart and kidneys and everything. I know that because the doctor has explained it all to me.*

4.4.2.2. Diagnosis and causation

Many participants had little initial knowledge or understanding of diabetes at diagnosis.

P16G3: I knew nothing about it at all. When I did get it I had all the symptoms and I hadn't a clue what the symptoms meant. Not at all. It wasn't until somebody told my wife it could be diabetes and we went to the doctors and found out that's what it was. But up until then I hadn't got a clue.

The exceptions were those participants with experience of diabetes through friends or family.

P21G3: I had a couple of friends that had diabetes so I knew about it but mine was discovered on a routine visit to the vascular clinic.

There was often considerable delay in initial diagnosis.

P03G1: I retired from work ill, never been diagnosed with diabetes and lost something like nearly 3 stone in a year and I was convinced I had cancer... the doctors didn't pick it up until I was getting sick money and the DSS sent for me after 6 month to keep the sick money going, (I) walk in there, give a urine sample, sat in the waiting room and the nurse came out and said 'Oh I think I'd like you to go and see your own GP you've got sugar'. She never said diabetes, she said sugar. Well I walked out thinking 'sugar? That's diabetes, I haven't got cancer!'

P01G1: What I found going to the doctors, in the end he said 'Oh its psychosomatic, its in your head'. And this went on and I just got to the extent that I just didn't want to go out of the house. ...one day I went to the doctors and I hadn't been feeling well. This had been going on for some time, hadn't it, and I went over and I said to the

sister in the clinic, 'will you test me for sugar' and she said 'Yes... I will' and it was diabetes. The doctors hadn't picked it up.

The impact of being diagnosed with diabetes is considerable. Participants recalled their initial shock and denial to being told they had diabetes.

P23G4: I didn't know anything about it at all and I was completely devastated. I was in denial for ages after they told me. I thought it was the worst thing that had happened in my life to be honest.

P05G1: I knew nothing about it at all ... so I was completely numb.

However, the majority rapidly came to terms with and accepted the diagnosis.

P27G4: I don't look upon it as a nightmare. It's something that's happened and you have to get on with it.

P15G3: I just felt cheated. I felt why should it happen to me, but once it's diagnosed you just get on with it.

However, one participant expressed ongoing denial.

P14G3: If the doctor hadn't have told me I wouldn't have known any difference. I still don't feel as if I've got diabetes. It doesn't seem to affect me much really.

Participants attributed their diabetes to a variety of causes. Diabetes 'running in the family' was frequently cited although the concept of inheritance was not specifically mentioned.

P02G1: My grandmother had diabetes and my mother and my younger brother who died last year unfortunately and I can't go back any further than that but it seems to be in the family you know and it unfortunately struck me.

P13G2: really I wasn't surprised about being a diabetic because it runs in the family. My mother was a diabetic, my brother was a diabetic and he went blind through it. I lost my sister a fortnight ago and she was a diabetic but she used to cheat a lot.

Psychological and physical stress was mentioned across groups as a common cause of diabetes.

P16G3: I think my heart attack brought on the diabetes.

P05G1: I had a stressful job for years and also I was suffering from a bleeding ulcer. And looking back I think that was the beginning of it because there is nobody in my family that ever had diabetes.

P12G2: I put my wife's (diabetes) down to the shock of the operation and the stress it caused

A variety of other causes were suggested included eating sweet foods, being overweight, excess alcohol and lifestyle. No mention was made of internal organ failure.

P03G1: If you take mine ... I would say 90% due to just 2 things. I had about 12 or 14 cortisone injections for frozen shoulder and tennis elbow and ... there was tremendous stress at work

P01G1: Well, a friend gave me some rhubarb and I cooked this rhubarb and we were going to have it as a sweet and it was really sour so I put sugar on, more sugar, couldn't get any sweetness at all. And I took an awful lot of sugar in that one sweet and I think this was the start of the diabetes.

P27G4: I put on quite a lot of weight that's perhaps why I got it.

One fatalistic view was expressed.

P22G4: Maybe nobody knows and maybe its just one of those things that comes out in people.

4.4.2.3. Relationship with clinicians

A dichotomy of views towards physicians was expressed. Family doctors were seen as knowledgeable and caring, giving patients the opportunity to discuss concerns. Participants felt they had a good relationship with their doctor. They generally viewed the doctor as having a particular interest in diabetes.

P06G1: Our doctor ... She is very good and gives plenty of advice. But she specialises in it you see.

P04G1: Our doctor is very good. There are two doctors and she specialises in diabetes and she's really good.

P02G1: I try to make out exactly what I want to know and we discuss it and whether it's over his time or not it doesn't really matter to him. That's how doctoring should be.

P08G2: I'm lucky, I'm looked after by Dr B and I think I have a very good relationship with him. He is a great guy and I would think I

could ask anything and he tells me the ins and outs of everything. I wouldn't want to see anybody else really.

In contrast, some saw their doctor as having little interest in or knowledge of diabetes.

P07G1: The doctor doesn't know a thing about diabetes and if I talk to my doctor he says please talk to the nurse, I don't know anything about diabetes.

P26G4: I find that they don't explain things. Even our own doctor, didn't explain the pros and cons or anything. I only found out by reading the pamphlets.

P03G1: ... its very, very difficult to get the right information, even off your own doctor. ... The doctors themselves, to me, the ones I've had, three different ones over the last 15 years, don't seem to know a lot about the diet.

One person mitigated this recognizing that family doctors inevitably have different interests and that not everyone can be 'a diabetes expert.'

P05G1: Yes, well I suppose every doctor is good at something specialised.

Practice Nurses were seen as 'specialists, giving helpful advice although perceived to be very busy by some.

P07G1: The diabetic nurse, I'm on my third one, and each has been very very similar: dedicated, they know what they are doing and what

they are talking about and very full of advice. Excellent. That's my personal experience. Doctors nothing, nurses brilliant.

Diabetic specialist nurses again were seen as knowledgeable but busy.

P24G4: When I first went on insulin, she was the only diabetic nurse around here for 3000 people. But they do have more now. She's very approachable.

The few comments made about dieticians were negative.

P03G1: They send you to some young girl and she says you can have three slices of bread in the morning, you can do this and that ... and it doesn't work

P23G4: They sent me to see the dietician and I felt all they were saying was that I was too fat. ... I feel that the dieticians are enemies to me.

Their advice was not seen as useful but this has to be viewed in the context of dietary change being the most difficult area in which to make changes.

4.4.2.4. Desire to life a normal life

Participants felt they were able to live a normal life despite making some lifestyle changes.

P17G3: Apart from taking pills I don't see any difference in my life whatsoever. ... It doesn't run my life at all

P22G4: When I was diagnosed and they were talking to me in the hospital they said that really it shouldn't affect your life and you

should be able to live a normal life. And I really feel that I do live a normal life.

P03G1: ... I slowly got round to accepting it ... and like now I try to live, I play golf four times a week; I try to live a normal life.

Others saw the changes as more radical.

P19G3: I think it's a case of changing your way of life.

4.4.2.5. Compliance

Participants did not see compliance as a major issue in contrast to clinician's views. They tended to gauge benefit by the presence or absence of symptoms. This is illustrated in a discussion on glycaemic control.

P26G4: ... I feel its all very well for them to say you must be doing this and be in between these two markers, but when I've tried to get in between 4 and 8 I feel unwell.

P23G4: I find that.

P26G4: If I let it get a bit higher, I feel fine. I think my body is telling me what it needs. I tend to lie a bit and say Oh its fine because that's what they want to hear. They are not interested if you say I usually run about 12 they say that's not good. But if I increase the insulin and get the reading down, I feel unwell and I don't want to feel like that.

P23G4: I'm exactly the same as you. If it gets below a certain level I feel unwell. I have to have it more or less on 10 or 12.

P26G4: I feel better on 12 but they say it's too high. I've got to work and don't want to get up in the morning and feel bad.

P05G1: You know your own body.

4.4.2.6. Diet

Lifestyle changes are recognized as being difficult to successfully implement. Some people found major changes in diet to be necessary but for others simply omitting sweet items was felt to be enough. Adapting to these changes was easier for some than others.

P19G3: ... (a) completely different diet to what I was brought up with. My grandmother used to have a pork butchers shop (and) my grandfather went fishing so that's how I was brought up meal wise. Now, I eat fish but olive oil and not lard. I use flora pro active, just a complete change in diet.

P15G3: You get to a point sometimes when you think what the heck can I eat. You get bored with the same food ...

P08G2: With a bit of organisation it's no problem really.

P07G1: I have to watch my diet but not critically, it's not that limiting. I can eat almost anything ...

An extreme view was that of consciously not eating the correct types of foods.

P22G4: I feel great but I'm not living as they want me to live. I'm overweight, which is bad. I'm probably not eating the right food, which is bad, but I feel well.

4.4.2.7. Exercise

Exercise was prescribed but suggestions were often felt to be unrealistic. Getting older and physical problems limited the range of possible activities, the most popular form of which was walking.

> *P10G2: ... when I came to the clinic here for the first time she said 'do an hours brisk walk every day.' But my brisk walking days are gone. I can walk, but not briskly, my hips and knees are getting worn.*

4.4.2.8. Drug treatment

A progressive intensifying of treatment was recognized, progressing from diet alone through increasing numbers of tablets and eventually to insulin injections.

> *P08G2: I find it goes in steps. It started off diet controlled and it's gone to small medication to medium medication, and now to as much medication you can look at before going onto insulin.*

Some felt regimented by the need to plan tablet taking and injections.

> *P15G3: But you clock watch on account of your pills though.*

Others felt drug treatment interfered little with their daily routine.

> *P26G4: I found them fine and I find it quite easy to regulate my diabetes. I've just changed onto a quick action insulin now because I just take it when I eat. I find that's brilliant.*

> *P19G3: Quite good really. The tablets have just about settled me out. Certainly it doesn't have a major effect on my life. I'm still working*

and still active. The only change really to me is my diet and my family's diet.

4.4.2.9. Converting to Insulin

Those on oral treatment feared the introduction of insulin, particularly the idea of needles and injections.

P21G3: My doctor said I think its time you went on injections: I said 'no way!'

P07G1: My immediate reaction was 'No'. I'm not going to take any insulin. 'No! I'm 55, I've had a good life ...therefore I've had enough. If it means that I have to stick a needle in me twice a day for the rest of my life and eat small sandwiches etc then I'm not going to let me or my family suffer to live with somebody like that. ...but at first it was terrifying to think that you are going to have to register the whole of your life in-between injections.

Several patients stated that they had actively resisted the change to insulin over a prolonged period of time.

P15G3: No. My doctor tried to get me on (insulin) for about 18 months and I fought him. I kept saying we'll try another couple of months doing this and that and I was trying different ways, watching my diet a bit more, being a bit more strict.

The exceptions were the symptomatic patients who saw a potential benefit in switching to insulin.

P17G3: Whatever is good for me, that's it. I've got to go and see the doctor next week and it's going to be whether I go onto insulin or not. ... if it's going to make me feel better that's all I'm interested in.

P23G4: To be truthful I was glad in the end. The tablets and diet weren't controlling it and I was ill. ...The only other option was the insulin and I was glad and I did feel remarkably better when I went on it.

However, there was usually a rapid acceptance of insulin once started and it was generally seen as beneficial.

P06G1: Well, I wasn't keen but once I found out it was doing me good you just accept it.

P05G1: You accept it and get on with it. ...If they gave me the option now I would opt for insulin instead of the tablets.

Although insulin overall was seen as beneficial some could see no benefit in changing to insulin.

P10G2: I don't think there would be any (benefit) as far as I'm concerned.

P11G2: Not for me either: more of a hindrance or a nuisance. Tablets are no problem, but to have to stop everything and go through the process of checking your blood and then having to take your insulin injection 4 times a day.

Concerns were expressed regarding needles and injections.

P01G1: The first time I saw this was when I was working and going into a toilet and seeing one of the girls injecting herself with this great big glass thing and needle and I thought to myself 'Oh my God I don't think I could do that.' ...how on earth do you stick a needle in yourself, it's horrible!

P02G1: My grandmother used to use needles like that and I used to cry and her legs were just one mass of bruises.

Again these were mainly from the patients still on tablet treatments.

P16G3: I was petrified because I cannot stand hypodermic syringes; I'm terrified of them. I could be an international sprinter if somebody produced a needle. I thought about the needle business and thought I can't be doing with this. I said if it's a needle, just leave it, I've had a fair innings. That's the affect needles have on me. I'd have sooner have kicked the bucket. Just leave me.

Several participants expressed concern regarding the risk of hypoglycaemic episodes.

P10G2: What worries me is going into one of these hypos, being the only driver

P08G2: I suppose, living by myself, my other fear would be what would happen if I did go into a hypo?

Many had no knowledge of hypoglycaemia prior to their first episode.

P07G1: Exactly. It's ok when you've had one, you know what it is. But when you haven't had one before and nobody has described exactly how it shows itself then its difficult. ... I was getting hot and then the next thing I fell under the table and they carried me out and eventually got me to hospital. And that was my first hypo ...

P02G1: Well, I've never had a hypo or anything like that. I get the shivers and shakes every now and then but as I've said I carry something with me or I suck a sweet or something and it goes off, then I have something to eat.

Some saw Insulin as giving them increased control over their disease, while others saw the opposite.

P15G3: But then again, if I went on the injections then the insulin is in charge of me, whereas I'm still in charge of my tablets. If I go on insulin then that's ruling me isn't it. ... I fought it for over a year just because I didn't want insulin being in charge of me.

Personal experience and the experiences of friends were influential in forming participants' opinions on using insulin.

P15G3: Even so, I know somebody now who has been a diabetic since she was 19 and she's on insulin and she's had readings of 30 and 40 she said and she's been in hospital a couple of times because she's had lows of 1 point something. So I thought if she's been on it that long and still having problems, where does that leave me.

P13G2: I saw a chap in a restaurant a few months ago. ...I just happened to look over and he just took this pen out and went through his trousers. ...I've always thought it was more complicated than that. ...I thought, well the doctor keeps threatening me with insulin and it always frightens me a little bit but since I've seen that bloke I've thought, well, its nothing that!

P01G1: The first time I saw this was when I was working and going into a toilet and seeing one of the girls injecting herself with this great big glass thing and needle and I thought to myself 'Oh my God I don't think I could do that'

4.4.2.10. Self monitoring

Those on insulin saw monitoring their blood glucose as valuable in helping to reduce the risk of hypoglycaemia.

P07G1: ... taking a blood test is the only way you know how to regulate your intake of insulin. Without those blood tests you have no control whatsoever.

P15G3: Yes and I keep my recordings in a diary. ...I've been testing 4 times a day. Because if I have the grandchildren, I cannot put them at risk by me having a hypo ...

Some however were disillusioned with testing, finding it painful and not fulfilling any purpose. There was negative reinforcement. Tablet treated patients tested and saw no change in the readings despite their best efforts. Insulin treated patients similarly made adjustments to their insulin dosage and again found no benefit. A few patients had given up testing all together.

P03G1: I've stopped

P07G1: You've stopped but you are still taking your insulin. So you don't care? ....

P03G1: My hands got so sore that I gave it up. Well I wasn't happy about this business about (blood sugars of) 3 to 15 and that and I went to the doctor ... He said well for a fortnight can you do it morning, dinnertime, teatime, nighttime so I said ok then. So I went through this routine punching my fingers 4 times a day and at the end of the fortnight I go to the doctor and this was still floating from 3 to 15 and 12 and he looks at it and he said I can't make head nor tail of that: just stay on the same insulin as that you are now. I couldn't pick my (golf) club up for a week after that!

P21G3: I don't test my blood at all.

4.4.2.11. Barriers

Eating out posed problems for some participants. There was reluctance to dine out in restaurants some feeling embarrassment particularly with injecting in public.

P01G1: We just stopped going out and having meals because of it. I felt embarrassed by it ...

P05G1: You could do it at the table now because you can do it so quickly that the people surrounding doesn't even notice what you're doing I've gone to many restaurant where I've had to inject myself just took the thing, put it in and nobody even saw me doing it.

P07G1: This is very interesting to me because, like you, I'm restricted my dining out purely and simply on the fact of timing. If I have my injection before I leave the house, how long is it going to take the restaurant to give me the meal and so on.

P03G1: I mean, one chap that I sat next to, we were talking about injecting through your clothes and that's all he did. He just shoved it straight through his shirt and that's it.

Some did not want to be singled out as 'diabetic' while others actively broadcast the fact, feeling that being open about the problem made it easier to deal with.

P03G1: The people you associate with, if you tell them about your diabetes, I've found it's quite a joke. Some of them say 'Oh I could do with a bit of that'. I've never seen people take offence about it. You get sympathy

P22G4: When I was diagnosed and they were talking to me in the hospital they said that really it shouldn't affect your life and you should be able to live a normal life. And I really feel that I do live a normal life. I have to tell people at work in case anything happens, but I'd rather not let anybody know to be honest. I can deal with it on my own, I don't like to talk about it and I just get on with it.

Others saw no problem in dining out simply making minor adjustments to their menu, the commonest being to miss the sweet course.

P15G3: It doesn't bother me. I just watch what's on the menu. If I find something on my plate that I'm not meant to have I give it to my husband or leave it.

One working participant felt there was discrimination in the workplace, mainly in relation to ignorance about diabetes.

P23G4: I find that there is a little bit of prejudice, "Oh, she's diabetic!"

Family and friends were seen as giving both positive and negative messages in regard to self-management.

P27G4: I have a friend of nearly 40 years and every time I would go I used to like a little cake with a cherry in the middle she used to make and even when I go now she always asks if I want one and she knows full well that I can't. That makes me cross. However, my family is very good particularly my daughters and my little granddaughters aged 5 and 7 that know what Granny can or can't have. My husband is good.

4.4.2.12. Potential complications from diabetes

Loss of limb was a major concern expressed across the groups gleaned from personal experience or that of friends and acquaintances. Cataract, retinopathy and blindness were a worry to some.

P03G1: I think the biggest fear is when a lad who retired from work with me stubbed his big toe and 6 months later he died of gangrene and within 6 month he died and that frightened me to death and he just stubbed his toe

P07G1: I attended this hospital and the first time I attended, in the waiting room there were 3 young men around the mid 20's and each had had their big toe amputated and they were waiting to have their dressings changed. And that was my first experience in coming to the diabetic clinic in England and to see 3 young men with their big toes amputated and walking on crutches was absolutely terrifying ...

P01G1: A girl that lived in village A, she had hard skin on her feet and it cracked and she got poisonous gangrene and she had to have both of her feet amputated. She didn't last very long once that was done. That rather frightened me when I saw that, consequently I'm looking at my feet with a scraper all the time getting rid of hard skin. But that was my first experience. ...It's going to affect me feet and lose my feet and this sort of thing. That's my only worry because I've got very little and almost no feeling in my feet at all and they get tingly and they get hot yet my feet are like ice.

P24G4: I had something to do with it. My mum got it after my dad died but that was just diet controlled and she never took any notice of the diet really because she was in her 70s but she didn't die of the diabetes, she died of a heart attack

Although several participants had experienced heart disease and stroke the link between these and diabetes was recognized only by a few.

P01G1: And 3 years ago I had a heart attack and that was the result of the diabetes and 6 month after I had a triple bypass and that's how it's gone up to now.

P13G2: It is a serious problem. I think if you don't take your medication, like my sister who died a fortnight ago, it starts affecting the rest of your body like your heart and kidneys and everything. I know that because the doctor has explained it all to me.

4.4.2.13. Locus of control

Decision-making was regarded as the doctor's responsibility. Participants showed anxiety in relation to taking responsibility themselves.

P15G3: I always leave myself in the doctor's hands it's a simple as that. He knows more about it than I do so I hope that what he suggests is going to be the best thing for me. All I can do is try it and if it doesn't work out - well ...

P07G1: Would we like a choice? Personally, I wouldn't ... I would always be concerned about did I make the right choice ... I would like the medical profession, in my opinion, to do their job and tell me what I should do rather than give me a choice.

4.4.2.14. Lay influences

Participants' beliefs were strongly influenced by their own past experience and also the experiences of friends and family. These 'lay aetiological perspectives' were particularly evident in regard to attitudes at diagnosis and strongly governed how people thought about complications. Attitudes to insulin were also significantly influenced.

P07G1: Can I give you my impressions before I was diagnosed? I only had very remote indications of somebody with diabetes. This was a colleague at work and my biggest impression was his

restricted diet. This is going back many years and at that time I was horrified to see him having for lunch very small sandwiches with very little filling and really critical amounts and he was restricted to that. If he felt like having a biscuit or something extra ... he had to refuse. And that to me was a terrible burden on any person's life to have to regiment his food ...

P13G2: Really the thing that frightens me most about being a diabetic is going blind. With my brother going blind through it.

P10G2: A's wife said to me, when I was telling her that I might have to go on it, she said you'd probably find it better once you got used to it.

P15G3: Even so, I know somebody now who has been a diabetic since she was 19 and she's on insulin and she's had readings of 30 and 40 she said and she's been in hospital a couple of times because she's had lows of 1 point something. So I thought if she's been on it that long and still having problems, where does that leave me.

4.4.3. Respondent validation

Participants were posted a summary of the research results and were invited to indicate their level of agreement with the findings on a five point Likert scale. Space was provided for additional comments on the reply slip. A reminder was issued after two weeks. 23 of the 27 participants responded (an 85% response rate). 21 of the 23 replies agreed or strongly agreed with the findings, with one respondent neither agreeing nor disagreeing and one strongly disagreeing with

the findings. The participant who disagreed with the results indicated that they felt diabetes had had a profound effect, viewing diabetes as '*affect(ing) your social life 100% and I found it hard to adjust to that.*'

The mean score for replies on the Likert scale was 4.2.

Other comments received were equally positive:

P08G2:I think the summary has 'hit the nail on the head.'

P15G3: Reading the report I felt as if I was back in the discussion

4.5. Discussion

4.5.1. Methodological issues

A qualitative approach was used, as this was an exploratory study of an area that has received little research attention. The object was to provide insights into participants' perceptions and interpretations of Type 2 diabetes and its management from the viewpoint of the poorly controlled patient. No claim is made in regard to generalisability given the sampling method. Our aim was more to expose the variety and diversity of interpretation.

Respondents were selected by their GP from their practice population of people with Type 2 diabetes in poor glycaemic control. All people agreeing to be approached regarding the study subsequently agreed to participate. Using a 'gatekeeper' [154], such as the GP in this instance, can introduce several problems. Firstly, there may be bias introduced by the gatekeeper choosing the 'most suitable patients,' e.g., the most eloquent or the most compliant patient. Secondly, an ethical issue, patients may be recruited without being given all the relevant information on which to give informed consent. This bias was limited to

the extent that General practitioners were asked to invite participants from a list of their failing diabetic patients from the diabetic register. Also, after their initial indication of willingness to participate, patients were given a full description of the study both orally over the telephone and a written explanatory leaflet by post before indicating their willingness to participate.

Systematic methods were used to increase the reliability and validity of the study. Participating practices were chosen from the four main geographical areas of the PCG. Stratification of focus groups was used regarding age and treatment type as it was felt on theoretical grounds responses may vary across these groups.

The researcher facilitating the groups being a GP introduces a potential for bias. Responses may have been different to a non-health professional. The GP researcher may in some circumstances be viewed as an 'expert' with an expectation of providing information, or may be seen as a 'judge' making moral judgments on participants and thus inhibiting comments[155]. However, a conscious effort was made to avoid these roles. The participants were not previously known to the researcher, and in such group discussion, there is a tendency for the group discussion to 'dilute' the effect of the researcher's persona as participants address each other during the discussion[154].

4.5.2. Main findings

Type 2 Diabetes was generally perceived as a mild disease. This has implications for how participants manage their diabetes. The Health Belief Model[92, 93] of illness behaviour has been shown to apply across a variety of medical conditions[94]. This postulates that two of the key factors affecting the likelihood of a person following advice are the perceived severity of the

condition and the perceived vulnerability of the person to the disease. Viewing diabetes as a mild disease is therefore likely to reduce adherence to both lifestyle change and drug treatment. Why did participants see their diabetes as a mild disease? Most expressing this view equated lack of symptoms to 'mildness' of their disease, as Murphy and Kinmonth put it: "no symptoms, no problem!" In their interview study of 46 people with Type 2 diabetes they found two variations in patients' perceptions of the seriousness of their diabetes: the extent to which patients primarily orientated themselves towards symptom control (a mild disease) or toward prevention of complications (a serious condition)[113].

The impact of being diagnosed with diabetes is considerable. Many people suffer symptoms of depression, anxiety and social withdrawal. Most work in this area has concentrated on children and adolescents suggesting that up to one third suffer significant psychological distress but that by the end of the first year virtually all recover[87]. In adults with Type 2 diabetes psychological distress is also observed but again sufferers tend to return to previous levels of functioning after adjustment[156]. The pattern of initial despondency followed by gradual acceptance and recovery was described in our groups. This should not be underestimated as the psychosocial impact of diabetes has been shown to be one of the best five predictors of mortality, ahead of many clinical indicators[71].

Participants perceived stress and the tendency for diabetes to run in the family as the commonest causes for their diabetes. There have been few studies looking at patients' views on the cause of their diabetes. Those that have, have investigated the views of minority groups[102, 103, 157, 158]. It is of interest to note the similarities in the ideas put forward. British Bangladeshis cited heredity

and stress to be commonly held causes of diabetes[157]. An ethnographic study of American Vietnamese people with Type 2 diabetes also highlighted stress as a major perceived cause[158]. In a study of Mexican-Americans, Hunt found heredity and diet frequently mentioned but qualified by an attempt to relate these to personal experience through provoking factors such as behaviours or events[102]. Stress has not been shown to directly influence the onset of Type 2 diabetes but animal studies have found stress interacts with obesity to produce glucose intolerance and hyperglycaemia[159].

Lifestyle issues are notoriously difficult to address. There were two themes to participants' views on dietary change. There were those who felt minimal change was necessary, simply avoiding sweet foods, and therefore viewed dietary change as having little impact. The second group saw the dietary change necessary as a total change to their normal practice and hence as a great imposition. Co-morbidity with increasing age was seen as a barrier to exercise with clinicians often setting unrealistic targets.

Conversion to insulin was seen as a last resort, was dreaded and all too often actively delayed as long as possible by participants. Barriers put forward were the fear of needles and injections, the inconvenience, particularly socially, the fear that insulin would be somehow more controlling than oral treatment and the risk of hypoglycaemia. Despite these barriers most participants saw insulin as beneficial mainly as a means of improving well-being. This concurs with the earlier work of Hunt et al. in an interview study of low-income Mexican-American Type 2 patients[160].

Concerns regarding complications stemmed from personal or lay influence. Seeing relatives or friends with amputations or visual impairment influenced

participants' anxieties towards complications more than health professionals' advice. The lack of appreciation of cardiovascular disease as a major diabetic complication (despite several members having personal experience of heart disease and stroke) is of concern.

Participants had at least one healthcare professional that they could relate to who was valued as a reliable source of advice. For some it was their GP, for others it was the practice or diabetic specialist nurse. However, participation in decision-making in the consultation was acceptable only to a minority. More involvement in the decision-making process has been shown to improve outcomes[161, 162]. Participants' attitudes may reflect the older age groups involved. Future generations may be more consumer-orientated and less willing to uncritically accept their doctors' advice. It is of interest that Peyrot found devolving control to health care professionals (an external locus of control) had a negative effect on diabetes control, whereas control lying with significant others such as relatives had a more positive effect[108].

How does the patient make decisions on self-care? The traditional bio-medical model sees the doctor / patient encounter as central, with the doctor as the 'expert' who 'knows best' and the patient as the passive, obedient recipient of that advice. In this context compliance is the norm and non-compliance is seen as deviant behaviour, the fault of the patient. However, default is in the eye of the beholder. Compliance was not a major issue for participants. To the patient the consultation is but one small part of the decision-making process. Other sources of medical advice are likely to be sought. Advice and treatment is received against the background of previous experience and belief. Lay informants contributed significantly to participants' beliefs about diabetes with

health professionals infrequently cited. This concurs with Greenhalgh's findings in Bangladeshi diabetic patients[157]. As Greenhalgh pointed out there may be more similarities than we at first surmise between diabetic groups across cultural or other divides. There is a danger that investigators may be so focused on finding something new or different that they fail to recognize the similarities, a concept Silverman terms 'tourism'[163]. Professional advice is likely to be discussed with family or friends before a 'cost-benefit' decision is made on whether to accept, wholly or in part, that advice. Patients use this 'reasoned decision-making' to make the best decision that they can[79]. As Stimson reflected "we therefore have to take account of the patient as a decision making individual living in a culture from which he is receiving information about health and illness[75]." Patients' beliefs are constantly being remodelled in an active process with the receipt of new information from both lay and professional networks.

There was a strong desire to live as normal a life as possible. An earlier study of fairly well controlled Mexican American diabetic patients noted patients' concern with the experiential and social aspects of living with diabetes contrasting this with health care professionals' preoccupation with glucose control and instruction on self-care behaviours[164]. Participants made sense of diabetes by fitting it into their daily routine, in the most part resisting the tendency for diabetes to control their lives while avoiding physical symptoms. In this study participants often made decisions based on symptom control. Some participants feeling unwell when their blood sugars were well controlled graphically illustrated this. They made a conscious decision to run higher blood sugars to avoid this malaise. Hunt found similar influences in an interview study of 51

Mexican American informants with type2 diabetes[76]. Murphy and Kinmonth found patients were either orientated to avoidance of short term symptoms such as malaise, tiredness or frequency of micturition, or to avoiding complications such as gangrene or blindness[113]: the former representing a short-term symptomatic approach, the latter a longer term preventive approach.

4.5.3. Implications for practice

It is clear that any population of people with diabetes will contain a diverse range of personal interpretations of the disease. Any strategy for care will need to explore, respect and build on these perceptions.

Empowering patients, giving patients the means to make informed decisions about their own care, has received more attention of late[165]. Where patients have been encouraged to participate in their care through asking their own questions outcomes can be improved[162].

We can no longer assume that poor outcomes are due to ignorance or lack of motivation[76]. We need to explore not only what people are doing, but also why they behave in the way they do.

This study of people with poorly controlled Type 2 diabetes suggests that their beliefs differ little from those of the general diabetic population maintained on diet only or oral therapy[113]. The beliefs of patients on oral drugs or insulin treatment were similar, out with the higher levels of anxiety that the oral drug groups had towards starting insulin. These beliefs also concur with many of the core beliefs seen in minority groups explored in previous studies.

The gap between patient and health professional perspectives has been documented[122]. An appreciation of the patient's beliefs and the underlying

lay aetiological perspectives is required if we are to successfully influence diabetes self-management. Interventions can then be better tailored to patients' needs. It is of concern that participants in this study based their decisions on the presence or absence of symptoms; lack of symptoms equating to good control. Consequently they viewed diabetes as a mild disease because they had few if any immediate symptoms. Beliefs are dynamic and open to influence by both professional and lay influences. Establishing patient beliefs should enable clinicians to provide context relevant information that is acceptable to patients and more likely to encourage behavioural change and help reduce the conflict and frustrations that surround the 'non-compliant' patient[113].

Chapter 5

5. The Failing Diabetic in Primary Care: health care provider beliefs and attitudes.

5.1. Introduction

In the United Kingdom, Type 2 diabetes affects 1.8 million people with an estimated 1 million currently undiagnosed[3]., comprising 2-4% of the population and up to 10% of those over 65 years of age. It causes significant mortality and morbidity, particularly from coronary heart disease, stroke, renal failure, blindness and lower limb amputations. It has major economic consequences with doubling of secondary care costs and for those of working age, significant loss of earnings. Many of these patients are elderly and the majority is cared for in primary care. Glycaemic control is often poor and there appears to be reluctance on the part of both patient and their doctors to tackle the problem when maximal oral treatment is failing[144]. The recent UKPDS study has shown that good glycaemic control can reduce morbidity from microvascular complications by 25%[128], and that tight blood pressure control can further reduce morbidity as well as reducing diabetes associated deaths by 32%[166]. Changing elderly and often frail patients to insulin therapy is not always seen as desirable because of concerns about the patient's ability to cope with the regime[167]. However, many patients feel better on insulin and the elderly generally do cope well with insulin[168, 169].

An assumption that doctors base their management strictly on medical science has been made, particularly with the current emphasis on evidence-based medicine [115, 116]. Ley, reviewing work on compliance of pharmacists, doctors and nurses found a high level of non-compliance: lack of knowledge, errors of interpretation and deliberate disregard due to beliefs or social

pressures being cited as some of the reasons for discrepancy. Doctors' beliefs have been shown to have a significant effect on outcomes. Kinmonth, in a questionnaire study of 34 general practice trainers, found that they had a more pessimistic outlook on diabetes than that found in an earlier study of hospital doctors[119]. They perceived that the disease carried greater risks and were less confident that tight blood glucose control would reduce those risks. Doctors have also been shown to vary in their beliefs. Weinberger compared 12 physicians who were 'more successful' with 12 physicians who were 'less successful' in achieving good glycaemic control in their diabetic patients[121]. Knowledge did not discriminate between the two groups but their beliefs about diabetes did. The successful group believed more strongly that strict blood glucose control would reduce the risks of complications.

Significant discrepancies have also been shown between doctor and patient goals for treatment. D'Eramo-Melkus, surveying 54 patients and their physicians, found discrepancies of 54% in overall treatment goals with a 57% and 43% discrepancy in the specific goals of weight loss and blood glucose levels respectively[123]. In a study of 47 Type 2 diabetic patients, nurses' attempts to exert considerable control during consultations were shown to be counterproductive and contribute to poorer outcomes[127].

Current guidelines clearly state that when good glycaemic control is not achieved on maximal oral treatment then insulin should be considered [170]. However, in practice, patients are seen who have continued in very poor control for long periods of time. It often appears there is collusion between doctor and patient to avoid insulin therapy[144, 171]. What difficulties and uncertainties do doctors have in treating the failing Type 2 diabetic patient particularly regarding

insulin treatment? It is this dilemma that the present study seeks to address. Understanding the attitudes and beliefs of primary care clinicians involved in diabetes care is important if implementation of current guidelines is to be improved.

5.2. Aims

This study sets out to describe the beliefs and attitudes of primary care clinicians (general practitioners and practice nurses) towards the care of people with Type 2 diabetes in poor glycaemic control on maximal oral treatment.

5.3. Method

5.3.1. Setting

The study was undertaken in North East England, an area with above average unemployment (6.7% v 3.9% for Great Britain). There were high rates of ischaemic heart disease and cancer, high levels of deprivation and higher than average general practice list sizes. The subjects were general practitioners and practice nurses working in primary care in Durham and Tees Health Authority areas. Durham has a population of 630,000 and Tees HA a population of 555,835. GP provision is around 49 per 100,000 population for both areas, in the lowest tertile of the country (46 to 64 per 100,000 population)[172].

5.3.2. Subjects

Ethical approval was obtained from the local research ethics committee. A list of general practices and general practitioners (GP) was obtained from the Health Authority, a list of GP trainers on the local Vocational Training Scheme and a list of Practice Nurses from a local Primary Care Group area. Practices were telephoned asking to speak to an available partner. The study was briefly

outlined and if that doctor could not participate they were asked to nominate one of their partners who was subsequently similarly contacted. No specific attempt was made to enrol doctors with a special interest in diabetes and only one doctor per practice was recruited as a purposive sample. Doctors agreeing to participate were then sent written information on the study. Similarly, GP trainers were contacted by telephone and invited to participate. Practice Nurses from all practices within the local PCG area and meeting regularly as part a Practice Nurse Support Group were invited, one from each general practice.

5.3.3. Focus group interviews

A qualitative explorative approach was felt to be most appropriate given the paucity of studies exploring primary care clinicians' views on diabetes care. Focus groups were used for their ability to allow participants to pursue their own concepts and priorities while allowing exploration of how points of view are constructed and expressed. They are particularly suited to the study of attitudes and experiences around specific topics[154]. The focus groups were held in an informal quiet meeting room with a relaxed atmosphere, in practice premises or in a university department.

5.3.4. Group Process

Refreshments were provided prior to the discussions. I introduced myself as a local GP conducting research into the management of Type 2 diabetes. However, I previously knew a number, but not all, of participants. The discussion was directed by a set of semi-structured open questions (appendix 9). The definition of what constituted a failing diabetic patient was intentionally not specified at the outset so as to obtain participants' own definitions and interpretations. Initial questions were designed to put people at ease and

establish group cohesion. These were followed by general questions leading in to more specific issues. With consent the groups were recorded for later transcription. Confidentiality was stressed with no individual identifiable in the final report.

5.3.5. Data analysis

The process used was similar to that used in Chapter 4. Participants were encouraged to freely discuss their views and opinions on Type 2 diabetes within the broad areas covered. The audio recordings were transcribed in full and entered into the qualitative computer software programme QSR NUD.IST vivo for analysis. Each group was initially analysed independently and then comparisons made across groups. Analysis began after the first focus group was held to allow emergent themes and concepts to be incorporated and explored in subsequent focus groups. An iterative approach to coding following the 'editing organizing style' described by Miller and Crabtree[147] was used. Codes were developed directly from the text by identifying relevant categories and themes in an iterative process between the text and the organizing process, bearing many similarities to grounded theory[148]. The transcripts were coded independently by the researcher (DAJ) and an experienced primary care researcher (APSH).

5.3.6. Validity and reliability

The approach followed reflected that used in Chapter 4. Full transcripts of the focus groups were used for the analysis. The qualitative computer software programme QSR NUD.IST vivo was used to assist with consistency and reproducibility of coding and cross-referencing. Purposive sampling was used to maximize variation and ensure representative groups were studied. It was

felt on theoretical grounds that views might differ between general practitioners and practice nurses because of their different backgrounds. GP trainers might be expected to be more up-to-date with recent developments in diabetes being concerned with teaching chronic disease care including diabetes management to their trainees. Focus groups were therefore drawn from all three groups of clinicians. Two independent analyses were performed on the same data to improve reliability. Reliability was also assessed by comparing statements within and across groups[149].

Confirming and disconfirming views were sought (deviant case analysis)[148] where views contrary to the researchers' explanatory scheme are given fair account, examined and why they might vary was discussed[151]. Respondent validation was used to feed back the findings to participants to confirm that they represented a reasonable account of their experience[152].

5.4. Results

Four focus groups were held involving 23 clinicians. Two focus groups with GP participants (groups 1 and 2) were held and separate focus groups held for practice nurses (group 3) and GP trainers (group 4). A total of fifteen general practitioners and eight practice nurses participated. There were between four and eight participants in each group. Original quotations were coded by type of clinician (D/N = doctor or nurse), gender (M/F), identification number, focus group number (e.g. FG3), and transcript paragraph number.

Table 10 GP demographics

Number (female)	Years qualified	MRCGP held	Training Practice	GP Trainer
15 (4)	12-41yr	12	7	4

Table 11 PN demographics

Number (male)	Years Qualified	Years in post as PN	Diabetic qualification*
8 (0)	6-28	2-14	7

Six out of seven held the ENB 798 diabetes qualification from the English National Board.

Table 12 - Summary of Results (*W = weak, M = moderate, S = strong support)

Theme	Construct		Collective support*	**Opposed views***
Organization of care	Place of diabetic care	Diabetic care should be delivered in primary care.	S	Nil
	Changing roles	Team approach, routine care devolved to nurses with a changing GP role.	S	Nil
	Resources	Need for increased resources to deliver changes.		
Attitudes to care	Attitude to diabetes	Enthusiasm for active management.	S	Nil
	What is a failing diabetic?	Uncertainty of definition.	S	Nil
	Whose fault is it?	A need to avoid apportioning blame.		
	Empowerment	Patients need to be empowered to take more control of their diabetes.	M	W
	Conversion experience	A major life event could influence diabetic control.	S	Nil
			M	Nil
Non-compliance	Clinician attitude	Difficulty judging compliance, with wide estimates of the scale of the problem.	S	W
	Patient attitude	Misunderstanding, ignorance or intentional decision?	S	Nil
Use of insulin	Benefit of insulin therapy	Insulin viewed positively by clinicians.	S	Nil
	Delay in instituting insulin	Patients seen as very reluctant to convert to insulin.	S	Nil
			M	W
	Initiating insulin	Doctors delay decision to start insulin.	M	W
		A role for the DSN in primary care.	S	Nil
Social factors	Family	Effect on diet	M	W
		Lay networks' sometimes spurious advice.	M	W
Ethnic minority groups	Cultural norms	Difficulty understanding and dealing with cultural differences in lifestyle.	M	Nil
	Communication	Language difficulties hamper effective communication	M	Nil
	Interpreters	Use of family members as interpreters can introduce family tensions to the consultation.	M	Nil
	Doctor frustration	The above difficulties can lead to significant doctor frustration to the detriment of patient care.	M	Nil
Treatment goals	Target setting	Targets need to be achievable to act as an incentive.	S	Nil
	Polypharmacy	The need for multiple drug therapy was seen as a major difficulty.	M	W
	The elderly	How aggressive should care be.	S	Nil

5.4.1. Themes identified

5.4.1.1. Organizational issues

5.4.1.1.1. The place of care

There was a strong feeling across the groups that Primary Care was the best place for routine diabetic care. It was seen as able to provide better care in regard to continuity, consistency, commitment and accessibility. Total care by the primary care team was seen as preferable for the majority of patients; with a minority requiring secondary care for more complex problems and very few requiring shared care.

> *'I think that the general tenure of the articles one reads is that if primary care can do it well it is probably a lot better than the routine hospital clinics that I used to go to as a student and as a houseman where it was a bit of a chore.'DM01/FG1/63*

> *'I believe we do provide a better service than the hospital and the patients have told us so...' 'DM01/FG1/63*

> *'We probably have fewer, now than ever, being referred to the hospital. I can probably count on one hand those patients who now have formal shared diabetic care with the hospital...' DM02/FG1/66*

> *'I think that care in general practice is probably much more consistent. In hospital outpatients we get the next SHO who does a six month job... I don't think they are really particularly involved in what is going on, whereas in a General Practitioner setting I think you have more continuity of care with both practice nurses and doctors who are there usually for years and years. The set up is friendlier and more accessible to patients.'DF03/FG1/69*

'I think that in the absence of serious complications I see no reason why it (diabetes) shouldn't be dealt with almost entirely in general practice.'DM07/FG2/73

5.4.1.1.2. Changing roles

An issue arose as to who should be responsible for the delivery of diabetic care in the practice situation. Increasingly, General practitioners were devolving routine care to the Practice Nurses.

'Our diabetes care is mainly given by one of our Practice Nurses and one of the other partners. We always do a joint clinic, although most of the care is done by the Practice Nurse.'DF20/FG4/38

'The care is largely devolved to the Practice Nurse.'DM22/FG4/54

'In our practice,... more and more routine monitoring is being done by the practice nurse'DM01/FG1/22

With the practice nurse looking after routine care, some doctors saw their role changing to look after the more complex issues. The question of intermediate care was raised in relation to doctors with a particular interest in diabetes holding PCG wide specialist clinics to both improve quality of care in primary care and to allow secondary care to concentrate on patients with complex problems.

'You've got to be an enthusiast... the enthusiast probably gets superb results, you know, he's intensely interested.'DM08/FG2/263

'Things that I think we do now... ought to be ... passed on to nurses so that the role of the General Practitioner, I believe, has to be changed.'DM07/FG2/73

I think with primary care pilots, different ways of providing care, ... you may actually get a community diabetic clinic rather than a practice diabetic clinic.'DM08/FG2/91

5.4.1.1.3. Resources

There was recognition that to actively manage Type 2 diabetes to current and future guidelines requires an increased input from all members of the diabetes team. The increasing numbers of patients diagnosed with diabetes was also seen as putting a strain on already stretched resources. It was felt that increased resources would be required in primary care to cope with this demand. This need was particularly highlighted in relation to the initiation of insulin therapy.

'I don't think we have the resources to commence people on insulin. We don't have the free time' NF12/FG3/340

'As we get more and more diabetics in our practice the nurse kind of groans every time you find another diabetic, they're just so busy at the moment,'DF20/FG4/100

'It's the time resource which is a problem, not necessarily the management of that individual's diabetes.'DM22/FG4/188

'I don't think we have enough specialist diabetic nurses. You get the impression that there's a feeling of helplessness almost.'DM07/FG2/205

Community resources for chiropody and dietetics were seen as inadequate with many participants' practices having insufficient support often with long waiting times for assessment.

'I think our problem is the resources you get - not enough dieticians' DM23/FG4/1005

'You take months and months to try and persuade someone to actually become a little bit more active and introduce the idea of actually doing something like LEAP (exercise on prescription scheme), and they go down to the fitness centre and they've got weeks and weeks to wait.' NF13/FG3/821

'We have audited it ... there are not enough chiropody appointments'. NF12/FG3//36

5.4.1.2. Attitudes to care

5.4.1.2.1. Enthusiasm

Doctors and nurses were enthusiastic about diabetes care, feeling they could deliver a first class service in primary care if adequately resourced.

'I think we are pedalling pretty fast on this. We've got lots of encouragement from the hospital consultant and the diabetic liaison nurse and the PCT (Primary Care Trust) is also encouraging us. We are, I think most of us, we are in the health promotion bit for diabetes which is not a financial incentive.'DM01/FG1/357

'You've just got to keep on trying really haven't you, with the failing diabetic.'DF03/FG1/590

However, it was recognized that not all doctors subscribed to this view and that some may accept lower standards.

'There, you know, are the partners who are quite happy at people running along with glycated haemoglobins of 9% or whatever and blood pressure of 170/95'DM23/FG4/750

Doctors saw nurses as enthusiastic and knowledgeable about diabetic management.

'We are delegating a lot to the nurse, we've got a very enthusiastic nurse.'DF04/FG1/78

'One of our Nurses has developed a really strong interest in diabetes and takes a great interest in it.'DM23/FG4/77

5.4.1.3. Defining the failing diabetic

There was some confusion as to what constituted a failing diabetic patient. Some saw it as a patient problem with issues around compliance and education. To others it was associated with disease progression out with the patients' control.

'A failing diabetic is often just failing because they don't realise it's important to be looked after.'DF06/FG2/97

'There is definitely another failing type who just reckons that the task is insurmountable and doesn't bother to try,'DM10/FG2/99

Some gave a more formal, biochemical definition of failure.

'Anything (HbA1c) between 7 and 8 is borderline and anything over 8 being poor control...'DM10/FG2/105

'If glycosylated haemoglobin is over 7 and they're on full dosage of sulphonylurea and metformin' DM23/FG4/256

The ethical dilemma of the patient poorly controlled on oral treatment who, after full counselling, decides not to go onto insulin was raised. Is this a failing diabetic?

'The fully counselled patient who doesn't want to go on insulin but has an unacceptable glycosylated haemoglobin, where do they fit into this, are they a failure?'DM21/FG4/263

Other patients were seen as being overwhelmed by what was being required of them.

'But they think, 'I can't do it at all, I'll just give in and not bother.'DF/06/FG2/101

5.4.1.4. Blame

Blame was mentioned in several contexts both in relation to the patient and the health care professionals.

'You always blame compliance and other problems on the patient or put the blame on you (yourself for) not doing it properly. You never quite know how the land lies.' DM10/FG2/237

5.4.1.5. Empowerment

It was felt that patients needed to be empowered to take responsibility for their own diabetes and that compliance issues were to some extent negated by patients informed decisions not to comply.

> *'The better motivated ones are really into it and they take great pride in showing you their book and their values and it reinforces, I think, they've got control.'DM01/FG1/346*

> *'I sometimes can see an improvement in compliance when they switch to insulin which underlines the fact that they contribute to the management of their illness. And they decide they've got to contribute a bit more to the management of their illness.'DM05/FG2/241*

> *'The patient's got to feel they are doing something, that they're managing it.'DF06/FG2/322*

> *'I think we've given a lot of diabetics control of their diabetes. In the past, it used to be the doctors and nurses that looked after them.'NF15/FG3/227*

> *'We're the gate keepers; we're giving them permission to take it on.'NF12/FG3/656*

5.4.1.6. A conversion experience

Some saw the need for a major event, such as a myocardial infarction or chronic leg ulcer, to effect good compliance: a conversion experience. Others thought shock-aversion therapy with explicit pictures of unpleasant complications was needed.

5.4.1.7. Non-compliance

5.4.1.7.1. Clinicians' attitudes

Clinicians found it difficult to assess levels of compliance and understand the size of the problem.

> *'It's difficult to know how much they are complying and whether their sugars are being controlled.'DM10/FG2/237*

> *'I think they comply reasonably well with tablets but I don't think they comply at all with diet.'DM21/FG4/946*

Polypharmacy was recognized as having a significant adverse effect on compliance.

> *We know compliance is worse the more things people have to take and the more complicated their regimes are.'DF20/FG4/400*

Views varied widely on the size of the problem.

> *'Was there a figure... just a few weeks ago...was it that 2/3 of Type 2 diabetics don't redeem their prescriptions?' DM19/FG4/380*

> *'I don't find compliance a great problem... on the whole I would say compliance is pretty good in terms of medication..'NF15/FG3/577*

5.4.1.7.2. Patient attitudes

Some difficulties in this area were felt to be related to a lack of basic education about diabetes and its treatment.

> *'I don't think it's always deliberate, is it?'NF12/FG3/584*

'...People that possibly have come in with the idea that they've got diabetes and if they take this course of tablets they will get rid of it, and then they stop taking it purely because it hasn't been explained to them sufficiently in the first place, they haven't grasped the fact that that's it, they've got it for life.' NF15/FG3/576

'The ones that actually genuinely say, "oh, I stopped taking those blood pressure tablets because I thought it was all right now" They're the genuine - they're not the problem... you can educate them.' NF12/FG3/597

Misunderstanding of provided information was also seen as influencing compliance.

'Misunderstandings cause the problem. Polypharmacy with hypertension is causing us an awful lot of problems, because there isn't the time to explain properly to them, half the time they don't remember - they need it writing down ... that they're having something added in and not changed... so there's a lot to do with the education in the first place when it's been prescribed, and I think you've got to keep reiterating that because they just forget, don't they?'NF18/FG3/579

A group of patients were seen to be keen to comply with advice. However, the difficulty of maintaining this effort, even for this motivated group, in the long-term was recognized.

'Some people are like that...I mean, once you've told them something, that's it. They toe the line. Not like the rest of us that cheat.'NF18/FG3/320

'Some people's compliance is to be very keen at first but when it becomes a chronic illness, they seem to lose interest'DM05/FG2/253

'Yes, there are no obvious consequences of not controlling it well to start with, are there? They don't realise.'DF06/FG2/251

'I mean it's a complete pain to have diabetes. ... you always have to be thinking about yourself, the way that other people don't. When are you going to eat? When are you going to have your injections?'DM08/FG2/287

Some patients were felt to be consciously disregarding advice, but their right to choose was recognised.

'I think one of the real difficult things with medications is if you know from your computer screen that they haven't ordered a prescription for the past five months and their control is really, really poor, and you're asking them about what medication they are taking and they are hand on heart saying, yes, they're taking it and they're describing it to you. There's nothing you can do...'NF13/FG3/609

'You can always tell when you get a death and there's 3 carrier bags full of stuff comes back in... So, maybe our failing diabetics aren't (taking their medication). But that's their choice isn't it?' NF12/FG3/598

'If you say, "it's a long time since you've had a prescription" - "oh, I had a backlog". And you think, where did you get the backlog from. It's very, very difficult, but, again, it's their choice.'NF13/FG3/610

5.4.1.8. Insulin

5.4.1.8.1. Insulin was viewed positively

Insulin therapy was seen as beneficial for the Type 2 diabetic patient in poor glycaemic control.

'I'm sure it's a good thing and I'm sure some of our people on oral hypoglycaemics that should be on it aren't on it ... it's a good thing to change them earlier rather than leave it... having had another year or so with high blood sugar levels which really aren't doing them much good.'DM01/FG1/171

'You can't beat insulin. It's the gold standard'DM02/FG1/288

5.4.1.8.2. Delay in initiating insulin

There was reluctance to initiate insulin treatment. In the past this had been linked to a lack of belief in the efficacy of insulin in this context. Here it was more related to a lack of familiarity with the practicalities of initiating insulin treatment.

'It's just that step in my own personal repertoire of things that I would rather put off. I think I subconsciously put it off more than I should.'DM01/FG1/171

'I'm the same as you in stalling suggesting changes to insulin. I think because of the advice we used to get re insulin resistance.'DM02/FG1/180

'I wouldn't actually take this decision myself ... partly, because it's a long time since I have done it'DM08/FG2/133

Patients were seen as very reluctant to start insulin. Health care professionals perceived patients as highly resistant to starting insulin, seeing it as representing failure and associating it with complications. The concept of collusion between doctor and patient in avoiding insulin was also raised.

'They've often been on oral hypoglycaemics for years and years and they nearly all know other diabetics who have been on insulin and have had major complications, and they see that as the beginning of a slippery slope. That's their resistance to insulin. They see that as being their point of failure almost. I think that some patients can be very persuasive to us to let you say you don't want me on insulin. The patients don't want to go on it. So there is a joint tendency that they don't go on it.'DM02/FG1/204

'I think probably they think it's the end, that's it, there's nothing else they can have after that.'NF12/FG3/304

5.4.1.8.3. Patients' fears

Clinicians saw patients as having two major fears regarding insulin, namely, a fear of needles and injections and a fear of hypoglycaemia.

' Surely, one of the biggest barriers is this fear of going onto needles for the rest of your life.'DM23/FG4/431

'It's a major step up in the perception of the patient. Now we've got to have injections'DM08/FG2/184

'I think the effect of getting older is that they hate the idea of hypoglycaemia as well. They get very frightened of that.'DF/04/149

'Fear of hypoglycaemia is another factor, we've got several patients I can think of who deliberately run their sugar high because they're terrified about having a hypo... it's just difficult to influence them.'P05G4

However, opposite views were expressed.

'...Patients find the idea of going on to insulin less problematic than they used to do. Whether that's because we prepare them... or whether there's more immediate information available... but it doesn't seem to be too much of a problem.'DM19/FG4/532

5.4.1.8.4. Support to initiate insulin

There was a perceived need for more support to facilitate the introduction of insulin. The role of the Diabetic Specialist Nurse in this context was highlighted.

'I certainly don't have the experience ... putting patients on insulin, what dose and when'DF04/FG1/499

'I think I need my hand held a little bit on that one. That's basically my attitude.'DM01/FG1/177

'It's (initiating insulin) where the diabetic liaison nurse is so invaluable. It make that step much easier to take.'DM01/FG1/171

'It's the process of getting them onto the insulin ... that's where we need the support... I certainly don't have the experience as you

rightly said, putting patients on insulin, what dose and when, we need a diabetic liaison nurse and she is going to be swamped'DF04/FG1/499

'If there is a problem with the diabetes we can usually sort it out between ourselves. That is, the General practitioners, the practice nurses and the diabetic liaison nurse.'DM02/FG1/66

'(Diabetic Liaison) Nurses are helpful ... they have the confidence where I don't in starting insulin'DM06/FG2/138

'We find her (the Diabetic Liaison Nurse) far more useful than the medical team at the Hospital,'DM23/FG4/83

5.4.1.9. Social influences

Family and friends were felt to exert significant influence over diabetic patients behaviour. This was generally seen in a negative light, particularly towards eating habits.

...The husband doesn't want to eat what she eats. So she has to cook different meals. DF03/FG1/224

'You know it's people who mean well say, "Go on have one, you know one doesn't matter ". I'm sure that they are easily persuaded. I think it's a lot to do with people around you.' DM05/FG2/122

Oh, it's very relevant, especially if you are a man and don't do any of the cooking. You just get what the wife gives you. DF06/FG2/311

Yes, I think so. I mean, more adversely than good, I think, if quite often they will come back with a tale saying "oh, so and so told me I

shouldn't be having this" and they're actually sticking to a really good diet, but there's these myths that are still going about and they'll get the wrong information from family and friends. NF15/FG3/450

5.4.1.10. Ethnic minority groups

Ethnic minority groups were perceived as presenting particular problems. Culture was seen a major influence with regard to body image and eating habits. The strong extended family exerted a particularly important influence.

'I think there might be a cultural thing that some people in the Indian subcontinent who regard being thin as being poor and being well built and fat as like successful ... they seem to not worry about being overweight and this has terrible consequences for them. They don't like the idea of having to slim right down again to be fit.'DM02/FG1/116

'It's just a totally different ball game isn't it, you just don't know what their underlying cultural beliefs about - about insulin therapy or giving injections'DM23/FG4/927

'I found race as well - a lot of the Indian people don't want to know about Insulin, they'll do absolutely anything rather than go on to insulin. It's supposed to be something to do with their culture isn't it, it's seen as a failure or something.'NF13/FG3/462

'We see patients twice a year and the family and friends are there all the time, you know, I mean, we are supposed to be more powerful figures, but I mean, it's quite difficult to overcome very different beliefs within the family.'DF20/FG4/919

5.4.1.10.1. Communication

Language difficulties were highlighted across the focus groups. Relationships with authoritarian figures, such as doctors, were felt to be more paternalistic and unquestioning than the more open, discursive relationship currently espoused in the UK.

'I mean, but also the ethnic groups often have different ways of communicating with doctors and nurses, aren't they, because there's a much more traditional, you just tell people what to do, there's not so much a tradition of negotiation.'DF20/FG4/937

'I suspect like Caucasians they choose what advice they take, and what not, and it all somehow gets mixed up in the interpretation of the translation...'DM22/FG4/958

5.4.1.10.2. Interpreters

The older Asian patient often had a poor grasp of English requiring an interpreter in the consultation. It was common for a younger member of the family to accompany a parent or grandparent to act as an interpreter. This was seen as a potential cause of difficulty and misunderstanding between doctor and patient and as a potential source of friction within the family.

'I find that the Asian groups, they're bringing an interpreter along ... usually a daughter or a son ...I think there's a lot of aggravation within families.'NF18/FG3/550

'(The) other big problem group is the Asian community. Family and friends there are very big influences ... it's always triangular consultations, it's a nightmare.'DM21/FG4/895

5.4.1.10.3. Frustration

Clinicians felt their lack of insight into the cultural aspects of the lives of ethnic minority patients hampered their ability to deliver good diabetes care and caused a degree of professional frustration. Perceived cultural beliefs were felt to be contradictory to current medical practice particularly in regard to body image.

'My other impression is that some of our foreign patients, Indians, Eastern Europeans, have an attitude problem. I'm sure it's not just communication because they can speak English, but they seem not to make an effort with diet, exercise and sticking to things. They seem to do badly as well.'DM01/FG1/104

'But, I mean, communication, they don't even speak the language, you've got a hell of a problem before you start,'DM21/FG4/896

'The ones who are really difficult are the ... young 'Westernverts' who have all been brought up in this country with a local accent, they're just totally suspicious of doctors, you know, Caucasian, you find.'DM23/FG4/950

5.4.1.11. Treatment

5.4.1.11.1. Achievable goals

The need to set achievable goals for treatment and the need for advice to be based on good evidence was emphasized, giving the example of the changing dietary advice over recent years.

'If you are going to try to alter people's lifestyles ... there's got to be good evidence that it's justifiable.'DM08/FG2/529

'Twenty or thirty years ago there was not a lot of evidence, but we put people on low carbohydrate and high fat diets, God! We probably did more harm than good!'DM08/FG2/520

5.4.1.11.2. Polypharmacy

The need for tighter control of not only glycaemia but also blood pressure and lipids was recognized. However, the inevitable polypharmacy that this leads to was highlighted as a concern both to patients and to clinicians themselves.

'Well, the frightening thing that's happened since the UKPDS is someone will come in to the clinic and the haemoglobin A1 is 7.8 and their blood pressure is 160/100 and the cholesterol is 6.2, and you think, well, how do I introduce the subject to 15 new tablets.'DM17/FG4//754

' I find (it) difficult telling people "You were okay but now I've got new guidelines and you need to have more medication.' DF03/FG1/431

'Polypharmacy with hypertension is causing us an awful lot of problems, because there isn't the time to explain (it) properly to them'NF18/FG3/579

There was recognition that this was not a universal view and that there were colleagues who might accept lower standards.

'There's also the doctor equation, isn't there? ... all the partners who are quite happy with people's blood pressure of 170/95 - there's that in the equation as well'DM23/FG4//750

5.4.1.11.3. Insulin and the elderly

The question of insulin therapy for the elderly engendered a range of opinions. Some felt treatment should be fairly aggressive regardless of age.

'There is no reason, age or not, why you should not be in better control.'DM08/FG2/128

'...you're not going to want to think you've been written off because you're 70 are you?'NF18/FG3/328

'I always say that as long as they are under eighty they are not old as far as I am concerned.'DF03/FG1/163

'...the elderly... They will often benefit from going on to Insulin. You might not actually improve their glycaemic control very much, but you will improve their symptoms, so it's worthwhile...'NF18/FG3/425

Others advised caution feeling that the elderly patient's ability to cope with more complicated regimes was often limited. There was concern over the higher risks of side effects and their potential for greater harm in the elderly.

'There are certain exceptions but the vast amount of people who are elderly they're not going to manage this...'DF04/FG1/265

'Older people cope with change much less well... can get much more confused... you do get hypos and potential side effects which can be very worrying... it raises the whole temperature of the situation. I think that you've got to be very certain the person understands he's going to be able to cope with it emotionally and intellectually...'DM08/FG2/199

A realistic estimation of the potential benefit to the elderly person of intensifying their treatment was felt to be necessary. Balanced against this was the need to assess the individual's capabilities, co-morbidities and social circumstances in drawing up a management plan.

> *'You know the old lady... her eyesight's very poor and she is dead set against insulin therapy. One wonders whether she will cope with injections...'DM07/FG2/124*

> *'I'm not going to hit an 80 year-old with complications (with insulin).'NF12/FG3/300*

> *'I think it depends on the person and their ability to enjoy life... You've got to be realistic, haven't you?'NF10/FG3/334*

> *I think you've got to look at the individual, and it's up to them, some people wouldn't want to go on the insulin, but it's a decision for the patient...'NF18/FG3/425*

5.4.2. Participant validation

The full results and discussion sections of the study were posted to participants inviting their comments and their overall level of agreement on a five point Likert scale. A reminder letter was sent after two weeks. 21 of the 23 participants replied, representing an 87% response rate. Two participants were not contactable having moved abroad. All 21 replies indicated agreement or strong agreement with the results. The mean Likert score was 4.24. Comments reinforced the strong support for primary care diabetes management but with concerns about the resource issues and the need for a primary care role for the specialist diabetic nurse. The difficulties of managing diabetes in ethnic

minorities were emphasized regarding communication and culturally relevant dietary advice.

5.5. Discussion

5.5.1. Methodological issues

There has been a relative paucity of information relating to clinicians' attitudes and beliefs in the area of Type 2 diabetes, particularly towards those patients who are in poor glycaemic control. Earlier questionnaire studies have looked at the beliefs of secondary care physicians about diabetes in general or Type 1 diabetes in particular[120, 121]. Views of General Practitioner trainers have been retrospectively compared to those of hospital physicians in a further questionnaire study[119]. This study specifically sought the beliefs of primary care clinicians towards Type 2 diabetes. As this was an exploratory study with the aim of exposing the variety and diversity of clinicians' views a qualitative approach was felt to be appropriate. Focus groups have not been used specifically in this area but have several potential advantages. Clinicians, used to small group discussion in their service work, would be at ease in this situation. Focus groups with their interactive approach allow participants to develop and refine their opinions. The influence of the researcher as a GP was also minimized as discussed below.

Given the methodological approach, no claim to generalisability was made in this study, but systematic methods of data collection and analysis were used to increase validity and reliability.

The researcher, as a fellow GP known to a number of the participants, introduces a potential for bias. Chew-Graham and colleagues investigated this

in the context of semi-structured interviews with primary care physicians [155]. Where the interviewer was recognized as a clinician interviews were broader in scope, providing richer and more personal accounts. The general practitioner was at times identified as an 'expert' and as such a judge of clinical decision-making. However, they were also seen by some to be judging the morality of decisions made by clinicians in their work. In the present study these potential biases were reduced by the choice of a focus group approach, which diluted the effect of the researcher's persona as participants tend to address each other during the discussions[154]. Moments were recognized within the groups when there were attempts to impose certain roles on the researcher, particularly that of the 'expert'. These were consciously resisted with questions being reflected back to the group.

5.5.2. Main findings

All groups felt general practice was the preferred place for care for the majority of people with Type 2 diabetes. They felt total care was practical for the uncomplicated patient with relatively few patients requiring shared care. This contrasts with many models of care suggested that have shared care between primary and secondary care as a major component. However, recent national policy with financial incentives to practices providing organized diabetes care has been influential[173]. Primary care was seen as offering several advantages. General practitioners and practice nurses were seen as enthusiastic and capable of providing high quality care and indeed this has been previously demonstrated[174]. The unique long-term relationships possible in general practice between patient, doctor and nurse were seen to be of particular value given the complexities of diabetes management. The need to

keep up to date with the rapid advances being made in diabetic care was seen as essential and there was a realization that not every general practitioner in a practice could be expected to be able to do this and there was a need for a degree of specialization.

However, resources were flagged up as a major obstacle to care. Doctors found diabetes care to be time consuming with inadequate time available for the increasing number of patients being diagnosed. With increasingly organized care in general practice, the detection rate for diabetes has increased significantly[175]. The annual consultation rate for diabetic patients in general practice is around double that of the average patient[175]. Insulin therapy creates its own resource implications. Some participants experienced long waiting times to access secondary care for initiation of insulin therapy. Community resources for chiropody and dietetics were seen to be unable to provide an adequate service for all patients. Increasing input from diabetic specialist nurses (DSNs), nurses, doctors and dieticians was seen as inevitable. The knock on effect on district nursing time was highlighted with the need for education for the housebound and for once or twice daily visits to give insulin injections to a substantial number of infirmed patients living alone.

Doctors were felt to be willing to devolve the majority of routine diabetic care to practice nurses who were seen as knowledgeable and enthusiastic. A developing role for the DSN as part of the primary care team was seen, contrasting with their more traditional hospital based secondary care role. Both doctors and nurses referred directly to the DSN where access was available. The DSN was seen as a valued resource, particularly at the time of initiating insulin therapy. With the widening role of the PN the general practitioner's role

was seen to be changing. The possibility of developing an intermediate role, with a small group of interested doctors running community specialist clinics was mooted. Indeed, this is now being seen in several other areas such as minor surgery and dermatology at the Primary Care Group level.

Insulin was seen as an effective treatment, which contrasts with earlier studies [119]. The publication of the landmark UKPDS trial is likely to have influenced this [128]. There was, however, a perceived reluctance to initiate insulin. In the past this was associated with concerns over efficacy but in this study it was related more to a perceived skills deficit, with lack of experience and training in insulin initiation. The DSN was seen as a potential means of overcoming this hiatus.

The suitability of insulin therapy for the elderly Type 2 diabetic patient generated a range of opinions. Many felt age, per se, should not be a barrier and that insulin offered advantages even in many over 80-year olds. This is in line with current evidence[176]. Others highlighted instances where insulin had been started inappropriately in frail patients with multiple pathology and a short life expectancy. All groups stressed the need to make a global assessment of the individual patient taking into account social circumstances, the patient's views and the potential benefits of treatment.

The need for patients to 'own' and take responsibility for their diabetes was felt to be important. Empowering patients to feel in control of their condition was seen as an important task for health care professionals. Realistic and achievable targets were seen as important if patients are to feel in control of their diabetes.

Ideas on how to define the failing diabetic patient varied considerably. Some saw this in strict glycaemic terms based on glycosylated haemoglobin readings, while others equated failure with lack of compliance or lack of understanding. There has been a similar lack of clarity and variety of definition in the literature[28, 36, 177]. Caution in translating trial results to individual patients was mentioned. It was felt these were not always representative.

Views varied regarding compliance with treatment. There was agreement that compliance was better for drug treatment than for diet or exercise. Some felt compliance with drug treatment was high, while others recalled studies suggesting up to two thirds of patients fail to take their medication regularly. Compliance was felt to be related to lack of information or education for some patients. Polypharmacy with multiple drugs for diabetes, hypertension and hyperlipidaemia was raised as a cause for concern, particularly regarding compliance issues. Compliance was a source of much frustration for doctors, difficult to assess, and a potential source of conflict with patients.

Participants saw diabetes as an important and serious disease. However, patients were perceived as viewing diabetes as a mild disease and that education was failing. It was felt patients gave diabetes a low priority and that this affected compliance. This equates with the 'no symptoms, no problem' patients described by Murphy[113]. Participants saw patients as being very reluctant to start insulin, fearing needles and the risk of hypoglycaemic episodes. They felt some patients saw insulin as representing failure, 'the end of the road', associating it with the inevitability of complications. Earlier literature does suggests that clinicians tend to be more pessimistic than

patients and overestimate the barriers patients have in complying with treatment[119, 122].

It was felt patient education needed to be improved to recognise the seriousness and progressive nature of diabetes. Some saw this happening through direct education; others felt shock tactics were necessary presenting patients with the dire consequences of severe diabetic complications. The 'conversion' experience of a major event such as a myocardial infarction or leg ulcer was seen as a boost to compliance, albeit late in the day. The need to be aware of the patient's own agenda was stressed.

Ethnic minorities were seen as a high-risk group that posed unique problems. Communication was seen as a major frustration and the use of interpreters, usually younger family members, was seen as an added problem where family agendas might colour interpretation. Interestingly, ethnic minority patients themselves, appear to have similar frustrations with the use of family members as interpreters[157]. Culture was perceived as hindering good diabetic control. There was a feeling that Asian culture viewed obesity as equating to wealth and this acted against weight reduction and dietary control. Bangladeshi people with diabetes have been shown to equate large body size with 'more health' while recognizing that 'too much health' is undesirable[157]. There appeared to be a general lack of understanding of ethnic minorities across the groups. By displaying, what on the surface, appear to be understandable frustrations doctors seem to have closed their minds to active and effective intervention in one of the neediest group of diabetic patients. There is some evidence from the transcripts that general practitioners disengage themselves from the active management of ethnic minority patients. Patients of ethnic Asian origin are

seen as a 'closed group' with whom 'normal' dialogue and clinical intervention is problematical and barriers are difficult to overcome. Ethnic minority populations are small in the practice populations of the participants and this may help to explain some of the misconceptions.

Differences might have been anticipated between the views of general practitioners without a particular interest in diabetic care and nurses specifically involved in diabetic clinics. General practitioner trainers might be more aware of issues surrounding diabetes care because of their teaching role. However, the themes discussed were expressed across the groups.

5.6. Conclusions

Overall, there appears to have been a change in how Type 2 diabetes is viewed in primary care. It was previously seen as a mild disease where tight glycaemic control was not necessary. Here, it is viewed as a serious disease in need of energetic treatment. Reluctance to initiate insulin is still apparent but the reasons have changed. In the past doubts existed about the efficacy of insulin for the Type 2 patient. Here insulin was seen as efficacious but there was resistance due to a skills deficit, a lack of confidence and experience in initiating insulin. There was evidence of Balint's concept of collusion between patient and doctor to avoid insulin which both regarded as problematic[178]. Compliance with the diabetes regime unearthed elements of uncertainty, guilt and blame. The size of the problem on the whole was underestimated and there was much discussion on whose problem it was and what should be done about it. Was it the doctor's or nurse's fault for not providing adequate education, or was the patient to blame for wilfully not following advice? Patient autonomy was highlighted and how this impinges on compliance discussed. Is

a patient who consciously makes an informed decision not to follow advice, non-compliant? The merits of a shorter happy life versus a longer but restricted life were discussed.

5.7. Implications for practice

This study suggests general practitioners were very positive about primary care management of Type 2 diabetes. They felt that high quality care could be provided for the majority of patients within primary care. Practice nurses were seen to have the skills and enthusiasm to take on much of the routine care of diabetic patients. However, the increasing diabetes workload was recognized which, together with the current inadequate and patchy provision of support services as regards dietetic and chiropody input, gave concern for the future. A large increase in resources was felt to be necessary. This is reinforced by the recent publication of the requirements of the National Service Framework for diabetes, which supports the increasing role of primary care in providing a better diabetes service[179].

With more patients requiring insulin at an earlier stage, secondary care will be unable to cope with the major increase in workload generated. Primary care will need to take on much of this work. There appears to be a willingness and enthusiasm to embrace the challenge but we identified a skills deficit with general practitioners reluctant and somewhat fearful of initiating insulin treatment themselves. This has educational implications. The development of a community role for the DSN was seen as necessary as a direct support for primary care clinicians, possibly linked to a community diabetes clinic run by general practitioners with a special interest in diabetes. Indeed, the need for a degree of specialization in diabetes was seen as an increasingly necessary

measure in dealing with the complexities of modern diabetes care. Increasingly one or two doctors within a group practice are likely to take on this role.

With the recognition that compliance with treatment is increasingly poor given the current complex treatment regimes and resultant polypharmacy, it was recognized that we needed to be adopting a more patient-orientated approach. Patients' perspectives and beliefs need to be identified, and used to empower them to take greater control of their own illness. The challenge is to translate this into routine diabetic practice.

Chapter 6

6. The management of the failing diabetic patient: can consensus be reached?

6.1. Introduction

A dilemma exists with regard to the management of people with Type 2 diabetes who are poorly controlled on maximal oral drug treatment. The landmark United Kingdom Prospective Diabetes Study (UKPDS) has shown that tight blood glucose control can reduce microvascular diabetic complications by up to 25% but fell short of showing a statistical reduction in cardiovascular disease morbidity or mortality[128]. However, several studies have suggested a link between high blood glucose levels and increased mortality[141, 180, 181]. The benefits to the patient of switching to insulin injections have been debated[167, 182]. There is an acknowledged reticence on the part of both patient and clinician to take this step resulting in patients remaining in poor glycaemic control for prolonged periods[144]. Views of patients and clinicians have been explored earlier in this thesis but how do these perceptions translate into everyday diabetes management? This study examines how these decisions are made in general practice and hospital diabetic clinics.

6.2. Aims

To ascertain the views of general practitioners (GPs), practice nurses (PNs), diabetologists, and patients in a group setting and to explore if a cogent management plan for people with Type 2 diabetes in poor glycaemic control on maximal oral therapy could be achieved.

6.3. Method

A meeting was arranged on the local university campus attended by patients, nurses and physicians and chaired by APSH. The structure was that of an informal round table discussion but the aim was to attempt to drive the participants towards a possible consensus plan.

6.4. Process

The results of the previous studies were presented, giving an outline of clinicians' and patients' beliefs. The discussion was then opened with clinical vignettes to stimulate debate. The meeting was audio recorded. A secretary was present to make notes to facilitate later transcription of the recording. The transcripts were analysed independently by both researchers. In addition, DAJ (the author) conducted one to one interviews with general practitioners and hospital consultants to widen the debate. The findings were fed back to participants and comments invited to provide participant validation.

6.5. Results

The consensus group was composed of three people with Type 2 diabetes, three general practitioners, two practice nurses, two diabetologists, a diabetic specialist nurse, and a public health physician. In addition, two general practitioners and two hospital physicians were interviewed separately.

6.5.1. Common themes

6.5.1.1. Lifestyle is difficult to influence

All groups of clinicians recognized their impotence at changing patients' lifestyle.

"I feel that talking to people; you can only ask so much of them dietary wise, if you make the control so rigid they are just not going to adhere to it." N01-143

"The simple things are to lose weight on a diet, which is not simple, stick to a diet, which is not simple, and to stop smoking, which is impossible! So all the time as doctors, we're telling patients not to do this and that and to do something they don't really want to do." C02-93

6.5.1.2. Whose fault is it?

Clinicians felt that patients could easily blame themselves for their 'failing' diabetes; that they were not trying hard enough with diet and exercise. It was also felt to be all too easy for clinicians to blame patients, that they were not complying with advice, and that this needed to be countered.

"Many patients do feel they're to blame don't they." NO3-55

"I think you've got to be very careful that you don't start to blame the patient otherwise you are just going to alienate them. ... I think it's making sure that the patient doesn't feel that they are letting you down. You have responsibilities to each other." N02-199

"Diabetes is a progressive illness and a deterioration in your indices and your measurements doesn't mean you are less of a person or a naughty person or a sinner ... but it is part of the process." GP02-124

6.5.1.3. Decision-making

Patients were not keen to switch over to insulin therapy but were accepting of this if their doctors advised it. They saw this very much as the doctor's decision by which they would abide. Patient participants' comments included:

> *"I think in the last analysis, I think the doctor is the one who decides when the time is ready. I would go along with that but I say I wouldn't be too happy but I would go along with it.2 P01-367*

> *"Well he's always given me that decision; I've never ever questioned it." P03-212*

All groups of clinicians felt that some form of joint decision-making should take place. They felt they were responsible for providing and interpreting relevant information and empowering the patient to make a choice.

> *"I think we should approach this as a partnership not as a sort of teacher/pupil relationship where the doctor says you've got to do this, but to empower the patient by explaining the nature of it... It has to be a partnership where the patient, the person with diabetes should I say, understands as much about diabetes as they need to know, as they want to know and then the decision is theirs." C02-93*

Clinicians raised the issue of compliance with treatment. This was interpreted both as a patient fault and as part of the decision-making process with patients making the final decision.

> *"That's the point we have missed, very strict compliance... She (the DSN) went to the person's house and kept on visiting and eventually*

found out it was a compliance problem above anything else." GP01-163

"There's another aspect of compliance and that is the information we have about compliance of patients from a study in Tayside called the DARTS study ... only a proportion of the patients are actually taking home enough tablets to give themselves ... what we are seeing are patients voting with their feet, to coin a phrase, or not voting with their feet, in not going to the pharmacy to collect the treatment. So they must feel well enough without it." C01-165,173

6.5.1.4. What is the value of insulin?

Current evidence was felt to have perhaps overemphasized the value of insulin treatment for the patient. What were the real benefits and risks to the patient?

"I have to tell you that I'm unimpressed by the evidence that very good control of Type 2 diabetes is necessarily what everyone would automatically choose for themselves." C01-105

"But I ask myself what would I do? Would I personally feel that I would rush to go on insulin at the earliest opportunity and intensively treat myself and I say probably not." C01-109

"Insulin is guaranteed to bring it down to normal if you take enough and if you take precautions not to have a hypo, but you are stuck with injections and you are probably stuck with weight gain and there isn't a quick fix on this. It's a very complex problem, which is why I like to share it with a patient." C02-115

"You've got to be convinced that you're actually going to make his life better by suggesting that he does tighten up on the control... I think this is what we've got to go for, to try and give him some idea of what his options really are and what its going to mean for him and offer him the choice." C01-203

6.5.1.5. Uncertainty on when to introduce insulin.

General practitioners and patients both felt that they put off making the decision to start insulin.

"I'd rather stop on tablets because I'm feeling alright but one day I might have to go on insulin." P02-58

"As long as things stay as they are I'd like to stay off insulin as long as I can." P01-68

"Very often we would agree that perhaps we would not make the referral yet, but we'll watch things over the next 4-6 months." GP02-132

However, general practitioners and nurses believed they were now referring patients for insulin earlier than they would have done previously.

"I think consultant A will attest to the fact that he gets loads more referrals now than before. I think if months ago you'd asked me the question I'd have teased them along, whereas I don't now." GP02-240

"I feel it (referrals) perhaps has gone up because the nurses' knowledge has increased and so you discuss it more with the doctor." N01-153

Consultants also expressed uncertainty when considering starting insulin in the asymptomatic patient.

"We all struggle though ... its not just the nurses and primary care physicians that are struggling because that patient comes to hospital so I go through the same rigmarole." C01-157

6.5.1.6. Motivation

Patients' motivation was seen as paramount in relation to successfully switching to insulin treatment. It was recognized that many patients did not possess the will to change and uncertainty on how best to manage these patients was voiced. Consultants felt this area was best explored initially in primary care before referral.

"Don't you think the whole thing boils down to motivation on behalf of the patient?" GP03-175

"The crunch comes is if you've got a patient who is asymptomatic and not too concerned really. I think the motivation issue is the key issue. Unless you feel you are referring them to be motivated you see, which is a pretty dubious concept, when you come to a diabetes clinic... You've then got to be convinced that the patient feels that there is an advantage for them and that decision has to be gone through to some extent with the patient in primary care because otherwise you simply have a cut off point, of HBA1C or blood sugar,

and lots of people get sent to the hospital clinic who really didn't want to go." C01-275,279

6.5.1.7. Lack of resources

Lack of adequate resources was seen as a barrier to good patient care in this area, both in the primary and secondary care arenas.

"I can't initiate it (insulin therapy) in primary basically because of my own lack of skill and the lack of skill in my team I have around me." GP02-124

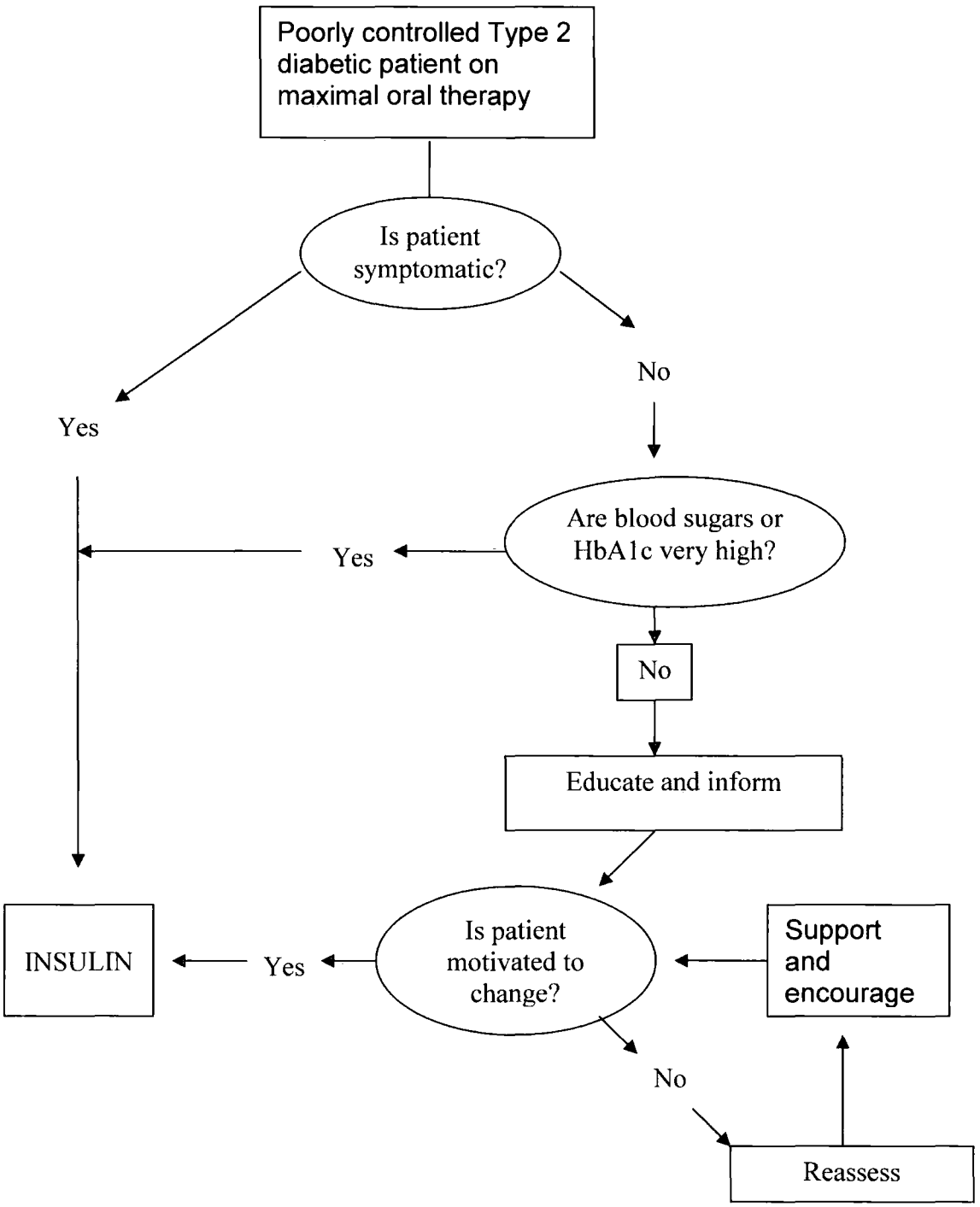
"But there isn't time in the universe between now and the crack of doom to explain this in detail." C02-115

6.6. Consensus management plan

The group discussed the options available for treating poor glycaemic control in the Type 2 diabetic patient on maximal oral treatment. The potential barriers to effective treatment were explored. Initiating insulin treatment was seen to be useful but not necessarily in every instance. There was complete agreement on its use for the symptomatic patient and when very high levels of blood glucose were present. When patients were asymptomatic, with moderately elevated blood glucose levels, consensus was less clear. Here patient views and motivation were seen to play an important part. Several tentative options were explored and a final plan was agreed.

Figure 7 Consensus management plan

Drawing on participants views, a flow-chart for the consensus management of the patient with poorly controlled Type 2 diabetes was arrived at:



6.7. Discussion

Diabetic care may appear to be an exact science but this group showed it to be quite a difficult concept to engage with.

6.7.1. Who does what and where?

The management plan threw up as many questions as answers. Although there was agreement that the symptomatic patient would benefit from insulin, much confusion and uncertainty remained in relation to the management of the asymptomatic patient (the majority of patients). General practitioners had difficultly deciding when to refer, and surprisingly, given their authoritative role in diabetic management, hospital physicians equally had many reservations. Decisions could not be made solely on grounds of high blood glucose levels.

Initiation of insulin treatment was seen as a secondary care activity. General practitioners did not feel they had the skills or resources to take on this work.

However, hospital physicians felt the limited available resources were already stretched and they had difficulty in managing the current secondary care workload, particularly in regard to informing and involving the patient in the decision process. If earlier intervention is instituted, the number of patients referred to secondary care is likely to overwhelm available resources.

A strong argument could be made for some form of intermediate care involving general practitioners with a special interest in diabetes to run community clinics together with diabetic specialist nurses. Whichever route is chosen resources would have to be made available to support the initiative.

6.7.2. Risk assessment

An important question raised regarded the presentation of information on risk to the patient. This has ramifications across many other areas of medical practice where risks have to be quantified, expressed and evaluated. There appear to be discrepancies between patient and physician assessment of risk. Physicians have tended to overestimate the diabetic patient's reluctance to accept insulin[119, 122]. Devereaux et al found similar discrepancies when looking at the acceptability of antithrombotic therapy for stroke prevention in atrial fibrillation[183]. Patients were willing to accept a lower risk reduction than physicians, to accept treatment, and also to accept a higher risk of side effects from treatment. How do we convey the concept of risk to the patient?

6.7.3. Shared decision-making

How should decisions on medical management be made? The concept of a partnership between patient and doctor is widely accepted and indeed has been adopted as national policy[184]. The exact form of this partnership is debated. Byrne and Long found the traditional paternalistic model in which 'the doctor knows best' was most commonly used[185]. The opposite of this traditional model is the 'informed choice' model. Here, the patient is presented with the relevant information and the decision-making process is vested entirely with the patient. This may lead to marked patient anxiety or even feelings of abandonment[186]. A middle ground is represented by 'shared decision-making' in which both parties actively participate in the decision-making process[187]. However, it is not a skill that is adequately taught in medical training. It requires the availability of reliable information and a readiness of patients to accept an active role in the process. Type 2 diabetes does have

many areas where this approach is applicable. However, the information needs to be made available and easily accessible particularly at the primary care level.

Patients in this group deferred to medical advice. It could be argued that this was due to these patients adopting the accepted medical role in the presence of doctors. However, similar views were expressed in patient focus groups held earlier. Consultants were surprisingly liberal in their advice, not presenting the traditional, more didactic opinion. Not every patient is happy to take on this active participation in decision-making and patient wishes need to be assessed and respected at the outset, otherwise needless anxiety and anguish may be engendered. So, in practice how feasible is shared decision-making? Elwyn et al have enumerated the difficulties with this approach[188], most importantly the extra time required, the lack of easily available risk information, and the lack of the necessary doctor skills. They concluded that new ways of communicating risk and improved communication skills were needed.

6.8. Conclusion

The management of people with poorly controlled Type 2 diabetes who are on maximal oral treatment is not straightforward and some uncertainty is evident. Shared decision-making between patient and clinician was seen as desirable. However, empowering the patient to share decision-making required readily accessible, reliable information, a change in health care provider consulting behaviour and a significant increase in resources to accomplish. The roles of

community and secondary care need to be reassessed to make best use of available resources for the benefit of the diabetic patient.

Chapter 7

7. Insulin treatment for Type 2 diabetes: what is the impact on quality of life?

7.1. Introduction

Type 2 diabetes is a progressive disease characterized by deterioration in glycaemic control over time for the majority of patients despite intensification of treatment[31]. The United Kingdom Prospective Diabetes Study demonstrated that tight blood glucose control in newly diagnosed Type 2 diabetes reduced microvascular complications by up to 25 percent although not statistically reducing cardiovascular morbidity or mortality[128]. However, a positive relationship between higher blood sugars and increased mortality has been demonstrated in several studies[181, 189]. Strict glucose control is therefore generally recommended[10]. However, interpretation biases have been highlighted suggesting an overoptimistic interpretation of the evidence[190]. When maximum oral treatment fails to control blood glucose, insulin by injection is usually necessary.

Discrepancies have been demonstrated between patient and clinician views on the priorities of diabetes care[101, 122, 123, 191, 192]. Clinicians are often concerned more with blood glucose control and inducing patients to improve their self-care procedures (diet, exercise, and drug treatment) whereas patients are more concerned with how they feel and their ability to maintain a normal life[164]. These quality of life (QoL) issues are particularly relevant to the introduction of insulin treatment with the need for injections and stricter blood glucose self-monitoring. Several studies have looked at QoL with the introduction of insulin. Some have shown improved QoL with better glucose

control[193, 194] while others have not[195-197]. Most studies have used generic instruments such as SF-36[198] but it has been argued that whilst such instruments allow comparisons across diseases they may be less suitable for measurements within a disease type[199]. Validated disease-specific measures of QoL are now available for diabetes[200]. This study used the Audit of Diabetes Dependant QoL (ADDQoL – described below) where patients rate only personally applicable life domains, indicating importance and the impact of diabetes[199]. It is likely therefore to give a more accurate reflection of the impact of diabetes specifically[201]. The Diabetes Treatment Satisfaction questionnaire [202] (DTSQ – also described below) was used to assess patient satisfaction with treatment, before and after the introduction of insulin therapy.

7.2. Aims

To compare the quality of life and glycaemic control of Type 2 diabetic patients in poor glycaemic control on maximal oral therapy, who elect to start insulin treatment with those who decide to continue oral treatment.

7.3. Study design

A prospective, parallel cohort study of people with Type 2 diabetes in poor glycaemic control referred for consideration of insulin treatment, comparing patients transferring to insulin with those who decide to continue on oral therapy.

7.4. Method

Ethical approval was obtained from the local medical ethics committee.

7.4.1. Subjects

Type 2 diabetic patients with failure of oral hypoglycaemic treatment referred routinely by their general practitioners to the hospital diabetic service for consideration of insulin therapy. Failure was defined as a glycosylated haemoglobin (HbA1c) of >8% over a period of at least twelve months, despite maximal doses of a sulphonylurea and/or metformin.

7.4.2. Setting

Two district general hospitals in the North-East of England were chosen as not currently undertaking diabetes research that would compromise the proposed study and were accessible to the researcher: the Memorial Hospital Darlington, County Durham and Bishop Auckland Hospital, Bishop Auckland, County Durham. They serve a population of 99,900 and 87,400 from Darlington Primary Care Trust (PCT) and Durham Dales PCT respectively (2001 National census figures). The age distribution of the population is similar to the national average, 98% white ethnic origin, 48% male, and unemployment slightly higher than the national average at 4%. The prevalence of known diabetes is around 3.2%, which again is close to the national average[3]. The diabetes service was provided at each site by an endocrinologist / general physician running outpatient clinics supported by two diabetes specialist nurses (DSN).

7.4.3. Process

Patients being considered for insulin therapy were referred directly to the diabetic clinic by their general practitioner and seen by the DSN. Initial consultations reviewed dietary advice, self care activities and oral treatment and these were maximized where possible. Insulin therapy was fully discussed

and a joint decision with the patient made as to whether or not to start insulin therapy, and which regime was used. The standard regime was to use a single daily injection of basal insulin analogue. A twice-daily injection of mixed insulin or, on occasions, a basal bolus regime was considered, depending on patient requirements and lifestyle. Insulin therapy was initiated and closely supervised by the DSN. She remained in touch with the patient until optimum control was achieved and then the patient was returned to the care of their general practitioner.

At the initial consultation, the study was explained to the patient by the DSN and time was provided to answer any queries. This was backed up by a written study information leaflet (Appendix 12). Informed consent was obtained and routine baseline demographic, clinical and laboratory data collected (Appendix 15). Patients were then asked to complete the study questionnaires.

Patients changing to insulin usually maintained one or more of their oral drugs. Metformin was continued for its ability to minimize the dose of insulin required and limit weight gain normally associated with the introduction of insulin. Sulphonylureas were continued if the patient was intolerant of metformin to again limit the insulin dose required. Continuing oral drugs facilitated the use of a simple basal insulin regime where this was felt appropriate. Patients deciding not to start insulin continued on maximal oral treatment.

Table 13 Study baseline data recorded for each participant

Demographic data

Study ID number	Living alone
Surname	Ethnic origin
First name	Occupation
Date of birth	Income group
Sex	Smoking status
Marital status	

Medical history

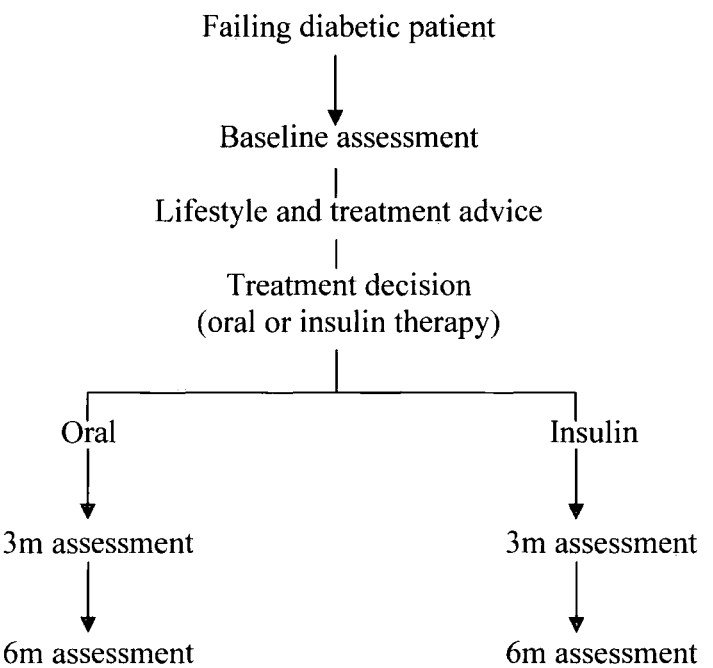
Duration of diabetes	Angina
Diabetic medication	Heart failure
Retinopathy	Peripheral Vascular Disease
Nephropathy	Stroke/transient ischaemic attack
Neuropathy	Locomotor pathology
Hypertension	Pulmonary pathology
Myocardial Infarction	Psychosocial pathology

Measurements

Height	HbA1c
Weight	Fasting plasma glucose
BMI	Fasting lipid profile
Waist-to-hip ratio	Total cholesterol
Systolic blood pressure	Hdl cholesterol
Diastolic blood pressure	Ldl cholesterol
	Triglycerides

All patients, regardless of treatment option, were followed up after three and six months. Questionnaires, clinical and laboratory data were repeated at each visit.

Figure 8 Study process flow-chart



7.4.4. Instruments

The importance of distinguishing between health status and quality of life is important when looking at a disease specific intervention such as change in type of treatment, particularly change from oral drugs to insulin therapy, with the need for frequent blood glucose monitoring and daily injections. Generic measures, though shown to be valid and reliable are influenced by significant morbidity, whether related to diabetes or not[201], and are less sensitive to smaller changes in relation to disease specific change[203]. Therefore they may miss important QoL changes when assessing the effect of change of

treatment. A patient may make sweeping lifestyle changes that they feel will improve their health, yet may impose restrictions on, for instance, their social life that may significantly reduce their overall quality of life.

Health status questionnaires measure how patients feel about their physical and mental health. People who feel their health is poor may also feel that their quality of life is also poor, but not necessarily so. It is possible that good health is maintained at the expense of QoL, with increased limitations particularly socially, and with increased anxiety about their health. Equally, patients may recognize their poor health yet still achieve a good QoL. The need for a specific measure of QoL is evident. One that is disease specific, by filtering out variables such as other co-morbidity, gives a more sensitive instrument to detect effects such as treatment change on QoL in chronic diseases such as diabetes. Change in QoL is important to detect, particularly if negative, and may affect areas such as compliance.

7.4.5. The Audit of Diabetes – Dependant Quality of Life (ADDQoL)

The ADDQoL questionnaire[199] was chosen as being a diabetes specific instrument with the novel facility to take in to account the importance of the various domains to the individual patient (including the ability to exclude areas not relevant to that individual). It measures general quality of life, the overall impact of diabetes on quality of life, and quality of life across 18 specific domains. Each domain is scored on a seven-point scale from -3 to +3. The domain is then rated for importance to the individual patient, from very important (3) to not at all important (0). Weighted scores are then calculated by multiplying the domain score by the importance score. The overall ADDQoL

score is calculated as the sum of the weighted ratings of applicable domains divided by the number of applicable domains. Scores may therefore range from -9 (maximum negative impact of diabetes) to +9 (maximum positive impact of diabetes).

Table 14 Summary of the 18 domain specific ADDQoL items and response options.

"If I did not have diabetes.....	..would (be).....
...my working life and work-related opportunities*	very much better – very much worse
...family life*	very much better – very much worse
...my friendships and social life	very much better – very much worse
...my sex life*	very much better – very much worse
...my physical appearance	very much better – very much worse
...the things that I can do physically	very much increased – very much decreased
...my holidays or leisure activities	very much better – very much worse
...ease of travelling (local or long distance)	very much better – very much worse
...my confidence in my ability to do things	very much increased – very much decreased
...my motivation to achieve things	very much increased – very much decreased
...the way society at large reacts to me	very much better – very much worse
...my worries about the future	very much decreased – very much increased
...my finances	very much better – very much worse
...my need to depend on others for things I would like to do for myself	very much decreased – very much increased
...my living conditions	very much better – very much worse
...my freedom to eat as I wish	very much increased – very much decreased
...my enjoyment of food	very much increased – very much decreased
...my freedom to drink as I wish (e.g. sweetened hot or cold drinks, fruit juice, alcohol)	very much increased – very much decreased
*these items include a 'non-applicable' response option	

7.4.6. The Diabetes Treatment Satisfaction Questionnaire (DTSQ)

Initial treatment satisfaction was measured using the DTSQ (status) questionnaire. Treatment satisfaction scores tend to be high generally and there was concern that a 'ceiling effect' may occur, confounding response to treatment change. The DTSQ (change) version was developed to prevent this. The DTSQ consists of six questions covering satisfaction with current treatment, treatment convenience, treatment flexibility, understanding of diabetes, recommending treatment to other diabetic patients, and satisfaction to continue present treatment. Each question is scored on a seven-point scale from 0-6 for the DTSQ status instrument, and from -3 to +3 for the DTSQ change instrument. Total score for each instrument is the sum of the individual scores (range 0-36 and -18 to +18 respectively). Two separate questions address perceived hyperglycaemia and perceived hypoglycaemia.

The DSN recorded the baseline data on to a proforma by hand. The proforma and questionnaires were then passed to the researcher (DAJ) and the data entered onto an SPSS spreadsheet for analysis.

7.5. Study Outcomes

A change to diabetes treatment involving daily injections and more frequent self-blood sampling is seen by many patients as a major hurdle to overcome. Variable results from previous work purporting to measure quality of life have given variable results. Many, in fact, were measuring health status as mentioned earlier. The study outcomes were based on changes in measures of quality of life and satisfaction with treatment. It was felt that a sensitive disease specific measure was required to investigate the effect that changing to insulin

therapy had on patients. The ADDQoL questionnaire was chosen to fulfil that role. How happy patients were with their treatment was also felt to have implications for longer-term compliance with treatment. The DTSQ was chosen as a well-validated instrument to measure this. Overall glycaemic control was measured to judge the effectiveness of the treatment change. Previous work suggests that this is not directly related to QoL.

7.5.1. Summary of study outcome measures.

a) The change in quality of life scores, as measured by the ADDQoL diabetes specific questionnaire.

b) The change in the DTSQ scores.

c) The change in glycated haemoglobin (HbA1c).

7.6. Sample size

The study was designed to detect a one percent change in HbA1c with 90% power at the 5 percent significance level. This required a study population of 60 patients, 30 in each group. We envisaged a recruitment of 3-4 patients per month from each site to achieve the desired study population over a period of up to 10 months.

7.6.1. Analysis

Data were entered into the SPSS 11 statistical software programme using a double entry technique. Data before and at the end of the study were compared using Student's t test and chi-squared tests as appropriate.

7.7. Results

7.7.1. Recruitment

The sample was calculated to need a recruitment period of ten months. However, it became clear that this would not be achieved and the study period was initially extended by a further three months. Recruitment remained low and the period was again extended by three months. At the end of this period (15 months from the start) a decision was made to close recruitment. The analysis is based on the numbers achieved at this stage. Reasons for recruitment difficulties are discussed below.

Choice of participant sites for the study was initially limited by involvement of several local hospital diabetic units in an ongoing research trial that would have compromised this study. Initially two recruitment sites were used but recruitment from one site (BAGH) was very poor despite regular encouragement. Only two patients were recruited from this site. This may have been related to a number of local practices beginning to initiate insulin themselves and the DSN adopting more of an outreach approach to support them in the community. A decision was made to continue with recruitment from a single site (DMH) and extend the recruitment period. However, recruitment remained slow with a significant drop out rate despite reminders being sent.

46 patients were enrolled into the study instead of the anticipated 60 patients, but only 20 patients completed the three-month assessment and 23 patients completed the six-month assessment. Only 14 patients completed both assessments. Of those patients completing assessments, 34 commenced insulin therapy and 12 remained on oral therapy alone. Because of these

limited numbers the study does not achieve the 90% power expected. The results obtained for the insulin group are, however, presented as a pilot study to inform future work.

The demographics and co-morbidity shown in tables 15 and 16 approximate to those found in the general Type 2 diabetic population who are in poor glycaemic control as illustrated by the North Tees figures discussed earlier in Chapter 3.

Just over half the patients were male, the majority living with their spouse, with only a small minority of smokers.

Table 15 Demographic details of insulin treated patients

	Number	Percent
Female	15	44%
Married	27	82%
Living alone	3	9%
Current smoker	2	6%

The high incidence of hypertension and ischaemic heart disease found mirrors that of the general diabetic population. The low study incidence of microvascular complications, particularly retinopathy suggests under-reporting. There was also a low reported incidence of other morbidity unrelated to diabetes.

Table 16 Co-morbidity of insulin treated patients

	N	Percent
Hypertension	25	74%
Myocardial infarction	4	12%
Angina	10	29%
Heart failure	7	21%
Peripheral vascular disease	3	9%
Stroke	1	3%
Locomotor problems	1	3%
Pulmonary pathology	1	3%
Psychosocial problems	3	9%
Retinopathy	4	12%
Nephropathy	1	3%
Neuropathy	4	12%

Medication at entry to the study again followed standard practice with three quarters of patients taking metformin or sulphonylureas, in combination if tolerated (Table 17).

Table 17 . Medication at entry to study

	Number	Percent
Metformin	24	71%
Sulphonylurea	25	78%
Glitazone	13	41%
Acarbose	1	3%

The study population was aged around 60yrs, having had their diabetes for almost 9yrs, and in poor glycaemic control with an HbA1c of over 9%. They were not overweight (BMI =24), differing from the average Type 2 diabetic population. Full baseline data are shown in Table 18. Blood pressure and lipids were well controlled.

Table 18 Baseline data at entry to study

	N	Mean	Std Deviation
Age (yrs)	34	60.6	12.47
Duration diabetes (yrs)	34	8.8	6.48
BMI	34	24.7	5.06
Systolic BP (mmHg)	34	138.9	19.07
Diastolic BP (mmHg)	34	79.8	8.09
HbA1c (%)	34	10.0	1.40
Total cholesterol (mmol/l)	34	4.7	0.83
Hdl cholesterol (mmol/l)	31	1.3	0.39
Ldl cholesterol (mmol/l)	30	2.4	0.75
Trigycerides (mmol/l)	34	2.5	1.18

7.7.2. Main outcome measures

Glycaemic control (HbA1c) improved significantly at three months by just over one percent and this was maintained at six months (Table 19). However, weight, increased by a mean 1kg and 5.6kg at three months and six months respectively (not statistically significant).

Table 19 Outcome scores for questionnaires, glycaemic control and weight for insulin patients

	n	Initial score	Final score	t	df	Sig
QA(sd)0-3m	20	0.25(0.967)	0.30(1.380)	-.170	19	0.867
QA(sd)0-6m	24	0.71(1.160)	0.88(1.296)	-.811	23	0.426
QB(sd)0-3m	20	-1.60(1.046)	-1.65(1.046)	0.203	19	0.841
QB(sd)0-6m	24	-1.67(0.917)	-1.33(1.01)	-1.282	23	0.213
ADDQOL(sd) 0-3m	20	-2.12(1.578)	-2.76(2.097)	1.675	19	0.110
ADDQOL(sd) 0-6m	23	-2.00(1.721)	-2.54(2.269)	1.511	22	0.145
DTSQstatus(sd)	32	27.1(7.08)				
DTSQchange(sd) 3m	21		10.3(7.40)	6.395	20	0.000
DTSQchange(sd) 6m	25		11.5(6.00)	9.599	24	0.000
HbA1c%(sd) 0-3m	20	9.9(1.27)	8.9(0.84)	4.014	19	0.001
HbA1c%(sd) 0-6m	24	9.9(1.46)	8.6(1.60)	3.201	23	0.004
Weight kg(sd) 0-3m	18	83.3(16.49)	84.3(18.01)	-.823	17	0.422
Weight kg(sd) 0-6m	25	80.5(14.15)	86.9(22.54)	-1.394	24	0.176

There were two single item QoL questions. Present QoL on entry to the study (QA) was assessed as slightly better than the mid line ('neither good nor bad') and did not change significantly during the study. QoL if the person had not had diabetes (QB) was assessed as -1.6, being between 'a little better' and 'much better', again showing no significant change over the study period.

The initial ADDQoL scores showed a positively skewed distribution towards a small negative effect of diabetes on QoL. No participants scored a positive score.

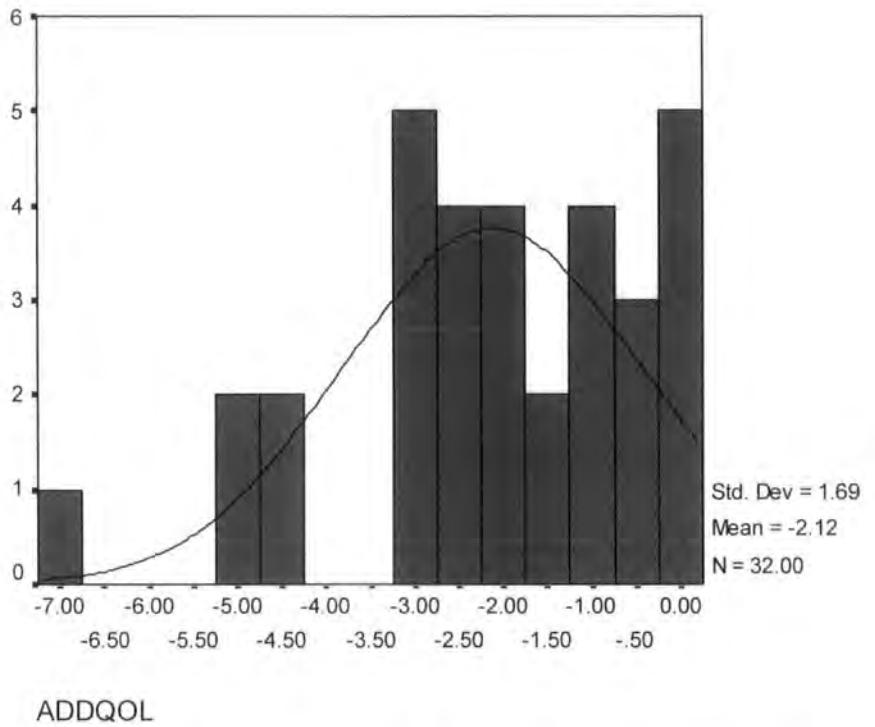


Figure 9 ADDQoL scores at 0m, with normal distribution curve

At 3 months the ADDQoL scores remained positively skewed, but less so than at the start of the study.

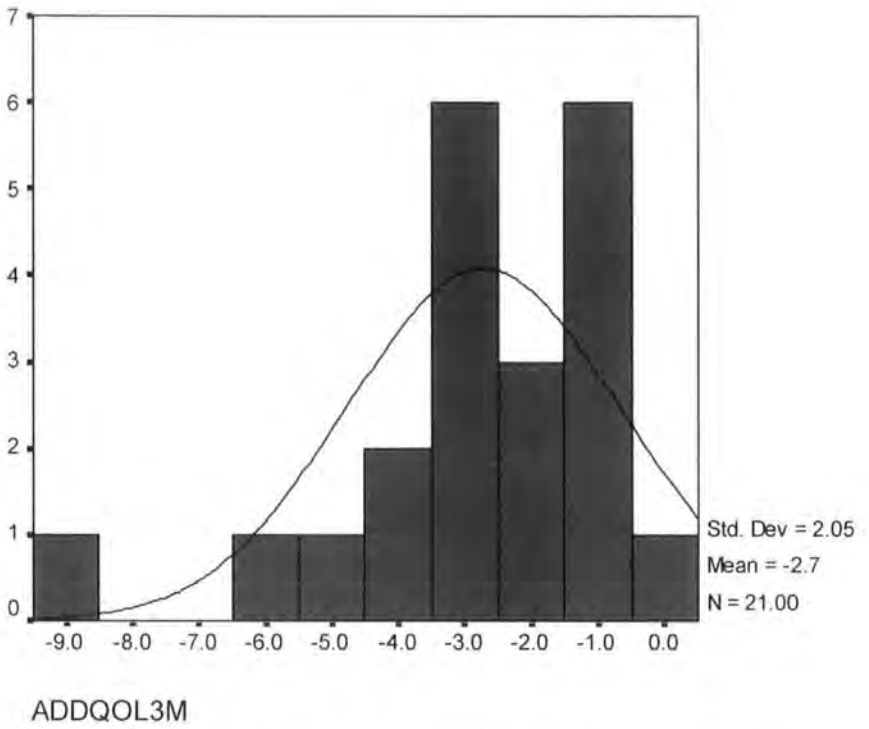


Figure 10 ADDQoL scores at 3m, with normal distribution curve

The 6-month ADDQoL scores remained very similar to those obtained at 3 months.

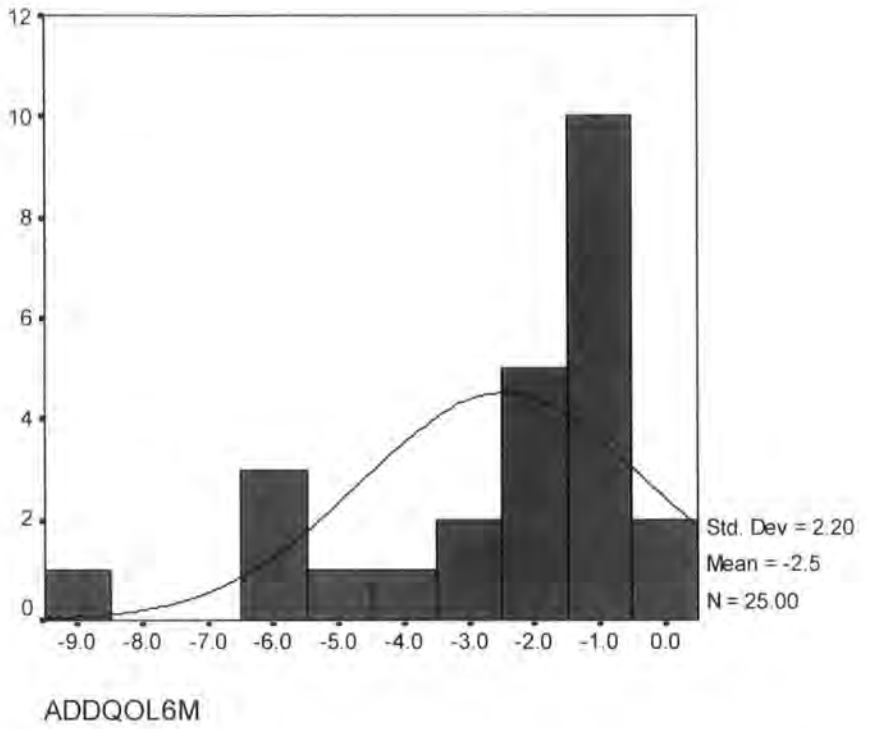


Figure 11 ADDQoL scores at 6m, with normal distribution curve

The main ADDQoL and DTSQ scores were positively skewed from the expected normal distribution. Therefore data were transformed using reflection and square root to produce a more normal distribution prior to use of the t-test for analysis.

The ADDQoL quality of life measure is scored on a scale of -9 (maximum negative impact of diabetes) to +9 (maximum positive impact of diabetes). Initial scores showed a very small negative impact that increased slightly but not significantly during the study.

Treatment satisfaction measured by the DTSQs (status) is scored from 0-36. Satisfaction with treatment scores at enrolment was high at a mean (sd) of

27.1(7.08). The DTDQc (change) was used to assess change in satisfaction at 3 and 6 months. This showed a 10 and 12 point change respectively, both figures being significant at the p>0.000 level, indicating an increase in satisfaction with treatment after starting insulin therapy.

Perceived frequency of hyperglycaemia and hypoglycaemia are measured separately in the DTSQ. Initial perception of frequency of hyperglycaemia was high at over 5 (maximum of 6), while the perceived frequency of hypoglycaemia was very low at 0.57 (maximum of 6). The values changed insignificantly over the study period.

7.8. Discussion

The poor recruitment and high drop out rate limit the conclusions from the study. The study was 'blighted' by fast moving changes to the management of diabetes within the primary car environment after the study was launched.

7.8.1. Problems with recruitment centres

The study period was a time of change in the NHS and with hindsight an over-optimistic expectation of the hospital staff was made. The implementation of the Diabetes National Service Framework (NSF)[22] highlighted the need for improved glycaemic control and the introduction of the new General Medical Services contract[204] for general practice had the effect of concentrating a greater proportion of diabetes care in the community. Relying on only two sites for recruitment (with only one site effective) was a mistake, but the obvious option at the start of the study. The very poor recruitment from one of the sites is likely to have been influenced by an increasing trend to insulin initiation within general practice noted in that area; cognizance of this may have altered the

choice of recruitment sites. Unfortunately, these factors were beyond our control once the study commenced.

7.8.2. Recruitment

Recruitment from the main site (DMH) averaged three patients per month. This was at the lower estimate for recruitment allowed for in the study plan. However this was only half that needed and the study had to be closed for practical reasons before the estimated 20 months that would have been needed to enrol the desired 60 patients. Stretching the fieldwork to 20 months would have meant doubling the study duration from the originally planned ten months; in the end we were able to continue recruitment for 15 months. These problems were also symptomatic of dropping levels of patient participation in research studies. Questionnaire returns have dropped from the 70% level previously expected, often to levels as low as 30% in some studies.

7.8.3. Drop-out rate

The drop out rate was higher than expected and would have required a significant increase in patients recruited to obtain the required number of participants to fulfil the power requirement of the study. The return rate of questionnaires was poor. Initially it was proposed that participants would complete questionnaires in the waiting room prior to their appointment with the DSN. However, clinic time was an issue and participants were given the questionnaires to complete at home. Subsequently many were forgotten when patients returned for their next appointment or, the appointment was missed altogether. Reminders were posted to those who did not return the questionnaires and where possible, telephone contact was made to encourage

return of all questionnaires. 53% failed to complete the three-month questionnaire and 33% the six-month questionnaire. The picture was further complicated by the fact that only 31% completed both questionnaires, thereby preventing comparison of results at three and six months. With hindsight it may have been better to have simplified the study design and to have made only one post-treatment assessment at 6 months.

Few of our patients opted to stay on oral therapy. This probably reflected selection at the primary care level by general practitioners and practice nurses prior to referral: essentially these were patients being channelled for conversion to insulin.

The improvement in glycated haemoglobin of 1% concurs with earlier work[31], as does the associated weight gain of up to 5.6kg (although not statistically significant in this study).

Quality of life was perceived as slightly negative at the initial stage, with a small non-significant deterioration over the study period. Earlier work has given conflicting results but often did not use disease specific instruments[193, 194, 196, 197, 199]. Satisfaction with treatment was generally high on oral treatment yet improved significantly on insulin therapy.

A direct association between glycaemic control (HbA1c) and QoL has not been confirmed[195, 197]. However, the presence of symptoms of hyperglycaemia can predict the strength of association between glycaemic control and QoL[197]. It would possibly have been useful to have used a diabetes symptom checklist in our study to assess this potential influence. The perceived level of hyperglycaemia as measured in the DTSQ was high but did not change during

the treatment period. The modest fall in HbA1c of 1% in our study would go some way to explain the low level of perceived hypoglycaemia reported.

Patients changing to insulin therapy tend to be in poorer glycaemic control and have a lower BMI than patients continuing on oral therapy[197]. Our study population supported this regarding BMI, and similarly showed a significant reduction in HbA1c on insulin, at the expense of weight gain.

It is increasingly realized that diabetic complications are related to total glycaemic exposure rather than current glycaemic levels[205]. Even small improvements in glycaemic control can bring significant benefits in health and health costs. Health status may improve but concern remains about the effect of more intensive treatment on the effects on patients' QoL. Research into tighter targets for glycaemic control needs to assess diabetes specific QoL to fully assess the impact of such treatment.

7.9. Conclusion

The study was limited by low recruitment. This was a significant learning point. It was largely out of our control as these changes occurred after the study was launched. Nonetheless, with hindsight, it may have been better to have conducted the study within the primary care setting directly. In the current climate the trend in diabetes care has shifted significantly towards primary care including the initiation of insulin.

Within the constraints of the reduced subject numbers the following points were ascertained:

a. In routine hospital care, the initiation of insulin resulted in a small but significant improvement in glycaemic control of one percentage point in glycosylated haemoglobin but at the expense of weight gain.

b. The introduction of insulin treatment was not associated with a change in perceived quality of life after three or six months of treatment.

c. Patient satisfaction with treatment was high on oral treatment despite poor glycaemic control but improved significantly after the change to insulin therapy.

Chapter 8

8. Discussion

This research was conducted to gain a better understanding of the plight of the diabetic patient in poor glycaemic control despite maximal tolerated oral therapy. The aim was to ascertain the size of the problem, to understand both patient and health carers' views about diabetes and in particular their views around the thorny issue of starting insulin treatment, to look for a consensus on management, and to address issues of the effect on quality of life when patients are changing to insulin therapy.

The overwhelming evidence from the literature stresses that lifestyle advice and treatment advances alone cannot achieve the best outcomes for patients. An understanding of patient and health care professionals' beliefs and motivations is required if we are to achieve our aim of helping the person with diabetes to live a long and healthy life free of diabetic complications. The particular situation of the Type 2 diabetic patient in poor glycaemic control on maximal oral therapy has been little explored in the primary care setting. This research aimed to obtain further information about this group of patients, exploring their beliefs and those of their carers and to examine specific quality of life issues around insulin initiation.

This thesis follows a sequence: an evaluation of the extent of diabetes and the failing diabetic problem in the locality, followed by qualitative work to gain the views and perspectives of people with diabetes and their clinicians. This was followed by the creation of a consensus-based

management plan with both patients and clinicians consulted. A pragmatic clinical study on the quality of life issues for diabetic patients who were in poor glycaemic control and might need conversion to insulin was then conducted.

8.1. Data

The analysis of the existing North Tees database indicated that almost 60% of people with Type 2 diabetes were in poor glycaemic control and that 60% of these were not on insulin therapy. It suggested a lack of maximisation of treatment. Of those poorly controlled patients on oral treatment 46% were on only one drug, rather than a full range of two or three drugs. The majority of patients in this category were still cared for by their general practitioners (84%). However, more of those with poorer control had secondary care input compared with those in good control (35% v 15%). It highlighted the need for more intensive treatment with probable greater use of insulin. This would be associated with major workload and resource implications.

The research based on the North Tees register can be criticised for having been based on a retrospective database, with information only available a year after recording. However, this is the inherent nature of any disease database. An independent worker trained in data extraction collected the data directly from primary care records, and this greatly increased the quality and reliability of the data. The coverage was extensive and the findings were representative of the diabetic population as a whole. The database was created prior to the NICE guidelines[204]

having been released and before the publication of the National Service Framework for diabetes[22]. The duration of the research in this thesis necessarily draws upon data from that period, and perhaps usefully, paints a picture of the diabetic population before the interventions in the various general practice contracts and their requirements. As the thesis progressed many of the arguments and problems over poor diabetic control have altered or even evaporated – the current mode of data collection, audit and reimbursement based on clinical outcomes has cut through the paradigms which otherwise came in the way of ensuring good control. Nonetheless, the basic issue about decision making in poorly controlled diabetic patients is a salient one.

Chapter 4 was a qualitative study of patients' attitudes and beliefs. The main finding was that diabetes was essentially regarded as a mild illness and the most important outcomes for patients were to be symptom free, and to feel and to be treated as normal individuals.

This may appear obvious on first reading. However, not many clinicians and carers were aware of patients' own priorities. In a field where biochemical and clinical outcomes are regarded as paramount it is obvious to see how there would be a conflict, or at the very least, a cross-purpose between the wishes of the patient and those of their doctors. 'Well-being' as an outcome is more familiar to patients than to doctors: a genuine partnership needs to be based on a mutual understanding and appreciation of goals. There are indications now that diabetes management programmes are more aggressive and bear

heavily upon the patient to conform to clinicians' views and regimens. Paradoxically, the role of the patient and patients' wishes may be more marginalized than before in light of the new general practice contract with payments for achieving quality targets. Again, these developments superseded many of the basic premises of this thesis. However, such premises are worthy of revisiting lest we forget what our patients really want.

With hindsight, from the methodological viewpoint, it might have been more productive to have used in-depth interviews rather than focus groups, or a combination of the two for this study. This may have provided additional information with improved triangulation. However, the focus groups, done with due rigour, did allow the essential constructs to emerge. Again, although more research has been published since our study was performed, ours was one of the first to explore patients' views in this way in primary care.

Chapter 5, in contrast with chapter 4, considered the care providers' viewpoint. In particular, the general practitioners and practice nurses invariably felt that patients underestimated the nature and seriousness of diabetes, seeing it as a mild disease. The clinicians viewed insulin treatment positively but felt patients actively resisted such treatment. Concerns were expressed around the areas of patient compliance with the multiple drug therapy required to treat diabetes and the difficulties of treating patients from ethnic minorities. Again, the methodology could have used interviews rather than focus groups. However, the findings

were valid as groups of participants in several focus groups gave their views and there was good correlation between the groups. The participants were purposively sampled but this alone does not reduce the validity of the findings. A possible problem was that the researcher led the focus groups. This could be seen as a possible source of bias, as being seen as an 'expert' may have influenced views expressed with the possibility of judgement passed on clinical decision-making. However, the use of focus groups dilutes the effect of the researchers persona as participants address each other during discussions[154].

Following research with diabetic patients and with clinicians, the next phase was to ascertain if consensus could be reached about the management of people with poorly controlled Type 2 diabetes. Local stakeholders in the care of people with poorly controlled diabetes were invited to a group discussion, including patient representatives. Emerging themes included difficulty in making lifestyle changes and concern that patients blamed themselves for 'failing'. This bordered on having moral implications, in that it was felt patients often felt they were letting family or carers down, with expressions of guilt for not conforming to diabetic regimes. Doubt was expressed about the universal adoption of insulin treatment for these patients, particularly regarding the point at which insulin should be introduced. The place of patient empowerment and shared decision-making was emphasised but patient representatives still very much saw the decision-making process lying with the doctor. The study could be criticised for having been based on a convenience sample of some of those involved in diabetes care and not

representative of the wider national perspective. However, the findings did reflect the views of the local diabetic community on how it perceived current services and how improvements in those services could be made to achieve better care. Indeed, similar teams provide most care across the country.

Approaches to consensus management require a 'buy-in' from both those who are likely to require care and those delivering care. This particular project was unique in the North East of England – there were no recorded prior instances of clinicians and patients both working together to reach consensus on management. The dynamics of this group were fascinating – the patients, normally used to a carer-user relationship, were invited to a meeting where all had apparently equal status. The evolving dynamic of the group enabled the patients to be more frank about what they saw as their priorities. In turn, the clinicians were open in terms of what they saw as pragmatic management decisions rather than tightly bio-medically bound solutions.

Chapter 7 considered the quality of life and glycaemic control in patients who elected to commence insulin, compared to those who did not. This study was "blighted" by a number of significant problems. Foremost was the advent of the new General Medical Services contract (nGMS) Quality and outcomes Framework (QoF) for diabetes[204] and a turnaround in the way poorly controlled diabetes care was managed. The nGMS contract was introduced in 2004. The QoF was a predetermined set of criteria for management of chronic medical conditions designed to

improve quality of care and using, for the first time, outcomes to determine practice remuneration. In diabetes this involved targets for glycaemic control as well as for blood pressure and lipid levels. This had the effect of reducing the number of patients entering the study and the duration of data collection had to be extended twice. In addition, one centre, which had agreed to participate in the study, in the end, supplied only two patients. The reasons for this were not exactly clear but were likely to be related to changes in clinical workload with a shift in work away from secondary care towards primary care. In effect the study required salvage at mid-point. This was done by extending the duration of data collection.

The study explored quality of life issues around insulin initiation for Type 2 diabetic patients. The main outcomes were that glycaemic control was improved modestly but at the expense of weight gain. Satisfaction with treatment, high initially, improved further on changing to insulin. Quality of life scores, which were slightly negative at the beginning of the study, showed a further small negative swing, although this was not statistically significant on the measures used.

8.2. Changes in diabetic management over the last 10 years.

This thesis was conceived at a time of significant political initiatives aimed at improving health care within the NHS. In 1998 the UK government launched a ten-year strategy for quality improvement throughout the NHS[206]. The concept of clinical governance was introduced as part of this strategy, placing attention equally on

accountability for existing care and improving future care. This was followed by national guidelines for chronic disease management, the national service frameworks (NSF). The NSF for diabetes was published in 2001 setting minimum standards for diabetes care for the health services in England[207], with further advice on implementation of the framework being issued in 2002[208]. The landmark UKPDS study[128, 166], published in 1998, confirmed the benefit of more aggressive treatment of both glycaemia and hypertension. This was implemented in primary care subsequently. Over this period, the National Institute for Clinical Excellence (NICE) issued technical guidance on various aspects of the care of Type 2 diabetes, notably on glycaemic control, patient education models, hypertension, and lipid management. Most recently, financial incentives for improved chronic disease management, with a strong emphasis on diabetes, were introduced as part of a new contract for general practice starting in April 2004.[209]. The effect of these initiatives has been to increase awareness of diabetes standards of care and bring about improvements in care through education, audit and incentives, particularly in primary care. Patient empowerment and education have been encouraged and efforts made to standardise educational input.

Inevitably, the environment in which the thesis was conducted changed immeasurably as the work proceeded. However, the conclusions remain valid if to some extent overcome by developments.

An example of the shift in diabetic management has been the redefinition of poor glycaemic control. This is now seen as a prevalent HbA1c of >7mmol/l (or even >6.5mmol/l in some instances) and practices are under pressure to actively manage and attain such levels. This is in part linked to remuneration issues and has rewritten the management plans for diabetes, as well as for many other measurable indices for other chronic conditions.

8.3. Conclusions

This thesis highlights the importance of understanding and applying patient views and perceptions and being able to reconcile these with those of clinicians about the management of diabetes. Within the constraints of the methods used, and not withstanding the new initiatives in diabetes management, the following conclusions were drawn:

Patients greatly value a sense of wellbeing even at the expense of future problems. Normality and the need to be seen to be living a normal life was a high priority.

Clinicians are well cognisant of the limitations of their management. Not withstanding the relatively tough outcomes proposed as a consequence of the UKPDS study and NICE guidelines, they are in fact, willing to be reassuringly flexible in their approach.

A consensus-based approach involving patients and clinicians in a condition such as diabetes is challenging. The divide between the 'users' and the 'carers' is a wide one in terms of information, knowledge, and

aspirations. Clinicians were not clear-cut in their attitudes towards insulin initiation.

The use of insulin in a cohort of failing diabetic patients did not produce an overwhelmingly positive outcome and the modest gain in glycaemic control was at the expense of weight gain.

Inevitably, the 'new' changes in diabetic management have superseded some of the ideas and precepts of this thesis but this research reinforces the central role of the patient in any care-management system.

8.4. Areas for future research

These include the need to ascertain diabetic patients' views of the current, more tightly targeted regimes, whether these are potentially at conflict with their desire for 'normality' in living, and what problems are associated with tighter management regimes. Overall compliance and outcomes are still likely to be influenced by patient factors. Also, the current system of data recording and outcome measures (such as glycaemic control and HbA1 levels) offer a wealth of opportunities for research in terms of clinical outcomes. As the prevalence of diabetes rises and patients become more active participants in their management this is a rich seam of potential research on patient directed management issues. **Technical factors are likely to be less important than human factors in diabetic patients remaining healthier for longer.**

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10. Appendices

Appendix 1 – Patient Beliefs Invitation

19 October, 2000

Dear Forename

Meeting: How do people feel about their diabetes?
Venue: North Tees Hospital Education Centre
Date: 12 December 2000, 2pm.

I am a local GP with a special interest in diabetes. I am looking at how we can improve diabetes care in General Practice in our area. Your GP practice is helping me with this.

We need to know how people feel about their diabetes. Can you help?

To get peoples' views we are holding a number of meetings. I would like to invite you to one of these. The meeting will be held in the Education Centre at the North Tees General Hospital, directions are enclosed. Reasonable travelling expenses (up to £25) can be paid.

The meeting will last about an hour. The group will consist of up to 8 people. The discussion will be confidential and only the researcher will hold any information.

I hope you will be able to help us with this important work. Enclosed are two information leaflets giving details about the study together with a consent form. Please complete the reply sheet and return it the envelope enclosed to let me know if you can help.

Please bring the completed consent form with you to the meeting.

Attending the meeting is entirely voluntary and refusing will in no way affect your normal care.

Thank you for your help,

Yours sincerely

Dr David Jeavons.

Appendix 2 – Patient Beliefs Leaflet

Taking part in Research

Information for patients about the study

Late onset (Type 2) diabetes: a study of patients' views

An invitation to take part in this study

You are being invited to take part in a research project. Here is some information to help you decide whether or not to take part. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything you do not understand or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Diabetes is a very common problem. It affects many people in later life. Managing diabetes usually needs changes to diet, exercise and often tablets or insulin. This study looks at how people feel about their diabetes and its treatment. We hope to use this information to help improve local diabetes care for the future.

Why have I been chosen?

You have been chosen randomly from the North Tees Diabetic Register. This is a list of all people with diabetes treated in General Practice or hospital in the area. You are one of about 40 people chosen to attend one of these small group meetings.

Who is organising the study?

This study is funded by the NHS and run by Dr David Jeavons and Professor Pali Hungin. Both are General Practitioners in the local area. The study will take four weeks to complete.

What will happen to me if I take part?

You will be invited to a meeting with up to 7 other people who like you have diabetes. Reasonable travelling expenses will be paid if required. The meeting will last about one hour. Tea and coffee will be served beforehand The meeting will be very informal allowing people to talk about the experiences and views mentioned. The meeting will be organised by Dr Jeavons and recorded so that the points made are not overlooked.

What are the potential risks and benefits from taking part in this study?

The main benefit from this study is the opportunity to discuss how you feel about diabetes and hear other peoples' views. There are no specific risks.

Is my doctor being paid for including me in the study?

No, there is no payment to your doctor.

What if something goes wrong?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you have any cause to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

Confidentiality - who will know I am taking part in the study?

Your General Practitioner has been asked only if it would be suitable to invite you to this meeting. Some people may be too frail or ill with other problems to attend. Dr Jeavons will keep all information from the meeting strictly confidential.

Local Research Ethics Committee (LREC) approval?

The North Tees LREC has reviewed and approved this study.

What will happen to the results of this study?

The results of this study may be published in one of the well-known medical journals. We would expect the article to be published 9 to 12 months after the end of the study. If you would like a summary of the study if and when it is published please ask. Of course, you will not be identified in the article.

Contact for further information

Please feel free to contact Dr David Jeavons at the Centre for Health Studies, University of Durham, 32 Old Elvet, DH1 3HN. Tel. 0191-374-1840. If you require independent advice about any aspect of the study please discuss it with your own doctor.

What to do now

Thank you for taking the time to read this leaflet. If you can help please return the enclosed postcard adding your telephone number if possible, in case we need to let you know of any last minute changes.

Appendix 3 – Patient Beliefs Consent Form

Study number: 34/99-2000

CONSENT FORM

Title of project: **Late onset (Type 2) diabetes: a study of patients' views**

Name of researcher: **Dr David Jeavons**

Please initial box

1. I confirm that I have read and understand the information sheet dated 28.11.00..... ☐

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

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

Name of patient	Date	Signature

Dr David Jeavons Researcher	Date	Signature

Appendix 4 – Patient focus group questions for oha group

Introduction

No right or wrong answers
Seeking different views and opinions
Meeting is confidential
One person speaking at a time, for the recording

Opening question

Tell us your name, where you live and what your favorite hobby is.

Introduction

Looking back, what were your impressions of diabetes before you developed it?

What did you know about it?

Belief model

With what you know now, how serious a problem do you feel diabetes is?

Diabetes can cause complications; how likely do you feel you are to develop any of these?

What do you see as the benefits of looking after your diabetes well?

Feel better
Avoid complications

What are the problems or difficulties with controlling your diabetes well?

Initial reaction

How did you feel when you were told you had diabetes?

How did you adapt?
Shock, denial, emotion?

Lay beliefs

What do you yourself feel caused you to develop diabetes?

Wt
Inherited
Bad diet
Lack of exercise

Medication

How effective do you feel diabetic medicines are?

Do you have any worries about taking about taking medication long term?

Barriers

How difficult was it to make changes?

What things do you feel get in the way of managing your diabetes?

Family
Friends
Eating out

What effect do family and friends have on you managing your diabetes?

Good or bad?

Doctor / patient relationship

When you go to see the doctor or nurse about your diabetes, how useful do you find the visits?

Can you ask questions easily?
Do they listen to your concerns?
Do you have enough time?
Are goals realistic?How could these be improved?

Would you rather the doctor make decisions for you or would you rather be given choices?

Significant others

When you have been given advice do you talk it over with anyone afterwards before deciding to follow the advice?

What effect do family and friends have on you managing your diabetes?

Good or bad?

Insulin

How would you feel about insulin treatment if it was suggested for you?

Shock, rejection, failure
More serious phase of illness , complications

How do think your doctor feel about insulin?

What do you see as the benefits of insulin treatment?

What worries you about insulin treatment?

Needles
Hypos

How in control do you feel about managing your diabetes?

Do you experiment with diet or treatment to find out what suits you best?
Do you control your diabetes or does it control you?

How easy is it for you to live a normal life?

Appendix 5 – Patient focus group questions for insulin group

Introduction
No right or wrong answers
Seeking different views and opinions
Meeting is confidential
One person speaking at a time, for the recording

Opening question
Tell us your name, where you live and what your favorite hobby is.

Introduction
Looking back, what were your impressions of diabetes before you developed it?
What did you know about it?

Belief model
With what you know now, how serious a problem do you feel diabetes is?
Diabetes can cause complications; how likely do you feel you are to develop any of these?
What do you see as the benefits of looking after your diabetes well?
Feel better
Avoid complications
What are the problems or difficulties with controlling your diabetes well?

Initial reaction
How did you feel when you were told you had diabetes?
How did you adapt?
Shock, denial, emotion?

Lay beliefs
What do you yourself feel caused you to develop diabetes?
Wt
Inherited
Bad diet
Lack of exercise

Medication
How effective do you feel diabetic medicines are?
Do you have any worries about taking about taking medication long term?

Barriers
How difficult was it to make changes?
What things do you feel get in the way of managing your diabetes?
Family
Friends
Eating out

What effect do family and friends have on you managing your diabetes?

Good or bad?

Doctor / patient relationship

When you go to see the doctor or nurse about your diabetes, how useful do you find the visits?

Can you ask questions easily?
Do they listen to your concerns?
Do you have enough time?
Are goals realistic?

How could these be improved?

Would you rather the doctor make decisions for you or would you rather be given choices?

Significant others

When you have been given advice do you talk it over with anyone afterwards before deciding to follow the advice?

What effect do family and friends have on you managing your diabetes?

Good or bad?

Insulin

How would you feel about insulin treatment if it was suggested for you?

Shock, rejection, failure
More serious phase of illness , complications

How do think your doctor feel about insulin?

What do you see as the benefits of insulin treatment?

What worries you about insulin treatment?

Needles
Hypos

How in control do you feel about managing your diabetes?

Do you experiment with diet or treatment to find out what suits you best?
Do you control your diabetes or does it control you?

How easy is it for you to live a normal life?

Appendix 6 - Patient Beliefs Validation 1

NETHERLAW SURGERY

Dr. David A. Jeavons
Dr. Susan M. Waterworth
Dr. Andrew F. Michie
Dr. Andrea B. Jones

353141

350938
Mr Campbell Q. Lees
Practice Manager

28 Stanhope Road
Darlington
Co. Durham DL3 7SQ
Telephone: (01325)380640
Appointments: (01325)

Fax: (01325)

Date

Name and address

Dear

Re: Late onset (Type 2) diabetes: a study of Patients' views.
Teaching Centre, North Tees Hospital, Hardwick, Stockton on Tees

Thank you again for attending one of the discussion groups for this study.

We have now been able to look at the results of the meetings. I enclose a summary of the main ideas and feelings expressed in the groups. It would be very helpful to have your comments on this as to whether or not you agree with them. There is space at the end of the summary sheet for your comments. If you have any other comments not covered by the summary please feel free to add these as well. A self-addressed envelope is enclosed for your reply. A prompt reply would be very helpful if at all possible.

Thank you again for your help with this important work.

Yours Sincerely

Dr David A Jeavons.

Appendix 7 Patient Beliefs Validation 2

NETHERLAW SURGERY

Dr. David A. Jeavons
Dr. Susan M. Waterworth
Dr. Andrew F. Michie
Dr. Andrea B. Jones

353141

350938
Mr Campbell Q. Lees
Practice Manager

28 Stanhope Road
Darlington
Co. Durham DL3 7SQ
Telephone: (01325)380640
Appointments: (01325)

Fax: (01325)

Date

Name and address

Dear

Re: Late onset (Type 2) diabetes: a study of Patients' views.
Teaching Centre, North Tees Hospital, Hardwick, Stockton on Tees

Thank you again for attending one of the discussion groups for this study.

Before Christmas I wrote asking for your comments on the results of the group meetings that we held last year. I have had some replies but I realise life is always hectic over the Christmas period. If you have not replied already I would be grateful if you could look at the enclosed summary of the main ideas and feelings expressed in the groups. It would be very helpful to have your comments on this as to whether or not you agree with them. There is space at the end of the summary sheet for your comments. If you have any other comments not covered by the summary please feel free to add these as well. It would be helpful if you could sign the reply slip, but it is fine if you prefer not to. A self-addressed envelope is enclosed for your reply. A prompt reply would be very helpful if at all possible.

Thank you again for your help with this important work.

Yours Sincerely

Dr David A Jeavons.

Appendix 8 - Late onset (Type 2) diabetes: a study of Patients' views: a summary of results

A number of concepts were identified relating to how people saw their diabetes and how they managed it.

Impact of the diagnosis of diabetes

- Little was known about diabetes before diagnosis
- Diabetes was seen as a mild disease
- The initial reaction was of shock and denial

Why did I develop diabetes?

- 'it runs in the family' was frequently mentioned
- 'Stress' – both psychological (especially work stress) and physical (illnesses) was often mentioned
- Other causes – overweight, too much sugar

Role of professionals

- Doctors were generally seen as helpful, especially if they were seen to have an 'interest in diabetes.'
- Nurses were seen as 'specialists' in diabetes.

Managing diabetes

- Diet changes:
  - Some participants felt that only minor changes to diet were necessary
  - Others felt major changes to their diet were necessary.
- Exercise:
  - Often unrealistic targets were set for exercise
  - Many found physical problems stopped them exercising
  - The commonest form of exercise was walking.
- Insulin:
  - There was strong initial resistance to starting insulin
  - There were worries about needles, injections and low sugar 'hypoglycaemic' attacks
  - Once started insulin treatment was rapidly accepted
  - Insulin treatment was seen as beneficial
- Self-monitoring
  - Seen as necessary to avoid symptoms and maintain good control
  - Sometimes seen as more trouble than it's worth

Complications

- Loss of limb (amputation) and subsequent death worried many
- Eye problems were a concern for some
- Heart disease was not seen as a particular complication of diabetes

How people coped with diabetes

- Participants made sense of diabetes by fitting it into their daily routine

- They drew on personal experience and the experiences of friends and family when making decisions
- Professionals (doctors and nurses) advice was less often mentioned when making decisions about diabetes
- Doctors' advice was discussed with family or friends and then weighed up (benefits against disadvantages) before deciding whether to follow the advice
- There was a strong desire:
    - to live as normal a life as possible
    - to avoid physical symptoms

Conclusions

Diabetes was regarded as a mild disease. However, participants were attempting to control their diabetes but with a strong desire to live a normal life and avoid physical symptoms. Family and friends contributed significantly to participants' beliefs about diabetes with health professionals infrequently quoted.

An appreciation of patients perspectives is required if we are to successfully improve diabetes self-management.

Your comments

Please tick the statement that you most agree with:

- ☐ I very strongly agree with the summary
- ☐ I strongly agree with the summary
- ☐ I neither agree nor disagree with the summary
- ☐ I disagree agree with the summary
- ☐ I strongly disagree with the summary

Please add any other comments below (continue overleaf if necessary):

Appendix 9 – HCP Focus Group Questions

Questionnaire

Basic demographics: year of qualification, mrcgp, trainer, training practice.

Opening

Can I start by asking everyone in turn to introduce themselves? Tell us where you practice and what you most enjoy doing when you are not working?

Introductory

Type 2 diabetes is a common problem taking up increasing amounts of our time in general practice.

1. How is diabetic care delivered in your practice?

Transition

2. What do you see as our role in diabetes care? How much of diabetic care should we be involved in?

All too many patients are poorly controlled.

3. How would you define the Failing Diabetic?

Level of control?

Key

4. How do you feel yourself when you are faced with one of these people with poorly controlled Type 2 diabetes?

How confident are you?
How optimistic do you feel managing the failing diabetic patient?

5. How do you manage the failing patient?

What goals do you set?

6. How do you feel about insulin therapy for Type 2 diabetes?

What do you see as the benefits and disadvantages, the pros and cons, of insulin?
How do you feel patients view the prospect of insulin therapy?

7. Many of these patients are older. Does this affect your management?

8. We here a lot about patient compliance these days. How much of a problem do you find this?

What do you find affects compliance?

9. What do you see as the barriers to good diabetic care?

From the patient's point of view?
Prompt list effect of family
Friends (significant other)
hcp

Summary

Ending

10. Do you feel there are any important areas that we have not touched on?

Vignettes

Mrs Brown

Age 65yr. Obese BMI 34. HbA1c 11%, hypertension, previous MI
On max gliclazide and metformin, weight increasing
Husband out of work and financial difficulties

Mr White

62yr old, overweight BMI 28, hypertensive. HbA1c 10%
On max gliclazide and intolerant of metformin, weight steady
After dinner speaker attending frequent functions

Appendix 10 – HCP validation 1

NETHERLAW SURGERY

Dr. David A. Jeavons
Dr. Susan M. Waterworth
Dr. Andrew F. Michie
Dr. Andrea B. Jones
Dr Andrew J. Baines
380640

353141

350938
Mr Campbell Q. Lees Practice Manager

28 Stanhope Road
Darlington
Co. Durham DL3 7SQ

Telephone: (01325)

Appointments: (01325)

Fax: (01325)

21 February 2002

Name and address

Dear Firstname

Re: The Failing Diabetic Patient in Primary Care

Thank you once again for participating in one of the focus group discussions discussing primary care clinicians views on management of the failing Type 2 diabetic patient.

We have now analysed the results, a summary of which I enclose. I would very much appreciate your feedback on the accuracy of the summary and any further comments you feel would be helpful.

Please feel free to annotate the summary and / or add comments on the sheet provided and return them in the sae provided. I have included a simple scale on which to indicate your overall level of agreement with the summary. All replies will be strictly confidential and not identified in any future report.

I appreciate that this is a further demand on your already busy schedule and as a small token I enclose an Oddbins voucher with which I hope you will enjoy a bottle of wine with me!

Once more thank you for your help with this study, which we hope to publish in the not too distant future.

Yours Sincerely

Dr David A Jeavons.

Appendix 11 – HCP Validation 2

NETHERLAW SURGERY

Dr. David A. Jeavons
Dr. Susan M. Waterworth
Dr. Andrew F. Michie
Dr. Andrea B. Jones
Dr Andrew J. Baines
380640

353141

350938
Mr Campbell Q. Lees
Practice Manager

28 Stanhope Road
Darlington
Co. Durham DL3 7SQ

Telephone: (01325)

Appointments: (01325)

Fax: (01325)

15 Apr. 2002

Name and address

Dear Firstname

Re: The Failing Diabetic Patient in Primary Care

I would very much appreciate your views on the accuracy of the enclosed summary. I hope you received my earlier mailing including the Oddbins voucher! I have taken the liberty of enclosing a further copy of the summary and sae for your reply.

Thank you once again for participating in one of the focus group discussions discussing primary care clinicians views on management of the failing Type 2 diabetic patient. We have now analysed the results. I would very much appreciate your feedback on the accuracy of the summary and any further comments you feel would be helpful.

Please feel free to annotate the summary and / or add comments on the sheet provided and return them in the sae provided. I have included a simple scale on which to indicate your overall level of agreement with the summary. All replies will be strictly confidential and not identified in any future report.

I appreciate that this is a further demand on your already busy schedule but your help is greatly appreciated. Once more thank you for your help with this study, which we hope to publish in the not too distant future.

Yours Sincerely

Dr David A Jeavons.

Appendix 12 – Patient information leaflet

Taking part in Research
Information for patients about the study

Poorly controlled Type 2 diabetes: Choice of treatment and quality of life.

An invitation to take part in this study

You are being invited to take part in a research study. Before you decide it is important for you t understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything you do not understand or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Diabetes affects many people in later life. Often tablets do not control diabetes sufficiently well. Insulin is then considered. A decision has to be made to change to insulin or continue on tablets. How do people decide? How does it affect peoples' lives? Do they feel better for starting insulin? What changes occur to the control of their diabetes? We hope to answer these questions. The study will last six months. The information will be used to improve local services.

Why have I been chosen?

All people with diabetes referred by their GP to the diabetes clinic who may need insulin treatment are being asked to help. About sixty people will be asked to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form. It you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

You will be asked to complete two questionnaires when you attend the hospital diabetic clinic. This should take ten to fifteen minutes. The questions ask about the effects diabetes has on your quality of life and how satisfied you are with your treatment. You will be asked to repeat these again after three and six months. Your normal care in the diabetic clinic will not be altered by taking parting the study.

What are the potential risks and benefits from taking part in this study?

There are no specific risks from taking part in this study. Information obtained from the study will be used to help improve the local service.

What if something goes wrong?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you have any cause to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

Confidentiality - who will know I am taking part in the study?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information that leaves the hospital will have your name and address removed so that you cannot be recognised from it. Your own GP will be informed that you are taking part in the study.

What will happen to the results of this study?

The results of this study may be published in one of the well-known medical journals. You will not be identified in any report or publication. We would expect the article to be published 9 to 12 months after the end of the study. If you would like a summary of the study if and when it is published please ask. The study is run by Dr David Jeavons (a local GP), and Dr Barnes and Dr McCulloch (diabetic specialists), with the help of Professor Hungin (an experienced GP researcher).

Who is organising and funding the research?

The study is sponsored through an NHS Research and Development grant. The research is overseen by the Centre for Integrated Health Care Research, Durham University. The doctors involved are not paid for including patients in the study.The North Tees LREC has reviewed and approved this study.

Contact for further information

Please feel free to contact Dr David Jeavons at Netherlaw Surgery, 28 Stanhope Road, Darlington, tel. 01325-380640, with any queries.

If you require independent advice about any aspect of the study please discuss it with your own doctor.

Thank you for taking the time to read this leaflet. If you can help please read and sign the attached consent form. You will be given a copy of the information sheet and a signed consent form to keep.

Appendix 13 – Insulin QoL Consent form

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Poorly controlled Type 2 diabetes: choice of treatment and quality of life.

Name of Researcher: **Dr. D. A. Jeavons**

Please initial boxes

1. I confirm that I have read and understand the information sheet dated 10/08/2003 (version 1.1) for the above and have had an opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐

Name of Patient	**Signature**	**Date**
Researcher	Signature	Date

Appendix 14 – Insulin QoL Data form

QoL and referral for insulin therapy

Dr DA Jeavons

ID number
Surname
firstname
dob

Demographic data

sex	male	female		
marital status	single	married	widowed	divorced/seperated
living alone	yes	no		
ethnic origin	white	asian	black	mixed - specify:
occupation				
spouse's occupation				
smoking status	never smoked	smoker	ex-smoker	

Medical history

hypertension	yes	no	
mi	yes	no	
angina	yes	no	
heart failure	yes	no	
pvd	yes	no	
stroke/tia	yes	no	
locomotor pathology	yes	no	if yes, details
pulmonary pathology	yes	no	if yes, details
psychosocial pathology	yes	no	if yes, details
duration of diabetes	yes	no	
retinopathy			
nephropathy	yes	no	
neuropathy	yes	no	
medication	yes	no	

Measurements

height (cms.)	HbA1c
weight (kgm.)	fasting plasma glucose
bmi	fasting lipid profile
waist (cms)	total cholesterol
hip (cms)	hdl cholesterol
sbp	ldl cholesterol
dbp	triglycerides

Appendix 15 –Insuin QoL Review Data

QoL and referral for insulin therapy

Study no. D.....
Date completed ___/___/___

Medication			
metformin	yes / no		
sulphonylurea	yes / no		
glitazone	yes / no		

Measurements			
height (cms.)		HbA1c	
weight (kgm.)		lipid profile	
waist (cms)		total cholesterol	
hip (cms)		hdl cholesterol	
sbp		ldl cholesterol	
dbp		triglycerides	

Changing to insulin	yes	no	
if so continuing:			
metformin	yes	no	
sulphonylurea	yes	no	

Appendix 16 – ADQoL questionnaire

ADDQoL

This questionnaire asks about your quality of life and the effects of your diabetes on your quality of life. Your quality of life is how good or bad you feel your life to be.

Please shade the circle which best indicates your response on each scale.

There are no right or wrong answers; we just want to know how you feel about your life now.

I) **In general, my present quality of life is:**						
O	O	O	O	O	O	O
excellent	very good	good	neither good nor bad	bad	very bad	extremely bad

For the next statement please consider the effects of your diabetes, its management and any complications you may have.

II) **If I did not have diabetes, my quality of life would be:**						
O	O	O	O	O	O	O
very much better	much better	a little better	the same	a little worse	much worse	very much worse

Please respond to the 18 more specific statements on the pages that follow.

For each statement, please consider the effects of your diabetes, its management and any complications you may have on the aspect of life described by the statement.

In each of the following boxes:

a) shade a circle to show how diabetes affects this aspect of your life;

b) shade a circle to show how important this aspect of your life is to your quality of life.

Some statements have a "not applicable" option. Please shade this "not applicable" circle if that aspect of life does not apply to you.

1a)	**If I did not have diabetes, my working life and work-related opportunities would be:**							
	O very much better	O much better	O a little better	O the same	O a little worse	O much worse	O very much worse	O not applicable
1b)	**This aspect of my life is:**							
		O very important	O important	O somewhat important	O not at all important			

2a)	**If I did not have diabetes, my family life would be:**							
	O very much better	O much better	O a little better	O the same	O a little worse	O much worse	O very much worse	O not applicable
2b)	**This aspect of my life is:**							
		O very important	O important	O somewhat important	O not at all important			

3a)	**If I did not have diabetes, my friendships and social life would be:**						
	O very much better	O much better	O a little better	O the same	O a little worse	O much worse	O very much worse
3b)	**This aspect of my life is:**						
		O very important	O important	O somewhat important	O not at all important		

4a)	**If I did not have diabetes, my sex life would be:**							
	O very much better	O much better	O a little better	O the same	O a little worse	O much worse	O very much worse	O not applicable
4b)	**This aspect of my life is:**							
		O very important	O important	O somewhat important	O not at all important			

5a)	**If I did not have diabetes, my physical appearance would be:**						
	O very much better	O much better	O a little better	O the same	O a little worse	O much worse	O very much worse
5b)	**This aspect of my life is:**						
		O very important	O important	O somewhat important	O not at all important		

6a)	**If I did not have diabetes, the things I could do physically would be:**						
	O very much increased	O much increased	O a little increased	O the same	O a little decreased	O much decreased	O very much decreased
6b)	**This aspect of my life is:**						
		O very important	O important	O somewhat important	O not at all important		

7a)	**If I did not have diabetes, my holidays or leisure activities would be:**						
	O very much better	O much better	O a little better	O the same	O a little worse	O much worse	O very much worse
7b)	**This aspect of my life is:**						
		O very important	O important	O somewhat important	O not at all important		

8a)	**If I did not have diabetes, ease of travelling (local or long distance) would be:**						
	O very much better	O much better	O a little better	O the same	O a little worse	O much worse	O very much worse
8b)	**This aspect of my life is:**						
		O very important	O important	O somewhat important	O not at all important		

9a)	**If I did not have diabetes, my confidence in my ability to do things would be:**						
	O	O	O	O	O	O	O
	very much increased	much increased	a little increased	the same	a little decreased	much decreased	very much decreased
9b)	**This aspect of my life is:**						
		O	O	O	O		
		very important	important	somewhat important	not at all important		

10a)	**If I did not have diabetes, my motivation to achieve things would be:**						
	O	O	O	O	O	O	O
	very much increased	much increased	a little increased	the same	a little decreased	much decreased	very much decreased
10b)	**This aspect of my life is:**						
		O	O	O	O		
		very important	important	somewhat important	not at all important		

11a)	**If I did not have diabetes, the way society at large reacts to me would be:**						
	O	O	O	O	O	O	O
	very much better	much better	a little better	the same	a little worse	much worse	very much worse
11b)	**This aspect of my life is:**						
		O	O	O	O		
		very important	important	somewhat important	not at all important		

12a)	**If I did not have diabetes, my worries about the future would be:**						
	O	O	O	O	O	O	O
	very much decreased	much decreased	a little decreased	the same	a little increased	much increased	very much increased
12b)	**This aspect of my life is:**						
		O	O	O	O		
		very important	important	somewhat important	not at all important		

13a) If I did not have diabetes, my finances would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse
O	O	O	O	O	O	O

13b) This aspect of my life is:

very important	important	somewhat important	not at all important
O	O	O	O

14a) If I did not have diabetes, my need to depend on others for things I would like to do for myself would be:

very much decreased	much decreased	a little decreased	the same	a little increased	much increased	very much increased
O	O	O	O	O	O	O

14b) This aspect of my life is:

very important	important	somewhat important	not at all important
O	O	O	O

15a) If I did not have diabetes, my living conditions would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse
O	O	O	O	O	O	O

15b) This aspect of my life is:

very important	important	somewhat important	not at all important
O	O	O	O

16a) If I did not have diabetes, my freedom to eat as I wish would be:

very much increased	much increased	a little increased	the same	a little decreased	much decreased	very much decreased
O	O	O	O	O	O	O

16b) This aspect of my life is:

very important	important	somewhat important	not at all important
O	O	O	O

17a)	**If I did not have diabetes, my enjoyment of food would be:**						
	O very much increased	O much increased	O a little increased	O the same	O a little decreased	O much decreased	O very much decreased
17b)	**This aspect of my life is:**						
		O very important	O important	O somewhat important	O not at all important		

18a)	**If I did not have diabetes, my freedom to drink as I wish (e.g. sweetened hot and cold drinks, fruit juice, alcohol) would be:**						
	O very much increased	O much increased	O a little increased	O the same	O a little decreased	O much decreased	O very much decreased
18b)	**This aspect of my life is:**						
		O very important	O important	O somewhat important	O not at all important		

If there are any other ways in which diabetes, its management and any complications affect your quality of life, please say what they are below:

Appendix 17 – DTSQ (change)

The Diabetes Treatment Satisfaction Questionnaire (change): DTSQc

For the past few months you have been taking part in a diabetes treatment study. At the start of the study you may have had a change of treatment. Today we would like to know how your experience of your current treatment (including medication and diet) has changed from your experience of treatment before the study began. Please answer each question by circling a number on each of the scales to indicate the extent to which you have experienced changes. If you have experienced no change, please circle '0'.

1. How satisfied are you with your current treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

2. How often have you felt that your blood sugars have been unacceptably high recently?

much more of the time now	3	2	1	0	-1	-2	-3	much less of the time now

3. How often have you felt that your blood sugars have been unacceptably low recently?

much more of the time now	3	2	1	0	-1	-2	-3	much less of the time now

4. How convenient have you been finding your treatment to be recently?

much more convenient now	3	2	1	0	-1	-2	-3	much less convenient now

5. How flexible have you been finding your treatment to be recently?

much more flexible now	3	2	1	0	-1	-2	-3	much less flexible now

6. How satisfied are you with your understanding of your diabetes?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

7. How likely would you be to recommend your present treatment to someone else with your kind of diabetes?

much more likely to recommend the treatment now	3	2	1	0	-1	-2	-3	much less likely to recommend the treatment now

8. How satisfied would you be to continue with your present form of treatment?

much more satisfied now	3	2	1	0	-1	-2	-3	much less satisfied now

Please make sure that you have circled one number on each of the scales.

Appendix – 18 DTSQ (status)

The Diabetes Treatment Satisfaction Questionnaire: DTSQs

The following questions are concerned with the treatment for your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks. Please answer each question by circling a number on each of the scales.

1. How satisfied are you with your current treatment?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

2. How often have you felt that your blood sugars have been unacceptably high recently?

most of the time	6	5	4	3	2	1	0	none of the time

3. How often have you felt that your blood sugars have been unacceptably low recently?

most of the time	6	5	4	3	2	1	0	none of the time

4. How convenient have you been finding your treatment to be recently?

very convenient	6	5	4	3	2	1	0	very inconvenient

5. How flexible have you been finding your treatment to be recently?

very flexible	6	5	4	3	2	1	0	very inflexible

6. How satisfied are you with your understanding of your diabetes?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

7. Would you recommend this form of treatment to someone else with your kind of diabetes?

Yes, I would definitely recommend the treatment	6	5	4	3	2	1	0	No, I would definitely not recommend the treatment

8. How satisfied would you be to continue with your present form of treatment?

very satisfied	6	5	4	3	2	1	0	very dissatisfied

Please make sure that you have circled one number on each of the scales.