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DIABETIC PATIENT EDUCATION AND MOTIVATION

VOLUME 1

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SUMMARY

Diabetes mellitus is a condition which requires a high degree of patient co-operation in self-management to achieve optimal glycaemic control. The concept of patient education, to enhance the treatment and management of diabetes, is well recognised. Several diabetes education programmes have already been described, but increased knowledge of diabetes did not necessarily result in improved self-management or glycaemic control. Other factors, such as attitudes and motivations, may therefore be particularly important. The aims of the present study were to investigate the influence of patients' attitudes to diabetes, and to develop motivational aspects which enable the application of knowledge to enhance self-management and compliance with treatment. Thirty-one insulin-dependent diabetic (IDD) patients entered into a 12 month educational programme, particularly designed to increase motivation. Patients' attitudes to diabetes, their knowledge and self-management skills were assessed using questionnaires and practical tests, and parameters of glycaemic control were measured. The progress of these patients was compared at intervals with a closely matched group of 25 control IDD patients who continued to receive routine clinic care. Patients completing the educational programme achieved better glycaemic control ( $p < 0.05$ ), greater knowledge ( $p < 0.001$ ), more favourable attitudes ( $p < 0.03$ ) and increased competence in management skills ( $p < 0.02$ ) compared with the control group. Evaluation procedures indicated that the programme was acceptable to the patients, and was successful in terms of increasing patient motivation. Six months after completion of the programme, glycaemic control deteriorated, although knowledge, attitudes and management skills were unchanged. This might reflect the withdrawal of extrinsic motivation, attention and supervision provided during the programme. It is recommended that consideration be given to the development of patients' intrinsic motivation to achieve maximum benefit from diabetes education programmes.

Key Words: diabetes mellitus, education, motivation, attitudes glycaemic control

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## ABBREVIATIONS

DE/MP	Diabetes Educational/Motivational Programme
SG	Study Group
CG	Control Group
NG	New Group
NA	Non-Attended Group
GMC	Geraldine Maria Cowan - Diabetes Educator
HBGM	Home Blood Glucose Monitoring
HbA <sub>1</sub>	Glycosylated Haemoglobin
% IBW	Percentage Ideal Body Weight
u/kg	Units of insulin/body weight (kg)
CNA%	Percentage clinic non-attendance in previous four years
SEG	Socioeconomic Group
IDD	Insulin-dependent diabetes
DAS	Diabetes Attitude Scale
DKQ	Diabetes Knowledge Questionnaire
MCQ	Multiple Choice Questionnaire
LMD	Dr. L. Debney - University Psychologist

## 1. LITERATURE REVIEW

## 1.1 Introduction

Diabetes mellitus is a disorder affecting carbohydrate, lipid and protein metabolism. It is characterised by hyperglycaemia and usually glycosuria. The condition may be due to an 'absolute' or 'relative' deficiency of the hormone insulin, which produces insulin dependent or non-insulin dependent diabetes respectively<sup>(1)</sup>. This text is concerned particularly with insulin dependent diabetes mellitus, also called type 1 diabetes. This chapter introduces the concept of diabetes and considers the chronic and acute complications which the patient may incur.

Diabetes is a condition which demands effective 'self'-management by the patient in order to improve the prognosis. The subject of diabetic management is considered, and focusses on the major factors which may affect and influence this, including patient education about diabetes, motivation and its influence on compliance, and attitudes towards diabetes.

## 1.2 Historical Considerations

The clinical features of diabetes were recognised as early as the 3rd Century B.C. by the physician Demetrius of Apamiez and the concept of diabetes was formulated.<sup>(2)</sup> Later in the first Century A.D., Aretaeus of Cappadocia described diabetes as a 'mysterious disease', and in the 5th Century diabetes was thought to be a form of dropsy. In 1674, Thomas Willis discovered that the urine of patients suffering from diabetes had a sweet taste; he attributed this to an unusual mixture of salts and sulphur in the blood. In 1777, Matthew Dobson demonstrated chemically that the sweet taste was due to the presence of sugar in the urine, and in the 18th Century the word

'mellitus' - as sweet as honey, was added, the condition then being known as diabetes mellitus.<sup>(2)</sup>

It was not known which part of the anatomy was responsible for producing diabetes until 1889 when Oskar Minkowski and Josef von Mering found that the characteristic symptoms of diabetes developed in a pancreatectomised dog.<sup>(3)</sup> Prior to this discovery, Paul Langerhans (1869) had described the islands of cells within the pancreas, which he called 'islets of Langerhans'. Subsequently, it was suggested that these cells secreted a substance which controlled carbohydrate metabolism and which was associated with diabetes.<sup>(4)</sup>

At the end of the 19th Century and early in the present Century, much work was carried out in an attempt to isolate this substance from the islet cells of the pancreas. In 1921, Fredrick Banting, Charles Best and James Collip prepared a pancreatic extract they called 'isletin'. They injected the extract into a pancreatectomised dog and successfully demonstrated how this relieved the symptoms of diabetes.<sup>(4)</sup> Further purification of bovine isletin extract was carried out, and in 1922 this bovine pancreatic extract, termed insulin, was given to Leonard Thompson - the first diabetic patient to receive insulin therapy.<sup>(5)</sup> The discovery of insulin has been described in detail.<sup>(6)</sup>

### 1.2.1 Insulin Action

Biochemical studies have subsequently established that insulin is a polypeptide hormone synthesised and secreted by the B cells of the pancreatic islets of Langerhans. This hormone is normally released in response to ingestion of nutrients, particularly glucose,

and exerts anabolic effects on carbohydrate, protein and lipid metabolism.<sup>(7-9)</sup> Insulin plays a crucial role in the control of blood glucose homeostasis by facilitating the uptake of glucose into muscle and fat cells. In the muscle cells glucose is utilised as an energy source or is stored as glycogen, and in the fat cells the glucose is metabolised to other substrates.<sup>(10)</sup> In the liver, insulin inhibits glucose release and promotes glycogen storage, thereby controlling blood glucose concentrations.<sup>(11)</sup> Insulin controls lipid metabolism by inhibiting lipolysis which therefore maintains low concentrations of circulating free fatty acids.<sup>(12)</sup> The main effect of insulin on protein metabolism is to promote the formation and maintenance of body protein, and to inhibit protein degradation.<sup>(13,14)</sup> The central role of insulin in metabolism has been described briefly, to emphasise its importance.

### 1.2.2 Insulin Therapy

The discovery of insulin and its metabolic effects was followed by successful therapeutic use from 1922 onwards. However, there were still problems associated with the first insulins used, including allergies, insulin resistance and lipoatrophy.<sup>(15)</sup> These were due to impurities such as pro-insulin, glucagon, somatostatin, and other hormones originating from the gut.<sup>(16)</sup> With improvements in purification techniques it became possible to produce much more pure, less 'antigenic' insulins, and in the 1970's 'highly purified' monocomponent insulins were produced.<sup>(17)</sup> These refinements in the purity of insulins since 1922 have been advantageous in making insulin resistance and insulin allergies uncommon and have greatly reduced the incidence of lipoatrophy.<sup>(18)</sup> The higher purity of

insulin preparations has enabled small reductions in doses of insulin to be made.<sup>(19)</sup>

The earliest insulins were soluble, short acting types prepared from porcine or bovine pancreas. It proved difficult to maintain good diabetic control due to the short duration of action of these insulins, and fairly rigid insulin regimes were required, often imposing restrictions on the patient's lifestyle.<sup>(20)</sup> This problem was substantially reduced with the development of long-acting insulins by Hagedorn in 1936 and intermediate-acting insulins in 1940. Then in the 1950s insulin zinc suspensions were introduced with a wide range of duration of action.<sup>(21)</sup> These advances allowed improvements in diabetic control to be achieved, and more flexible insulin regimes could be adopted with greater consideration for the individual's lifestyle.

Further progress in insulin production has taken place recently. The biosynthesis of human insulin using recombinant D.N.A. techniques,<sup>(22)</sup> and the production of semi-synthetic human insulin by chemical modification of porcine insulin,<sup>(23)</sup> has enabled the commercial introduction of human insulin. This insulin provides a further source of insulin which has non-immunogenic properties and acts similarly to monocomponent insulins.

It is apparent that many improvements have been made concerning the purity and range of insulin types available. However, the way in which insulin is administered has remained virtually unchanged, and still requires subcutaneous insulin injections or infusion. Alternatives, such as taking insulin orally, have proved unsuccessful due to partial or total proteolysis of the insulin<sup>(24)</sup>

but nasal administration or in the form of suppositories may be worthy of further development.<sup>(25)</sup> Recent developments in insulin delivery include continuous insulin infusion by a pump mechanism worn on the outside of the body.<sup>(26)</sup> These infusion pumps do not contain a glucose sensor but are pre-programmed to deliver insulin at a continuous rate, they are described as 'open loop' delivery systems. Many problems still exist with the use of such pumps, including the psychological effects, risk of infections and the expense involved.<sup>(27)</sup>

At present much research is being directed into developing a system which is sensitive to blood glucose concentrations, and provides feedback to the pump which responds by delivering insulin to achieve an appropriate circulatory level of insulin required. This is described as a 'closed loop' system or 'artificial beta cell', since it mimics the role of the beta cells in the pancreas. However, there are major difficulties concerned with this type of device which include the size and the quantity of blood required for continuous sampling by the glucose sensor.<sup>(28)</sup> Although many research centres are investigating novel approaches to insulin delivery, exogenous insulins, injected subcutaneously and in a suitable regimen, remains the current therapy for controlling the majority of insulin dependent diabetic patients.

Insulin treatment can 'almost' normalise the carbohydrate, lipid and protein metabolism in diabetic patients and has provided a major improvement in their prognosis and survival. However, it is well recognised that many patients can develop chronic complications of diabetes,<sup>(29)</sup> this is discussed in section 1.2.1. Much research



has been conducted to establish the aetiology and to prevent these complications, and it is probable that a number of factors are involved.<sup>(30,31)</sup> One such factor which clearly enhances the onset and severity of at least some of these complications is hyperglycaemia, which indicates poorly controlled diabetes.<sup>(32)</sup>

### 1.3 Diabetic Complications

The complications of diabetes are mainly disturbances in the vascular system. These consist of:

- (i) microvascular disease - affecting the retina, kidneys and peripheral nerves,<sup>(33)</sup> and
- (ii) macrovascular disease - affecting larger blood vessels particularly coronary, carotid and lower limb vessels.<sup>(34)</sup>

#### 1.3.1 Microvascular Diseases

The association between microvascular disease and diabetes was established in 1936 when it was shown that structural and functional changes occurred in the glomerular capillaries of diabetic patients.<sup>(35)</sup> Subsequently it was found that similar changes occurred in the retina and peripheral and autonomic nervous systems of many diabetic patients, thus, three major types of microvascular disease exist:

- (i) retinopathy<sup>(36)</sup>
- (ii) nephropathy<sup>(37)</sup>
- (iii) neuropathy<sup>(38)</sup>

### Retinopathy

Retinopathy is the most common long-term complication of diabetes.<sup>(39)</sup> Structural changes occur in the blood vessels on the retina. Basement membrane thickening and dilatation of the capillaries are common features.<sup>(40)</sup> These may result in further changes which can lead to impaired vision. Other retinal changes which account for some of the clinical and pathological features of retinopathy are discussed elsewhere.<sup>(41)</sup>

### Nephropathy

Nephropathy affects the glomerular capillaries in the kidneys and is also associated with thickening of the basement membrane of these capillaries. Further alterations can occur such as increased permeability of the vessels and the deposition of fibrin.<sup>(42)</sup> Other features of nephropathy are discussed in detail elsewhere.<sup>(37)</sup>

Although the aetiology of retinopathy and nephropathy is not fully understood, it is known that basement membrane thickening, a feature of both conditions, is enhanced by hyperglycaemia.<sup>(42)</sup> This finding may be an indication that better glycaemic control may reduce the onset of retinopathy and nephropathy.<sup>(43-45)</sup>

### Neuropathy

Neuropathy affects the peripheral and autonomic nervous systems and involves degenerative changes in the nerves which can result in functional defects.<sup>(46,47)</sup> Peripheral neuropathy affects

the nerves and muscles, particularly of the lower limbs. Features associated with peripheral neuropathy are pain, loss of sensory function, delayed nerve conduction and muscle wasting (diabetic amyotrophy).<sup>(48)</sup> Autonomic neuropathy is usually accompanied by peripheral neuropathy. It can affect many systems in the body including: gastrointestinal tract, urogenital system, cardiovascular system and the sudomotor centre.<sup>(48)</sup>

The aetiology of the pathological features of neuropathy is thought to be metabolic, microvascular or a combination of both.<sup>(49)</sup> It has been suggested that the metabolic defect may be a result of increased activity of the sorbitol or polyol pathway,<sup>(50)</sup> subsequently causing Schwann cell damage and abnormal myelin sheath synthesis.<sup>(38)</sup> Since this pathway of sorbitol metabolism is not dependent on insulin, it is suggested that increased activity of this pathway in diabetics is related to insulin deficiency or hyperglycaemia.

The microvascular factor is another consideration in the aetiology of neuropathy. The nutrient vessels to the nerves become thickened and their eventual occlusion causes ischaemia and nerve damage.<sup>(49)</sup> It is possible that both the metabolic and vascular factors are responsible to a greater or lesser degree, and this may well be the basis for the various types of nerve damage.

Like nephropathy and retinopathy, the aetiology of neuropathy is uncertain. However, again there is evidence that hyperglycaemia can influence the onset of at least some forms of neuropathy,<sup>(43)</sup> reaffirming the importance of rigorous glycaemic control.

### 1.3.2 Macrovascular Disease

Disease of the larger blood vessels is not as specific to diabetes as microvascular disease, but it is more prevalent amongst the diabetic population.<sup>(51)</sup> The blood vessels affected are mainly in the peripheral, coronary and cerebral arteries, presenting as atherosclerosis.<sup>(52,53)</sup> Typically there are structural changes in the arterial walls which promotes the deposition of lipids and aggregation of platelets. These processes cause a gradual occlusion of the lumen, leading to a marked reduction in blood flow at the affected sites.<sup>(54)</sup>

The reason for the increased risk of atherosclerosis in diabetes is not clearly identified.<sup>(55)</sup> However, factors which increase the risk of atherosclerosis, such as hyperlipidaemia and hypertension, are also more common in diabetes, accounting for, in part, the higher incidence of atherosclerosis in diabetes.<sup>(56)</sup>

### 1.3.3 Diabetic Control and Complications

At present much interest is focussed on the relationship between microvascular complications and glycaemic control.<sup>(57-59)</sup> It has been noted that hyperglycaemia can enhance some of the biochemical changes involved in the microvascular diseases of retinopathy, nephropathy and neuropathy. In contrast, there is some evidence that in the short-term, improved glycaemic control can lead to deterioration of 'existing' microvascular disease.<sup>(60,61)</sup> This would support the view that 'prevention' of microvascular disease is the initial goal and that better glycaemic control can favour this.<sup>(62-63)</sup> However, microvascular disease does not bear a one to

one relationship with glycaemic control, it is thought to be of multifactorial origin, including genetic susceptibility.<sup>(58)</sup>

The association between macrovascular disease and diabetes is enhanced by the increased incidence of risk factors such as hyperlipidaemia and hypertension in diabetes. Hyperglycaemia, which is associated with increased hyperlipidaemia, may contribute, indirectly, to atherosclerosis in diabetes.

The role of hyperglycaemia in the manifestation of chronic diabetic complications has been discussed. There are strong implications that good glycaemic control can delay the onset, or at least reduce the severity of some of these complications. It is the opinion of many authors that improved glycaemic control should be one of the aims in preventing or reducing diabetic complications, and attempts to achieve good diabetic control should be a major goal in the management of diabetes.<sup>(62-67)</sup>

#### 1.4 Factors affecting Glycaemic Control

Management of diabetes entails achieving and maintaining a balance between insulin and diet.<sup>(68)</sup> This requires an understanding of the factors which cause fluctuations in blood glucose concentrations and knowledge of the appropriate measures to take in order to maintain optimal glycaemic control.<sup>(69)</sup>

The main factors influencing glycaemic control are:

- (i) diet
- (ii) insulin
- (iii) hypoglycaemia
- (iv) exercise
- (v) illness

The effects these exert on control and how these can be regulated are discussed in sections 1.4.1 - 1.4.5.

#### 1.4.1 Diet

In the past, the dietary treatment given to diabetics varied considerably. Prior to the introduction of insulin treatment the dietary recommendations have included: starchy foods and limewater, a high energy food diet, intermittent fasting, and Allan's starvation diet.<sup>(70)</sup>

After 1923 insulin treatment was initiated and it was recommended that dietary carbohydrate should be increased in order to 'balance' the insulin, but the amount and type of carbohydrate were still very much restricted. The principles of a restricted diet, which originated in the pre-insulin era, continued to be accepted up until the 1960's.<sup>(71)</sup> However, this restriction gave rise to a much higher fat consumption in the diabetic diet, resulting in a high fat/low carbohydrate diet. In the last decade there have been many reports and recommendations to change to low fat/high carbohydrate in the dietary treatment of diabetes.<sup>(72)</sup> It has been documented that a high fat intake, particularly of saturated (animal) fats, can increase the risk of cardiovascular disease,<sup>(73-74)</sup> and it is thought that a diet low in saturated fats can reduce this risk.<sup>(75)</sup> In view of the greater incidence of cardiovascular disease among diabetics, adherence to a low fat diet is believed to be particularly important.<sup>(72,76)</sup>

The change from a low carbohydrate to a high carbohydrate diet was introduced after reports that a glucose load is removed more efficiently following a higher carbohydrate meal.<sup>(77)</sup> Studies

demonstrated that a high carbohydrate diet is well tolerated without an increase in insulin requirements.<sup>(78,79)</sup> It is now accepted that the carbohydrate intake need not be severely restricted,<sup>(80)</sup> but that the type of carbohydrate and timing of meals are major factors influencing glycaemic control.<sup>(81-83)</sup>

Ingestion of carbohydrates causes an increase in the blood glucose concentrations which needs to be balanced by injecting insulin or taking exercise.<sup>(10)</sup> The aim of dietary treatment is to ingest small amounts of carbohydrate at regular intervals throughout the day, therefore avoiding extremes of a high or low blood glucose.<sup>(84)</sup> The effectiveness of this diet is dependent on the type of carbohydrate taken.<sup>(85)</sup> It has long been established practice to avoid refined carbohydrates, such as monosaccharides and disaccharides, because these are rapidly digested and absorbed causing 'peaks' in the blood glucose concentrations. More complex polysaccharides, such as starch sources of carbohydrate are recommended, e.g. bread, potatoes, rice. These take a longer period of time to be digested and absorbed and therefore cause a less pronounced increase in blood glucose concentration. More recently it has been recommended that vegetables rich in starch, which contain a high proportion of fibre, should be the main dietary source of carbohydrate,<sup>(86)</sup> e.g. uncooked vegetables, pulses and wholemeal bread and cereals. Fibre decreases the rate of digestion and subsequent absorption of glucose from the gastrointestinal tract.<sup>(87)</sup> This gives rise to a less pronounced increase in the post-prandial blood glucose concentration and has considerable benefits on glycaemic control.<sup>(88,89)</sup>

Another dietary recommendation is that sodium ('salt') intake is minimal.<sup>(72)</sup> This has arisen following reports that a high sodium intake may contribute to hypertension in genetically predisposed individuals.<sup>(90)</sup> Since diabetes is a known risk factor in the development of cardiovascular disease, a reduced sodium intake may confer some protection against hypertension and cardiovascular disease in diabetic patients.

In conclusion, the main dietary recommendations for the treatment of diabetes are: high carbohydrate intake, high fibre content, reduced fat intake and reduced sodium intake.<sup>(72)</sup>

#### 1.4.2 Insulin

Much progress has been made in the efficacy of insulin treatment of diabetes - see section 1.2.2. The major aim of insulin treatment is to maintain the blood glucose concentration as near to the normal range as possible.<sup>(91)</sup> The normal range is 3.5 - 8.0 mmol/l, and therefore the patient's insulin regime must be carefully planned to accommodate their normal lifestyle. Insulin regimes usually consist of once or twice daily injections,<sup>(92)</sup> and the duration of action of the insulin used is an important consideration when planning an insulin and dietary regime. For example, the insulin regime must be adjusted so that peaks in insulin action coincide with meal times when there will be increased carbohydrate intake. This approach is designed to avoid post-prandial hyperglycaemia and pre-prandial hypoglycaemia.<sup>(93)</sup>

It is essential that patients have an adequate understanding of the correct injection technique and the principles underlying the



design of their insulin regime if the patient is to contribute effectively in his/her own control.<sup>(94)</sup> In addition to lifestyle and daily circumstances, there are a number of factors which can cause variation by altering the rate of insulin absorption from the injection site into the blood stream.<sup>(95)</sup> This in turn can cause fluctuations in blood glucose concentration and may lead to unexpected hypoglycaemia or hyperglycaemia. It is important that patients are aware of these factors and know how to control them.

The rate of insulin absorption can vary with the injection site used,<sup>(96)</sup> and this can lead to significant variation in glycaemic control. Therefore, by alternating injection sites appropriately, unnecessary variation can be avoided. Injection technique is also important. This must be correct and consistent to ensure a constant rate of insulin absorption. Decreased insulin absorption can be caused by smoking,<sup>(97)</sup> due to vasoconstriction which is enhanced by the nicotine. Increased insulin absorption can occur when exercising, by rubbing the injection site or after taking a hot bath. All of these cause increased vasodilatation and increases blood flow.<sup>(98)</sup>

Insulin treatment, combined with dietary modifications, largely determines glycaemic control, and the equation 'Insulin + Diet = Blood Glucose', has often been used as the basis of diabetic control. However, it is now accepted that achieving glycaemic control is much more complex than this equation suggests, and that the effects of hypoglycaemia, exercise and illness on blood glucose concentration must also be considered.<sup>(99)</sup>

### 1.4.3 Hypoglycaemia

Hypoglycaemia or 'hypo' is a condition in which the blood glucose concentration falls below the normal range (3.0 - 7.0 mmol/l), and causes a reduction in glucose supply to the brain, typically experienced at glucose concentrations below 2 mmol/l.<sup>(100)</sup>

In the non-diabetic, the body's response to a decreasing blood glucose concentration is to reduce insulin secretion and increase glucose production.<sup>(19)</sup> In the diabetic person this does not occur because the injected insulin is released continuously from the subcutaneous site into the blood. There is no 'switch-off' mechanism, despite impending hypoglycaemia. Glucose production does not function as normal due to the suppression of hepatic gluconeogenesis by the insulin.<sup>(12)</sup> Therefore, it is possible for the blood glucose concentration to fall below the normal range and produce hypoglycaemia.<sup>(102)</sup>

Hypoglycaemia is treated by raising the blood glucose rapidly. Usually this is accomplished by drinking/eating glucose or some other form of refined carbohydrate. However, if the patient is unable to swallow, glucagon - a hormone which causes a rapid increase in glucose production through glycogenolysis and subsequently gluconeogenesis<sup>(12)</sup> - is injected intramuscularly.<sup>(103)</sup>

Hypoglycaemia elicits a number of characteristic symptoms, some of which are due to increased autonomic nervous activity.<sup>(104)</sup> The main symptoms are: sweating, irritability, hunger, weakness and tingling of the mouth. Insulin-dependent patients must be aware of these symptoms and the appropriate measures to take in the event of a hypoglycaemia reaction. Patients should also be informed about the unsound practices which may increase the risk of hypoglycaemia, for

example, an unprepared change in exercise, carbohydrate intake or alcohol intake, and know how to cope with these occasions.<sup>(105)</sup>

The after-effects of hypoglycaemia can make glycaemic control more difficult, but prevention and proper management of hypoglycaemia by the patient will result in better control.<sup>(106)</sup>

#### 1.4.4 Exercise

Exercise is another factor which can have a marked effect on glycaemic control.<sup>(107)</sup> Exercise causes increased uptake and utilisation of glucose in the muscles, enhances insulin absorption from injection sites and improves glucose tolerance in controlled diabetes.<sup>(108)</sup> Subsequently there is a decrease in blood glucose concentration, and exercise is therefore considered an important feature in the treatment of diabetes.<sup>(109)</sup> However, increased physiological activity increases the risk of hypoglycaemia and therefore it is essential that patients are informed of this and know how to prevent hypoglycaemia, therefore enhancing the benefits of exercise.<sup>(110)</sup>

Exercise also lowers serum triglyceride and cholesterol levels. Thus, it may also reduce the risk of macrovascular disease.<sup>(111)</sup> It is clear that exercise has both short and long-term benefits and it is essential that patients are aware of these and encouraged to include a suitable amount of exercise as part of their treatment programme.

#### 1.4.5 Illness

Intercurrent illness affects glycaemic control and often causes hyperglycaemia, with or without ketonuria.<sup>(112)</sup> Patients

should be informed of these effects and how to maintain a reasonable level of glycaemic control during illness. For example, by increasing the insulin dose appropriately, the hyperglycaemic effects can be countered.<sup>(113)</sup>

It is apparent that many factors must be considered to achieve and maintain optimal glycaemic control. Adequate patient knowledge about these factors and how they should be managed is vital.<sup>(114)</sup> This requires health education and, more specifically, diabetes health education. These issues will be discussed in sections 1.5.1 and 1.5.2.

#### 1.5 Patient Education

In many illnesses, particularly chronic diseases such as asthma, hypertension, heart disease and diabetes, the major part of the treatment is carried out by the patient themselves in collaboration with their physician. Thus, a high level of responsibility is usually required for successful day to day management.<sup>(115)</sup> Such participation is only possible if patients are provided with the appropriate information and training, and are sufficiently motivated to contribute to their treatment/management. Therefore, patient education is recognised as an essential component in the treatment of many diseases.<sup>(116,117)</sup>

In recent years, more emphasis has gradually been focussed on developing and conducting patient health education programmes relating to the major chronic diseases and general preventative medicine.<sup>(118-121)</sup> The aims of these are to help patients to accept and understand their illness, and to provide necessary

information concerning the practical aspects of self-management.<sup>(112)</sup>

However, although education is an essential pre-requisite for patient co-operation, 'knowing is not doing', and knowledge does not guarantee compliant behaviour.<sup>(123)</sup> It is reported that efforts to improve health by increasing knowledge alone are rarely successful. It is recommended that education programmes should be orientated towards behaviour and its modification.<sup>(117,124)</sup> Therefore, consideration must be given to those factors which affect health-related behaviours,<sup>(125)</sup> including:

- (i) Social and environmental aspects, i.e. family, friends, work
- (ii) Attitudes, i.e. beliefs, feelings
- (iii) Psychological issues, i.e. emotions, fears, depression.

The aims of patient education have been described. It is evident that this requires not only the provision of information, but consideration of other factors which may affect the patient's behaviour and achievement of educational objectives. These aspects will be reviewed in the following sections 1.5.1 - 1.7.3.

#### 1.5.1 Diabetic Patient Education

Following disappointing results with some of the very first insulin treated patients in 1921, E.P. Joslin - the eminent American Diabetologist - pointed out that insulin therapy was "a waste of time and money unless the patient was thoroughly instructed to manage his own case".<sup>(126)</sup> In the 1920s, Joslin was a pioneer of diabetes education. He produced a diabetic manual 'for mutual use of doctor

and patient', and established a 'live-in' teaching clinic and other educational programmes.<sup>(127)</sup> Also in the 1920s, R.D. Lawrence - from King's, London, another pioneer of diabetic education - edited a manual entitled 'The diabetic life: its control by diet and insulin'. He stated that 'the diabetic patient must be his own doctor, dietitian and laboratory technician. Hence, education is the single most important aspect of treatment'.<sup>(128,129)</sup> Therefore, as early as the 1920s, diabetic education was recognised as an essential component in the treatment of diabetes, and efforts were made to provide some form of education/instruction.<sup>(130)</sup>

In the early days, much of the diabetes education was unstructured and lacked definitive objectives, and studies in the 1950s and 1960s documented a persistent lack of understanding of diabetes and its management among patients and their families.<sup>(131,132)</sup> These studies emphasised the necessity for more effective educational processes. Subsequently, the introduction and the development of more structured and co-ordinated programmes has taken place in most hospitals or clinics caring for diabetic patients.<sup>(133-135)</sup>

There are various ways of conducting patient education programmes, for example, instruction can be given to groups or on an individual basis, patients may learn as in-patients or out-patients, presentation may be lectures, discussions or demonstrations or a combination of these, and a variety of teaching and audiovisual aids may be used such as videos, computers, slides, overheads, books, pamphlets or models. The merits of these approaches will be discussed and evaluated in section 1.6.

The content of education programmes basically remains the same with the essential 'hard core' knowledge forming the basis of the

curriculum, i.e diet, insulin, monitoring and hypoglycaemia.<sup>(136,137)</sup>

This is usually supplemented with information concerning acute and chronic complications, exercise, illness and other practical aspects of management. Patients are encouraged to be responsible for their own well-being. The provision of this information enables them to make appropriate adjustments in treatment so that optimal diabetic control can be maintained. The content of diabetes educational programmes will be discussed in section 2.8.

Ultimately, the aim of any educational programme is to equip patients with adequate information and skills for effective self-management,<sup>(138)</sup> and in doing so, provide at least the foundation for achieving the best possible control. For this reason, the efficacy of educational programmes is usually evaluated by assessing diabetic control in patients who have participated in a programme, and this relationship between knowledge of diabetes and diabetic control is discussed in section 1.5.2.

#### 1.5.2 Patient Knowledge of Diabetes and Diabetic Control

Much interest has focussed on the relationship between knowledge of diabetes and diabetic control, and whether increased patient knowledge of diabetes favourably influences diabetic control. Although education programmes have been conducted for a considerable number of years, relatively little information is given concerning the effectiveness of these programmes in terms of diabetic control.<sup>(139)</sup> This lack of information may be attributed to the difficulties involved in assessing glycaemic control, and the time and expense required in education.<sup>(140)</sup> However, in recent years it has become apparent that evaluation is essential to assess the

effectiveness of programmes in terms of the benefits for patients, the economic feasibility and the efficacy of the educational methods used.<sup>(141,142)</sup> Subsequently, most educational efforts are now evaluated, at least in terms of effects on diabetic control.

There are various methods used to assess glycaemic control. These include: urine and blood glucose tests,<sup>(143,144)</sup> performed either at home by the patient or at the hospital, and a more recent test is to measure the amount of glycosylated proteins in the blood,<sup>(145,146)</sup> since these increase with poorer control. Also, more crude indicators of diabetic control have been used for evaluation, such as the frequency of hospital admissions or incidence of foot problems.<sup>(147)</sup> However, a major problem concerning the use of these assessments in evaluation is the difficulty in defining 'good control'. Thus, studies may adopt different criteria to indicate good, moderate or poor glycaemic control, and this has a significant effect on the conclusions of the study, thereby making comparisons between studies unreliable.

Various studies have investigated the relationship between diabetes education and diabetic control as assessed by some of the methods described. There are reports that improved diabetes education resulted in a significant reduction in hospital admissions, improved blood and urine glucose and glycosylated protein levels, and a decrease in the number of foot problems.<sup>(148-153)</sup> It is suggested that increased diabetic knowledge has a favourable effect on glycaemic control and that patients and hospital services benefit. However, other studies have found that increased knowledge was not associated with improved glycaemic control,<sup>(154-157)</sup> and it has



been suggested that an inverse relationship exists, i.e. greater knowledge associated with poorer glycaemic control.<sup>(158)</sup>

Conflicting evidence is presented concerning the effects of patient knowledge on glycaemic control. There are a number of reasons which may, at least in part, account for some of the variation in results reported, for example, different methods of evaluation which have been used. Questionnaires used to assess diabetic knowledge can show considerable variation. They may consist of direct questions or a multiple choice format, and the reading and comprehension levels can vary significantly among questionnaires. The depth of knowledge required may differ, and the scoring systems of questionnaires are another source of variation. Due to the lack of a standardised approach in the evaluation of knowledge, the interpretation of patients' knowledge of diabetes, as reported in the literature, is difficult. Moreover, various methods of assessing diabetic control have been used, some of which may reflect this more accurately than others. This introduces a further source of variation between studies, thus making comparisons unreliable.<sup>(147)</sup>

Some reasons which may account for the contradictory reports concerning the relationship between knowledge and glycaemic control have been discussed. However, the major feature which determines whether or not a relationship is demonstrated is compliance, or the application of diabetic knowledge in behaviour.<sup>(159,160)</sup> There are a number of factors which influence compliance and these should be considered in the design of patient education.<sup>(161,162)</sup> Increasing patients' knowledge and understanding is only one component of diabetic education. It also concerns the development of favourable

attitudes, beliefs, motivations and intentions - essential qualities for compliant behaviour.<sup>(163)</sup> However, in most studies, very little or no information is available concerning these aspects. It is possible that variation in the amount of attention given to developing these aspects in educational programmes is an underlying reason for inconsistent reports concerning the effect of knowledge on glycaemic control.

Benefits of diabetes education, in terms of improved glycaemic control, are only apparent when appropriate compliant behaviour is observed.<sup>(164)</sup> Factors which influence compliance, and methods to improve this will be discussed in section 1.6.

#### 1.6 Patient Compliance

As defined by R.B. Haynes,<sup>(165)</sup> 'compliance is the extent to which a person's behaviour (in terms of taking medication, following a diet, or carrying out lifestyle changes) coincides with medical advice or health advice'.

Poor compliance is a major problem in the treatment of many chronic diseases.<sup>(166)</sup> Non-compliance in diabetes drastically curtails the benefits of the treatment regime and causes considerable expense in hospital services.<sup>(167,168)</sup> Therefore, much interest has focussed on the subject of compliance, and more important, how to improve this.<sup>(169)</sup>

Compliance with diabetic treatment regimes is a complex problem to study because of the difficulties encountered in measuring compliance rates.<sup>(170,171)</sup> Also, poor compliance is not specifically related to any particular characteristics such as age,

sex, race, socio-economic group, etc., therefore non-compliance cannot be assigned to particular groups of people.<sup>(172)</sup>

Studies concerning compliance in a number of chronic diseases have been conducted, and it is established that there are four major aspects which influence and determine compliance with medical regimes.<sup>(167)</sup> These include:

- (i) psychological factors
- (ii) environmental and social aspects
- (iii) characteristics of the treatment regime
- (iv) patient-doctor relationship

Psychological factors concern the patient's personality, characteristics, and attitudes - emotions and beliefs.<sup>(172)</sup> Although personality traits are almost impossible to assess or change and usually must be accommodated, patients' attitudes and beliefs, which are based on their knowledge and understanding of the condition, can be altered using educational approaches.<sup>(173)</sup>

Environmental and social factors include the patient's lifestyle, work, financial and time constraints, and the influence of family and friends.<sup>(174)</sup> Problems originating from these can often be alleviated with or without the aid of social services. Social support for the patient can be improved by increasing the family involvement and seeking their co-operation to support and encourage the patient. Also, consideration of the patient's lifestyle and habits can help in the provision of more appropriate advice and even alternative recommendations when necessary. This is more likely to facilitate compliance.<sup>(175)</sup>

The third factor concerns the actual treatment regime the patient is asked to follow. It is reported that complex treatment

regimes which require considerable behavioural changes are most likely to be related to poor compliance.<sup>(170)</sup> It is recommended that patients be actively involved in the design of their treatment and are aware of 'why' they are restricted to a particular diet or need to alter their insulin dose for example. Realistic regimes which accommodate the individual person and a gradual introduction of such treatment and management plans, are important in reinforcing compliant behaviour.

Finally, it is well documented that the relationship between the patient and the health professional, i.e. doctor/nurse/dietitian, etc., is a major determinant of compliance.<sup>(177)</sup> It is advised that an understanding and caring approach should be used by the educator/doctor/nurse, etc. in order to encourage good rapport and free communication, essential to enhance patient co-operation needed for compliance.<sup>(178)</sup>

Features which influence and enhance compliance have been discussed. However, an area which has also been studied is the 'prediction' of compliance/non-compliance. Subsequently, the Health Belief Model (HBM) theory<sup>(179)</sup> was developed to explain and predict patient compliance. The HBM (Fig. 1.1) is a comprehensive assessment of the psychological, social, and behavioural determinants discussed earlier. Applying this model to diabetes, it was found that patients who believed in the seriousness of their condition, and who perceived the benefits of the treatment regime, demonstrated greater compliance.<sup>(180,181)</sup> The patient's beliefs about his/her condition is an important component of the HBM. A further theory predicts compliance solely on the basis of the patients' beliefs about their condition. This theory is the 'Health Locus of Control',<sup>(182)</sup> and

FIG. 1.1 HEALTH BELIEF MODEL (adapted from Becker and Maiman<sup>(179)</sup>)



recognised two types of patients:

- (i) those who perceive consequences and rewards as being dependent upon his/her own behaviour - this is called an internal locus of control
- (ii) those who feel that consequences or rewards are due to luck or fate and cannot be altered by their behaviour - this is called an external locus of control.

With respect to diabetes, it has been documented that greater compliance is associated with an internal locus of control.<sup>(183)</sup>

Thus, it is recommended that patients be encouraged to assume responsibility for their own diabetes, and to recognise the importance of 'self'-management.

Following research into the particular aspects which influence compliance, attempts have been made to define practical strategies which would enhance compliance,<sup>(184)</sup> some of which were considered earlier. These aim to:

- (i) provide accurate information on which to base beliefs and perceptions
- (ii) promote a more positive attitude towards health
- (iii) increase patient participation and responsibility for health
- (iv) accommodate social and environmental factors which may reduce compliance
- (v) develop motivation to achieve and maintain compliant behaviour.

'Educational' and 'behavioural' strategies which are recommended to enhance compliance with medical regimes will be

discussed. It is reported that using a combination of these methods can lead to significant improvements in compliance.<sup>(184)</sup>

### Educational Strategies

- (i) Content - determines patients' level of interest and understanding. The presentation should be as varied and imaginative as possible.<sup>(185)</sup> This is facilitated with audiovisual and teaching aids such as slides, videos, computers, etc.<sup>(186-188)</sup> The format can also be varied using individual and group meetings.<sup>(189)</sup>
- (ii) Structure of presentation - organising the subject material facilitates learning, especially if the information is concisely presented in discreet smaller sections.<sup>(190)</sup> Comprehension and readability of presentations should match the capability of the patients.<sup>(191-193)</sup>
- (iii) Active participation - promotes interest and thereby assists learning.<sup>(194-195)</sup> Group discussions and questionnaires encourage participation.<sup>(196)</sup>
- (iv) Reinforcement - is achieved by summarising both the key facts and repeating information. This also improves the recall of information.<sup>(197)</sup>

### Behavioural Strategies

- (i) Communication - the relationship between the patient and educator affects motivation to learn and comply with treatment. It has been shown that a caring and supportive attitude should be demonstrated.<sup>(198,199)</sup> To be convincing it is important to be sincere if persuasion is to be

effective. Communication is increased by letters and telephone calls and by promoting informal and sociable aspects of teaching.

- (ii) Achievement - is a known motivator of behaviour, e.g. exam results. Realistic goals, in terms of HbA<sub>1c</sub>, blood/urine glucose levels and knowledge skills could provide incentives for achievement.<sup>(200)</sup>
- (iii) Self-monitoring - allows the patient to observe and record results of self-management, and encourages involvement and self-responsibility.<sup>(201)</sup> Home blood/urine glucose tests provide self monitoring in diabetes.<sup>(202)</sup>
- (iv) Reward - has been shown to achieve significant improvements in compliance.<sup>(203)</sup> The accomplishment of personal goals or mastering difficult management skills can be rewarded in various ways, e.g. relief of symptoms such as thirst, praise, encouragement.
- (v) Contracting - the patient and educator can decide on particular goals in terms of management and control.<sup>(204)</sup> This provides the opportunity for achievement and reward, but contracting must be realistic and accommodate the individual. Goals such as particular HbA<sub>1c</sub> levels and blood glucose concentrations could be used.<sup>(205)</sup>
- (vi) Feedback - is essential in the learning process and patients should be informed of their progress in self-management.<sup>(206)</sup> Feedback can be provided with biochemical results concerning control, e.g. HbA<sub>1c</sub> levels or the results of knowledge questionnaires.



- (vii) Tailoring - is to adapt educational methods and recommendations to suite the individual patient.<sup>(207)</sup> This ensures that the patient's needs and preferences are considered.
- (viii) Reinforcement - is necessary to encourage patients to achieve and maintain compliant behaviour. Positive reinforcement is more effective than negative in achieving compliance.<sup>(207)</sup> This is provided by increased attention and supervision, encouragement and support from educator and peer group, convenient appointments and family support.<sup>(208)</sup>

Techniques reported to enhance patient compliance, and ways in which these could be introduced into diabetes education, have been discussed. However, despite education, when considerable changes in lifestyle are required, compliance may not always be achieved. Thus:

Seeing is not believing  
Believing is not knowing  
Knowing is not understanding  
Understanding is not doing

Lorenz<sup>(209)</sup>

Diabetic patients must be motivated if they are to benefit from increased education, and this is recognised as a vital aspect in diabetes care, and is discussed further in section 1.6.1.

#### 1.6.1 Motivation

This is considered in the Health Belief Model as a determinant of compliance. In this context, motivation concerns the patient's intentions to follow advice, willingness to seek medical care, positive health actions and general health values. It is reported

that poor or non-compliance is attributed to 'lack of motivation', and it is recommended that this should be assessed and increased in patient education.<sup>(210)</sup> A major goal in patient education is to initially provide 'extrinsic' motivation, i.e. from the educator and peer group, and to subsequently develop 'intrinsic' motivation, i.e. an inward quality of the patient.<sup>(211)</sup> Extrinsic motivation may be provided by encouragement, praise and support from the educator and peer group. Intrinsic motivation can be developed by increasing the patient's self-confidence and self-responsibility, and promoting family support and reinforcement. Other valuable motivational features include some of the behavioural and educational strategies discussed in section 1.6.

An important factor which affects both motivation and compliance, and which deserves consideration in education programmes, is the patient's attitude towards health and diabetes.<sup>(212)</sup> This concerns the patient's feelings, beliefs and behavioural intentions and how these influence behavioural compliance.

### 1.7. Attitudes

Behavioural compliance is influenced by many factors which were discussed earlier, and include the attitude of the patient, their feelings and beliefs. However, the relationship between attitude and compliance in diabetes has hardly ever been documented.<sup>(147)</sup> This section considers the definition and concept of attitude, the relationship between attitude and behavioural compliance, theories of attitude change and the role of attitude as a determinant of compliant behaviour in diabetes.

### 1.7.1 Attitude - Definition and Concept

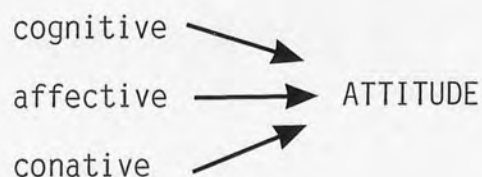
Considerable interest continues to be focussed on attitudes because psychologists argue that attitudes can be used to predict behaviour.<sup>(213)</sup> This has promoted the development of several different, similarly rated theories concerning the concept or definition of attitude. Allport (1935) defines attitude as 'a mental or neural state of readiness, organised through experience, exerting or directing a dynamic influence on behaviour'.<sup>(214)</sup> This infers that attitudes are psychological entities which are learned through experiences and which influence the behaviour of the individual.

Krech and Crutchfield (1948) defined attitude as 'an enduring organisation of motivational, emotional, perceptual and cognitive processes with respect to the individual's world'.<sup>(215)</sup> This is a multicomponent concept which proposes that attitude is based on the three stances of the human condition:

- (i) cognition - perceptions, beliefs
- (ii) affection - emotions, feelings
- (iii) conation - response, behaviour

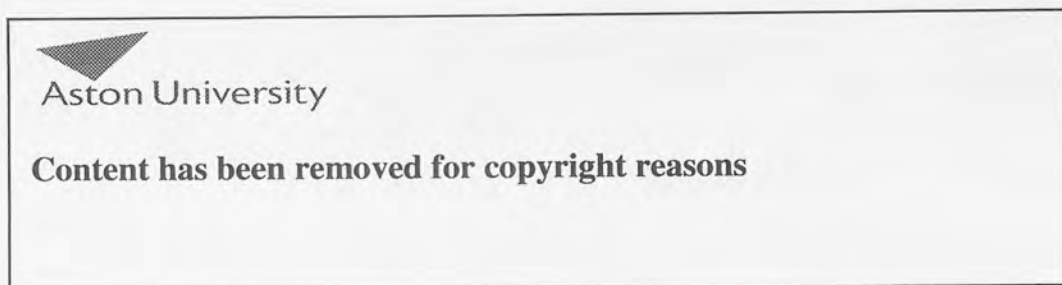
This concept suggests that attitude consists of these three components (Fig. 1.2).

Fig. 1.2 Components of Attitude



Fishbein and Ajzen (1975)<sup>(216)</sup> also consider these three attitude components, but regard attitude as the affective component which is only 'associated' with cognitive and conative aspects, i.e. beliefs, intentions, behaviours. This is illustrated in Fig. 1.3.

Fig. 1.3 Concept of Attitude proposed by Fishbein and Ajzen<sup>(217)</sup>



Several popular attitude concepts or definitions have been described to provide a background for the subsequent discussion. In conclusion, attitude is a subjective construct, for which there is no absolute or correct definition. Attitude is not a quantifiable entity, but can only be inferred.<sup>(217)</sup> How attitude is defined and used will depend on the observations/criteria on which the attitude is based.

Subsequent discussion concerning attitudes and diabetes is not based on any one particular theory, but takes into account the major attitude concepts presented here.

### 1.7.2 Attitude - Behaviour Relationship

The reason for considering attitudes towards diabetes was to investigate the extent to which compliance is influenced by attitudes and whether attitude measures could be used to predict compliance. In this discussion, compliance and behaviour are synonymous.

The relationship between attitude and behaviour has long been a controversial issue.<sup>(218)</sup> Although it has been reported that there is little or no evidence for attitude-behaviour consistency,<sup>(219)</sup> it is also documented that there is consistent relationship.<sup>(220)</sup> Two major theories accounting for attitude-behaviour consistency and inconsistency will be considered here.

The theory of 'reasoned action'<sup>(220)</sup> supports the attitude-behaviour relationship. This proposes that specific behaviour, e.g. compliance, is determined by intentions, which are influenced by attitudes and subjective norms, e.g. how other people would evaluate the behaviour.<sup>(221)</sup> This is illustrated in Fig. 1.4.

Fig. 1.4 Basis for the Theory of Reasoned Action  
(Fishbein 1975<sup>(220)</sup>)

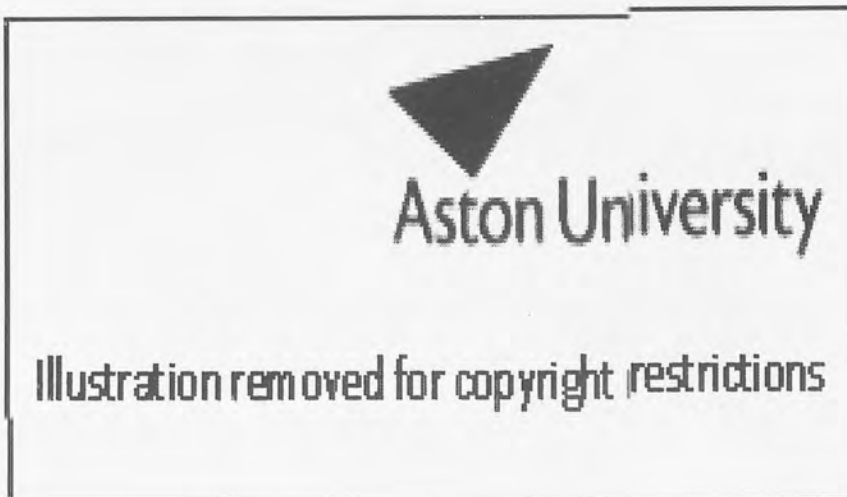


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This theory also considers those factors which influence attitude and subjective norms, such as beliefs. This is illustrated in Fig. 1.5.

Fig. 1.5    Theory of Reasoned Action    Fishbein (1975)<sup>(220)</sup>



However, it is known that 'dissonance' can exist between attitudes and behaviour,<sup>(222)</sup> e.g. a diabetic patient knows and believes that eating sweets causes a rise in the blood glucose concentrations, but continues to eat sweets. This is an example of dissonance between cognitive and conative components, and means that the total attitude measured does not predict the expected behaviour. Thus, it is suggested that the patient's behaviour is not predicted by attitudes, but is influenced by social norms, environmental constraints and other factors.<sup>(223)</sup>

Two theories have been described which account for consistent and inconsistent attitude-behaviour relationships. However, it is important to consider other factors which determine the type of attitude-behaviour relationship demonstrated.<sup>(224)</sup> These include: accuracy and validity of the attitude measurement, appropriateness of behaviour assessed, interval between collection of the two sets of data and the influences of social norms and other attitudes.<sup>(225)</sup> It has been suggested that when these methodological issues and other relevant factors are accounted for, the attitude-behaviour relationship appears relatively strong.<sup>(226)</sup>

Regarding the attitude-behaviour relationship in diabetes, it was surmised that either compliant behaviour is a component of attitude, or that it is influenced by attitude (affect) and cognitive elements. How patients' attitudes are measured and the criteria used to indicate compliance will determine whether an existing attitude-behaviour relationship is demonstrated.

This study investigates the influence of attitudes on compliant behaviour, therefore care was taken to choose an appropriate attitude measure and a reliable indicator of behaviour. This is discussed in sections 2.5 and 2.7.

### 1.7.3 Attitude Change

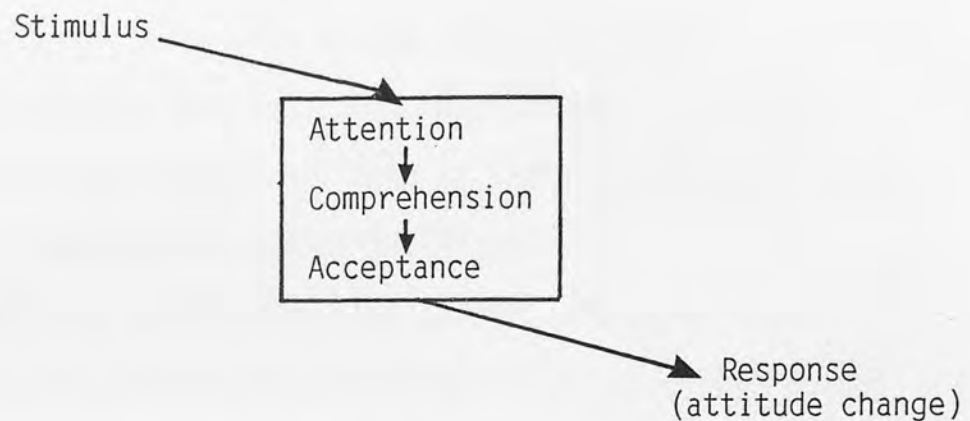
It is reported that attitude is an 'enabling factor' which influences compliance in diabetes.<sup>(227)</sup> Thus, it is reasonable to assume that a more favourable or positive attitude to diabetes enhances the patient's compliance with the treatment regime and management. Therefore, improved attitudes towards diabetes may

enhance the benefits of diabetes education and of the treatment regime.<sup>(228)</sup> For the development of more favourable attitudes, the patient may need to modify his beliefs, feelings, perceptions, etc. with respect to diabetes, and this introduces the subject of attitude change. Various theories exist concerning attitude change; these are described in other texts.<sup>(229-231)</sup> Only the theories of attitude change relevant to this study are discussed in this section. These include the 'learning theory' and the theory of 'cognitive dissonance'.

The learning theory, also called the 'incentive theory', is consistent with Allport's definition of attitude - 'learned through experience'.<sup>(232)</sup> In this theory three factors are important; attention, comprehension and acceptance.<sup>(233)</sup> Initially, the appeal or persuasion to alter the patient's attitude must be noticed - this involves the 'attention' component. Any persuasive communication or information must be presented in a form which is easily understood by the patient, therefore allowing 'comprehension'. Finally, to promote attitude change, the outcomes must provide reward, benefits or incentives, thus increasing the 'acceptance' of new or modified attitudes. The relationship between the three components of the learning theory are illustrated in Fig. 1.6.



Fig. 1.6 Learning Theory of Attitude Change <sup>(233)</sup>



Important features of this type of attitude change include:

- (i) Communication - the content, argument, appeals
- (ii) Source of information - credibility, attraction, expertise
- (iii) Environment - determines how well patient responds to message

The most popular theory of attitude change is that of 'cognitive dissonance'.<sup>(234)</sup> This is based on the existence of 'conflicting cognitions' - this is when the individual's knowledge of feelings, values, beliefs, attitudes and behaviours concerning a particular subject/object are dissonant. The theory proposes that cognitive dissonance is psychologically uncomfortable and motivates the individual to modify behaviour or attitudes in order to reduce dissonance. This type of attitude change depends on creating inconsistencies among cognitions. This can be achieved with the

presentation of new information and may serve as the stimulus for attitude change.<sup>(235)</sup>

The methods pertaining to the theories discussed, including persuasive communication, rewards, comprehension, etc. were introduced into the educational/motivational programme conducted in this study. These are described in section 2.8.

Attempts to change attitudes are not always effective.<sup>(236)</sup> Some individuals are not easily persuaded and may be intransigent to change. Therefore, to modify attitudes, the patient's self-evaluation and existing attitudes must be considered to enable an appropriate selection of methods, e.g. coercive or aversive persuasion, information content, etc.<sup>(237)</sup>

Attitudes may influence the acquisition of diabetic knowledge and related compliance, and the formation of attitudes is affected by existing knowledge and compliance behaviours. Therefore, attitude is an important component in the education and motivation of diabetic patients, and attitude is a unique feature in this study.

## 1.8 Reasons for Study

The preceding discussion has described insulin-dependent diabetes with respect to treatment, complications, control and practical problems. The high degree of patient responsibility and self-management in the control of diabetes has been stressed, and the importance of diabetes education has been emphasised. However, studies have shown that diabetes education does not necessarily lead to improved control, and that compliant behaviour in self-management is influenced by other factors. Motivation is a key factor determining patients' efforts in self-management, and attitude is a

component which affects motivation, intention and compliance. Thus, it is suggested that adverse attitudes towards diabetes may prevent the maximum potential of diabetes education.

It is evident that patients' knowledge of diabetes and attitude towards diabetes can influence glycaemic control. Previous studies have considered separately the relationship between diabetic knowledge and glycaemic control, and between attitudes and glycaemic control. The present study investigates the 'inter-relationship' between these three factors and other sociodemographic factors in insulin-dependent diabetes. The study also includes the design and evaluation of an educational programme which introduces specific motivational/behavioural features which have been reported to enhance compliance. The programme is evaluated in terms of patients' preferences and educational needs and the effects on diabetic knowledge, attitude and glycaemic control have been assessed.

## 2.1. Introduction

The purpose of this study was to investigate the relationship between the variables mentioned above. The study was conducted in a hospital setting, and the data were collected from a sample of patients. The study was designed to be descriptive and exploratory, and the results are presented in the following sections. The study was conducted in a hospital setting, and the data were collected from a sample of patients. The study was designed to be descriptive and exploratory, and the results are presented in the following sections.

## 2. PATIENTS, METHODS AND STUDY DESIGN

The study was conducted in a hospital setting, and the data were collected from a sample of patients. The study was designed to be descriptive and exploratory, and the results are presented in the following sections. The study was conducted in a hospital setting, and the data were collected from a sample of patients. The study was designed to be descriptive and exploratory, and the results are presented in the following sections.

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## 2.1 Introduction

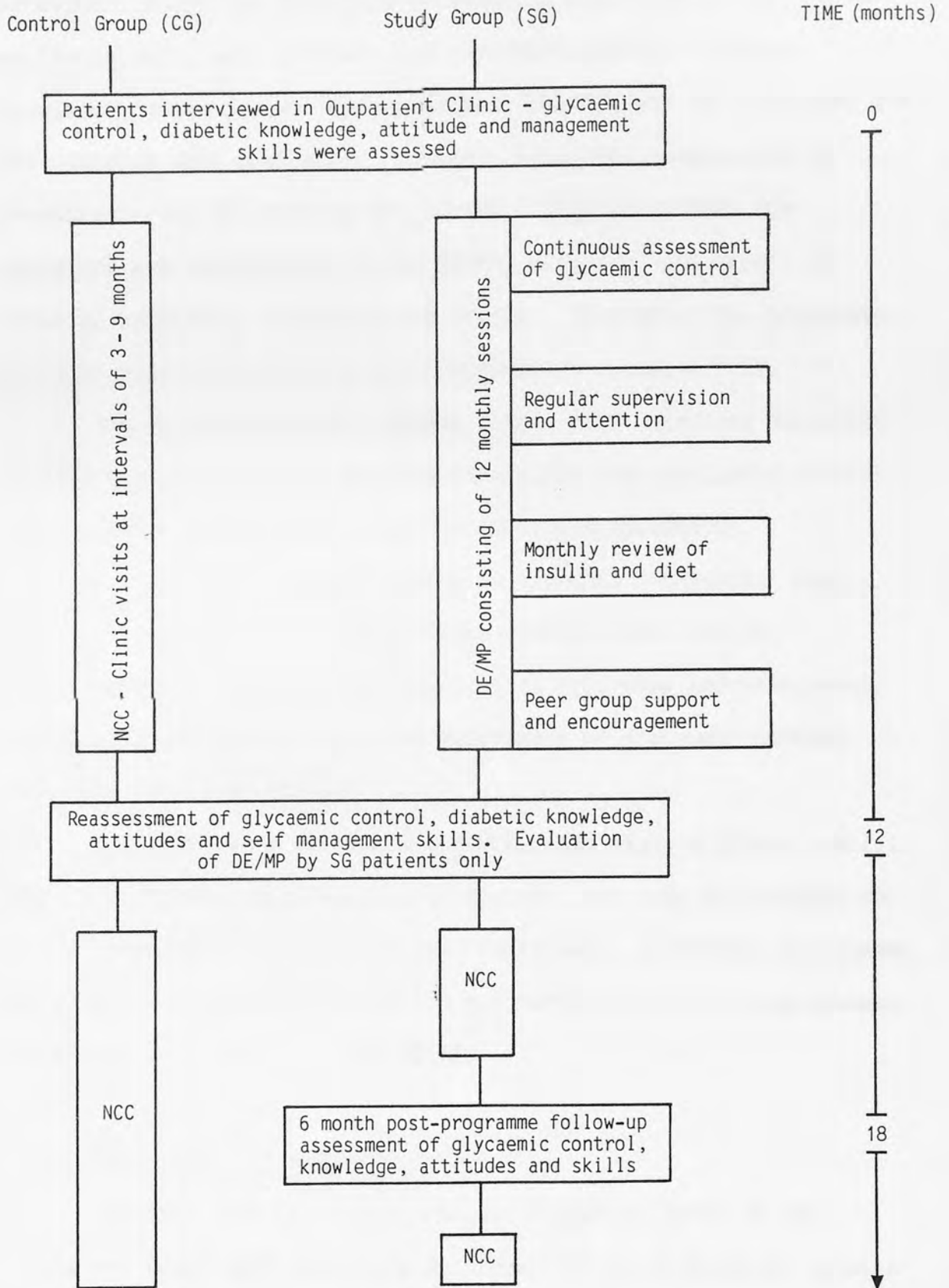
In this chapter, the study design and recruitment procedures are described. Methods used to assess glycaemic control, knowledge, attitudes, self-management skills and sociodemographic variables are discussed, and the development of knowledge questionnaires and attitude scales is documented. Also, the objectives and design considerations of the diabetes educational/motivational programme (DE/MP) are described, and evaluation of programme effectiveness and educator skills are detailed. The chapter concludes with a description of the statistical analyses used to compare the assessment parameters and sociodemographic variables.

## 2.2 Study Design

The study involved insulin-dependent patients who were recruited from the weekly Diabetic Outpatient Clinic in the Outpatients Department at Dudley Road Hospital, Birmingham. The patients were initially allocated to either a Study Group (SG), which participated in the DE/MP, or a Control Group (CG), which continued with normal clinic care (NCC) only. Patients were interviewed and assessed for glycaemic control, diabetic knowledge, attitudes towards diabetes and self-management skills. The study design is illustrated in Fig. 2.1.

SG patients entered into the DE/MP which consisted of 12 monthly sessions in which different aspects of diabetes treatment and management were considered. Both individual and group sessions were held, and social aspects of the programme were encouraged. Various strategies were used to enhance patient motivation in learning and

Fig. 2.1 Study Design of the Diabetes Educational/Motivational Project



NCC = normal Clinic care

DE/MP = diabetes education and motivation programme

behaviour; these are discussed in sections 2.8.4 and 2.8.5. At 12 months patients were assessed for glycaemic control, diabetes knowledge, attitude and self-management skills, and the programme and the educator were evaluated. Patients were then re-assessed to investigate the maintenance of glycaemic control without the attention and supervision of the DE/MP, retention and recall of diabetic knowledge, attitudes and skills. Throughout the programme, patients continued with the usual outpatient clinic visits.

The CG continued with normal clinic care only, and therefore visited the clinic at 2-9 monthly intervals, when glycaemic control was monitored using blood and urine glucose measurements, supplemented by HbA<sub>1c</sub> determinations at selected intervals. Diet and insulin were also reviewed at the normal clinic visits. Approximately 12 months after the initial interview and assessment, CG patients received a follow-up assessment of glycaemic control, knowledge, attitude and skills.

Assessments of glycaemic control, knowledge, attitude, skills and various other sociodemographic factors were made at 0 months to ensure comparability of the SG and CG patients. A further assessment was made at 12 months to establish any differences occurring between the groups as a result of the DE/MP.

### 2.3. Recruitment of Patients

Patients were recruited from the Diabetic Clinic in the Outpatient Department at Dudley Road Hospital in Birmingham, between April 1984 and February 1985. Criteria for recruitment were:

1. Insulin treated from the time of diagnosis.
2. Age <60 years.
3. Duration of diabetes >1 year.
4. Ideal body weight <130%.
5. No serious complications such as proliferative retinopathy or renal impairment (serum creatine <200 mmol/l).
6. Not pregnant.
7. Adequate understanding of English.

With the permission of the Consultant Physician at the Diabetic Clinic, the medical records of insulin-dependent patients due to attend the weekly clinic were examined.

Patients who fulfilled the criteria stated above were listed as suitable for the study and were interviewed where possible.

Criterion number 7 - 'an adequate understanding of English' - was necessary in this study because assessments required patients to answer questionnaires, and it was felt that completion via an interpreter may lead to biased or unreliable responses. Therefore patients who were unable to understand or speak English, as recorded in the medical notes, were excluded from the study. An adequate understanding of English was ascertained by ensuring the patient's ability to read and comprehend literature with a reading age of approximately 11 years.

Also, data concerning the following factors were obtained from the patients' medical records:

1. Sex - male or female.
2. Age - years.
3. Duration of diabetes - years.



4. Marital status - patients were categorised as either single, married or divorced/separated.
5. Ethnic group - patients were classed as either caucasian, West Indian or Asian.
6. Social class - this was based on the Office of Populations Survey Index,<sup>(238)</sup> which used 5 social classes based on occupations. The class of housewives was based on their husband's occupation, and that of students was based on parents' occupations or a missing value was recorded where inadequate or unsubstantiated information was obtained. Many patients were unemployed and these patients were assigned to a separate group - unemployed (U/E).
7. Weight - expressed in kilograms (kg) and converted to the % ideal body weight using Taylor's graphs (Appendix 1).
8. Height - expressed as centimetres (cm).
9. Insulin type and dose - the insulin or combinations of insulins used was noted and the dose recorded in units. This was then converted to insulin dose per kg body weight for convenient comparison.
10. Clinic attendance - expressed as the percentage of defaulted clinic appointments in the four years previous to the interview. 'Clinic non-attendance' is abbreviated to CNA; for the purpose of this study, clinic non-attendance is expressed as the % CNA.
11. Hospital admissions due to diabetes - the total number of hospital admissions for diabetes was divided by the patient's duration of diabetes and is therefore expressed as the mean per patient/years of duration.

12. Previous clinic blood glucose profile - was calculated from the previous four non-fasted clinic blood glucose concentrations, and is expressed as mmol/l.

Prior to the interview, patients were randomly allocated to either the Control Group (CG) or Study Group (SG). After the interview, patients were asked to participate in their respective groups, i.e. SG to attend monthly group sessions and CG to continue with normal clinic care and follow-up interview. However, this method of allocation proved unsuccessful for several reasons:

- (i) Although initially SG and CG patient numbers were even, there were patients who agreed to participate in the SG but did not attend. Because clinics were held once weekly, it became difficult to recruit sufficient numbers of SG patients to conduct group sessions without leaving patients too long before contacting.
- (ii) Since there were patients who had agreed to participate but did not attend the programme, it was felt that there were CG patients entering the study who would have also not attended. Therefore, this allocation procedure might have provided an unreliable or invalid control group of patients.
- (iii) Some patients who were asked to participate in the SG expressed much interest and enthusiasm, but provided legitimate reasons for declining the invitation to participate. This was usually work commitments and it was felt that such patients were potentially valid control patients, but the original allocation procedure did not allow for this.

These difficulties were rapidly identified and another recruitment procedure was therefore adopted. In the interview, informal conversation was encouraged to obtain information about the patient's daily activities and lifestyle; each person was then invited to participate in the SG. Those patients who expressed interest in the programme, but declined to enter due to apparently genuine reasons such as work, travel, or family commitments, were allocated to the CG. Patients who agreed to participate and who attended the first group session comprised the SG. Patients who agreed to participate, but did not attend were not included in either group and were allocated to a third group - Not Attended (NA). Patients who declined to participate and who gave false or apparently contrived excuses for not participating, were also allocated to the NA group.

This recruitment procedure provided a reliable and valid CG and gave rise to a CG and SG which were comparable.

### 2.3.1 Interview

All patients who fulfilled the recruitment criteria and who attended the clinic were interviewed by GMC. The interviews were conducted in a consultation room in the Diabetic Clinic. Inevitably, the surroundings were clinical in appearance, but every effort was made to create a relaxed and informal atmosphere. Thus, the initial part of the interview was spent introducing the educator (GMC) and providing information concerning the study project. Patients were informed of the criteria for the interview, to reassure them that there was nothing wrong with them personally, since the initial reaction of many patients was concern over this issue. The project

was briefly described to patients as 'a study to find out which aspects of diabetes the patients needed to know about, and how the patients felt about their diabetes'. Although this description did not elaborate details of the project, it offered an accurate and uncomplicated reason for the interview.

Following the introduction, more informal questions were asked of the patient concerning his or her diabetes. For example, 'Have you had diabetes long?', 'How do you cope with your diabetes?' These were intended to encourage discussion and involvement by the patient. It was also important to check some of the sociodemographic data recorded from the medical records which may require update, e.g. employment, marital status. Questions were asked in a social context which avoided direct enquiries about a person's employment or marital status which may threaten their privacy. For example, a question to establish whether a person was employed was 'do you find you use much energy during the day?' This approach emphasises energy expenditure rather than the issue of employment, but responses generally provided adequate information concerning the patient's daily activities and employment status. Each interview was adapted to the individual patient, with appropriate modulation of the questions and discussions.

During the interview, each patient completed a diabetes knowledge questionnaire, an attitude scale and a short self-management status test. Glycaemic control was also assessed using HbA<sub>1c</sub> measurements. These methods are discussed in sections 2.4-2.7.

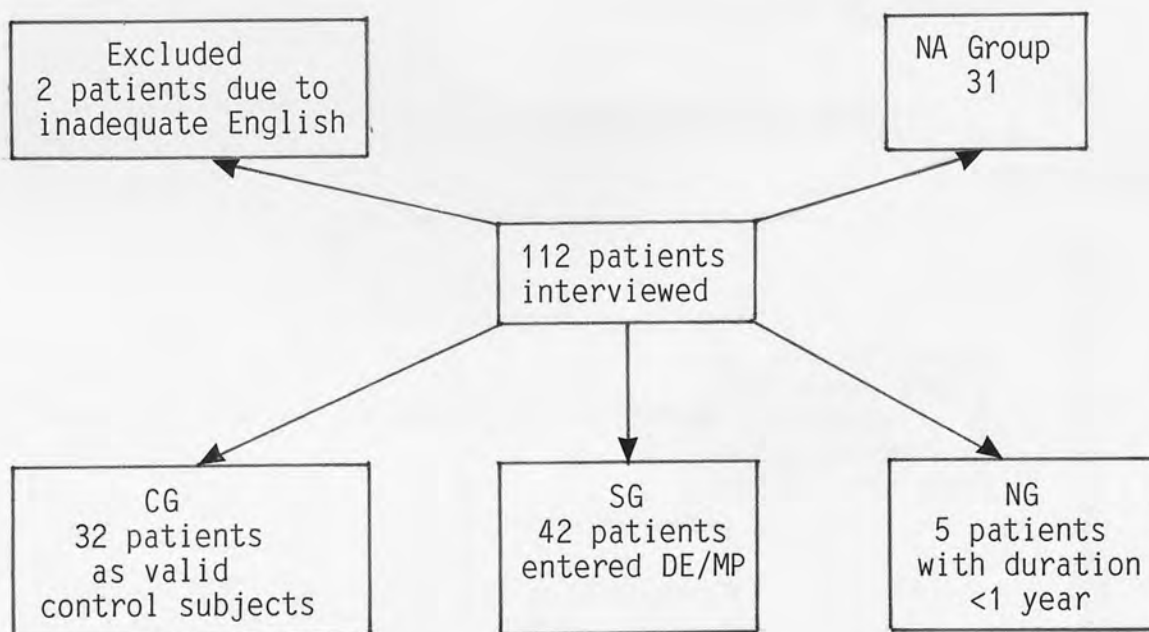
On completion of the questionnaires and status test, patients were thanked for their co-operation, and SG patients were asked for convenient dates and times on which they could attend sessions.



### 2.3.2 Patient Sample

A total of 112 insulin-dependent patients were interviewed in the clinic. Two patients were excluded because they showed an inadequate understanding of English and were unable to complete the questionnaires. A further 5 patients did not fulfill the recruitment criteria because they had a duration of diabetes less than 1 year. However, these patients did participate in the DE/MP and were studied as a separate group - the New Group (NG). Thus, 111 patients comprised four groups: SG - consisting of 42 patients who attended at least 1 session in the programme, CG - consisting of 32 patients, and NA group - including 31 patients who wished to exclude themselves or did not attend. Fig. 2.2 illustrates the patient group distribution.

Fig. 2.2 Patient Group Allocation



CG = Control Group; SG = Study Group;

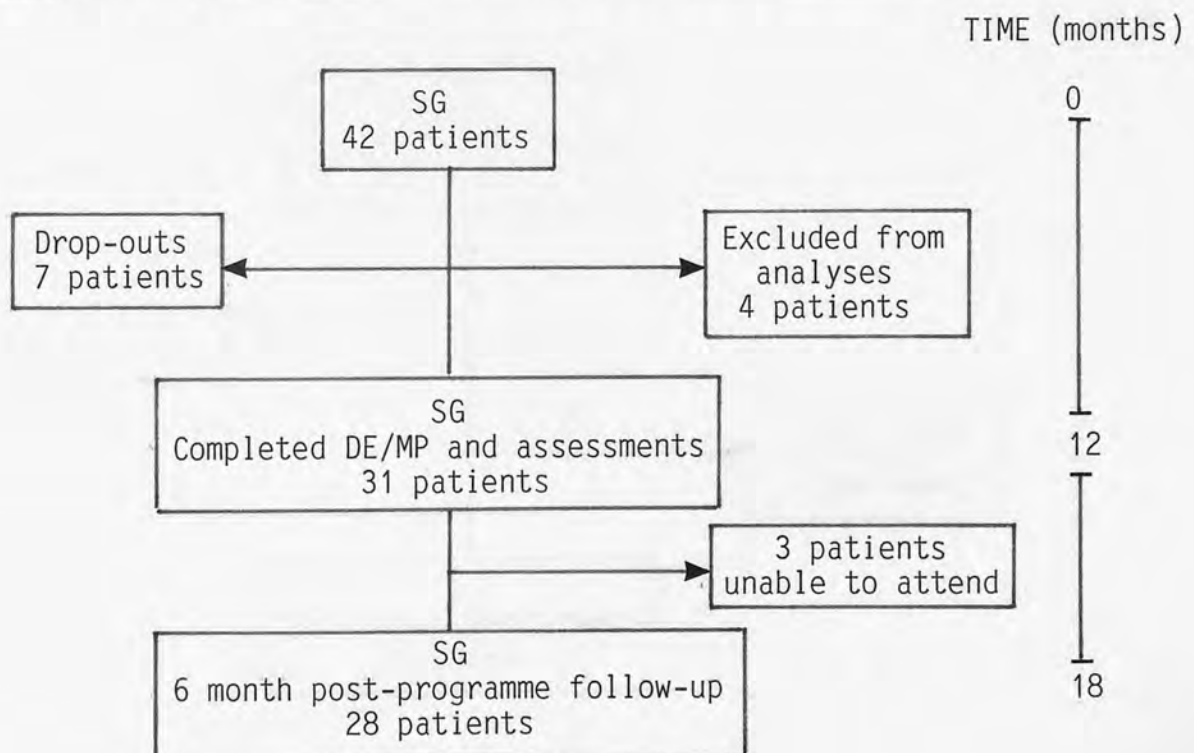
NG = New Group; NA = Not attended

## Study Group (SG)

The Study Group comprised 42 patients who attended at least one session in the DE/MP. During the course of the programme 7 patients 'dropped out' of the study. To investigate the reason for this, a short questionnaire, plus stamped addressed envelope, was posted to each of these patients. Reasons included: travel expense (1 patient), the room was too stuffy (1), had found employment (1), family problems (1), and 3 patients did not return the questionnaire. Also, 4 other patients who continued to attend the sessions were excluded from analysis due to pregnancy.

There were 31 patients who completed the programme and who were assessed at 12 months. Of these, 28 patients were re-assessed at 18 months. Reasons for not attending the follow-up were: moved to another county (1), pregnant (1), and ill-health (1). Fig. 2.3 illustrates the follow-up of SG patients from 0-18 months.

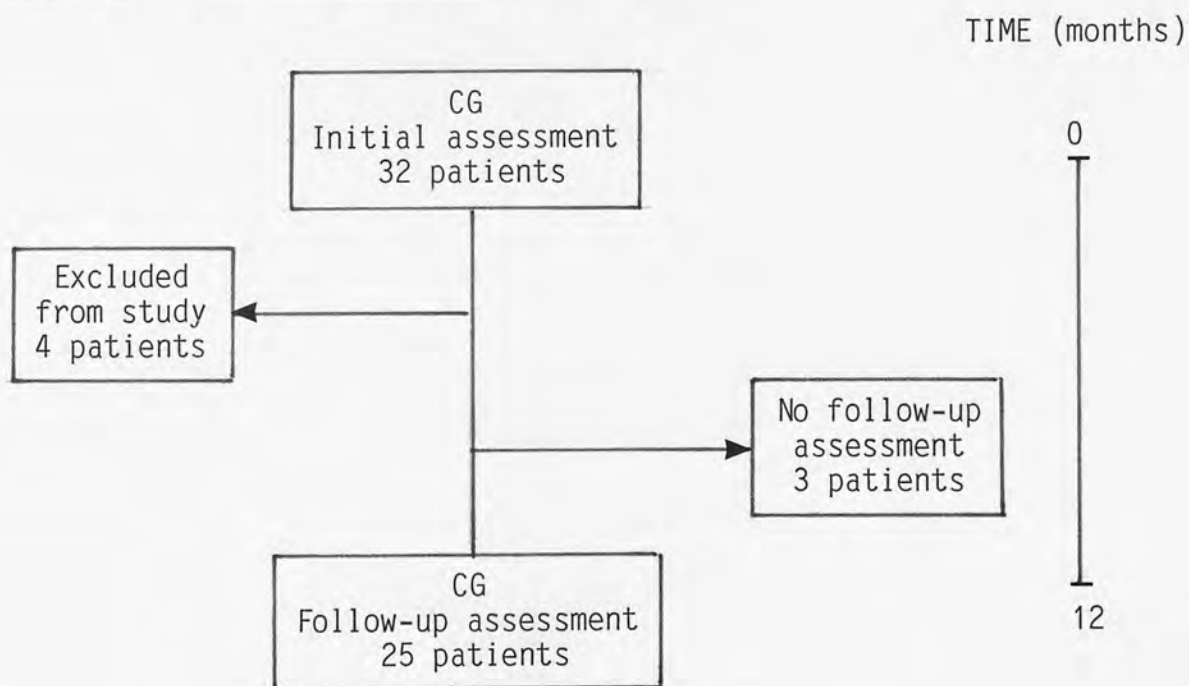
Fig. 2.3 Follow-up of SG patients from 0-18 months.



## Control Group (CG)

The Control Group initially consisted of 32 patients, but follow-up studies in the clinic indicated that 3 patients were 'no longer' insulin-dependent despite insulin treatment from diagnosis, and they were subsequently taken off insulin treatment. One patient with a duration of diabetes of 15 months was excluded from the study because it was thought that the patient was in the 'honeymoon' phase of diabetes when glycaemic control is improved. Although C-peptide levels were not measured, it appeared that there may have been some endogenous insulin secretion. These four patients were excluded from the Control Group analyses. The 12 month assessment which was conducted in the outpatient clinic involved only 25 patients because 2 patients did not attend scheduled appointments and 1 patient had moved away from the area. Fig. 2.4 illustrates the follow-up of CG patients.

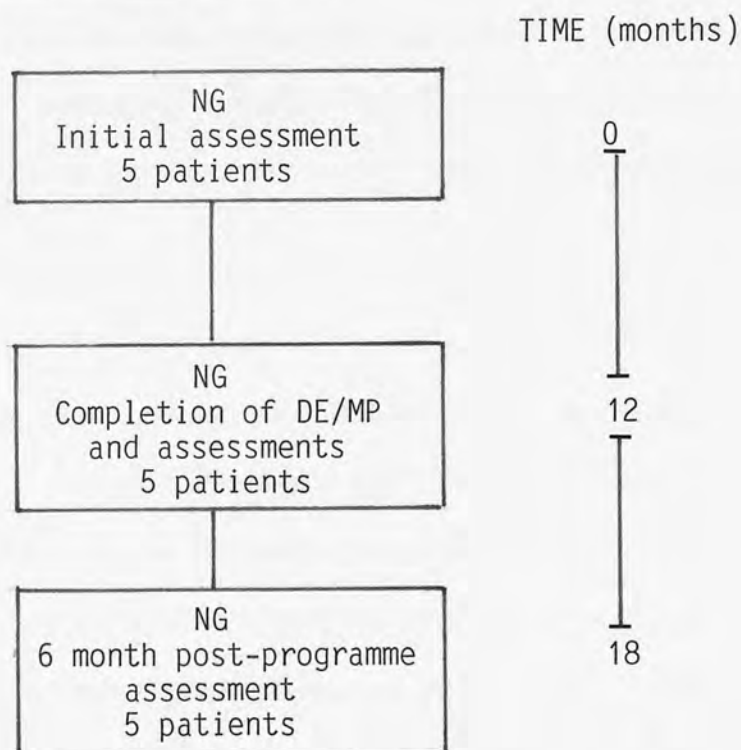
Fig. 2.4      Follow-up of CG Patients



## New Group (NG)

Five patients with less than 12 months duration of diabetes comprised the New Group. These patients had spent at least 2 days in the Diabetic Unit at Dudley Road Hospital and therefore had already benefited from some structured and planned diabetes education. Moreover, it was possible that glycaemic control was enhanced by 'honeymoon' endogenous insulin secretion at this stage. Hence, these patients were recruited into the NG to investigate whether the structured education given at the time of diagnosis influenced attitudes towards diabetes and whether this information could be recalled. The pattern of insulin changes, weight control and glycaemic control were monitored over the transitional period 6-24 months after diagnosis. Fig. 2.5 illustrates the follow-up of NG patients.

Fig. 2.5     Follow-up of NG patients





## Patients Not Attended (NA)

This group included 31 patients who either declined to participate or who agreed to participate but did not attend the sessions. This group were interviewed at 0 months, but were not assessed further.

Details of patients in the SG, CG, NG and NA groups are given in section 3.2.

## 2.4 Assessment of Glycaemic Control

### 2.4.1 Introduction

There are a number of ways to assess glycaemic control.<sup>(239)</sup> In this study it was vital to achieve quality control for consistency since assessments of glycaemic control were made over a 2 year period. Also it was essential that methods were accurate and straightforward, and without additional inconvenience to patients.

An index of short-term control was made, viz: blood glucose measurements, and to indicate long-term control, glycosylated haemoglobin (HbA<sub>1c</sub>) tests were used. These allowed reliable comparisons to be made between patient groups and of the individual patient during the DE/MP.

### 2.4.2 Blood Glucose Measurements

Blood glucose concentrations are measured routinely at clinic visits using the Boehringer Mannheim (BM) Reflocheck method.<sup>(240)</sup> This method is based on the enzymatic reaction of glucose oxidase/peroxidase with glucose in the blood to produce glucuronic acid which is linked to a colorometric reaction. A small 'drop' of capillary blood is placed onto a test strip containing these enzymes for 1

minute, and is then removed with cotton wool. During the subsequent minute, a colour change develops on the test strip, the intensity of which indicates the degree of enzyme activity. The enzyme activity, which is rate limiting, is dependent therefore on the concentration of glucose. The colour change is quantified by a colorimeter cell in the Boehringer Reflocheck which interprets the intensity of the colour change into corresponding units of glucose in mmol/l.<sup>(241)</sup>

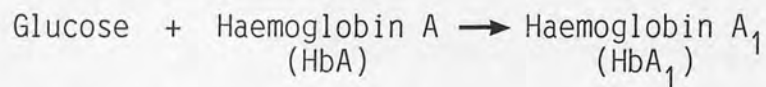
This test requires only a small drop of capillary blood and therefore many patients carry out blood glucose tests at home; this is known as home blood glucose monitoring (HBGM). The colour intensity is compared visually against a colour chart which illustrates the corresponding blood glucose concentration.

The non-fasted clinic blood glucose concentrations from the previous four clinic visits were taken from the patients' medical records. The interval between each test was between 2 and 9 months. Further blood glucose measurements were recorded for SG and NG patients, viz HBGM. However, initially the results were unreliable since some patients admitted that they only reported results which were in or near the normal range, despite my having urged patients to be honest. To overcome this problem, patients were requested to retain 'all' used test strips in a container and to present these at the following monthly session. It is reported that the colour change which develops on BM test strips is retained for up to six weeks.<sup>(242)</sup> Therefore, used test strips were compared visually and mean blood glucose concentrations were calculated at 8 and 10 months, as reported in section 3.3.8.

### 2.4.3 Glycosylated Haemoglobin (HbA<sub>1</sub>) Measurements

This test is a long-term index of glycaemic control which indicates the average blood glucose concentrations over a period of 1-3 months.<sup>(243)</sup> Haemoglobin A (HbA) is glycosylated by the addition of a glucose molecule, thus forming haemoglobin A<sub>1</sub> (HbA<sub>1</sub>) or glycosylated haemoglobin (Fig. 2.6).

Fig. 2.6 The formation of glycosylated haemoglobin

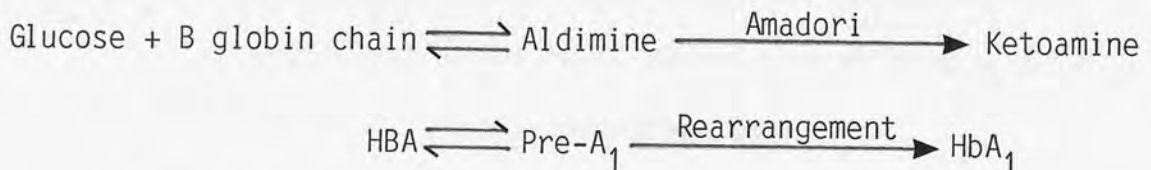


HbA<sub>1</sub> is measured and expressed as a percentage, and represents the proportion of HbA which has been glycosylated.

#### Glycosylation Process

The initial reaction involves the interaction of glucose with the <sup>-</sup>NH<sub>2</sub> terminal amino group of the betaglobin chain to form an aldimine linkage. This aldimine form of HbA<sub>1</sub>, also called pre-A<sub>1</sub>, undergoes an 'Amadori' rearrangement to form a stable ketoamine linkage (Fig. 2.7).<sup>(244)</sup>

Fig. 2.7 The chemical reactions involved in the formation of HbA<sub>1</sub>



The above reaction is spontaneous and non-enzymatic, and is a slow continuous process occurring during the lifespan of the red blood cell (approximately 120 days). It is dependent on two

variables - mean blood glucose concentrations and the duration of hyperglycaemia. Increased glucose concentrations cause the level of accumulated Amadori products on the haemoglobin to rise, and this occurs as a function of time until equilibrium is reached.<sup>(245)</sup>

The determination of HbA<sub>1c</sub> reflects a patient's average blood glucose concentration over a relatively long period of time. There is a high correlation between HbA<sub>1c</sub> and other measures of glycaemic control,<sup>(243)</sup> and thus HbA<sub>1c</sub> is widely used in the evaluations of blood glucose control in the outpatient clinic setting.

In this study, all HbA<sub>1c</sub> tests were carried out in the Biochemistry Department at Dudley Road Hospital, Birmingham, using the Glytrac<sup>TM</sup> electrophoretic method (Appendix 2.1). The normal range of HbA<sub>1c</sub> was reported as 6-9%, and the coefficient of variation was 3.9 for values in the normal range, and 3.45 for values above the normal range.

The advantages of using this test were:

- (i) It did not impose on the patient.
- (ii) It is a reliable measurement since the test is subject to strict quality control.
- (iii) It provided an average longer-term assessment to complement short-term indications of control from the blood glucose measurements.
- (iv) It provided a valuable source of feedback to patients concerning glycaemic control.

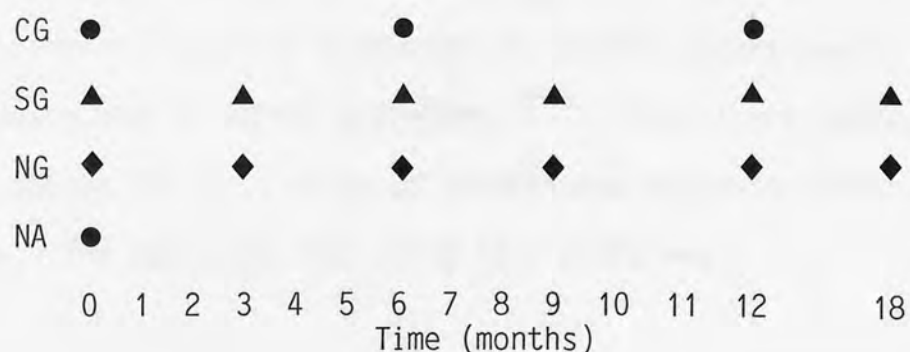
For the purposes of this study HbA<sub>1c</sub> levels <10% were considered to indicate good glycaemic control, levels between 10-12.9% to indicate moderate control, and levels of >13% as

indicating poor control; these were allocated a scale of 1, 2 and 3 respectively.

#### 2.4.4 Schedule of HbA<sub>1</sub> Measurements

Following the initial interview at 0 months, a venous blood sample was taken for blood glucose and HbA<sub>1</sub> tests. All samples were taken in the afternoon in the outpatient clinic, therefore avoiding possible diurnal variations. Subsequently, patients in the SG and NG attended monthly educational/motivational sessions at the hospital, and HbA<sub>1</sub> levels were measured on each visit. Most HbA<sub>1</sub> samples were taken in the afternoon which was the usual time for sessions. However, several measurements were taken in the mornings or evenings. CG patients were subsequently tested at 6 and 12 months. The 6 monthly test was either taken at a routine clinic visit or by sending a letter inviting the patient to attend the Outpatients Department (Appendix 2.2). The 12 monthly test was taken at the time of the reassessment interview in the outpatient clinic. The time at which HbA<sub>1</sub> determinations were made for each of the 4 groups is shown in Fig. 2.8.

Fig. 2.8 Time (months) of HbA<sub>1</sub> determinations in SG, NG, CG and NA Groups



To study the changes of glycaemic control in SG and NG patients participating in the DE/MP, monthly HbA<sub>1c</sub> values were used to calculate mean values at 1-3 months, 4-6 months, 7-9 months and 10-12 months.

HbA<sub>1c</sub> values for two of the SG patients were not used in the analyses of results because one patient commenced insulin pump therapy whilst continuing with the DE/MP and another patient showed a sickle cell haemoglobin variant which rendered the HbA<sub>1c</sub> measurements unreliable.<sup>(246)</sup>

## 2.5 Attitude Assessments

### 2.5.1 Introduction

Attitudes influence the formation of intentions and subsequent actions. Therefore attitude measurement is an important aspect in many areas of study.<sup>(247)</sup> Attitude measurement is difficult, partly due to the number of different attitude concepts or definitions which exist, but it is accepted that attitudes are 'inferred by what people say or do'.<sup>(217)</sup> Several methods are currently used to measure 'inferred attitudes'. These include: physiological methods, direct questions and attitude statement scale techniques.<sup>(248)</sup> The latter method was used in this study. There are various attitude scale techniques such as the Thurstone scale, Guttman's scale, Stephensen's Q Sort Measurement, Osgood's Differential and the Likert scale. These are described in detail elsewhere.<sup>(249)</sup> The Likert scale method was chosen for this study to investigate patients' attitudes to diabetes. The rationale for using this scale was:

1. It is an appropriate method for comparing attitudes of two or more groups and comparison of mean attitude change in a group, as required for the present study.
2. Construction of a 'Likert scale' is easier than most other methods and requires less time to prepare.
3. There is a high correlation with other elaborate scaling methods.
4. Acceptable levels of reliability can be achieved with relatively few items or statements.

#### 2.5.2 Likert Scale Method

This method involved presenting the patients with a series of statements about diabetes, which were clearly favourable or unfavourable towards aspects of diabetes. For each statement there is an attitude continuum as shown in Fig. 2.9.

Fig. 2.9     Attitude Continuum

I strongly agree    I agree    undecided    I disagree    I strongly disagree

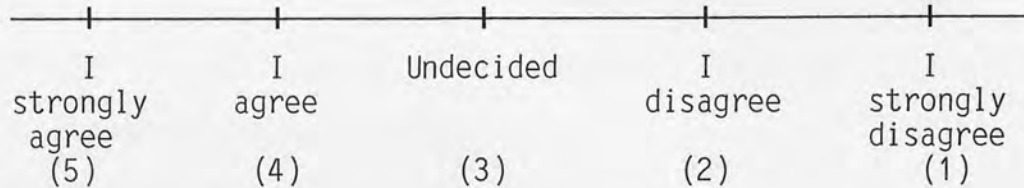
Patients were asked to respond to each statement by indicating the extent to which they agreed or disagreed. The five response categories were allocated weights of 5, 4, 3, 2 and 1, depending on whether it is a positive or negative statement (Fig. 2.10).<sup>(250)</sup>

Fig. 2.10 Positive and negative statement

Scoring of:

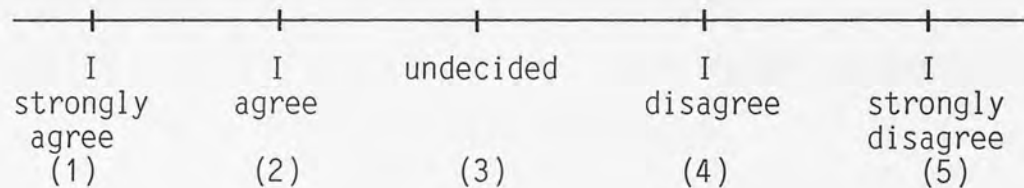
Positive statement

I can do anything I set out to do, even though I have diabetes:



Negative statement

Having diabetes is a great disadvantage in life:



The total score is obtained by summing the scores for individual statements. Thus, this method is also called the method of 'summated ratings'.<sup>(251)</sup> Higher scores indicate a more favourable attitude and lower scores a more unfavourable attitude. This scoring system was used in all subsequent attitude scales discussed herein.

It is essential that statements or items in the scale adequately reflect attitudes to diabetes and that they comprise a valid and reliable scale on which to measure attitudes to diabetes.<sup>(252)</sup> For this reason a pilot study was conducted which served to increase the accuracy of the final scale adopted. The Diabetes Attitude Scale 1 (DAS1) was designed for the pilot study, and the construction and use of this will be described.



### 2.5.3 Pilot Study

DAS1 was a preliminary investigation of patient feelings, beliefs and behaviour with regard to particular aspects of diabetes treatment as discussed in sections 1.4.1 - 1.4.5. Based on these treatment and management aspects, a number of objectives were constructed for use in attitude statements. These are listed below:

1. Is depressed about diabetes
2. Accepts diabetes and treatment
3. Complies with diet and insulin
4. Extent of compliance with doctors/nurses advice
5. Accepts responsibility for blood/urine tests
6. Foresees an optimistic future by the prevention of complications
7. Accepts the importance of diabetic control
8. Acknowledges diabetes in everyday life, e.g. carries glucose
9. Is happy with life despite diabetes
10. Perceives diabetic control as own responsibility.

Based on these objectives, 30 attitude statements were composed. This comprised the DAS1 (Appendix 3.1).

The pilot test, DAS1, was completed by a sample of 24 insulin-dependent diabetic (IDD) patients in the Outpatient Clinic. Patients were randomly selected, the only criterion being that they were insulin treated. Patients were asked to respond to each statement by marking an 'X' at the appropriate interval along the agreement/disagreement continuum. The individual statement scores and the total test scores for each patient were recorded.

The objectives in conducting this pilot study were to identify and retain only those statements which demonstrated properties which enhance validity and reliability of a scale.<sup>(253)</sup> This aimed to

provide a more accurate measure of attitudes towards diabetes. The selection of the statements or 'items' is based on 'item analysis' which will be discussed.

#### 2.5.4 Item Analysis of DAS1

This describes a number of statistical procedures carried out in the development of questionnaires and attitude scales. It involves an evaluation of the individual item properties such as homogeneity, inter-item correlation and item difficulty which ultimately affect the reliability and validity of the questionnaire or scale. Results of these analyses allow identification and selection of the 'best' items or statements for the development of a reliable and valid questionnaire or scale. Various types of item statistics can be performed, these are described elsewhere.<sup>(254)</sup> For the purpose of the pilot study, the selection of items (statements) was based on indices of discrimination between high and low scoring groups. This indicates whether high and low scoring groups respond differently to a particular item, and therefore determines the discriminating power of the test items. Items which do not discriminate between high and low scoring groups are eliminated and the item pool is reduced.

Discriminatory analysis was computed for the test items contained in DAS1. High and low groups were formed on the basis of total scores obtained on DAS1. Both groups consisted of 6 patients (25%). The mean score for each item was calculated for the two groups, and the differences were compared using the Mann-Whitney non-parametric test. Results are shown in Appendix 3.2.

The results of this analysis demonstrated that only 7 of the 30 statements had a significant discriminating power ( $p < 0.05$ ). The poor discriminatory power of most statements was accounted for, at least in part, by the small number of patients in the high and low groups ( $n = 6$ ). To compensate for this, the upper limit of significance was taken as  $p < 0.10$ , which thereby selected a further 6 statements. Also, 1 other statement was retained and modified and 2 statements concerning diet and the family were included. The statement numbers selected and retained are shown in Appendix 3.3.

In total, 16 statements were selected for the development of a further diabetes attitude scale - DAS2.

#### 2.5.5 Discussion

The pilot study, using DAS1, provided the basis for selection of statements to be included in the attitude scale - DAS2. Consideration of valuable comments and recommendations from patients and staff prompted several changes in the attitude scale. Some statements were re-worded to avoid any ambiguity and all statements were made more personal by the addition of the prefix 'you' instead of 'I'. Readability and layout of the questionnaire was improved by increasing the spacing between statements. The pilot study was an important prerequisite in the development of DAS2 because it allowed consideration of the subjects' (patients) comments to enhance the compilation of a more clear and comprehensive scale.

#### 2.5.6 Development of Diabetes Attitude Scale 2 - DAS2 and DAS2m

DAS2 (Appendix 3.4) finally consisted of 16 statements, most of which were selected from DAS1 on the basis of discriminatory

analysis. This scale was used to develop a modified scale - DAS2m for the assessment of patients' attitudes at the initial 0 month interview (refer to section 2.3.1). The statements reflect affective, conative (behavioural) and cognitive aspects of attitudes,<sup>(215)</sup> as indicated by the initials A, B and C respectively, as shown in the scale. However, there has been controversy concerning the existence of these attitude components.<sup>(214)</sup>

In this study, distinctions between attitude statements were made in order to investigate the 'multicomponent' attitude theory (refer to section 1.7). This was tested by factor analysis and is discussed in section 2.5.8.

It is recommended that there were equal proportions of positive and negative statements in an attitude scale<sup>(252)</sup> and to ensure this, several statements were restructured. There were 16 statements in the scale, therefore the maximum score was  $5 \times 16 = 80$ , and the minimum score was  $1 \times 16 = 16$ , results are expressed as raw scores.

#### 2.5.7 Item Analysis of DAS2

The items contained in a scale relate to the validity and reliability of the test, and therefore psychometric analysis of the individual items is essential to ensure these qualities. Hence item analysis was carried out to indicate the discriminatory power of item, the validity and reliability of the scale.

##### 2.5.7 (a) Discriminatory Analysis

This was discussed in section 2.5.4 and concerns the ability of the items to discriminate between high and low scoring patients.

The objective of the test was to select and use only those statements which demonstrated a significant ( $p < 0.05$ ) power of discrimination.

The test was conducted using the responses of 25 (27%) of patients obtaining the highest total scores and 25 (27%) of patients obtaining the lowest total scores on DAS2. A Mann-Whitney test was performed to determine the 'between group' difference for each item. Results are shown in Appendix 3.5. It was found that 15 out of the 16 statements demonstrated significant discriminating powers ( $p < 0.05$ ). Statement number 2 did not discriminate and was therefore excluded from further psychometric analysis and from patient results. DAS2 was modified in that statement number 2 was omitted, therefore the scale was subsequently referred to as DAS2m (Appendix 3.6).

#### 2.5.7 (b) Validity

This refers to the 'extent to which a test measures what it is supposed to measure', and can be tested by various procedures.<sup>(255)</sup> In the case of DAS2m, validity was assessed by the degree of internal consistency or homogeneity of the test items, this is also called 'content validity'. This was measured by determining the item-total score correlation coefficients for the 15 statements remaining in the scale. The Spearman rho ranked correlation test was used and results are shown in Appendix 3.7. All items (statements) demonstrated a significant correlation ( $p < 0.05$ ) with the total test scores and correlation coefficients ranged from 0.29 to 0.69. Such a degree of internal consistency indicates an adequate measure of content validity of the DAS2m.

### 2.5.7 (c) Reliability

This refers to the accuracy and consistency of a test and is usually expressed as a reliability coefficient<sup>(256)</sup> which is the proportion of true variance in the obtained scores which varies between 0 and 1. In the present study, Cronbach's coefficient alpha<sup>(257)</sup> was used to calculate the reliability of DAS2m. This method brings together several formulae of reliability into a generalised equation:

$$\alpha = \left[ \frac{n}{n-1} \right] \left[ 1 - \frac{\sum V_i}{\sum V_t} \right]$$

where: n = number of items or statements

V<sub>i</sub> = variance of items/statements

V<sub>t</sub> = variance of total scores

The reliability of DAS2m using the items scores of 92 patients was calculated using the Cronbach's formula as shown here:

$$\alpha = \left[ \frac{15}{15-1} \right] \left[ 1 - \frac{28.30}{87.52} \right]$$

$$\alpha = 0.72$$

The reliability coefficient of DAS2m was 0.72 which is considered to be an acceptable level using this method,<sup>(254)</sup> and therefore DAS2m was deemed to be a reliable scale with which to assess attitudes to diabetes.

### 2.5.8 Factor Analysis of Attitude Components of DAS2m

The test items were originally categorised into 3 components - affective, behavioural (conative) and cognitive (refer to section 2.5.6). To test the hypothesis that these distinct attitude components were present in the DAS2m, factor analysis was performed. This procedure examines the number of underlying or inferred factors responsible for the co-variance among the observed item (variable) scores.<sup>(258)</sup> Principal factor analysis with interactions, using oblique rotation, was computed using the Statistical Package for the Social Sciences (SPSS) programme.<sup>(259)</sup> This method takes into account the imperfect reliability of the variables. Also, rotation of the solution distributes the variance more evenly among the factors, therefore improving the final factor solution.<sup>(260)</sup> Exploratory analysis was initially carried out which produces the number of factors equal to the number of variables, and Eigen values are given. These are estimates of the variance accounted for by all the factors, and are the criteria on which to decide the number of factors to extract. Only those factors with Eigen values greater than 1 are usually extracted. In the case of DAS2m there were 5 factors which were considered, these accounted for 66% of the variance among items. Factoring was continued with a 5 factor solution and a factor pattern matrix was produced which shows the regression weights of these factors on the variables - these are called 'factor loadings' (Appendix 3.8). Variables which have a factor loading greater than 0.3 were accepted as correlated to and attributed, at least in part, to that particular factor. Appendix 3.9 shows the distribution of the variables (items) among the extracted factors. Examination of these groups showed that several

of the factors contained items which concerned particular attitude areas. For example, factor 1 included items stating the negative aspects of diabetes and factor 2 contained items concerning the family and diabetes. The factors and their associated attitude areas are illustrated in Table 2.1.

Table 2.1 Factor areas associated with DAS2m

Factor Number	Item Number	Attitude aspects (abbreviated)
1	2	Diet does not help
	4	Unfair having diabetes
	6	Can do anything you set out to
	8	Diabetes takes up too much time
2	1	Happy with life
	10	Diabetes is well controlled
	11	Regular meals are difficult
	13	Do not like insulin and diet
3	14	Family understands diet
	15	Family help with diet
4	3	Carry glucose sweets
	7	Increase insulin with infection
	9	Interest in own glucose control
5	5	Less careful when on holiday
	12	Eat more carbohydrate than needed

The Table indicates that 4 of the underlying factors reflect particular attitude components: factor 1 - negative or unhappy aspects of diabetes; factor 3 - family understanding of diet; factor 4 - positive intentions concerning diabetes; factor 5 - inappropriate behavioural aspects. Factor 2 contained items which reflected both positive and negative aspects and could not be categorised as a specific area.



Factor analysis was carried out to investigate the hypothesis that three attitude components (affective, behavioural and cognitive) existed in the DAS2m. Results of this analysis demonstrated that the observed variation between items was not due to the presence of these three components, but that 5 factors were found which accounted for all the items (variables), all of which could be defined. The underlying factors appeared to make distinctions between positive and negative attitude components rather than those suggested earlier, i.e. affective, behavioural and cognitive.

#### 2.5.9 Discussion - DAS2m

DAS2m was used to assess attitudes to diabetes at 0 months. Psychometric analysis of the scale demonstrated acceptable levels of validity and reliability. However, following the development and use of DAS2m, a pilot attitude scale developed at Charing Cross Hospital (Appendix 3.10) was reviewed which focussed attention on a number of issues not considered in the present scale. These included: how the person viewed hypoglycaemia, the effects of diabetes on the family and perceptions of how the public reacted to diabetes. After further discussion with the author of the Charing Cross scale (Mr. Keith Meadows), it was decided to include some of these aspects in a modified scale and also to improve the presentation of the new scale which was called Diabetes Attitude Scale 3 (DAS3). This is contained in Appendix 3.11.

#### 2.5.10 Development of DAS3 and DAS3m

The purpose of DAS3 was to measure attitudes to diabetes in the SG, CG and NG patients at the 12 month assessment. Initially the

scale consisted of 20 attitude statements, 10 of which were derived from DAS2m, and a further 10 based on the Charing Cross scale. Equal numbers of positive and negative statements were used. The maximum score obtainable was  $20 \times 5 = 100$ , and the minimum score  $20 \times 1 = 20$ , using the scoring system described previously (section 2.5.2). Since only some of the statements in DAS3 had undergone previous item analysis before use, this is sometimes known as a 'Likert Type' scale. However, psychometric analysis, similar to that used in DAS2 was performed on the test items in order to select and use statements which constituted a validated and reliable score - which was subsequently called DAS3m.

#### 2.5.11 Item Analysis of DAS3

The same procedures used in the development of DAS2m were carried out. These included discriminatory analysis, the measurement of validity and reliability and factor analysis.

##### 2.5.11 (a) Discriminatory Analysis of DAS3

The purpose of this test and method used are discussed in section 2.5.4. This test was performed on the 20 attitude statements (items) using the results of the 12 month assessment undertaken by 59 patients. High and low scoring groups consisted of 14 (24%) and 15 (25%) of patients respectively. The between group differences for each item was tested using the non-parametric Mann-Whitney test. Results of this are shown in Appendix 3.12. This demonstrated that 14 out of the 20 statements significantly discriminated ( $p < 0.05$ ) between high and low scoring patients. Of the 6 items which failed to discriminate, 4 were new statements which had not undergone

previous analysis. However, 2 statements had previously been retained in DAS2 on the basis of discriminatory analysis. For purposes of further item analysis and consideration of results of the 12 month assessment, only those statements which discriminated were retained. This comprised a modified scale which is subsequently referred to as DAS3m, and contains only 14 items (Appendix 3.13).

#### 2.5.11 (b) Validity of DAS3m

The method used to test validity of DAS2m was also used for DAS3m (refer to section 2.5.7 (b)). The internal consistency of the test was determined by measuring the item-total score correlation for the 14 remaining items. Results are shown in Appendix 3.14. All statements demonstrated a significant correlation ( $p < 0.05$ ) with the total scores, the coefficient of correlation ranged from 0.27 - 0.65. This demonstrated the internal consistency of the items and indicated an acceptable degree of content validity of the DAS3m.

#### 2.5.11 (c) Reliability of DAS3m

This was estimated using Cronbach's coefficient alpha - discussed in section 2.5.7(c). Coefficient alpha was calculated using the item and total score variances of scores obtained by 59 patients on DAS3m. Results of this are shown in Fig. 2.11.

Fig. 2.11 Cronbach's coefficient alpha for DAS3m

$$\alpha = \left[ \frac{14}{13} \right] \left[ 1 - \frac{11.51}{33.61} \right]$$

$$\alpha = 0.69$$

The reliability coefficient  $\alpha$  was 0.69. This indicates that an acceptable level of reliability was achieved for DAS3m, and that the scale provided a satisfactory measure of attitudes at 12 months.

#### 2.5.12 Factor Analysis of DAS3m

Exploratory factor analysis was performed to investigate the underlying factors responsible for the co-variation among items. Principle factoring with interactions, using oblique rotation, was performed using the Statistical Package for the Social Sciences (SPSS) at Aston University. This method is discussed in section 2.5.8. The initial factor solution gave rise to 5 factors with Eigen values greater than 1. These accounted for 60% of the variance between items. Factoring was continued using a five factor solution and a factor pattern matrix was produced (Appendix 3.15), which shows the 'factor loadings' onto each item. Similar to DAS2m, those factor loadings greater than 0.3 were assumed to be attributed, at least in part, to that particular factor. Appendix 3.16 shows the distribution of variables (items) among the five factors. Examination of these items associated with each factor revealed a less defined pattern of attitude areas than was found in DAS2m. For example, factor 1 contained items pertaining to the disadvantages of diabetes, yet also contained an item indicating that diabetes was not an inconvenience in life. Table 2.2 shows items and attitude areas associated with the factors.

Table 2.2 Factor areas associated with DAS3m

Factor Number	Item Number	Attitude Aspect (abbreviated)
1	1	Disadvantage in life
	2	Can take part in everything
	3	Nuisance to the family
	5	Can control own diabetes
2	4	Better to know as much as possible
	6	Too much fuss about control
	7	Diabetic Clinic important
3	8	Less careful when on holiday
	12	Eat more carbohydrate than need
	13	Diet too difficult to keep to
4	10	Would increase insulin with infection
	11	Too much fuss about complications
5	9	Blood/urine tests important
	14	Injections are not a problem

It is apparent from Table 2.2 that the factors do not indicate very specific underlying attitude areas. However, factors 2 and 5 were associated with positive and responsible attitude aspects important in diabetes. Also, factor 3 contained only items enhancing the inappropriate behavioural aspects.

Factor analysis of DAS3m inferred that 5 factors were responsible for the co-variance among items. Although distinct attitude areas within these factors could not be identified, 3 of the factors did associate with particular areas of the attitude scale. These were: responsibility of diabetes, negative behavioural intentions and the positive aspects of management.

### 2.5.13 Discussion - DAS3m

DAS3m contained 14 items which were demonstrated to constitute a reliable and valid scale - as discussed. This scale was used to assess attitudes to diabetes at 12 and 18 months during the study. The results of these are described in section 3.4.2. Results are expressed as raw scores, where a maximum score was  $5 \times 14 = 70$  and minimum score was  $1 \times 14 = 14$ . Attitude scores constitute an ordinal scale and therefore analysis of attitude scores was carried out using non-parametric statistical methods (refer to section 2.10.2).

## 2.6 Knowledge Assessments

### 2.6.1 Introduction

Patients' knowledge of diabetes was assessed initially at 0 months and reassessed at 12 months in SG, CG and NG patients, and a further assessment was conducted at 18 months in the SG and NG only. The objectives of these assessments were to:

1. Determine the patients' educational needs on which to plan the DE/MP.
2. Investigate the association between diabetes knowledge and other characteristics such as attitudes and glycaemic control.
3. Investigate differences in diabetes knowledge among the four patient groups.
4. Test the assimilation and understanding of information presented to patients in the DE/MP.
5. Examine the recall and retention of information in SG and NG patients following the DE/MP.

Various methods can be used to assess diabetic knowledge such as questionnaires, interviews, observations and searches.<sup>(261)</sup> For the purpose of this study, questionnaires were used because they provide a more quantitative measure.

Several previous studies have documented the design and use of diabetes knowledge questionnaires.<sup>(262-264)</sup> These have been reviewed and assisted in the development of questionnaires in the present study. However, it has been said that 'each study using questionnaires is unique, and must be tailored to fit the individual circumstances of that study', therefore several reasons prompted the development of questionnaires intended specifically for this study:

1. Assessments of knowledge, attitude and self-management skills were conducted in the Outpatient Clinic where time constraints were imposed. It was important that the patients did not feel they would 'miss their turn in the queue' or that they had been detained for longer than necessary. However, a relatively short questionnaire was designed which could be administered easily in the clinic environment. Also, it was felt that this would reduce the occurrence of hurried responses and help to avoid boredom which might result from a more lengthy questionnaire.
2. It is vital that the reading and comprehension level of health care literature is appropriately matched to the population for which it is intended. In West Birmingham, the average reading age is 11 years,<sup>(265)</sup> thus one of the aims of this study was to produce and use questionnaires and literature which matched these levels. This avoids intimidation and embarrassment

which may occur with more difficult questionnaires. Also this ensured that diabetic knowledge was being assessed rather than the patients' general knowledge.

In the present study, two diabetes knowledge questionnaires (DKQ) were developed; DKQ which was subsequently modified to DKQ1m and used to assess diabetes knowledge at 0 months, and DKQ2, also modified to DKQ2m which was used to assess knowledge at 12 and 18 month assessments.

#### 2.6.2 Development of DKQ1 and DKQ1m

Various types of questions can be used to assess knowledge, e.g. dichotomous questions, open-ended questions, filling in the blank questions and multiple choice questions.<sup>(266)</sup> A multiple choice question (MCQ) format was chosen for this questionnaire because it is one of the most flexible and effective test formats.<sup>(267)</sup> Also, all items contain the option 'I do not know' which reduces guessing.

The subject areas to be tested and the types of questions or items to be used in the questionnaire were derived from such sources as a literature review of diabetes education (refer to sections 1.5-1.5.2) from the diabetes learning objectives used at Dudley Road Hospital (Appendix 4.1), and from a questionnaire used in a previous study by GMC (Appendix 4.2). A list of 27 items of knowledge was drawn up on which to formulate a pre-test questionnaire (Appendix 4.2). This questionnaire was administered to several members of the nursing and medical staff involved in diabetes care, dietitians, and in-patients from the Diabetic Unit. They were asked to comment on



the questionnaire and the items presented, bearing in mind that the aim was to reduce the number of items contained in the questionnaire. Comments were received concerning the repetitiveness of particular items, question wording, ambiguity and level of difficulty. These comments served as valuable indicators for the selection of knowledge items contained in DKQ1 (Appendix 4.4).

In the present study it was not possible to conduct a pilot study, therefore, initially the selection of items for DKQ1 was based on the comments and recommendations from patients and staff, and the expertise of a University psychologist (LMD). Subsequently, psychometric tests (refer to section 2.5.4) were performed on completed questionnaires in order to select items which constituted a reliable and valid questionnaire. Thus, although patients completed DKQ1, the actual results are based on the modified questionnaire - DKQ1m.

DKQ1 consisted of 11 items which considered the 5 major areas of diabetes management discussed in sections 1.4.1-1.4.5. These were:

Subject	Item Number
1. Blood glucose control	3,6
2. Insulin	1,2
3. Diet	10,11
4. Hypoglycaemia	4,5
5. Basic care	7,8,9

The multiple choice items consisted of two parts: the stem, which presents the problem as an incomplete statement or question, and the list of possible options. The title page contained clear

instructions for completion of the questionnaire. Easier items were presented first, to avoid early discouragement, and each item was clearly numbered with boxes adjacent to each option.

### 2.6.3 Scoring of DKQ1

One of the objectives of the questionnaire was to discriminate between patients on the basis of diabetic knowledge. Because the questionnaire was short, this function was enhanced by including more than one correct option in several of the items (nos. 5, 6, 8, 10 and 11). The remaining questions contained only one correct answer. Therefore, the number of possible incorrect and correct options varied, which subsequently influenced the number of incorrect or correct options made by 'chance'. To correct for this variation among item options, a scoring system was adopted which took into account the number of 'possible' correct and incorrect options. Thus, corrected scores were obtained for each items using the equation below:

$$\text{corrected score} = \left[ \frac{x}{X} \right] - \left[ \frac{y}{Y} \right]$$

where: x = number of actual correct options chosen  
X = number of possible correct options  
y = number of actual incorrect options chosen  
Y = number of possible incorrect options

In using this equation, positive values were allocated for correct responses and negative values for incorrect options. Each item has a range of positive scores between 0 and 1, and a range of

negative scores between -0.1 and -1. These adjusted items scores were added together to obtain the total raw score, and subsequently converted to percentage scores in which they are expressed in the Results section.

The 'I do not know' options were awarded a value of zero and therefore were omitted from the adjustment equation and from the item or total scores.

The scoring system described has been used for all subsequent questionnaires in this study, although maximum raw scores vary, total scores are expressed as percentages.

#### 2.6.4 Item Analysis of DKQ1 and DKQ1m

This consisted of a number of psychometric tests which identified the most appropriate items to be used in DKQ1m, and to investigate the validity and reliability of the modified questionnaire - DKQ1m. Several tests were performed, some of which have been discussed in section 2.5.7.

##### 2.6.4 (a) Discriminatory Analysis of DKQ1

As discussed in section 2.5.4, this is a test which identifies and retains only those items which significantly discriminate between high and low scoring groups. High and low scoring groups consisted of 27% of patients with the highest total scores and 27% of patients with the lowest total scores. The total number of patients completing the questionnaire was 96, thus the high and low groups each consisted of 26 patients. A Mann-Whitney test was carried out to establish the between group differences for each item, thereby determining the discriminatory power of the items.

Results of this test are shown in Appendix 4.5. It was found that 9 out of the 11 items discriminated significantly ( $p < 0.05$ ) between high and low groups. Question numbers 2 and 4 did not discriminate and were therefore excluded from further analysis and results. DKQ1 was therefore modified and is subsequently referred to as DKQ1m (Appendix 4.6).

#### 2.6.4 (b) Validity of DKQ1m

Reasons for measuring validity are described in section 2.5.7 (b). To determine the validity of DKQ1m two methods were used which provided information concerning internal consistency (content validity) and external validity<sup>(268)</sup> of the test. The content validity of DKQ1m was assessed by estimating the item-total score correlations using the results of 96 patients (refer to section 2.5.7 (b)). The Spearman rho ranked correlation test was used and results are shown in Appendix 4.7. All items demonstrated a significant correlation with the total score ( $p < 0.05$ ), and  $r_s$  coefficients ranged from 0.26 - 0.64. Thus, DKQ1m demonstrated internal consistency which indicated an adequate measure of content validity.

External validity is a measure of the extent to which the test relates to 'performance' concerning questionnaire items.<sup>(268)</sup> A common problem arising with this type of validation is the lack of suitable criterion on which to make a correlation with the test score. In this study a practical skills test was carried out at the time of completion of the questionnaires (refer to section 2.7). This reflected the behavioural aspects of diabetes knowledge and was therefore used as the criterion on which to assess external or

concurrent validity. This was measured by calculating the correlation coefficient between the total DKQ1m scores and the total scores in the skills test by 96 patients. The coefficient of correlation was calculated using Pearson's correlation test, this was  $r = 0.38$  ( $p < 0.001$ ). This coefficient is interpreted as the 'validity coefficient' for DKQ1m, and provided evidence of the external validity of DKQ1m. However, this value was not corrected for attenuation, which is due to the lack of reliability of the external criterion - skills test, and it is possible that a higher validity coefficient could be obtained.

#### 2.6.4 (c) Reliability of DKQ1m

As discussed previously (section 2.5.7(c)), reliability refers to the accuracy and consistency of a test, and this can be measured using Cronbach's coefficient alpha (refer to section 2.5.7(c)). The reliability coefficient for DKQ1m was determined by this method and was based on the results of 96 patients. Estimation of Cronbach's  $\alpha$  for DKQ1m is shown in Fig. 2.12.

Fig. 2.12 Cronbach's reliability coefficient for DKQ1m

$$\alpha = \left[ \frac{k}{k-1} \right] \left[ 1 - \frac{\sum V_i}{\sum V_t} \right]$$

where:  $k$  = number of items  
 $V_i$  = variance of item scores  
 $V_t$  = variance of total scores

$$\alpha = \left[ \frac{9}{9-1} \right] \left[ 1 - \frac{2.13}{3.84} \right]$$

$$\alpha = 0.50$$

Reliability of DKQ1m was estimated as 0.50. It is recommended that for excellent reliability  $\alpha$  should exceed 0.70. However, it is well documented that such a reliability is difficult to achieve with such a small number of items as in DKQ1m.<sup>(269)</sup> Therefore, it was considered that the reliability of DKQ1m was attenuated as a result of the small item pool, and that the reliability of DKQ1m was acceptable for the purpose of this study.

#### 2.6.4 (d) Item Difficulty of DKQ1m

Item difficulty, also known as the facility index, is based on the proportion,  $\rho$ , of subjects (patients) who answer the item correctly. Thus, the greater the  $\rho$  value the easier the item<sup>(270)</sup>.  $\rho$  can vary between 0 and 1, i.e. when all patients answer the item correctly,  $\rho = 1$ , or when all patients answer the item incorrectly,  $\rho = 0$ . To determine the  $\rho$  value for a multiple choice questionnaire, the value must be corrected for 'chance' success. However, this correction had previously been made for DKQ1m, therefore  $\rho$  was obtained by calculating the proportion of patients who obtained the maximum score of 1 on each item. This provided an index of the item difficulty and results are shown in Appendix 4.8. It is recommended that difficulty levels should approach  $\rho = 0.50$ <sup>(270)</sup> since maximum discrimination or variability results from the items, and enhances the reliability and validity. However, it is difficult to have each item in a test with a  $\rho = 0.50$ , where, as stated previously, it is intended that the initial items are relatively easier (for example,  $\rho = 0.70$ ). Therefore, it is usual to construct an 'average' item difficulty for a test, in which an optimum  $\rho$  value would be 0.50. The average item difficulty for DKQ1m was 0.46, which demonstrated

a satisfactory level at which the test discriminated between patients.

The results (Appendix 4.8) also showed that the initial items presented in DKQ1m had  $p$  values exceeding that of the average difficulty level. This supports the earlier proposal to include relatively easier items in the earlier stages of the questionnaire (refer to section 2.6.2).

#### 2.6.5 Administration of DKQ1m

DKQ1m was completed by the patients in a treatment room in the Outpatients Clinic. Only the investigator (GMC) and the patient (plus accompanying relatives) were present. The instructions displayed on the title page were repeated verbally to all patients, and the instruction 'remember you may choose more than one option' was emphasised. Occasionally patients requested further explanation of the test items, this was provided by GMC. However, great care was taken to ensure that the choice of phraseology or facial expressions did not give clues or hints which could influence the option chosen. This was important to ensure controlled administration of the questionnaire.

#### 2.6.6 Discussion - DKQ1m

The development of a short diabetes multiple choice questionnaire has been described. The DKQ1m, formulated by discriminating analysis, demonstrated appropriate measures of consistency, validity and item difficulty. However, the reliability

DKQ1m was attenuated due to the relatively small number of items included, although the development of a reliable questionnaire containing only 15 items has been reported previously.<sup>(262)</sup>

It was felt that the reliability of DKQ1m could be improved considerably by increasing the number of test items in the questionnaire. Subsequently, a further diabetes knowledge questionnaire - DKQ2, was developed. Similar psychometric tests, as performed on DKQ1 and DKQ1m, were conducted in order to formulate a valid and reliable questionnaire which was subsequently called DKQ2m. This was used to measure patient knowledge at the 12 month reassessment. The development of this questionnaire will be described in sections 2.6.7 - 2.6.10.

#### 2.6.7 Development of DKQ2 and DKQ2m

The purpose of DKQ2 was to develop a reliable and validated questionnaire - DKQ2m, on which to assess diabetes knowledge in SG, CG and NG patients at 12 and 18 months. DKQ2 consisted of all items contained in DKQ1m, and further items were derived from objectives stated in the DE/MP (supplement), and from a pilot questionnaire developed at Charing Cross Hospital by Keith Meadows (Appendix 4.9). With the assistance of a psychology lecturer (LMD), statements/questions and options relating to these objectives were devised. Finally DKQ2 consisted of 20 multiple choice items, this is contained in Appendix 4.10.

Although DKQ2 contained 20 items, the subject areas remained the same as those of DKQ1, these were as follows:



<u>Subject</u>	<u>Item numbers</u>
Blood glucose control	11 - 15
Insulin	1 - 4
Diet	5 - 10
Hypoglycaemia	16
Basic care	17 - 20

The format and scoring of DKQ2 was similar to that of DKQ1 (refer to sections 2.6.2 - 2.6.3), although the maximum total score of DKQ2 was 20.

#### 2.6.8 Item Analysis of DKQ2 and DKQ2m

Discriminatory analysis was performed on DKQ2 to select the most appropriate items to be contained in DKQ2m. Subsequently, item difficulty, validity and reliability coefficients were determined for DKQ2m.

##### 2.6.8 (a) Discriminatory Analysis of DKQ2

This procedure was described previously for DKQ1 (section 2.6.4 (a)). The responses of 60 patients completing DKQ2 at 12 months were used to determine the discriminating power of the items. High and low scoring groups were formed on the basis of total scores obtained, each of which consisted of 16 (27%) patients. Between group differences for each item were calculated using the Mann-Whitney test. Results are shown in Appendix 4.11. It was shown that 17 out of the 20 items discriminated significantly ( $p < 0.05$ ) between the groups. Question numbers 12, 13 and 19 did not discriminate and were excluded from further item analysis and patient results. The DKQ2 was therefore modified and is subsequently referred to as DKQ2m (Appendix 4.12).

#### 2.6.8 (b) Validity of DKQ2m

Measurement of validity was discussed in section 2.6.4 (b), and the same methods were used to estimate validity of DKQ2m. Item consistency of the test items was determined by measuring the item-total correlation coefficient using the results of 60 patients. Results are shown in Appendix 4.13. All but one item demonstrated a significant correlation ( $p < 0.05$ ); these ranged from 0.32 - 0.75. Item number 2 was only weakly correlated with the total test score,  $r = 0.19$ . Subsequently this was excluded from the item pool. The remaining 16 statements confirmed the internal consistency and content validity of the test.

The external validity coefficient or concurrent validity was also determined by measuring the correlation between DKQ2m and the practical skills test taken at 12 months. Pearson's correlation coefficient,  $r = 0.44$ , indicated a significant correlation ( $p < 0.001$ ) between DKQ2m and the external criterion (skills test). Also the validity was not corrected for attenuation caused by lack of reliability indices of the skills test, and it is possible that the validity coefficient is underestimated.

#### 2.6.8 (c) Reliability of DKQ2m

Reliability of DKQ2m was determined using the Cronbach coefficient alpha which is discussed in section 2.5.7 (c). Results were obtained using the responses of 60 patients and calculation of  $\alpha$  is shown in Fig. 2.13.

Fig. 2.13 Cronbach's reliability coefficient for DKQ2m

$$\alpha = \left[ \frac{k}{k - 1} \right] \left[ 1 - \frac{\sum V_i}{\sum V_t} \right]$$

where: k = number of items  
Vi = variance of item scores  
Vt = variance of total scores

$$\alpha = \left[ \frac{16}{16 - 1} \right] \left[ 1 - \frac{3.71}{17.06} \right]$$

$$\alpha = 0.83$$

Reliability was shown to be  $\alpha = 0.83$ , which is a considerable improvement on DKQ1m and which demonstrates a high degree of accuracy of DKQ2m.

#### 2.6.8 (d) Item Difficulty of DKQ2m

Procedures used to estimate item difficulty,  $\rho$ , were discussed in section 2.6.4 (d), and are also used in the case of DKQ2m.  $\rho$ , which is the proportion of patients answering the question correctly, was estimated using the responses of 60 patients who answered the 16 items in DKQ2m. Results are shown in Appendix 4.14.  $\rho$  values range from 0.28 - 0.85, with the highest  $\rho$  values appearing in the initial four items, indicating that easier items were presented first. The average item difficulty was  $\rho = 0.61$ . This was slightly greater than in DKQ1m and may be due, at least in part, to the improvement in diabetes knowledge in patients who participated in the DE/MP. The item difficulty of the test was considered adequate for the purpose of discrimination between patients concerning diabetic knowledge.

### 2.6.9 Administration of DKQ2m

CG patients completed the questionnaire in a treatment room of the Outpatient Clinic. SG and NG patients completed DKQ2m in a seminar room in which the DE/MP sessions were held. Conditions of administration of the questionnaire were similar in that all patients were seated, only the interviewer (GMC) and the patient (plus accompanying relatives) were present and instructions were repeated verbally to each patient. Therefore, every effort was made to minimize variation in the administration format.

### 2.6.10 Discussion - DKQ2m

The development of a reliable and validated questionnaire - DKQ2m, has been described. Considerable improvement in the reliability and validity coefficients were achieved compared to DKQ1m. This was thought to be due to the increased number of items. DKQ2m was used to assess patient knowledge at 12 and 18 months and results are expressed as adjusted percentage scores and are described in section 3.5. The scores represented an ordinal scale measurement and therefore statistical analysis of results was carried out using non-parametric tests.

## 2.7 Self-Management Skills

### 2.7.1 Introduction

Although cognitive elements were tested using DKQ1m and DKQ2m, an assessment of behavioural skills was also required to identify deficiencies in self-management skills and to serve as a criterion for testing the validity of DKQ1m and DKQ2m. A self-management skills test was designed and used to assess patients at 0, 12 and 18

months of the study. Therefore, this test was used to compare the practical skills of the NG and SG who had completed the DE/MP and those of the CG who had not received any formal diabetes education.

Although the test was used to obtain a statistical value on which to base the validity of the cognitive tests, and to yield valuable information regarding patients' requirements in the DE/MP, it also provided an opportunity to check patients' understanding of the standard '100 units/ml' insulin strength which was introduced at the time of this study. The introduction of this system required patients to use a different insulin syringe and to change the way they measured insulin units. Thus, it was important to ensure that this system had been understood and that correct insulin doses were being administered.

#### 2.7.2 Development of Self-Management Skills Test

There are three major areas of diabetes management in which practical knowledge and co-operation are essential:<sup>(272)</sup>

1. Insulin - drawing-up and injecting insulin
2. Diet - selection of carbohydrate exchanges
3. Blood/urine glucose testing - carrying out correct procedure and interpretation of test results.

Test items derived from these areas were based on a performance evaluation test developed at the University of Michigan.<sup>(273)</sup>

Behavioural skills examined were simple and manageable and therefore could be easily carried out in the time available.

Patients were asked to demonstrate competence in each of the following three areas:

Insulin - patients were asked to draw up their regular morning dose of insulin. A 1 ml or 1/2 ml syringe was provided and both clear (short-acting) and cloudy (long-acting) types of insulin were available. The following features were observed:

- (i) adds air to insulin bottle
- (ii) accurate insulin dose
- (iii) removal of air bubbles

After re-capping the insulin syringe, patients were then asked to indicate, using the syringe, the angle at which they would normally inject. One of the following observations was recorded:

- (i) angle of approximately  $90^{\circ}$
- (ii) angle of  $45^{\circ}$  -  $80^{\circ}$
- (iii) angle of less than  $45^{\circ}$

Diet - patients were asked to identify four carbohydrate exchanges from a selection of model foods on display (Fig. S5 Supplement). The carbohydrate exchanges present were:

- 1/3rd of a pint of milk
- 1 orange
- 1 apple
- 1 potato

Blood/Urine Glucose Testing - clinic procedure did not provide an appropriate opportunity for urine or blood glucose determination by the patient. Therefore patients were asked only to indicate what they considered to be the ideal blood/urine glucose range or concentration as displayed on the side of the test strip container. Blood or urine test strips were used depending on the normal test procedure the patient carried out.

### 2.7.3 Scoring of Self-Management Skills Test

To assist in the recording of scores during the test a practical assessment sheet was designed on which allocated points and comments could be noted (Appendix 5). The allocation of points for each task is listed below:

<u>Practical task</u>	<u>Points</u>	<u>Section total score</u>
<u>Insulin</u>		
Adds air to insulin bottle	1	] 5
Draws up correct insulin dose	1	
Removes air bubbles	1	
Injection angle 90°	2	
Injection angle 45° - 90°	1	
Injection angle >45°	0	
<u>Diet - identifies</u>		
Third of a pint of milk	1	] 4
Orange	1	
Apple	1	
Potato	1	
<u>Test - indicates</u>		
Concentration of urine glucose as negative	1	] 1
Concentration of blood glucose 4 - 10 mmol/l	1	

Maximum Total Score = 10

In sections concerning insulin and blood/urine glucose tests, either positive or zero scores only were awarded. However, in the

diet section, minus 1 point was allocated for every non-carbohydrate containing food type chosen.

The maximum score was 10 points. Results of the skills test, which appear in Section 3.6 are expressed as raw scores shown here.

#### 2.7.4 Self-Management Skills - Discussion

This test assisted in the development of the DE/MP and in the validation of knowledge questionnaires. No reliability or validity studies were carried out because the test was intended to provide ancillary information for the development of the DE/MP, and the nature of the test rendered it unsuitable for the study of reliability and validity.

The test was used in all 0, 12 and 18 month assessments. The concise nature of the test allowed easy administration. The tasks were considered to be relatively simple and manageable, and it was felt that these qualities enhanced the patients' confidence and willingness to participate in the assessment interviews.

### 2.8 Diabetes Educational/Motivational Programme (DE/MP)

The structure and content of the individual components of the DE/MP used in the present study are contained in the Supplement accompanying this Thesis. This section concerns the design and development of the programme and the setting in which it was conducted.

#### 2.8.1 Introduction and Aims

Diabetes education alone does not necessarily improve glycaemic control, and increased motivation is required for patients



to implement their knowledge in diabetes self-management (section 1.6.1). Thus, the aims of the study were to design and implement a programme which contained diabetes education with motivational and behavioural features, to enhance patients' motivation to learn and comply with treatment recommendations. It was also intended that the programme would be practical, inexpensive and could be conducted with minimal inconvenience to the patient.

The development of the DE/MP was based on an extensive review of the literature including: general educational strategies, behaviour, compliance and motivation. Nursing staff from the Diabetic Unit of Dudley Road Hospital assisted in constructing learning objectives and the content of the DE/MP.

#### 2.8.2 Programme Setting

The programme consisted of monthly sessions concerning diabetes and its management. All sessions were conducted by the investigator, who held the title of 'Diabetic Educator', and was introduced to the patients informally as 'Gerry' (GMC).

Most sessions were held in a group format consisting of between 3 and 7 patients. This provided a novel teaching approach, it allowed patients to learn from each other and often encouraged acceptance of new information presented.<sup>(274)</sup> Also, peer groups enhanced the social aspects of the programme. Three individual sessions were also conducted to introduce an individual approach to teaching/learning<sup>(275)</sup> and to promote the personal aspects of the programme. Considerable effort was made to emphasise the social and enjoyment aspects of the programme. The sessions were conducted in a Seminar Room away from the main hospital area, thereby avoiding the

usual clinic or ward environment in which patients may feel uncomfortable and imposing. Coffee and biscuits were served at the beginning of each session to make the patients feel welcome and relaxed. Groups were seated in a semi-circle and the educator was seated in a position which completed the circle without appearing too close or threatening. Thus, in this setting patients could learn about diabetes in a congenial, rather than pedagogical, atmosphere.

To encourage attendance the sessions were arranged at the most convenient dates and times possible for the patients. One group of patients attended in the evening, and many of the individual sessions were held on Saturday mornings. An informal letter (e.g. in Appendix 6.1) was sent to each patient one week prior to each session. Also, patients were telephoned to remind them several days beforehand. This maintained a high level of communication and continuity between each session. Several patients were discreetly reimbursed with bus travel expenses after it was discovered that one person had dropped out of the study because she could not afford the travel costs. The programme setting was intended to encourage participation, enjoyment and communication between the peer group and educator. Thus, some motivational and behavioural aspects are apparent in the programme setting.

### 2.8.3 Design and Methods

The programme consisted of eleven sessions which considered different topics related to the treatment and management aspects of insulin-dependent diabetes, and a twelfth session concerned evaluation of the DE/MP. The topics considered in the programme are listed here:

1. Introducing diabetes
2. Diet
3. Insulin
4. Hypoglycaemia
5. Diabetic Control
6. Exercise and Illness
7. Ketones and Hyperglycaemia
8. The New Diet
9. Complications of Diabetes
10. New Developments in Research
11. Practical Problems in Management

The topics were presented in this order to ensure an understanding of the most fundamental components in treatment, such as diet and insulin, before progressing to more complex subjects. Each session was conducted in accordance with a teaching plan which details the aims, objectives, resources, content and summary for each session. The teaching plans of the eleven sessions listed are contained in the Thesis Supplement. An example of the type of plan used is shown here.

#### TEACHING PLAN

- Topic: The title of the topic to be discussed
- Time: Duration of session - usually 1 - 1 1/2 hours
- Format: Either group or individual
- Resources: List of teaching/audiovisual aids to be used, e.g. food models, video, slides, pamphlets.

### Aims:

Description of major aims of the session, for example 'to introduce group members to each other and to create a relaxed and informal atmosphere'.

### Objectives:

A list of statements defining proposed achievements of the patient after the session. These objectives are couched in terms of overt behaviour (explain, discuss, demonstrate) rather than non-observable qualities (understand, know, appreciate). For example, in session 2 'the patient will be able to explain the effect of dietary carbohydrate on the blood glucose'.

### Transition:

Several questions, chosen to improve the recall of information presented in the previous session. For example, in session 4 'what is the aim of insulin treatment?' concerns the subject discussed in session number 3.

### Content:

A description of how the information is to be presented, e.g. in session 5 'demonstration of the correct procedure for blood glucose testing using BM test strips', and in session 6 'distinction between the terms hyperglycaemia and hypoglycaemia'.

### Summary:

A revision of the key facts derived from the information presented is outlined to reinforce learning, e.g. in session 7 'illness can cause your body to produce more glucose' and 'NEVER' stop your insulin'.

### Discussion:

Several open-ended questions were formulated to encourage group participation and self-expression, whilst reinforcing the information presented, e.g. in session 9 'do you think of complications when your control is poor?' or 'does the thought of complications frighten you?'

### Motivational Aspects:

A description of the type of motivational features of the session is given, e.g. in each session patients were informed of previous HbA<sub>1c</sub> levels and support and encouragement was provided. In session 8 a buffet meal and wine were provided when discussing diet.

### Evaluation:

A descriptive account of the outcome and findings from the session was made immediately so that necessary changes could be included for subsequent sessions. The evaluation was based on the total number of groups or individual sessions for each topic, e.g. in session 10 'patients were very eager to know more about research developments'.

### Script:

The content of the session is detailed in a form suitable for presentation to the patients.

This type of plan was devised for each session to provide a definitive set of objectives upon which to build the content. These objectives were of three types.<sup>(276)</sup>

- (i) Cognitive - dealing with knowledge
- (ii) Affective - dealing with attitudes, emotions, values and feelings
- (iii) Psychomotor - dealing with skills.

To achieve the objectives in each session, recommended educational and behavioural strategies reported to enhance learning, learning motivation and behavioural modification were used, as discussed in general terms in section 1.6. This section describes how the techniques were implemented in the DE/MP.

#### 2.8.4 Educational Strategies

Information content and organisation: Imagination and variety were introduced by conducting both individual and group formats, supplemented with learning/audiovisual aids, including models, slides, pamphlets (illustrated in Thesis Supplement) and videos. Each session considered a different topic and the information was presented in an organised manner.

Brevity: Although the duration of the sessions was approximately one to one-and-a-half hours, the actual formal presentation time was usually half-an-hour, or occasionally three-quarters of an hour, therefore not exceeding the maximum concentration time.<sup>(277)</sup>

Primary Principles: In each session the most important aspects of the subject were introduced initially and emphasised in different ways with practical examples.

Reinforcement: The organisation provided ample opportunity for reinforcement of the information in various ways, e.g. testing recall in the transition phase, repeating information in a different manner in the summary and discussion.

Readability: Pamphlets were produced specifically for the DE/MP, with reading ages of approximately 11 years. This was accomplished using the Fry Readability.<sup>(278)</sup> Other chosen sources of literature were also appropriate to the comprehension capability of the patients.

Comprehension: The content and wording of the presentations was simplified to ensure an understanding by patients of all educational abilities. This is illustrated in the scripts of sessions 1 - 11 contained in the Thesis Supplement.

Active Participation: In all sessions patients were asked questions in the transition and discussion periods to encourage participation. Patients were involved in the learning process, e.g. in session 8 patients partook of a buffet meal to enable participation and to facilitate practically-orientated discussion when considering the new diet. In session 3 patients demonstrated the procedures for drawing up and injecting insulin.

#### 2.8.5 Behavioural Strategies

Communication: The educator was a lay person with insulin-dependent diabetes. This enhanced a relaxed and trusting relationship because it was considered that patients would feel that their problems would be more readily appreciated. Good rapport was established by

demonstrating a friendly, sincere and caring attitude, and an understanding of individual problems and needs. Session plans (Thesis Supplement) illustrate communication strategies in the transition and discussion periods.

Reminders: Patients received an informal letter noting the time/day of next session and a telephone reminder one day before the session.

Tailoring: Two individual sessions were held to provide an opportunity to assess the patients' preferences, requirements and attitudes. Thus, these sessions were tailored to suit the individual, e.g. how to adjust insulin doses was only discussed when it was felt that the patient could cope with such changes, and glycaemic control and specific aims were discussed in relation to each patient.

Self-monitoring: Home blood glucose testing was carried out by all patients. Interpretation and discussion of results occurred at each session to enhance the benefits of self-monitoring.

Contracting: Individual goals, in terms of HbA<sub>1c</sub> levels and blood glucose concentrations, were agreed with each patient, and progress was discussed at each session.

Achievement: The individual goals in terms of glycaemic control provided incentives for achievement and satisfaction. Also, learning achievements were provided for in the transition periods in which questions were asked concerning the previous topic discussed, and in



session 2 a simple diet questionnaire (Thesis Supplement) was completed and results provided.

Reward: Initially all patients were given a one year membership of the British Diabetic Association free of charge, plus an educational book and other pamphlets, and a free buffet meal. Continual encouragement, praise and support were given throughout the sessions for positive progress.

Feedback: The results of HbA<sub>1c</sub> tests were given to patients at the beginning of each session, thereby providing feedback concerning glycaemic control. Home blood glucose monitoring was a source of immediate feedback for patients at home. Results of the diet questionnaire in session 2 and discussion in each session provided feedback concerning improvements in knowledge of diabetes.

Reinforcement: Positive reinforcement was introduced in the sessions by the increased attention and supervision from the educator. Convenient appointment times were arranged with patient groups to encourage attendance, provision of blood glucose testing equipment served as reminders, and peer group and family support was encouraged.

The educational and behavioural strategies described here were selected as those of special importance because they focussed on the patient's own learning rather than on the educator and instruction. Patients were encouraged to assume an active role in the learning process to foster self-confidence and self-responsibility in managing

their diabetes. This was intended to facilitate patient adaptation of a more internal health locus of control, in which the patient feels responsible and in control of his/her own health.<sup>(182)</sup>

Although most sessions were held in a group format, it was necessary to consider the educational abilities, needs, values, motivations and beliefs of each patient. Thus, as a general principle, many of the considerations described here were adapted and modified progressively throughout the programme. This was a continuous updating process to provide the best possible match between perceived individual needs and the provision for attainment of those needs.

## 2.9 Evaluation

### 2.9.1 Introduction

Evaluation is necessary to assess the potential benefits of, and requirement for, diabetes education,<sup>(279)</sup> and is an essential consideration in the development of education programmes. In this study, programme effectiveness was evaluated by assessing glycaemic control, diabetic knowledge, attitudes and self-management skills, as discussed in sections 3.3-3.6. This type of evaluation, which occurs after the programme, is known as 'summative' evaluation.<sup>(280)</sup> It is also essential to conduct continuous evaluation during the course of the programme, to monitor the methods used, and where necessary, implement changes designed to improve the programme. This is known as 'formative evaluation',<sup>(280)</sup> and produces information which contributes to the development and efficacy of the programme. In the DE/MP the transition period provided a vehicle for formative evaluation, by assessing patient understanding of previous topics.

Resulting from this evaluation, various changes were made in the way information was presented, e.g. inclusion of more examples and hypothetical but pertinent examples in various sessions, increased attention to emotional/attitudinal aspects. Formative evaluation of each session is described in session plans 1 - 11 in the Thesis Supplement. This section concerns summative evaluation of the DE/MP in terms of the patients' assessment of the programme content, usefulness and structure, and the suitability of the educator.

Six month evaluation was also conducted to investigate the type of problems, number of admissions and patients' views concerning follow-up educational sessions.

#### 2.9.2 Evaluation of the DE/MP

The DE/MP was designed specifically for the purpose of this study and has not been subject to any previous evaluation. Thus, the main reason for this evaluation was to obtain a qualitative assessment of the DE/MP from the patients, which could be used to modify and improve the structure and content of the programme.

A questionnaire was designed to investigate the patients' opinions concerning the programme (Appendix 6.2). Questions concerned aspects such as:

Usefulness

Enjoyment

Learning achieved

Time intervals between sessions

Duration of sessions

Number of sessions

Group/individual sessions

Likes

Dislikes

Perceived effects on glycaemic control

Perceived effects on behaviour.

Questions were presented in a multiple choice format with 3 or 4 rating options, e.g.

The group sessions were held at monthly intervals.

Do you think the time interval between sessions was:

too long

too short

about right

Patients were asked to tick the option which they felt was appropriate and were encouraged to be honest in their responses. The patients completed the questionnaire in session number 12 which was conducted as an individual session. Several questions were included to ascertain: the type of diabetes education the patients had previously received, whether the patient had carried out HBGM before the programme, to determine the number of patients who were not members of the British Diabetic Association (BDA) before the programme and to investigate reasons for non-membership. Results of this evaluation are discussed in section 3.9.1.

### 2.9.3 Evaluation of the Educator

It is fundamental to a programme of this nature to ascertain the precise role of the educator. Thus, patients' opinions and views concerning the educator were taken fully into consideration. A short questionnaire (Appendix 6.3) was formulated to investigate the following aspects:

- (i) quality of instructionn
- (ii) communication skills
- (iii) competence in knowledge
- (iv) age preference

The multiple choice questionnaire was mailed to each patient on completion of the 12 month DE/MP. It was accompanied by a letter from the Diabetes Consultant (Appendix 6.4) requesting patients to complete the questionnaire, and a stamped addressed envelope was enclosed. Patients were not asked to identify themselves on the questionnaire, thereby encouraging honest and reliable responses. Results of the evaluation are discussed in section 3.9.2.

#### 2.9.4 Six Month Follow-up Evaluation

The purpose of this evaluation was to investigate patients' well-being at 6 months after completion of the DE/MP. Individual sessions were held in the Seminar Room in the hospital's Teaching Department. A short questionnaire was designed (Appendix 6.5) to enquire about:

- Problems related to diabetes
- Hospital admissions - after the completion of the DE/MP
- Alterations in insulin dose (made by patient)
- Perceived benefits of refresher session.

The questionnaire was administered verbally since factual responses were required and not ratings which may have been biased in the presence of the educator.

Results of the follow-up evaluation are discussed in section 3.9.3.

## 2.10 Statistical Analysis

Data obtained during this study concerns five major aspects: patient details, glycaemic control, diabetic knowledge, attitudes and self-management skills, which assume both interval and ordinal (ranked) scales. Thus, both parametric and non-parametric statistical tests were used in the data analysis.

There are three assumptions that underlie the use of parametric techniques:<sup>(281)</sup> 1. that the population distribution is normal, 2. that there is homogeneity of variance, and 3. the data is at least interval.

However, much of the data presented in this Thesis does not specify to these conditions and therefore non-parametric tests of significance were also used. Depending on the nature of the underlying measurement or scale, data were broadly categorised into two types: 1. parametric (continuous), and 2. non-parametric (discontinuous) as shown in Fig. 2.14:

Fig. 2.14      Parametric and non-parametric types of data

<u>Parametric</u>	<u>Non-parametric</u>
Age (years)	Sex
Duration (years)	Marital status
Hospital admissions (year/duration)	Ethnic group
Weight (kg)	Social class
Ideal body weight (%)	Insulin type
Clinic non-attendance (%)	Diabetic knowledge (%)
Insulin dose (U/kg)	Attitudes
Blood glucose concentration (mmol/l)	Management skills
Glycosylated haemoglobin (%)	

When parametric and non-parametric sets of data were compared, non-parametric tests were used.

Statistical analyses were performed using the Minitab Statistical Computer programme,<sup>(282)</sup> and the Statistical Package for the Social Sciences (SPSS)<sup>(259)</sup> at the University of Aston in Birmingham.

### 2.10.1 Parametric Techniques

These tests were appropriate for analysis of data in the left-hand column of Fig. 2.13. Various tests were undertaken to compare individual and total group data. The level of significance was set at  $\alpha = 0.05$ , and is expressed as the probability level  $\rho$ , as obtained from the statistical tables by Fisher and Yates.<sup>(283)</sup> Only those  $\rho$  values  $< 0.05$  are documented.

#### Tests:

1. The difference between two samples was estimated using the Student's t-test. This tests the significance of the difference between the two means and is based on the t-statistic.<sup>(284)</sup> This was a two-tailed test of significance where degrees of freedom =  $n_{\text{sample 1}} + n_{\text{sample 2}} - 2$ .

An example using this test was the comparison of the Study Group and Control Group concerning HbA<sub>1c</sub> levels.

2. The difference between related samples (pairs) was estimated using the Related t-test.<sup>(284)</sup> This measures the difference between two sample means which are related or contain the same cases. This was a one-tailed test where degrees of freedom =  $n_{\text{pairs}} - 1$ .

An example using this test investigated the difference in HbA<sub>1</sub> levels at 0 and 12 months in the Study Group.

3. The variation between more than two groups concerning a particular variable was estimated using One way analysis of Variance.<sup>(284)</sup> This determines the difference between and among the group means by calculating the 'F' statistic, which is the 'between group' variance divided by the 'within group' variance. The value of F indicates the significance level of the between group variation. A one-tailed test was used where degrees of freedom = n groups -1, total n -number of groups.

An example of this test was the analysis of variance in HbA<sub>1</sub> levels between the Study Group, Control Group and Not Attended Group at 0 months.

4. The relationship between two variables was determined using the Pearson's Correlation Coefficient.<sup>(284)</sup> This coefficient varies between +1.00 and -1.00. A positive correlation is the association between high or low values on one variable with high or low values respectively, on another variable. A negative correlation is the association between high or low values on one variable with low or high values respectively, on another variable. This is called 'inverse' correlation or relationship. The coefficient r indicates the significance of the correlation between two variables. A two-tailed test was used, where degrees of freedom = n pairs -2.

An example of this test is the correlation between age and HbA<sub>1</sub> levels in the total group.



### 2.10.2 Non-Parametric Techniques

These tests were appropriate for analysis of data shown in the right hand column of Fig. 2.13, and also for the comparison between parametric (interval) and non-parametric (ordinal) data. The level of significance was set at  $\alpha = 0.05$  and is expressed as the probability level,  $\rho$ . Only those  $\rho$  values of  $<0.05$  were documented.

#### Tests:

1. The difference between two samples was estimated using the Mann-Whitney test.<sup>(285)</sup> This is a ranked test in which the 'sum of ranks' of two samples are compared. These are known as  $W_1$  and  $W_2$ . The Minitab Statistics programme was used to calculate values of either  $W_1$  or  $W_2$  from which the Mann-Whitney 'U' statistic can be obtained using further calculations

$$U = n_1 n_2 + \frac{n_1 (n_1 + 1)}{2} - W_1$$

where:  $n_1$  = number of cases in sample 1 (the smallest of the two samples)

$n_2$  = number in sample 2

$W_1$  = sum of ranks in sample 1

When sample size is  $>8$ , U approximates with the normal curve.

Therefore, the Z statistic can be calculated to obtain the appropriate level of significance:

$$Z = \frac{U - \mu U}{\sigma U}$$

The level of significance of Z can be found in statistical tables.<sup>(283)</sup> A two-tailed test would be used when no prediction has been made concerning the two samples. Mann-Whitney tests were computed using the Minitab Statistics programme which calculates the  $\rho$  value using the normal approximation described.

An example using this test is to investigate the difference between the Study Group and Control Group concerning attitudes to diabetes.

2. The difference between related samples (pairs) was calculated using the Wilcoxon test.<sup>(286)</sup> The difference between the first sample observations and the second are ranked, and these can be either positive or negative. The signed ranks which are smaller in number are summed to obtain the Wilcoxon statistic T. This test was calculated manually using the Minitab Computing System. The level of significance was determined using non-parametric statistical tables,<sup>(286)</sup> using a two-tailed test, when  $n$  = number of pairs with either positive or negative ranks.

An example of this test is the difference in management skills in the Study Group at 0 and 12 months.

3. The variation between more than two groups concerning a particular variable was calculated using the Kruskal Wallis test, which is analogous to a parametric one-way analysis of variance.<sup>(287)</sup> In this test the total number of observations are ranked and the test statistic 'H' is computed which measures the disparity between the sum of ranks for each group. H was calculated using the Minitab Statistical programme, which also adjusted for

ties, that is, where more than one observation attains a particular rank. The H statistic is distributed approximately as Chi square. Degrees of freedom = n groups -1. Therefore Chi squared tables<sup>(287)</sup> were used to ascertain the level of significance of the H statistic.

An example of this test is the variation between the Study Group, Control Group and Non-Attended Group regarding attitudes to diabetes.

4. The relationship or association between two variables was determined using Spearman's rank correlation coefficient rho, known as  $r_s$ .<sup>(287)</sup> The coefficient  $r_s$  varies between +1.00 and -1.00, where a positive correlation is the association of high or low values on one variable, with high or low values respectively on the second variable, and a negative correlation is the association of high or low values with low or high values respectively. The  $r_s$  coefficient was calculated using the Minitab Statistics programme. However, when using large samples, as in the case of this study, the significance of  $r_s$  is distributed as the Student's t. This was computed manually using the formula:

$$t = \frac{\sqrt{n - 2}}{1 - r_s}$$

Values of  $\rho$  were obtained using statistical tables,<sup>(287)</sup> where degrees of freedom = n pairs -2, using a two-tailed test.

An example of this test is the correlation between attitudes and knowledge in the total patient sample at 0 months.

### 2.10.3 Factor Analysis

This was used in the development of attitude scales (section 2.5), to investigate the underlying structure of the attitude statements. The factor analysis programme in the Statistical Package for the Social Sciences (SPSS) at Aston University was used. Principal factoring with iterations was computed, and this takes into account the imperfect reliability of the variables.<sup>(288)</sup> Also, oblique rotation was applied; this provides a more even distribution of the variance among the factors, therefore improving the final factor solution. Results of factor analysis are shown in sections 2.5.8 and 2.5.12.

## 2.1. Introduction

As outlined in the background chapter, 22 insulin-dependent diabetic patients were included in the present study, comprising four groups:

- (i) 11 patients who had participated in the DC/DP,
- (ii) 11 newly diagnosed patients enrolled with routine clinical care,
- (iii) 11 patients who had been enrolled in the DC/DP study in 1987-88 and who had been followed up in the DC/DP study,
- (iv) 11 patients who had been enrolled in the DC/DP study in 1987-88 and who had been followed up in the DC/DP study.

## 3. RESULTS

Diabetes mellitus is a chronic disease and the clinical course and self-management of the disease are highly variable. In the present study, the clinical course was assessed at 0, 12 and 18 months, and the clinical course was assessed continuously over the initial 12 months. The clinical course was assessed at 0 and 12 months only, and glycaemic control was assessed at 0, 12 and 18 months. The DC/DP group was assessed at 0, 12 and 18 months, and the DC/DP group was assessed at 0, 12 and 18 months, and the DC/DP group was assessed at 0, 12 and 18 months. The DC/DP group was assessed at 0, 12 and 18 months, and the DC/DP group was assessed at 0, 12 and 18 months.

It must be noted that the DC/DP group did not fulfill the study criteria and were therefore excluded from the present study.

Comparisons between the DC/DP group and the other groups are clearly stated.

This chapter describes the clinical course and group differences. The results of the DC/DP study are reported, together with a description of the DC/DP study. These aspects will be discussed in the following chapters.

### 3.1 Introduction

As detailed in the preceding chapter, 92 insulin-dependent diabetic patients were included in the present study, comprising four groups:

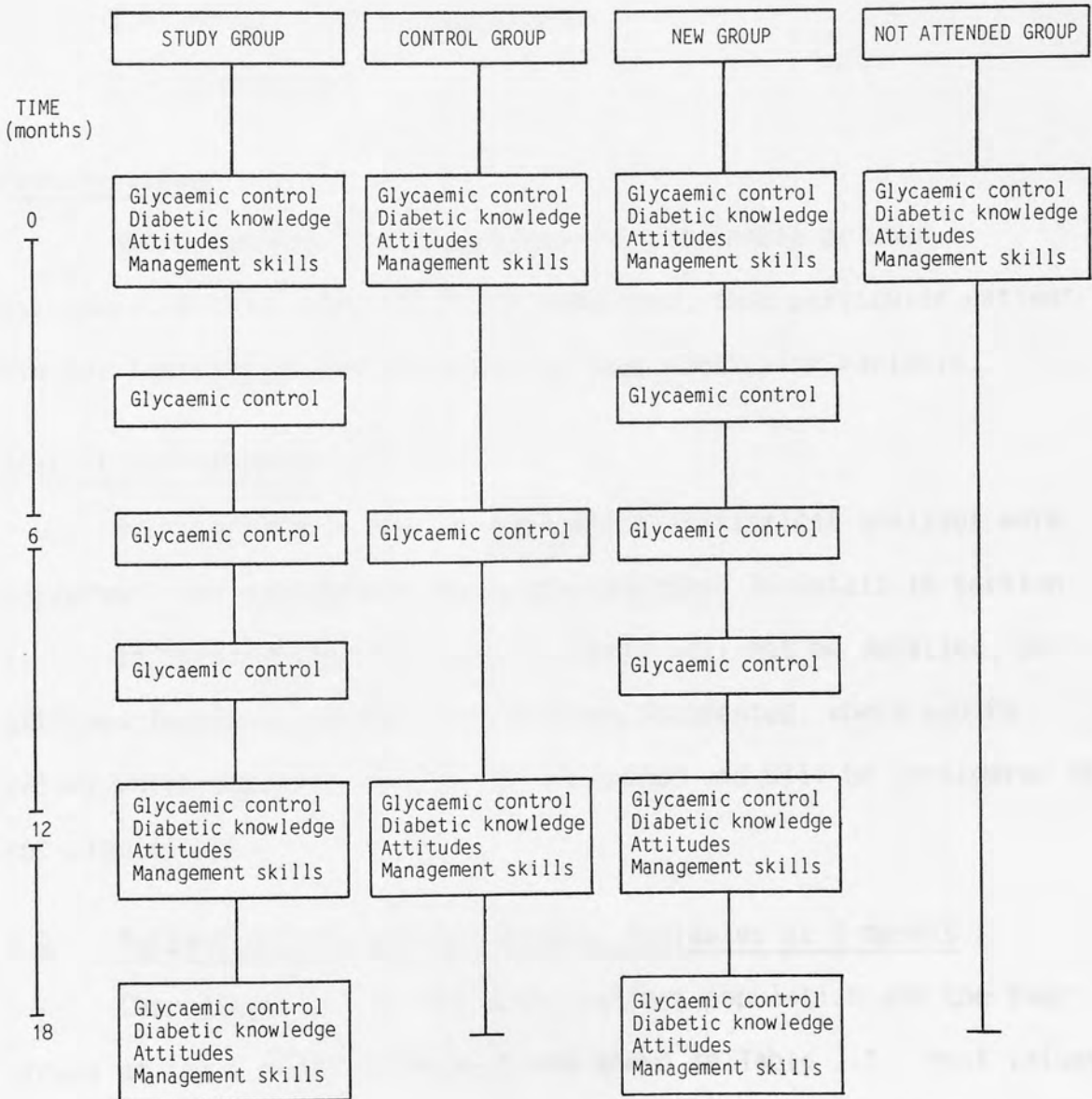
- (i) Study Group (SG) which participated in the DE/MP.
- (ii) Control Group (CG) which continued with routine clinic care.
- (iii) Not Attended Group (NA) which declined to participate or did not attend.
- (iv) New Group (NG) with a duration of diabetes less than 12 months.

Glycaemic control, diabetic knowledge, attitude to diabetes and self-management skills for all patients were assessed, as discussed in sections 2.1 - 2.9.8. The SG was assessed at 0, 12 and 18 months, and glycaemic control was monitored continuously over the initial 12 month period. The CG was assessed at 0 and 12 month only, and glycaemic control was also noted at 6 months. The NA group was assessed at 0 months only. The NG was assessed at 0, 12 and 18 months, and glycaemic control was monitored throughout the initial 12 months. The timings of assessments are summarised in Fig. 3.1.

It must be emphasised that the NG did not fulfill the study criteria and were therefore included as a separate group. Comparisons between this group and the other groups are clearly stated.

This Chapter describes the total patient population and group differences. The results of all assessments undertaken are reported, together with an evaluation of the outcome of the DE/MP. These aspects will be considered under the following headings:

Fig. 3.1 Summary of Assessments in the Four Groups



- 3.2 Patient details and demographic variables
- 3.3 Glycaemic control
- 3.4 Attitude to diabetes
- 3.5 Knowledge of diabetes
- 3.6 Self-management skills
- 3.7 Intercorrelations between assessment parameters
- 3.8 Miscellaneous comparisons
- 3.9 Evaluation

### Missing values

Where certain information was not obtainable or when assessment methods were not fully completed, that particular patient was not included in the analysis for that particular variable.

### Statistical Analysis

Both parametric and non-parametric statistical analyses were performed, and appropriate tests are described in detail in section 2.10. In this section, statistical tests will not be detailed, but attained levels of significance will be documented, where  $p < 0.05$ . Values which exceed 0.05 will not be quoted and will be considered as not significant.

#### 3.2 Patient Details and Demographic Variables at 0 months

Characteristics of the total patient population and the four groups at the 0 month assessment are shown in Table 3.1. Most values are expressed as the mean  $\pm$  standard error from the mean (SEM), and where appropriate, the range appears in parentheses. Frequency counts are shown for sex, race, socioeconomic group (SEG) and marital status.



**Table 3.1 Patient Characteristics of Total Patient Population and Four Subgroups**

Variable	Total Patient Group	SG	CG	NA	NG
Number	87	31	25	31	5
Sex	M - 54 F - 33	M - 16 F - 15	M - 18 F - 7	M - 20 F - 11	M - 3 F - 2
Age (years)	33.9 $\pm$ 1.4	32.0 $\pm$ 2.3	40.2 $\pm$ 2.5	30.6 $\pm$ 2.1	36.6 $\pm$ 6.3
Duration (years)	11.9 $\pm$ 0.9	11.7 $\pm$ 1.2	15.8 $\pm$ 2.3	8.9 $\pm$ 1.2	5.0 $\pm$ 1.6*
DNA %**	12.9 $\pm$ 1.7	11.5 $\pm$ 2.5	8.0 $\pm$ 2.8	17.9 $\pm$ 3.2	-
Hospital admissions (patient/year duration)	0.21 $\pm$ 0.06	0.13 $\pm$ 0.03	0.33 $\pm$ 0.23	0.20 $\pm$ 0.04	-
Race: <sup>+</sup>					
C	73 (84%)	26 (84%)	22 (88%)	25 (80%)	4 (80%)
A	6 (7%)	2 (6%)	1 (4%)	3 (10%)	1 (20%)
WI	8 (9%)	3 (10%)	2 (8%)	3 (10%)	0
SEG: <sup>‡</sup>					
1	4 (5%)	0	3 (12%)	1 (4%)	1 (25%)
2	8 (10%)	2 (7%)	4 (16%)	2 (7%)	0
3	32 (40%)	13 (48%)	11 (44%)	8 (28%)	2 (50%)
4	17 (21%)	4 (15%)	6 (24%)	7 (25%)	0
U/E	19 (24%)	8 (30%)	1 (4%)	10 (36%)	1 (25%)
Marital Status: <sup>∅</sup>					
1	33 (38%)	15 (48%)	5 (20%)	13 (42%)	1 (20%)
2	48 (55%)	12 (39%)	20 (80%)	16 (52%)	3 (60%)
3	6 (7%)	4 (13%)	0	2 (6%)	1 (20%)

Values expressed as the mean  $\pm$  SEM

\* Duration of diabetes in NG expressed in months

\*\* DNA% - the percentage clinic non-attendance in previous 4 years

+ C = Caucasian A = Asian WI = West Indian

‡ SEG taken from the Office of Populations Survey Index<sup>(238)</sup>, U/E = unemployed

∅ 1 = single 2 = married 3 = divorced/separated

Sex distribution, clinic non-attendance, race, SEG and marital status were similar in the SG, CG and NA groups. The mean age was greater in the CG than either the SG or NA group ( $p < 0.02$ ,  $p < 0.005$  respectively). A similar trend was apparent for the duration of diabetes, which was greater in the CG compared with the NA group ( $p < 0.01$ ), but was not significantly greater than in the SG.

Details of patients' weight, % ideal body weight, insulin dose and insulin type are given in Table 3.2.

Table 3.2 Details of Patients' Weight and Insulin at 0 Months

Variable	Total patient group	SG	CG	NA	NG
Weight (kg)	70.0 $\pm$ 1.4	67.9 $\pm$ 2.4	73.6 $\pm$ 2.5	69.4 $\pm$ 2.5	69.4 $\pm$ 2.9
% Ideal Body Weight	111.8 $\pm$ 1.5	112.0 $\pm$ 2.5	113.8 $\pm$ 1.9	109.0 $\pm$ 3.1	105.0 $\pm$ 7.8
Insulin Type*					
1	31 (35%)	10 (32%)	8 (32%)	13 (42%)	2 (40%)
2	31 (35%)	12 (39%)	6 (24%)	13 (42%)	2 (40%)
3	12 (14%)	5 (16%)	5 (20%)	2 (6%)	0
4	11 (13%)	2 (7%)	6 (24%)	3 (10%)	1 (20%)
5	2 (3%)	2 (6%)	0	0	0
Insulin dose (U/kg)	0.74 $\pm$ 0.03	0.80 $\pm$ 0.05	0.69 $\pm$ 0.05	0.73 $\pm$ 0.05	0.42 $\pm$ 0.06

Values expressed as the mean  $\pm$  SEM

\*Insulin type: 1 = premixed  
 2 = medium plus short-acting pork  
 3 = medium plus short-acting beef  
 4 = long/medium-acting only  
 5 = human insulin

The four patient groups were similar in body weight, ideal body weight and insulin dose. Insulin types were classified into five categories: 31 (35%) patients used pre-mixed insulins; 31 (35%) used medium plus short-acting pork insulins; 12 (14%) patients were using long plus short-acting beef insulins; 11 (13%) used long or medium-acting insulin only, and 2 (3%) patients used human insulin.

Patient details of the four groups, which are given in Tables 3.1 and 3.2, do not include patients who were subsequently excluded from the study (refer to section 2.3.2). These comprised 11 patients from the SG and 3 patients from the CG. However, it was noted that overall patient details were not altered when these patients were included in the 0 month assessment.

Details of the original patient groups at the 0 month assessment are shown in Appendix 7.1.

### 3.2.1 Patient Details at 12 month Assessment

Patient details, which were subject to change, were re-recorded at the 12 month assessment. These included: number of hospital admissions, body weight, % ideal body weight and insulin dose (U/kg). Table 3.3 shows the changes in these parameters at the 12 month assessment. This Table does not include the NA group.

Using paired analysis it was shown that the number of hospital admissions and mean insulin dose were not significantly changed in the three groups. However, body weight and % ideal body weight increased in the SG ( $p < 0.005$ ,  $p < 0.01$  respectively), although the CG, NG and total patient groups did not demonstrate significant change.

Table 3.3 12 Month Assessment of Admissions, Weight and Insulin

Variable	Total patient Group	Change 0 - 12 months	SG	Change 0 - 12 months	CG	Change 0 - 12 months	NG	Change 0 - 12 months
Hospital admissions (Patient/year duration)	0.26±0.07	+0.5	0.14±0.03	+0.1	0.38±0.23	+0.5	0	0
Weight (kg)	71.1±1.8	+1.1	69.5±2.4	+1.6*	73.0±2.7	-0.6	70.4±3.4	+1.0
% Ideal body weight	114.3±1.7	+2.5	114.4±2.7	+2.4*	114.2±2.1	+0.4	107.2±9.0	+1.4
Insulin dose (U/kg)	0.73±0.03	-0.01	0.79±0.05	-0.01	0.66±0.05	-0.03	0.42±0.06	0

Values expressed as mean ± SEM

\* p<0.01

### 3.3 Glycaemic Control

Glycaemic control was assessed using glycosylated haemoglobin (HbA<sub>1</sub>) measurements and blood glucose concentrations. HbA<sub>1</sub> tests were carried out at 0 months in all groups, the frequency of further determinations varied among the groups as illustrated in Fig. 2.8 in section 2.4.4. Blood glucose measurements were recorded at 0 months for all groups, using mean non-fasted clinic blood glucose concentrations from previous clinic visits (section 2.4.2). Additional blood glucose measurements, obtained from patients' home blood glucose tests, were recorded at 8 and 10 months in the SG and NG only. Results of these measurements will be considered in section 3.3.6.

#### 3.3.1 0 Month Assessment

HbA<sub>1</sub> and blood glucose concentrations for the total patient population and the four sub-groups are presented in Table 3.4.

Table 3.4 0 Month Assessment of Glycaemic Control

	Total patient group n = 87	SG n = 31	CG n = 25	NA n = 31	NG n = 5
HbA <sub>1</sub>	12.3 <sub>±</sub> 0.3	11.8 <sub>±</sub> 0.4	11.8 <sub>±</sub> 0.5	13.6 <sub>±</sub> 0.7	8.7 <sub>±</sub> 0.8
Scale*					
1	14 (18%)	8 (27%)	3 (12%)	3 (13%)	3 (60%)
2	34 (44%)	11 (38%)	15 (60%)	8 (35%)	2 (40%)
3	29 (38%)	10 (35%)	7 (28%)	12 (52%)	0
Blood glucose mmol/l	8.6 <sub>±</sub> 0.3	8.5 <sub>±</sub> 0.5	7.7 <sub>±</sub> 0.6	9.6 <sub>±</sub> 0.7	6.1 <sub>±</sub> 0.8**

Results expressed as the mean  $\pm$  SEM

\* Arbitrary scale of glycaemic control: 1 = good 2 = moderate 3 = poor

\*\*Mean of previous clinic blood glucoses following hospital treatment was between 2 and 4 visits

Mean HbA<sub>1</sub> for 29 patients, 2 patients excluded (refer to section 2.4.4)

The total patient population had a mean HbA<sub>1c</sub> of 12.3%. On the basis of % HbA<sub>1c</sub>, patients were assigned to good, moderate or poor control (refer to section 2.4.3). Results revealed that a considerable number of patients 29 (38%) were categorised as having poor glycaemic control, and only 14 (18%) were considered to be in good glycaemic control. Between group differences in HbA<sub>1c</sub> were demonstrated ( $p < 0.05$ ), and this was attributed to the relatively high HbA<sub>1c</sub> value in the NA group compared to the SG or CG ( $p, 0.03$ ,  $p, 0.03$  respectively), although the SG and CG were similar in % HbA<sub>1c</sub>. The NG had a HbA<sub>1c</sub> of 8.7% (range 7.1-11.1) and 3 out of 5 patients were classed as having good glycaemic control.

The mean non-fasted blood glucose concentration in the total group was 8.6 mmol/l. Comparisons between groups showed that the SG and CG were similar, but that the NA group had a higher blood glucose concentration compared to the CG ( $p < 0.03$ ) and the SG (NS).

At 0 months, the NA group appeared to have poorer glycaemic control, as assessed by clinical blood glucose and HbA<sub>1c</sub> levels, compared to the SG and CG. The SG and CG were similar, and were assumed therefore to be suitably matched for purposes of further comparisons of glycaemic control throughout the study. The NG showed reduced HbA<sub>1c</sub> and blood glucose concentrations compared with all other groups.

Glycaemic control in the SG and CG was similar to that of the original groups, where the SG  $n = 42$  and the CG  $n = 28$ . This is shown in Appendix 7.2. However, only those patients who completed the full 12 month assessment programme were considered in the statistical comparisons, to allow accurate paired analyses to be undertaken.

### 3.3.2 3 Month Assessment

This involved HbA<sub>1</sub> measurements in the SG and NG only. The assessment measure is the mean of the HbA<sub>1</sub> test results taken at 1, 2 and 3 months. The mean % HbA<sub>1</sub> and the mean difference in % HbA<sub>1</sub> at 3 months for the SG and NG are shown in Table 3.5.

Table 3.5    3 month assessment of HbA<sub>1</sub> in the SG and NG

	SG	NG
HbA <sub>1</sub> %	11.93 ± 0.40	8.4 ± 0.45
Mean difference 0 - 3 months*	+ 0.11	-0.34

Results expressed as the mean ± SEM

\* Negative signs indicate a decrease and positive signs indicate an increase in HbA<sub>1</sub>

HbA<sub>1</sub> levels of the SG and NG did not alter significantly during the initial 3 months of the DE/MP as shown by paired t-test analysis.

### 3.3.3 6 Month Assessment

The SG, CG and NG were included in this assessment. In the SG and NG, the HbA<sub>1</sub> value was derived from the mean of the HbA<sub>1</sub> measurements taken at 4, 5 and 6 months. Assessment of the CG was based on one HbA<sub>1</sub> measurement taken at approximately 6 months after the initial assessment. % HbA<sub>1</sub> levels in the SG, CG and NG are given in Table 3.6, and the mean changes from the 0 month assessments are shown.

Table 3.6 6 Month Assessment of the SG, CG and NG

	Total patient group	SG	CG	NG
% HbA <sub>1</sub> - 6 months	11.68 $\pm$ 0.31	11.62 $\pm$ 0.38	11.76 $\pm$ 0.5	7.72 $\pm$ 0.63
Mean difference 0 - 6 months	-0.68	-0.20	-0.06	-1.02

Results expressed as the mean  $\pm$  SEM

By paired analyses, the total group, SG, CG and NG did not show any significant change in HbA<sub>1</sub> levels from 0 to 6 months. Glycaemic control remained similar in the SG and CG, despite the participation of the SG in the DE/MP.

### 3.3.4 9 Month Assessment

This concerned the SG and NG only and the assessment measure is the mean % HbA<sub>1</sub> of the values recorded at 7, 8 and 9 months during the DE/MP. Results are shown in Table 3.7, together with the mean difference from 0 to 9 months.

Table 3.7 9 Month Assessment of the SG and NG

	SG	NG
HbA <sub>1</sub> %	11.15 $\pm$ 0.33	7.96 $\pm$ 0.73
Mean difference 0 - 9 months	-0.67*	-0.78

Results expressed as the mean  $\pm$  SEM \* p<0.02

As indicated by paired analysis, % HbA<sub>1</sub> levels decreased in the SG during the period 0 to 9 months (p<0.02), although the NG did



not demonstrate a significant change. Both the SG and NG had regularly attended the DE/MP.

### 3.3.5 12 Month Assessment

This involved the SG, CG and NG. HbA<sub>1</sub> values for the SG and NG were obtained from the mean of the HbA<sub>1</sub> measurements taken at 10, 11 and 12 months. Assessment of the CG was based on a single HbA<sub>1</sub> measurement taken at the 12 month interview. Results of this assessment and the mean % change from 0 to 12 months are shown in Table 3.8.

Table 3.8      12 Month Assessment of the SG, CG and NG

	SG	CG	NG
HbA <sub>1</sub> %	10.50 $\pm$ 0.35	11.63 $\pm$ 0.45	7.54 $\pm$ 0.47
Mean change 0 - 12 months	-1.31%*	-0.19%	-1.20%
Scale of control**			
1	13 (45%)	5 (21%)	4 (80%)
2	13 (45%)	14 (58%)	1 (20%)
3	3 (10%)	5 (21%)	

Results expressed as the mean  $\pm$  SEM

\* p<0.001

\*\* Index of glycaemic control: 1 = good, 2 = moderate, 3 = poor

Paired analysis demonstrated a significant reduction of % HbA<sub>1</sub> levels in the SG (p<0.001). In the CG, however, % HbA<sub>1</sub> remained unchanged at the 12 month assessment. The SG and CG exhibited significantly different HbA<sub>1</sub> levels at 12 months (p<0.05). The scale index of glycaemic control indicates that 13 (45%) SG patients were deemed as having good glycaemic control, compared to only 5 (21%) CG patients, and that only 3 (10%) SG

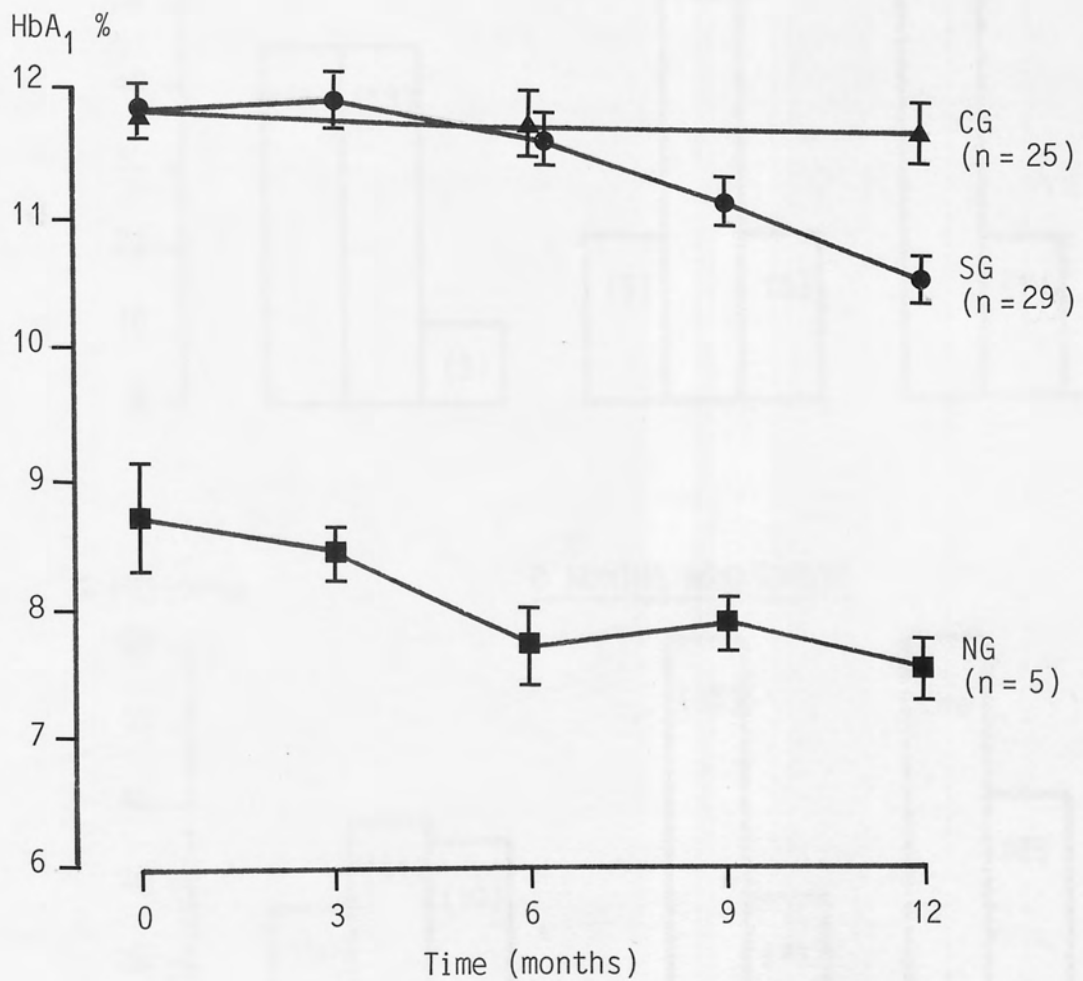
patients were poorly controlled at 12 months compared to 5 (21%) CG patients. In the NG, HbA<sub>1c</sub> levels were not reduced significantly, 4 (80%) patients demonstrated good glycaemic control and 1 (20%) moderate control. No NG patients were poorly controlled at either 0 or 12 months.

Figure 3.2 illustrates the mean % HbA<sub>1c</sub> levels of the SG and NG at 0, 3, 6, 9 and 12 months, and of the CG at 0, 6 and 12 months. Values are plotted as the mean  $\pm$  SEM. This emphasises that the decrease of HbA<sub>1c</sub> in the SG occurred between 6 and 12 months, when the mean HbA<sub>1c</sub> decreased from 11.15% to 10.5%. The difference of 1.13% in the HbA<sub>1c</sub> between the SG and CG is apparent in Figure 3.2. The NG demonstrated an initial decrease in HbA<sub>1c</sub> from 0 to 6 months. However, this tapered off between 6 to 12 months.

The distribution of patients in the 3 categories of the assessment scale altered during the time 0 to 12 months. Figure 3.3 illustrates the distribution of SG, CG and NG among the three categories of control at 0 and 12 months. An increased number of patients were classed as scale 1 (good glycaemic control) at 12 months, compared to the 0 month assessment. In the SG, this increase was from 27% to 45%, in the CG from 12% to 21%, and in the NG from 60% to 80%. The distribution of patients in class 2 (moderate control) was similar at 0 and 12 months, while the number of patients in class 3 (poor control) decreased in both the SG and CG by 25% and 7% respectively.

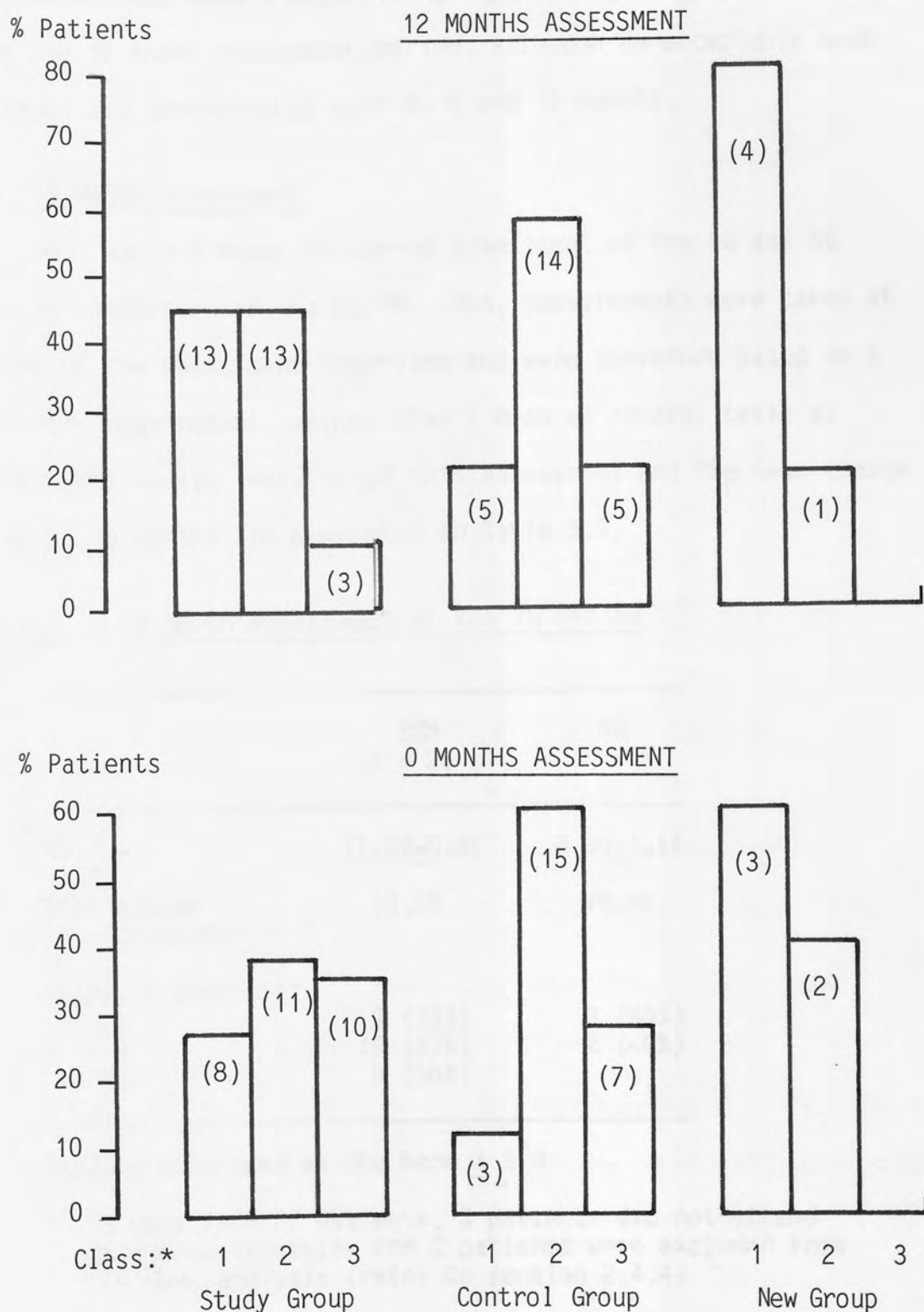
Glycaemic control in the SG, CG and NG over the period 0 to 12 months has been described. It is evident that the SG, members of which attended the DE/MP, achieved a significant improvement in glycaemic control during this time, compared to the CG in which

Fig. 3.2 HbA<sub>1</sub> assessments of SG, CG and NG



% HbA<sub>1</sub> levels in the SG (●), CG (▲) and NG (■)  
Values expressed as the mean  $\pm$  SEM

Fig. 3.3 Distribution of patients into categories of glycaemic control



Values expressed as % of patients; actual number of patients shown in parenthesis

\*Class of glycaemic control; 1 = good 2 = moderate 3 = poor

glycaemic control remained stable. The NG members who also attended the DE/MP did not show a significant improvement in glycaemic control during the 12 month assessment period, although an acceptable mean HbA<sub>1</sub> level was demonstrated both at 0 and 12 months.

### 3.3.6 18 Month Assessment

This was a 6 month follow-up assessment of the SG and NG following completion of the DE/MP. HbA<sub>1</sub> measurements were taken at the time of the assessment interview and were therefore based on a single HbA<sub>1</sub> measurement, rather than a mean of several tests as reported previously. Results of this assessment and the mean change from 12 to 18 months are presented in Table 3.9.

Table 3.9     18 Month Assessment of the SG and NG

	SG* n = 26	NG n = 5
HbA <sub>1</sub> %	11.09±0.45	8.30±1.14
Mean change 12 - 18 months	+0.59	+0.42
Scale of control**		
1	9 (33%)	3 (60%)
2	10 (37%)	2 (40%)
3	8 (30%)	

Results expressed as the mean ± SEM

\* SG comprised 27 patients, 3 patients did not attend follow-up interview and 2 patients were excluded from the HbA<sub>1</sub> analysis (refer to section 2.4.4)

\*\* Index of glycaemic control: 1 = good, 2 = moderate  
3 = poor

The SG showed a significant increase ( $p < 0.05$ ) in % HbA<sub>1</sub> level 6 months after completing the DE/MP. HbA<sub>1</sub> increased from 10.50% to 11.09%, although this did not return to the pre-programme level of 11.82%. The NG did not demonstrate a significant change in % HbA<sub>1</sub> from 12 to 18 months, with mean % HbA<sub>1</sub> levels of 7.5% and 8.3% respectively.

### 3.3.7 Summary of HbA<sub>1</sub> Assessments

At 0 months glycaemic control was similar in the SG and the CG, but notably poorer in the NA group. During the course of the programme, glycaemic control improved in the SG but not in the CG. The most notable improvement occurred after 6 months participation in the DE/MP. At 12 months, glycaemic control in the SG was significantly better than in the CG. At 18 months (6 month post-programme), the SG demonstrated poorer glycaemic control (increased HbA<sub>1</sub> levels) than at 12 months, although glycaemic control did not return to pre-programme standard.

Throughout the study the NG achieved optimal glycaemic control, and HbA<sub>1</sub> levels did not change significantly during the period 0 to 18 months.

### 3.3.8 Blood Glucose Concentrations

The mean clinic blood glucose concentrations in the SG, CG, NA and NG were discussed in section 3.3.1. In the SG and NG, HBGM also provided an assessment of glycaemic control at 8 and 11 months. HBGM was carried out in conjunction with clinic blood glucoses and HbA<sub>1</sub> measurements in participation with the DE/MP. The 8 month assessment was based on the mean of the blood glucose tests reported at 6, 7 and

8 months. Similarly, the 11 month assessment was derived from the mean of test results reported at 9, 10 and 11 months. Results of these assessments and the difference between the 8 and 11 month assessments are shown in Table 3.10.

Table 3.10      Home Blood Glucose Concentrations in the SG and NG

	SG	NG
8 month blood glucose (mmol/l)	7.11 $\pm$ 0.34	5.88 $\pm$ 0.66
11 month blood glucose (mmol/l)	6.90 $\pm$ 0.27	5.00 $\pm$ 0.53
Mean change: 8 - 11 months	-0.21	-0.88

Results expressed as the mean  $\pm$  SEM

The SG and NG did not demonstrate a significant change in blood glucose concentrations from 8 to 11 months.

### 3.4 Attitudes to Diabetes

Assessments of patients' attitudes to diabetes were undertaken at 0, 12 and 18 months. Attitude scales were developed specifically for the present study and this is discussed in section 2.5. Two scales were used: DAS2m, for assessment of attitudes at 0 months, and DAS3m for the assessment at 12 and 18 months. Results are expressed as raw scores, and statistical analysis was undertaken using non-parametric methods, as discussed in section 2.10. Assessments will be described in chronological order.

#### 3.4.1 0 Month Assessment

This was conducted using DAS2m (Appendix 3.6). Assessments were undertaken for the SG, CG, NG and NA groups. Scores ranged

between 15 (minimum) and 75 (maximum) and are expressed as mean scores (Table 3.11).

Table 3.11 Attitude Assessment taken at 0 Months

Total Patient Group (n = 87)	SG (n = 31)	CG (n = 25)	NG (n = 5)	NA (n = 31)
52.1 $\pm$ 1.0	50.5 $\pm$ 1.7	55.9 $\pm$ 1.8	57.8 $\pm$ 2.8	51.0 $\pm$ 1.7

Results expressed as mean  $\pm$  SEM  
Total group score does not include NG

The SG, CG and NA groups were similar in attitudes to diabetes and demonstrated comparability for further comparison of the SG and CG at 12 months. The NG showed a more favourable attitude compared to the SG ( $p < 0.01$ ). The mean total group score (excluding the NG) was 52.1.

The assessment of attitudes in the SG and CG described here only includes those patients who completed the study and who were reassessed at 12 months. However, results were not altered when the original patients were included, i.e. where SG n = 42 and CG n = 28. Results of the 0 month assessment, including these patients, are shown in Appendix 7.3.

#### 3.4.2 12 Month Assessment

Attitudes were reassessed in a 12 month interview in the SG, CG and NG. This was carried out using a different attitude scale than in the 0 month assessment; thus paired comparisons were not undertaken. The scale used was DAS3m (Appendix 3.13) which had a scoring range between 14 (minimum) and 70 (maximum). Results of this assessment are given in Table 3.12.



Table 3.12      Attitude Assessment taken at 12 Months

SG (n = 31)	CG (n = 25)	NG (n = 5)
56.6+0.9	52.9+1.3	57.8+1.8

Results expressed as the mean  $\pm$  SEM

Analysis of the results showed more favourable attitude scores in the SG compared to the CG ( $p < 0.03$ ), although the NG and CG were not significantly different. The SG and NG attained similar scores in this assessment, which contrasts with the initial assessment in which attitudes were poorer in the SG than the NG.

#### 3.4.3 18 Month Follow-up Assessment

This assessment concerned the SG and NG only. The DAS3m was used, as in the 12 month assessment, and scoring ranged between 14 (minimum) and 70 (maximum). Results of this assessment are given in Table 3.13.

Table 3.13      Attitude Assessment taken at 18 Months

SG (n = 28)	NG (n = 5)
54.9+1.1	61.2+1.4

Results expressed as the mean  $\pm$  SEM

Paired analysis showed that attitudes in the SG and NG were unchanged 6 months after completing the DE/MP. However, the NG had a

more favourable attitude compared to the SG ( $p < 0.01$ ), a feature which was observed at 0 months but not at 12 months.

#### 3.4.4 Summary of Attitude Assessments

Initially the groups (excluding the NG) were similar regarding their attitudes to diabetes, and it was indicated that the SG and CG were suitably matched to allow subsequent comparison. Following the 12 month study period in which the SG participated in the DE/MP and the CG continued with routine clinic care, the SG demonstrated a more favourable attitude to diabetes compared to the CG. Six months after completion of the DE/MP, attitudes in the SG did not deteriorate.

At 0 months the NG showed more favourable attitudes than the SG, but this was not apparent at 12 months. However, in the follow-up assessment, comparison of these groups demonstrated that the NG attained a more favourable attitude score than the SG. This can be attributed to the small decrease and increase in attitude scores obtained by the SG and NG respectively.

#### 3.5 Diabetes Knowledge

Measurements of patients' knowledge of diabetes were undertaken at 0, 12 and 18 months. Multiple choice questionnaires were used, the development of which is discussed in section 2.6. Two diabetes knowledge questionnaires (DKQ) were used; DKQ1m, used to evaluate knowledge at 0 months, and DKQ2m, used in the 12 the 18 month knowledge assessments. Results of the assessments are expressed as percentage adjusted scores. This is appropriate for multiple choice type questions since the procedure corrects for 'chance' success. The scoring system is discussed in section 2.6.3.

Results are illustrated as total group and individual group mean scores for the whole questionnaires and for the five individual subject areas including: blood glucose control, insulin, diet, hypoglycaemia and basic care (refer to section 2.6.2). Statistical analysis was undertaken using non-parametric methods as described in section 2.10.

### 3.5.1 0 Month Assessment

DKQ1m was used to assess knowledge of diabetes in the SG, CG, NG and NA groups. This was a short multiple choice questionnaire consisting of 9 items and is contained in Appendix 4.6. The maximum corrected score for each item was +1, and the minimum corrected score was -1. Total and subject scores have been converted to percentage corrected scores. Results of this evaluation of diabetes knowledge is presented in Table 3.14.

Table 3.14      Assessment of Knowledge at 0 Months

Subject Areas	Total Group* (n = 87)	SG (n = 31)	CG (n = 25)	NG (n = 5)	NA (n = 31)
Overall	58.0 $\pm$ 2.3	62.7 $\pm$ 3.4	60.1 $\pm$ 4.6	69.7 $\pm$ 5.0	49.9 $\pm$ 4.2
Blood glucose	59.5 $\pm$ 5.3	65.7 $\pm$ 5.6	60.1 $\pm$ 6.6	79.8 $\pm$ 8.1	49.5 $\pm$ 6.3
Insulin	74.7 $\pm$ 5.5	75.8 $\pm$ 9.5	82.0 $\pm$ 9.9	80.0 $\pm$ 20.0	67.2 $\pm$ 10.4
Diet	51.4 $\pm$ 3.1	57.8 $\pm$ 4.9	48.9 $\pm$ 5.6	74.1 $\pm$ 6.8	43.6 $\pm$ 5.7
Hypoglycaemia	60.7 $\pm$ 4.8	72.4 $\pm$ 6.9	60.4 $\pm$ 9.9	69.8 $\pm$ 18.7	48.1 $\pm$ 8.6
Basic care	54.8 $\pm$ 3.1	56.4 $\pm$ 4.8	60.0 $\pm$ 6.5	56.7 $\pm$ 15.5	49.0 $\pm$ 5.5

Results expressed as the mean  $\pm$  SEM

\*Total group not including the NG

The SG and CG were similar in their total and subject knowledge scores, thus suggesting unbiased recruitment procedures. Further, it was inferred that the SG and CG were suitably matched for subsequent assessment and comparison. The NA group attained poorer overall knowledge scores compared to the SG ( $p < 0.03$ ). Greatest overall and subject knowledge scores were attained by the NG, but these were not significantly different than in the SG, CG or NA groups.

Individual subject areas were similar among the four groups but comparison of the total patient scores,  $n = 87$ , between subject areas indicated considerable variation ( $p < 0.001$ ). Knowledge of insulin was greater than that of blood glucose control ( $p < 0.001$ ), diet ( $p < 0.001$ ), hypoglycaemia ( $p < 0.001$ ) or basic care ( $p < 0.001$ ). Dietary knowledge was also poor in comparison to blood glucose control ( $p < 0.03$ ) and hypoglycaemia ( $p < 0.004$ ), and basic care was poor compared to hypoglycaemia ( $p < 0.04$ ).

Although some variation may be due to the questionnaire design and item difficulty (section 2.6.4), the data indicate that dietary knowledge and basic care knowledge were poor in this group of patients, and were regarded as important aspects to be considered in the DE/MP.

The assessment of knowledge in the SG and CG described here only includes those patients who completed the 12 month study, and who were reassessed. However, results were not altered if the original patients were included, where SG  $n = 42$  and CG  $n = 28$ . Results of the 0 month assessment, including these patients, are shown in Appendix 7.4.

### 3.5.2 12 Month Assessment

Diabetes knowledge was reassessed at 12 months and involved the SG, CG and NG. A modified knowledge questionnaire was used - DKQ2m (Appendix 4.12), the development of which is described in section 2.6.7. This consisted of 16 multiple choice questions concerning the same subject areas as in DKQ1m. A similar scoring system was adopted whereby results are expressed as percentage corrected scores in the total and individual groups for the overall questionnaire and subject areas. Results of the 12 month assessment are presented in Table 3.15.

Table 3.15      Assessment of Knowledge at 12 Months

Subject areas	Total Group (n = 61)	SG (n = 31)	CG (n = 25)	NG (n = 5)
Overall	69.9 $\pm$ 3.3	79.1 $\pm$ 3.5	56.3 $\pm$ 5.7	78.4 $\pm$ 11.2
Blood glucose	63.6 $\pm$ 4.7	74.7 $\pm$ 5.9	45.8 $\pm$ 7.3	80.0 $\pm$ 12.5
Insulin	78.3 $\pm$ 5.1	81.2 $\pm$ 6.6	70.1 $\pm$ 9.3	100 $\pm$ 0.0
Diet	67.2 $\pm$ 3.8	78.1 $\pm$ 3.9	51.8 $\pm$ 6.6	73.6 $\pm$ 14.8
Hypoglycaemia	74.5 $\pm$ 5.1	77.7 $\pm$ 6.9	71.4 $\pm$ 8.1	69.8 $\pm$ 22.7
Basic care	71.7 $\pm$ 4.0	84.0 $\pm$ 3.5	56.6 $\pm$ 7.3	67.7 $\pm$ 18.1

Results expressed as the mean  $\pm$  SEM

Overall knowledge was considerably greater in the SG compared to the CG ( $p < 0.001$ ), which contrasts with the 0 month assessment in which the two groups were similar. No significant differences were found between the NG and CG, and between the NG and SG. Variation among three subject areas was found between the three groups: blood glucose control ( $p < 0.01$ ), diet ( $p < 0.02$ ) and basic care ( $p < 0.05$ ).

Similar to the 0 month assessment, knowledge concerning insulin was greater than blood glucose control ( $p < 0.009$ ), diet ( $p < 0.001$ ) or basic care ( $p < 0.008$ ), although knowledge concerning diet and basic care had improved since 0 months. Much of this variation might be due to the subject differences shown by the CG, since differences in the subject areas were less distinct in the SG or NG, as shown in Table 3.15.

### 3.5.3 18 Month Assessment

The SG and NG only, participated in a 6 month post-programme follow-up assessment. This was undertaken using DKQ2m, as used at 12 months. Results of this assessment are presented in Table 3.16.

Table 3.16      Assessment of Knowledge at 18 Months

Subject area	Total Group (n = 32)	SG (n = 27)	NG (n = 5)
Overall	83.3 $\pm$ 3.6	82.8 $\pm$ 4.1	86.2 $\pm$ 8.0
Blood glucose	80.9 $\pm$ 5.0	79.0 $\pm$ 5.8	91.1 $\pm$ 4.1
Insulin	88.5 $\pm$ 5.3	86.4 $\pm$ 6.2	100 $\pm$ 0.0
Diet	82.4 $\pm$ 3.9	81.1 $\pm$ 4.4	89.4 $\pm$ 9.0
Hypoglycaemia	80.6 $\pm$ 5.9	80.1 $\pm$ 6.7	83.2 $\pm$ 10.6
Basic care	83.1 $\pm$ 4.7	87.0 $\pm$ 3.9	62.2 $\pm$ 20.9

Results expressed as the mean  $\pm$  SEM

The SG and NG were similar in overall knowledge and subject areas. Paired analyses demonstrated that both groups attained knowledge scores similar to those at 12 months. The individual subject areas were again significantly different ( $p < 0.05$ ), and

knowledge concerning insulin was greater than blood glucose control ( $p < 0.02$ ) or diet ( $p < 0.006$ ).

#### 3.5.4 Summary of Knowledge Assessments

Since the SG and CG were initially similar in their cognitive knowledge skills, it was considered that the SG and CG were suitable for purposes of re-assessment and comparison. Following the 12 month study period in which the SG participated in the DE/MP and the CG continued with routine clinic care, the SG demonstrated considerably greater knowledge skills than the CG. This highlighted the benefits of participation in the DE/MP concerning diabetic knowledge.

The NG was not significantly different than either the SG or CG at 0 or 12 months, but attained satisfactory knowledge scores in both assessments.

Concerning individual subject areas, at 0 months the total patient group attained a comparatively high score for insulin, but scored poorly in sections concerning diet and basic care. Subsequently, increased attention was given to these subjects in the DE/MP. At 12 months, insulin again scored highly and diet and basic care were comparatively poor. However, this was mainly due to the subject variation within the CG, who did not participate in the DE/MP, since dietary knowledge and basic care were considerably improved in the SG and NG at 12 months compared to the 0 month assessment.

The 18 month assessment was undertaken to investigate the retention and recall of knowledge in the SG and NG patients who completed the DE/MP. No deterioration in knowledge was evident, and recall of diabetes knowledge was considered as excellent, since

overall scores were marginally higher than at 12 months. This indicated that knowledge was retained 6 months following the DE/MP.

### 3.6 Self-Management Skills

Self-management skills were tested using a short practical assessment of competence in insulin administration, dietary exchanges and urine/blood testing. The content of the practical skills assessment is discussed in section 2.7.

The skills test was undertaken by all groups of patients at 0 months, and repeated at 12 months in the SG, CG and NG. Further assessment was conducted at 18 months for the SG and NG.

Results of the test are expressed as raw scores as shown in Table 3.17. The scoring system represents an ordinal scale and therefore non-parametric statistical methods were used in the analysis of results. Between group differences were investigated using the Kruskal-Wallis one-way analysis of variance and the two sample Mann-Whitney test. Paired comparisons were made using the Wilcoxon matched pairs signed rank test.

Table 3.17     Scoring System used in the Self-Management Skills Test

	<u>Maximum Score</u>
Total	10
Insulin administration	5
Dietary exchanges	4
Urine/blood testing	1



### Measure of external validity

The practical skills test was also used as the criterion on which to test external validity of the multiple-choice questionnaire, as discussed in section 2.6.4(b).

#### 3.6.1 0 Month Assessment

Results of the skills test undertaken by all groups at 0 months are shown in Table 3.18.

Table 3.18      Assessment of Management Skills at 0 Months

Skills	SG	CG	NA	NG
Overall	7.9 $\pm$ 0.3	7.6 $\pm$ 0.31	8.0 $\pm$ 0.25	9.8 $\pm$ 0.2
Insulin administration	4.1 $\pm$ 0.11	4.0 $\pm$ 0.12	4.2 $\pm$ 0.13	5.0 $\pm$ 0.0
Dietary exchanges	3.0 $\pm$ 0.59	2.9 $\pm$ 0.24	3.6 $\pm$ 0.63	3.8 $\pm$ 0.2
Urine/blood testing	0.8 $\pm$ 0.07	0.7 $\pm$ 0.09	0.8 $\pm$ 0.07	1.0 $\pm$ 0.0

Results expressed as the mean  $\pm$  SEM

The SG, CG and NA groups were not significantly different in the performance of self-management skills at 0 months, and demonstrated comparability of the SG and CG for further assessment and comparison. However, the NG performed significantly better in management skills compared to the SG, CG and NA groups ( $p < 0.01$ ,  $p < 0.001$  and  $p < 0.008$  respectively). Also, differences in insulin administration were apparent between the NG and the SG, CG and NA groups ( $p < 0.009$ ,  $p < 0.005$  and  $p < 0.03$  respectively), dietary skills were greater in the NG than in the SG and CG ( $p < 0.004$ ,  $p < 0.004$  respectively), and blood/urine testing was performed more competently in the NG compared to the SG or CG ( $p < 0.004$ ,  $p < 0.004$  respectively).

Assessment of management skills in this section concerns only the SG and CG patients who completed the 12 month assessment. However, results were not altered if the original patients were included, where SG n = 42 and CG n = 28. Results of the 0 month skills assessment, including these patients, are shown in Appendix 7.5.

### 3.6.2 12 Month Assessment

The skills test was repeated at 12 months by the SG, CG and NG. Results of this are presented in Table 3.19.

Table 3.19      Assessment of Management Skills at 12 Months

Skills	SG (n = 31)	CG (n = 25)	NG (n = 5)
Overall	9.1 $\pm$ 0.2	8.1 $\pm$ 0.37	9.6 $\pm$ 0.24
Insulin administration	4.9 $\pm$ 0.06	4.5 $\pm$ 0.13	5.0 $\pm$ 0.00
Dietary exchanges	3.2 $\pm$ 0.18	2.9 $\pm$ 0.32	3.6 $\pm$ 0.2
Urine/blood testing	1.0 $\pm$ 0.03	0.8 $\pm$ 0.09	1.0 $\pm$ 0.00

Results expressed as the mean  $\pm$  SEM

The 12 month assessment showed that the total skills of the SG had improved compared to the 0 month assessment ( $p < 0.01$ ). Further comparison between the SG and CG reaffirmed this improvement ( $p < 0.02$ ). Concerning individual components of the test, only insulin administration was different in these two groups ( $p < 0.02$ ), and paired analysis did not demonstrate significant changes in these components by the SG.

The NG were competent in all aspects of self-management skills at 0 and 12 months; therefore, no significant changes had occurred.

The difference between the NG and CG remained the same as in the 0 month assessment ( $p < 0.03$ ). However, the NG and SG were similar at 12 months.

### 3.6.3 18 Month Assessment

The SG and NG completed the management skills test at the 6 months post-programme assessment. Results are given in Table 3.20.

Table 3.20      Assessment of Management Skills at 18 Months.

Skills	SG (n = 28)	NG (n = 5)
Overall	9.3 $\pm$ 0.19	9.5 $\pm$ 0.50
Insulin administration	4.9 $\pm$ 0.05	4.8 $\pm$ 0.25
Dietary exchanges	3.5 $\pm$ 0.14	3.8 $\pm$ 0.25
Urine/blood testing	0.8 $\pm$ 0.06	1.0 $\pm$ 0.00

Results expressed as the mean  $\pm$  SEM

Self-management skills in the SG and NG were similar to the assessment made at 12 months, and no deterioration in skills was evident.

### 3.7 Intercorrelations Between Assessment Parameters

The association between glycaemic control ( $HbA_1c$ ), diabetes knowledge, attitudes and self-management skills was investigated. Rank correlation coefficients were calculated using results of the

0, 12 and 18 month assessments. At 0 months, HbA<sub>1c</sub> levels were inversely correlated with knowledge of diabetes ( $p < 0.02$ ), indicating that lower HbA<sub>1c</sub> levels or improved glycaemic control was associated with greater knowledge. Knowledge was positively correlated with management skills ( $p < 0.01$ ), a feature which enhanced the validity of the knowledge questionnaire, as discussed in section 2.6.4. There was also a positive correlation between attitudes and management skills ( $p < 0.001$ ).

In the 12 month assessment, the positive correlation between knowledge and management skills was again demonstrated ( $p < 0.01$ ). However, associations between glycaemic control and knowledge, and attitudes and skills, previously found at 0 months, were not evident. A positive correlation was found between knowledge and attitudes ( $p < 0.01$ ), and an inverse correlation was found between HbA<sub>1c</sub> levels and management skills ( $p < 0.01$ ), indicating an association between glycaemic control and self-management skills.

At 18 months, the positive association between knowledge and management skills was repeated ( $p < 0.01$ ), but no other correlations, neither positive nor negative, were demonstrated.

The association between assessment parameters varied at 0, 12 and 18 months. Initially, glycaemic control was associated with diabetic knowledge ( $p < 0.02$ ), but this was not evident at either the 12 or 18 month assessments. Glycaemic control did not appear to be associated with any other parameter at either 0 or 18 months, but improved control was shown to be associated with greater management skills at 12 months ( $p < 0.01$ ). Knowledge and management skills were positively correlated in all assessments ( $p < 0.01$ ), and relates to the validity of the questionnaire. Knowledge also correlated with

attitudes in the 12 month assessment ( $p < 0.01$ ), but was not apparent in other assessments. Also, attitudes were associated with management skills at 0 months ( $p < 0.001$ ), but again this was not apparent at 12 or 18 months.

The variation found between the 0, 12 and 18 month assessments may be due, at least in part, to the modification of the knowledge and attitude scales used at 0 and 12 months.

### 3.8 Miscellaneous Comparisons

Assessments of glycaemic control, knowledge, attitudes and management skills taken at 0 months were considered in relation to patient details, as described in section 3.2. These include: age, duration of diabetes, sex, weight, insulin dose, insulin regime, socioeconomic group, race, marital status, clinic non-attendance, and admissions, and results will be discussed in this order. Statistical analyses included both parametric and non-parametric tests. These are discussed in section 2.10.

Age: No correlation was observed between patient's age and glycaemic control, knowledge, attitudes or skills.

Duration of Diabetes: There was a positive correlation between duration and knowledge ( $p < 0.05$ ) suggesting that patients with a longer duration of diabetes know more about the condition. However, duration was not correlated with glycaemic control, attitudes or management skills.

Sex: Assessment parameters for males and females were compared and are presented in Table 3.21.

Table 3.21      Assessment Parameters in Males and Females

Assessment Parameters	Males (n = 57)	Females (n = 35)
Glycaemic control (HbA <sub>1c</sub> %)	12.1 $\pm$ 0.4	12.1 $\pm$ 0.6
Knowledge (%)	53.1 $\pm$ 2.9	66.5 $\pm$ 3.4
Attitudes	52.4 $\pm$ 1.3	52.9 $\pm$ 1.6
Management skills	7.7 $\pm$ 0.2	8.4 $\pm$ 0.2

Results expressed as the mean  $\pm$  SEM

Glycaemic control, attitudes and skills were similar in males and females, but increased diabetic knowledge was demonstrated by the females compared to the males ( $p < 0.05$ ).

Weight: Actual body weight and % ideal body weight (IBW) were considered. Although % IBW did not show a significant correlation with any assessment parameters, actual body weight was inversely correlated with total management skills ( $p < 0.05$ ) and dietary knowledge ( $p < 0.05$ ). Further, it was shown that the diet component of the skills test was also inversely correlated with body weight ( $p < 0.01$ ). There was a strong indication that actual body weight was increased with poor dietary knowledge and skills. However, this does not take into account sex differences in body weight.

Insulin Dose: This was expressed as the units of insulin/body weight daily, i.e. U/kg. No correlation was found between insulin dose and glycaemic control, knowledge, attitudes or skills.

Insulin Regime: Five types of insulin regimes were used by patients. these are discussed in section 3.2. Human insulin was used by only 2 patients, and since this is a combination of short and medium-acting insulin (Humulin S and Humulin X), and with similar properties to pork insulin, it was felt that for the purposes of this comparison, human insulin and short plus medium-acting pork, could be paired as one category. Therefore, four insulin regimes were considered and compared with assessment parameters (Table 3.22).

Table 3.22 Comparison of Insulin Regimes and Assessment Parameters

Insulin Regime	HbA1 (%)	Knowledge (%)	Attitudes	Skills
Pre-mixed (Porcine) n = 31	12.8 <sub>±</sub> 6.0	54.5 <sub>±</sub> 3.4	50.8 <sub>±</sub> 1.9	7.9 <sub>±</sub> 0.3
Short + medium acting (Porcine/human) n = 33	11.8 <sub>±</sub> 0.5	59.5 <sub>±</sub> 4.0	55.0 <sub>±</sub> 1.3	8.4 <sub>±</sub> 0.2
Short + medium acting (Bovine) n = 12	12.6 <sub>±</sub> 0.6	63.6 <sub>±</sub> 6.0	49.3 <sub>±</sub> 2.7	7.1 <sub>±</sub> 0.5
Medium/long acting only (Porcine/beef) n = 11	10.9 <sub>±</sub> 0.8	58.8 <sub>±</sub> 8.1	53.4 <sub>±</sub> 2.6	8.2 <sub>±</sub> 0.5

Results expressed as the mean <sub>±</sub> SEM

Comparison between the insulin groups showed variations in glycaemic control, attitudes and management skills. Patients using medium or long-acting insulin only were in better glycaemic control than the group using pre-mixed insulin ( $p < 0.05$ ). Attitudes were more

favourable in patients using medium plus short-acting pork than the pre-mixed group ( $p < 0.05$ ) and this group also demonstrated more competent management skills than the group using short plus medium-acting beef insulin ( $p < 0.02$ ).

Socioeconomic Group (SEG): As categorised by the Office of Populations Survey Index criteria,<sup>(238)</sup> plus an additional category comprising those patients who were unemployed, SEG did not significantly affect glycaemic control and management skills in the five groups, although differences in knowledge and attitude were apparent (Table 3.23).

Table 3.23 Comparison of SEG and Assessment Parameters

SEG		HbA <sub>1c</sub> (%)	Knowledge (%)	Attitudes	Skills
1	n = 4	11.7 $\pm$ 1.5	76.6 $\pm$ 5.1	60.0 $\pm$ 2.2	8.4 $\pm$ 0.4
2	n = 8	12.2 $\pm$ 0.8	72.0 $\pm$ 7.3	51.4 $\pm$ 3.0	8.7 $\pm$ 0.4
3	n = 32	12.1 $\pm$ 0.6	57.5 $\pm$ 3.7	53.1 $\pm$ 1.9	7.6 $\pm$ 0.3
4	n = 17	12.7 $\pm$ 0.8	50.8 $\pm$ 3.0	53.8 $\pm$ 1.8	8.1 $\pm$ 0.4
6	n = 19	12.0 $\pm$ 0.5	57.4 $\pm$ 3.7	47.7 $\pm$ 2.0	7.8 $\pm$ 0.3

Results expressed as the mean  $\pm$  SEM

Increased knowledge was demonstrated by Group 1 compared to Group 3 ( $p < 0.05$ ), Group 4 ( $p < 0.05$ ) and Group 6 ( $p < 0.02$ ). Also, Group 1 demonstrated a more favourable attitude than Group 2 ( $p < 0.04$ ) and Group 6 ( $p < 0.006$ ). Attitude differences were also found between Group 4 and Group 6 ( $p < 0.03$ ). These comparisons indicate that both knowledge and attitudes vary among the socioeconomic groups.



Race: The patient sample comprised three ethnic groups: Caucasian (C), West Indian (WI) and Asian (A). No significant difference was found between these groups concerning the assessment parameters. Results of these group comparisons are shown in Table 3.24.

Table 3.24 Comparison of Race with Assessment Parameters

Race	HBA <sub>1</sub> (%)	Knowledge (%)	Attitudes	Skills
Caucasian n = 73	11.9 <sub>±</sub> 0.3	61.8 <sub>±</sub> 2.6	52.9 <sub>±</sub> 1.1	8.0 <sub>±</sub> 0.2
Asian n = 6	13.1 <sub>±</sub> 1.2	58.3 <sub>±</sub> 5.9	54.1 <sub>±</sub> 5.1	7.0 <sub>±</sub> 0.6
West Indian n = 8	13.5 <sub>±</sub> 2.0	48.7 <sub>±</sub> 6.5	47.4 <sub>±</sub> 2.5	8.2 <sub>±</sub> 0.7

Results expressed as the mean <sub>±</sub> SEM

Marital Status: Three groups were formed and included: single (S), married (M) and divorced/separated (D) patients. Comparisons were made with regard to the assessment parameters. Results are shown in Table 3.25

Table 3.25 Comparison of Marital Status with Assessment Parameters

Marital Status	HbA <sub>1</sub> (%)	Knowledge (%)	Attitudes	Skills
Single (n = 33)	12.3 <sub>±</sub> 0.5	51.5 <sub>±</sub> 3.4	51.6 <sub>±</sub> 1.6	7.9 <sub>±</sub> 0.3
Married (n = 48)	12.3 <sub>±</sub> 0.4	59.7 <sub>±</sub> 3.2	53.6 <sub>±</sub> 1.3	7.9 <sub>±</sub> 0.2
Divorced/separated (n = 6)	9.5 <sub>±</sub> 0.9	79.6 <sub>±</sub> 4.4	50.3 <sub>±</sub> 4.2	8.9 <sub>±</sub> 0.6

Results expressed as the mean <sub>±</sub> SEM

Between group analyses showed that glycaemic control was significantly better in the divorced group than either the single or married groups ( $p < 0.03$ ,  $p < 0.02$  respectively). Similarly, knowledge was greater in the divorced group compared to the single or married groups ( $p < 0.001$ ,  $p < 0.02$  respectively). Attitudes and skills were similar in the three groups.

CNA: This refers to the clinic non-attendance and is estimated as the percentage of failed clinic appointments in the previous four years. Glycaemic control, knowledge, attitudes and skills were not related to clinic attendance.

Hospital Admissions: This included only those admissions related to diabetes and was expressed as the number of admissions per year of duration. Assessment parameters were not associated with the number of hospital admissions.

### 3.9 Evaluation

The DE/MP and the educator were evaluated at the 12 month assessment. This was subjective evaluation based on the patients' responses to rating questionnaires, as discussed in section 2.9.2 and 2.9.3. Further evaluation was conducted at the 18 month follow-up assessment (discussed in section 2.9.4).

#### 3.9.1 Evaluation of the DE/MP

Results of the evaluation are illustrated in the right-hand margin of the questionnaire contained in Appendix 6.2. In this column the numbers of patients responding to each question are

recorded and the percentage number of patients appears within parenthesis. Thirty-four patients completed the questionnaire and results include both the SG and NG. Two patients, one from the SG and one from the NG, did not complete the questionnaire.

Concerning previous diabetes education, it was revealed that 27 (79%) patients had not received any organised form of instruction prior to the DE/MP, and that only 7 (21%) patients had participated in some planned and organised diabetes education. Of these 7 patients, 3 had benefitted from teaching provided in the Dudley Road Hospital Diabetic Unit, which had opened the previous year (November 1983). The remaining 4 had been instructed as in-patients on a hospital ward. All patients had been provided with information in the form of talks. Other resources included books and pamphlets (4 patients), slides (1), demonstrations (1), and video films (1). Thus, very little previous instruction had been given to the SG who participated in the DE/MP.

Concerning the perceived benefits of the programme, 29 (85%) patients thought it had been 'very useful'. The remaining 5 (15%) only thought it had been 'useful'. When asked about the learning scope of the DE/MP, 18 (53%) felt they had learnt 'a great deal' and 16 (47%) felt they had learnt 'quite a lot'. All patients were pleased at having joined the study; 32 (94%) agreed it had helped them to cope with social events, but 2 (6%) were undecided.

Questions were asked about the structure of the programme and it was found that 33 (97%) patients thought the time interval between sessions was convenient, and one patient thought this was too long. Twenty-seven (79%) patients were satisfied about the length of each session. However, 7 (21%) patients would have preferred more time in

each session. The number of sessions in the programme was 'about right' for most patients - 23 (68%), but 6 (17%) thought that more sessions were needed and 5 (15%) were not sure. Both individual and group sessions were held and it was revealed that 14 (41%) patients preferred a group format, 18 (55%) preferred some of each type and only 2 (6%) preferred individual meetings.

Question numbers 11 and 12 requested the patients to state those aspects of the programme which they particularly liked or disliked. Most patients cited at least one comment concerning the enjoyable features of the programme, many of which were mentioned by several patients. Examples of these comments are listed here. The content of each patient's comments have been summarised and the number of patients who made reference to the particular aspects listed are shown in parenthesis.

Examples of enjoyable features of the DE/MP as cited by patients:

- Able to relate to other people with similar problems (8)
- Discussing problems - whether large or small (6)
- Having a diabetic teacher (GMC) who understands (4)
- Informal atmosphere (3)
- The educational experience (3)
- Clear explanations (3)
- Models and films (3)
- Funny little drawings and slides (2)
- Help with diets (2)
- The coffee and company (1)

Several comments emphasised patients' appreciation of clear and comprehensible information, for example, one patient wrote 'the sessions were given in plain English, not littered with technical jargon'. Other comments indicated that patients valued the increased attention and supervision, for example, 'I was not chopped off in the middle of questions or queries'.

Only 3 (9%) patients stated aspects of the programme which were unsatisfactory. These are listed below:

Patients' comments concerning DE/MP

Work was a problem and the time factor

Would like the sessions to go on longer than 1 hour

Sometimes got a bit lost

Although only one patient made reference to the issue of work, several patients mentioned difficulties concerning this whilst attending the programme. Subsequently, an evening group was formed to accommodate those patients who were unable to attend during working hours. However, despite efforts to consider the patients' individual circumstances, one patient dropped out of the study due to difficulties at work.

All patients felt they had more control over their diabetes after participating in the programme. Various reasons were given to account for this, some of which are shown below. The comments have been summarised and the numbers of patients who made reference to the aspects listed are shown in parenthesis.

Comments accounting for increased control over diabetes:

More knowledge (15)

Timing of injection (8)

Altering insulin dose (8)

Know more about diets and fibre (5)

Teaching on special events, e.g. illness, parties (4)

More confidence (4)

Learning to test blood (3)

Injection technique (2)

Several responses to the question (13a) - 'Why do you feel you have more control over your diabetes?' indicated that patients had become more aware of the importance of controlling diabetes. For example, two patients wrote 'the sessions made me more interested and aware of my condition' and 'knowing WHY things happen'. Also, the need for re-education of patients with a long duration of diabetes was emphasised by one patient's comment - 'things change in 25 years'.

Patients were questioned about management of diabetes following the DE/MP. Most patients - 29 (85%) - considered themselves to be more careful since attending the programme. However 5 (15%) were not sure. Changes in patient self-management had been undertaken by 30 (88%), but 4 (12%) did not think any features of their diabetes management had altered. Many of the examples of management changes given by the patients were similar and were grouped in five main areas, which are shown below. The number of patients referring to each aspect is shown in parenthesis.

- Alter insulin dose (8)
- Monitor blood glucose more often (8)
- Better diet - low fat, high fibre (8)
- Time injections differently (5)
- More flexible and confident (5)

It is evident from the management changes which had occurred that patients were capable of undertaking considerable behavioural changes if the appropriate information and circumstances are provided. Increased flexibility was also apparent and is emphasised by the response of one particular patient - 'knowing how to adjust your insulin to suit your life, not the other way around'.

During the programme all patients were provided with a one year membership of the British Diabetic Association (BDA). Prior to the programme only 12 (35%) of patients were members of the BDA. Reasons for non-membership were varied: 12 patients admitted they 'couldn't be bothered applying', 2 thought it was too expensive, 1 patient didn't like the label 'diabetic', 1 patient didn't think it was worth the money and 1 patient didn't actually know about the BDA.

The majority of patients - 22 (65%) - had previously carried out home blood glucose monitoring, but 12 (35%) patients learned this whilst attending the programme.

On completion of the questionnaire, patients were invited to add further comment if they wished to do so. Remarks often reflected the patient's personal gains from the programme and expressed their enjoyment in participating in the programme. Several examples of these comments are shown below:

The programme should be continued to help others

Helpful (6 patients)

I enjoy my social life better and don't worry about an alcoholic drink

I wish I could have talked to someone 5 years ago

I can lead a normal life

Enjoyed the buffet

Taught me a lot - got rid of wrong ideas and beliefs

Being listened to with patience

Coffee was excellent and so was the course tutor!

### 3.9.2 Evaluation of Educator

Assessment of the educator was undertaken following completion of the programme. This was carried out by a confidential questionnaire which was mailed to each patient. The content of the questionnaire is discussed in section 2.9.3. Out of 36 questionnaires mailed, 34 were completed and returned to the Consultant in Diabetes. The questionnaire is contained in Appendix 6.3 and the patients' responses are indicated in the right-hand margin.

Question (1) asked patients to rate the quality of teaching by the educator (GMC). Thirty-one (91%) considered this to be very good, and the remaining 3 (9%) selected the category 'satisfactory'. Question (2) enquired about the communication skills of the educator; 27 (79%) patients considered her very easy to talk to, whereas 7 (21%) patients said only 'easy to talk to'. In response to question (3), 30 (88%) patients thought that the educator had answered 'all' their questions, whilst 4 (12%) only thought that 'most' of their



questions were answered. Most patients claimed to be satisfied with the way in which topics were discussed since 33 (97%) thought it was 'well explained', and only 1 patient thought 'it could have been explained better'.

The educator's age (22 years) was also considered since she was younger than 75% of the patients. Thirty-three (97%) thought that age did not matter, but one patient would have preferred someone older.

The quality of instruction, communication skills, competence and age of the educator were considered, and it was demonstrated that the majority of patients were very satisfied with the characteristics of the educator (GMC). Although the questionnaire did not ask for the patient's personal opinion, several patients provided additional comments which reflected an appreciation of the understanding of a person who was also diabetic.

### 3.9.3 6 Months Follow-up Evaluation

This was intended to investigate the patient's general well-being during the 6 month period immediately following the programme (refer to section 2.9.4). A short questionnaire was administered at the 6 month follow-up assessment. Three patients were unable to attend this follow-up appointment due to pregnancy, illness and a change in country of residence. Therefore 33 evaluation questionnaires were completed. The follow-up evaluation questionnaire is contained in Appendix 6.5 which also includes results in terms of patient responses.

Concerning glycaemic control during the previous 6 months, 17 (51%) of patients felt this had changed. Of these 13 (39%) said it

had improved and 4 (12%) thought it had deteriorated. Almost half the patients - 16 (49%) - thought that glycaemic control had remained the same during the 6 months. Most patients - 27 (82%) - said that no particular problems had occurred in the post-programme period. However 6 (18%) patients admitted that problems had arisen. These included: hypoglycaemia (3), arranging suitable injection times (1), foot problems (1), and being 'short of breath' (1).

Adjustment in insulin dose (without specific instruction from medical/nursing staff) had been undertaken by 26 (79%) of the patients. Reasons for these alterations are shown below:

Reasons for patients changing insulin dose:

<u>Reason</u>	<u>Direction of insulin change</u>	<u>Number of patients</u>
High blood glucose	↑	11
Illness	↑	7
Christmas Day	↑	6
Sport	↓	3
Hypoglycaemia	↓	3
Ketones	↑	2
Holidays	↑	2

During the follow-up period, 3 (9%) patients were admitted to hospital, in all cases the reason was unsuspected hypoglycaemia. A question asking whether patients would benefit from a refresher session showed that 31 (94%) patients were in favour of this and only 2 (6%) thought it was unnecessary. Finally, patients were asked to suggest ideas on how to improve the educational sessions. Only 9

(27%) patients responded and these recommendations are summarised below:

More information on new ideas and research (3)

More films and talks by other people (2)

More information on food and cookery (2)

More people and mixing of groups (2)

To see the same person every time (1)

Cream cakes! (1)

## Introduction

Previous studies have suggested that a greater understanding of diabetes and its complications improved glycaemic control,<sup>(1-3)</sup> which can reduce the risk of acute and chronic complications.<sup>(4)</sup> However, it has also been suggested that glycaemic control is not determined by knowledge alone.<sup>(5,6)</sup> Other factors which appear to be involved are of psychological well-being,<sup>(7,8)</sup> attitudes,<sup>(9)</sup> and motivation,<sup>(10)</sup> all of which influence patient compliance. The success of educational programmes, therefore, may well be affected by these factors and consideration of the contribution of each factor may enhance the benefits of diabetes education.<sup>(11)</sup> It

## 4. DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

1. To investigate the factors which influence patients' attitudes and motivation to control diabetes.
2. Design and develop a diabetes education programme which addresses psychological features intended to increase compliance.
3. Investigate the effects of such a programme on glycaemic control, attitudes, knowledge and self-management skills.
4. Evaluate the effectiveness of educational/motivational programme (MMP) in terms of patient preferences, perceived benefits and enjoyment.

## Recruitment and Selection Procedures

Recruitment procedures for patients entering the study, which are described in section 2.3.1, emphasise the care that was taken to ensure that control groups were similar. Selection criteria were:

## Introduction

Previous studies have suggested that a greater understanding of diabetes can facilitate improved glycaemic control,<sup>(127)</sup> which can reduce the incidence of acute and chronic complications.<sup>(67)</sup>

However, it has been suggested that glycaemic control is not determined by knowledge alone.<sup>(289)</sup> Other factors which appear to be involved include psychological well-being,<sup>(290)</sup> attitudes,<sup>(291)</sup> and motivations,<sup>(292)</sup> all of which influence patient compliance. The success of diabetes educational programmes, therefore, may well be affected by these factors and consideration of the contribution of each factor may enhance the benefits of diabetes education.<sup>(293)</sup> It was upon this background that the aims of the present study were developed, namely:

1. To investigate the factors which influence patients' attitudes and motivations towards diabetes.
2. Design and develop a diabetes education programme which emphasises motivational features intended to increase compliance.
3. Investigate the effects of such a programme on glycaemic control, attitudes, knowledge and self-management skills.
4. Evaluate the diabetes educational/motivational programme (DE/MP) in terms of patient preferences, perceived benefits and enjoyment.

## Recruitment and Allocation Procedures

Recruitment procedures for patients entering the study, which are described in section 2.3.1, emphasise the care that was taken to ensure that patient groups were similar. Selection criteria upon

which patients were recruited (section 2.3.1) restricted recruitment to insulin-dependent patients with a duration of diabetes greater than one year. While it might be suggested that the measurement of C-peptide levels is necessary to ensure that there is no significant endogenous insulin secretion and to confirm that the patients were truly insulin-dependent, it must also be remembered that all patients had been insulin-treated since diagnosis, and diagnosis had generally been made before middle age. Although C-peptide levels were not measured, a flexible system was adopted in which patients were excluded if the consultant suspected endogenous insulin secretion. This approach resulted in the exclusion of 4 patients. Although 5 patients were known to have a duration of diabetes less than 1 year, these were included in a separate group, the New Group (NG), and were not included in the comparisons of the Study Group (SG), Control Group (CG) or total group results. NG patients were considered separately to monitor insulin requirements, weight control and glycaemic control over the transitional period 6 to 24 months following diagnosis.

Other recruitment criteria adopted for the present study, such as the absence of complications and obesity, age <60 years, non pregnant and an adequate understanding of English, were introduced to avoid the potential bias that these criteria might give to glycaemic control and other assessment parameters.

The allocation of patients to the CG and SG described in section 2.3.1, emphasises the care taken to eliminate such sources of bias. However, the initial recruitment procedures, using random allocation, proved unreliable since some patients who were included in the CG may not have otherwise participated in the DE/MP. An alternative system

of allocation was therefore adopted in which patients who expressed disinterest in the study were not included in either the SG or CG. Thus, a third group, called the Non Attended (NA) group was formed, consisting of approximately one-third of the total number of patients interviewed. This illustrates the problems involved in reliable patient recruitment. However, it was felt that this was compensated by a more valid and reliable CG.

During the course of the programme, 4 of the SG patients became pregnant. Since this provides a particularly effective source of motivation, usually resulting in excellent glycaemic control,<sup>(294)</sup> these patients were excluded from analysis, thereby avoiding bias in glycaemic control and other assessments which could be attributed to pregnancy. A further 10 patients (14%) dropped out of the study. However, this was considered relatively small compared to previous reports concerning 'drop-out' rates.<sup>(295)</sup> Assessment parameters were not significantly different in these patients compared to the groups who completed the study, and it is possible that reasons given for discontinuing the programme were genuine.

#### Patient Details

An interesting feature of the composition of the groups was the greater age of the CG than either the SG or NA group, and a longer duration in the CG than the NA group. This was associated with a lower rate of unemployment in the CG (4%) compared with the SG (30%) and NA (36%) group.

These differences might reflect, at least partly, the recruitment procedures (section 2.3.1) in which patients who expressed interest and enthusiasm, but who were unable to attend due

to work commitments, were allocated to the CG. This could explain the lower rate of unemployment in the CG. It is conceivable that older patients, with a longer duration of diabetes, had achieved more permanent positions of employment.

Other patient details, including sex distribution, clinic non-attendance, hospital admissions, race, marital status, socioeconomic group, insulin dose, insulin regime and body weight, were similar in all three groups at the initial assessment at 0 months. At 12 months, after completion of the DE/MP by the SG, the significant increase in body weight and % ideal body weight was unexpected since these patients had received considerable instruction concerning weight control and the reduction of fat intake during the DE/MP. Although increased body weight was not accompanied by a significant increase in insulin dose, as recorded in patients' medical notes, many patients admitted to greater flexibility regarding insulin. This included making adjustments in insulin dose on occasions such as illness, hyperglycaemia and festive periods such as Christmas. It is possible that overall insulin doses were greater than actually reported in the medical records, and this may be associated with temporarily increased body weight. Also, improved glycaemic control was demonstrated in this group which, in the presence of a raised insulin dose, is theoretically likely to be associated with weight gain, since insulin promotes lipogenesis and inhibits lipolysis of adipose tissue.<sup>(9)</sup>

In view of the weight increase at 12 months, it is recommended that diabetes educational programmes should emphasise the combined effects of diet, insulin and exercise in achieving improved glycaemic control, rather than adjustments in insulin and diet only. This



might obviate inappropriate weight gain. Indeed, the importance of weight control should not be forgotten when advising patients concerning insulin alterations.

### Glycaemic Control

A central theme of the present study was glycaemic control, factors influencing this control and the effect of the DE/MP.

Glycaemic control in the total patient group, excluding the NG, as assessed by % HbA<sub>1c</sub>, was considered unsatisfactory, with a mean HbA<sub>1c</sub> of 12.4%, with 61 (82%) patients having HbA<sub>1c</sub> levels >10%, although similar results have been reported previously.<sup>(296)</sup> In comparison, the NG (duration of diabetes <12 months), had a mean HbA<sub>1c</sub> of 8.6%. This considerable difference between the groups might be due, at least in part, to the secretion of endogenous insulin - also called the 'honeymoon phase'<sup>(297)</sup> - in the NG which would enhance glycaemic control. Also, the NG was provided with a comprehensive diabetes education as in-patients in the Diabetic Unit at Dudley Road Hospital. However, the total group, excluding the NG, had not previously received this type of formal instruction. Most patients had in fact received very little instruction since the time of diagnosis. In the past, instruction was provided informally in the general hospital ward, but in November 1983 the Diabetic Unit in Dudley Road Hospital was opened. The improved quality of instruction and follow-up supervision may have been associated with improved control in the NG compared to the rather poor control in the total group.

It was of interest that glycaemic control varied with the insulin regimes and marital status of the patients. Although the

patient sample was not large, the effects were quite distinct. In particular, those having long or medium acting insulin only were in better glycaemic control than patients using pre-mixed insulin, and although pre-mixed insulins are easier to draw-up, it is indicated that they may be more restrictive in achieving glycaemic control. Short and medium insulins, which are unmixed, may allow more flexibility when altering insulin doses compared to the 'fixed' proportions of insulins in pre-mixed preparations. A further study to clarify the restrictions upon self-management, or at least self-adjustment of insulin dose, would be required to elaborate these possibilities. It might be suggested that patients using pre-mixed insulin were poorly controlled on previous insulins, which might contribute to the present observations. It is also feasible that patients using pre-mixed insulin were selected by the physician due to their lack of confidence when mixing insulins, and this might also be reflected in other aspects of self-management resulting in poorer control.

The differences in glycaemic control with marital status indicated better control in patients who were divorced or separated compared to either single or married patients. One might have expected the divorced group to have poorer control since it might be contemplated that these patients have increased emotional and social problems. However, social interactions with these patients provided evidence that most had been divorced or separated for more than three years, and they all appeared to be well adjusted in their lifestyles, and perhaps were even better able to cope with diabetes management than the single or married patients in the study.

### Comparison of Glycaemic Control Between SG, CG, NG and NA Groups

The SG and CG exhibited similar HbA<sub>1c</sub> levels and blood glucose profiles at the start of the study, and it was therefore assumed that these groups were suitably matched with regard to glycaemic control. The NA group, members of which declined to participate or failed to attend, had poorer glycaemic control than either the SG or CG. This might indicate that lack of interest and concern about diabetes is associated with poor control. This group also attained a comparatively lower mean knowledge score, possibly indicating that poor control was also associated with lack of understanding concerning the management of diabetes.<sup>(127)</sup> Indeed, the NA group appeared to show a potentially greater need for an educational/motivational programme, yet these patients refused to participate. Hence, as a recommendation to the hospital clinic and future studies, it is suggested that more effective recruitment procedures be developed to include these patients and thereby achieve maximum benefit from educational programmes. However, a further consideration is that those patients who do not wish to help themselves, or are not willing participants, would not respond to the educational and behavioural strategies used in the DE/MP, and that resources should be directed at those patients most likely to respond and benefit from such a programme. It is also possible that the NA group includes people who simply do not like institutions, hospitals, group therapy, attention or supervision, and alternative methods of instruction should be considered. For example, a 'distance learning' version of the educational programme could be developed in which the information is presented on videos and cassettes for home use, books and pamphlets. This may also

provide a means of increasing family involvement and support. Such a learning programme may also be appropriate for those individuals who would have liked to participate but who were unable to do so due to commitments such as family and work.

While the SG HbA<sub>1c</sub> remained similar at 0, 3 and 6 months, at the 9 and 12 month assessment, levels were significantly reduced, indicating a protracted lag period before glycaemic control improved. The CG were assessed at 0, 6 and 12 months and no significant change was observed during this time. The SG had significantly better glycaemic control at 12 months compared to the CG.

The results of the present study, notably the improvement in glycaemic control after 9 and 12 months, are consistent with other studies reporting improved glycaemic control with increased diabetic knowledge in insulin-dependent diabetics (IDD).<sup>(150-152)</sup> However, the 'types' of educational programmes used in these studies have all consisted of intensive teaching and treatment processes, some of which were provided as an in-patient service, and improved glycaemic control occurred almost immediately. In the present study, consisting of 12 monthly sessions, the relatively slow improvement may be attributed to the less intense type of programme used. Also, the order in which the subject matter was presented in the present study may be in part responsible for the rate at which a significant improvement in glycaemic control was demonstrated. Topics were introduced at monthly intervals and the more essential and basic concepts were considered early in the programme. Topics which required a background understanding of diabetes were only discussed after the fifth session. These

included blood glucose control, illness, ketones, and practical problems. The structure of the programme allowed a slower pace of learning and therefore a more gradual change in self-management and subsequent control, compared to intensive education programmes. There are also reports that intensive education and increased knowledge do not lead to improved glycaemic control,<sup>(154,155,298)</sup> and suggest that other factors, including rapport, self-responsibility, skills, attitudes and motivations, should also be considered. Indeed these qualities were important considerations in the DE/MP and their gradual development and observed improvement during the programme may have contributed to the delayed but favourable improvement in glycaemic control.

While the content of the education programmes may determine, to a large extent, whether glycaemic control is improved, it has been suggested by the Diabetes Education Study Group of the European Association for the Study of Diabetes (EASD), that motivation is a vital aspect in education.<sup>(300)</sup> Motivation is dependent upon cognitive skills, behaviour and attitudes, and these require consideration and development in diabetes education.<sup>(210)</sup> The manner in which motivation is developed and the attention given to achieving this varies from programme to programme. This may determine the extent to which knowledge is translated into appropriate action concerning the management of diabetes, and which subsequently affects glycaemic control. Thus, the type of motivation developed in educational programmes may influence control, and differences in motivation may account for some of the inconsistent reports concerning glycaemic control and knowledge of diabetes considered earlier. The DE/MP was intended to improve

knowledge, to enhance more favourable attitudes, to increase competence in management skills and to enhance patient motivation. This combined approach was successful by the assessments undertaken, since glycaemic control was improved during the 12 month duration of the programme. These results support recommendations cited earlier, that diabetes educational programmes should not only aim to increase knowledge and management skills, but should also facilitate the development and improvement of patients' attitudes and motivations, in order to enhance compliance and glycaemic control.<sup>(300)</sup>

#### Maintenance of Improved Glycaemic Control

The value of education programmes, such as the DE/MP, and the benefits of glycaemic control have been discussed, but a relevant issue which must also be considered is the long-term effects.<sup>(147)</sup> The effectiveness of an educational programme cannot be judged solely on short-term benefits, but also requires consideration of the maintenance of these benefits in the long-term. Although it has been reported that improved glycaemic control, achieved during a one week intensive education programme, was maintained for up to 22 months,<sup>(150)</sup> other reports have indicated that glycaemic control several months after completion of education was poor.<sup>(152,155)</sup> In the present study, a 6 month follow-up assessment demonstrated some deterioration in control in the SG, although % HbA<sub>1c</sub> had not increased to that level recorded prior to the programme. It might be suggested that such a deterioration could result from poor compliance due to loss of knowledge and understanding which was acquired during the programme. However, retention and recall of

diabetes knowledge was considered as excellent in the follow-up assessment, confirming the effectiveness of the teaching methods. Also, the assessment of attitudes and skills remained similar to that found at 12 months. Therefore, deterioration in glycaemic control cannot be attributed to a lack of knowledge, adverse attitudes or incompetent management skills in this group of patients. However, it is reported that an essential quality in achieving and maintaining glycaemic control is motivation,<sup>(163)</sup> as discussed in section 1.6.1. The inclusion of behavioural strategies designed to enhance motivation was a prominent feature of the DE/MP. Indeed, patient motivation was increased considerably during the programme, as revealed by personal observations and subsequent improvement in glycaemic control. This compares favourably with other programmes, such as the Young Leaders Project,<sup>(301)</sup> in which motivation and enthusiasm towards diabetes was also enhanced using similar behavioural methods, including: positive reinforcement, reward, achievement, peer group support and feedback. These features represent extrinsic motivation, that which is provided from an external source, and on completion of the programme these sources of motivation are no longer provided. On the basis of the results of this study, it is feasible to suggest that motivation was successively enhanced during the DE/MP using external sources. By extrapolation, it is possible that the patients' enthusiasm and desire to achieve and maintain compliance was lost without the provision of extrinsic motivation, consequently resulting in poorer control.

In contrast, recommendations concerning patient motivation have recently been stated by the Diabetes Education Study Group of

the EASD.<sup>(299)</sup> These recommendations emphasise the need to develop patients' intrinsic motivation, that is motivation from within themselves, and propose that this can be achieved by identifying and using the patients' intrinsic personal drives towards particular objectives.<sup>(299)</sup> Examples of aspects which may drive to motivate the person include: the achievement of a 'normal' lifestyle, identification with a peer group, achievement in a career, a good sex life and a good marriage or parenthood, all of which can be affected by the management and control of diabetes.

Intrinsic motivation cannot be assessed or measured easily, but it is suggested that reasons accounting for the observed results in the present study are the failure of the DE/MP to develop sufficient intrinsic motivation to maintain compliance, consequently resulting in a deterioration of glycaemic control. It is suggested that further research and consideration are required in the development of effective strategies which could identify and use patients' intrinsic motivation towards glycaemic control, and which would enhance the benefits of future educational programmes.

Other factors reported to affect compliance and glycaemic control were discussed in section 1.6. They include: psychological factors, environmental and social aspects, characteristics of treatment regime, and the patient-doctor relationship.<sup>(167)</sup> The interaction and effect of these features upon glycaemic control was not considered in the present study, but it is suggested that these can influence patients' attitudes, motivations and behaviour towards compliance and glycaemic control.<sup>(302)</sup> It is reasonable to suspect that one or more of these impinging factors may have contributed, at



least in part, to the observed changes in glycaemic control in this study.

Glycaemic control was assessed on the basis of home blood glucose monitoring (HBGM), using BM 20-800 Glycaemie test strips.<sup>(240)</sup> Although no significant changes in blood glucose concentrations were observed (section 3.3.8), the reliability of this type of assessment is questionable, since some patients admitted that they only recorded those values which were considered 'acceptable'. In this study patients were also requested to retain and present their used BM test strips, therefore results were also recorded by the educator. Again patients admitted that the results were not complete, and that they had disregarded those test strips which indicated a high blood glucose concentration. The most common explanations given for this was 'embarrassment' and the 'desire to do well'.

This example illustrates the caution which must be exercised in the interpretation of results as produced by the patient. Some previous studies have relied solely on the patients' blood/urine glucose test results to assess glycaemic control.<sup>(154,157)</sup> However, from experience in this study, the reliability of such results and their interpretation is questionable. The recent advent of the glycosylated haemoglobin (HbA<sub>1</sub>) test,<sup>(243)</sup> allows a more accurate and long-term measurement of glycaemic control, and was therefore the main parameter on which glycaemic control was assessed during the course of this study.

Glycaemic control has been discussed with regard to the changes during and after the DE/MP, and factors operating within the programme to account for these changes. Previous educational studies

involving insulin-dependent diabetics were also considered with respect to the achievement and maintenance of glycaemic control. It is apparent from the viewpoint of methodology, that comparison between the present study and previous studies is difficult and should be undertaken objectively. The content and structure of educational programmes are obviously varied, but very few studies actually document the protocol, or detail the content and methods used in the programme. For example, in the DE/MP, adjustments of insulin dose were 'advised' only for those patients who were considered capable, and even so, insulin regimens were not altered significantly since this was the responsibility of the physician. Therefore, the possibility of an inappropriate insulin regime contributing to poor control must also be considered, although during the course of the programme all HbA<sub>1</sub> results were recorded in the patients' medical records for the attention of the physician reviewing the patient. In other educational programmes, however, the insulin regimens may be altered considerably where the physician is involved in the teaching process. Also, the method by which glycaemic control is assessed varies; blood glucose levels, urinary glucose levels and HbA<sub>1</sub> measurements can be used. The effects of education on glycaemic control, as reported in various studies, may depend on the criterion used to assess control, and is a vital aspect to consider when comparing diabetes educational studies. These factors may account for some of the inconsistencies between different reports concerning the benefits of education. The provision of further information regarding the educational methods and a standardised measure of glycaemic control are necessary to allow a reliable comparison between studies.

## Diabetes Knowledge

Previous considerations in this discussion have made reference to diabetic knowledge and its association with glycaemic control in the present and other studies. Patients' knowledge of diabetes was assessed using multiple choice questionnaires, the development of which is described in section 2.6. The assessment at 0, 12 and 18 months served to: (i) investigate knowledge of diabetes in the total patient population and individual groups prior to the DE/MP; (ii) identify subject areas which were poorly understood to allow for greater consideration of these in the DE/MP; (iii) investigate the association between level of knowledge and other factors such as glycaemic control, attitudes and skills; and (iv) determine the effectiveness of the DE/MP in terms of patients' knowledge and understanding of diabetes.

Initially the total patient group, excluding the NG, gained a mean score of 58%, revealing a deficiency in patients' understanding of diabetes and its management. It was stated earlier that the majority of the total patient group had not received any organised form of diabetes education since diagnosis, and these patients had relied on 'piecemeal' types of instruction provided at routine clinic visits. The relatively poor knowledge scores attained may indicate the need for a more structured educational plan, and which provides re-education concerning various aspects of diabetes management which have been modified in recent years, e.g. diet and injection technique. A converse argument might be that low scores were due to a difficult questionnaire. The optimum level of average difficulty,  $\rho$ , for a multiple choice questionnaire is  $\rho$  0.50.<sup>(271)</sup> The knowledge questionnaire DKQ1, used in this assessment,

demonstrated an average difficulty level of  $p$  0.46, and therefore resided close to the recommended level. Thus, low scores attained in this assessment cannot be accounted for by the difficulty of the questionnaire, which supports the suggestion that the total patient group had an inadequate understanding of diabetes at the onset of the present study.

Particular subject areas in which a lack of knowledge was apparent included diet and basic care. However, variation in subject areas may not only be due to a deficiency in knowledge concerning these aspects, but also due to differences in individual question item difficulty levels, despite obtaining a satisfactory measure of average questionnaire difficulty. This highlights the caution necessary when interpreting questionnaire results, and emphasises the requirement for a more standardised approach to the measurement of diabetes knowledge. Other issues concerning questionnaire design could also affect the assessment of diabetes knowledge.<sup>(304)</sup> Readability and comprehension levels are important considerations;<sup>(302)</sup> if these are inappropriately high, results of the questionnaire may reflect the patients level of general knowledge rather than diabetes knowledge. To provide a more accurate and unbiased assessment, questionnaires were designed to accommodate lower reading and comprehension levels. This was facilitated by a relatively short questionnaire which avoided the use of unfamiliar technical or medical terms. It was felt that this level of comprehension provided all patients with an equal opportunity to attain scores on the questionnaire. Also, the validity and reliability of the questionnaire must be documented.<sup>(252)</sup> This indicates the

accuracy of the questionnaire and can have a significant effect on the results and interpretations. Satisfactory levels of reliability and validity were recorded for DKQ1 (refer to section 2.6.4). It is suggested that the development and use of a standardised knowledge questionnaire would assist in reducing the variation between studies attributable to these factors discussed.

Overall, diabetes knowledge was not affected by patient age, insulin dose, insulin type, race, clinic non-attendance, or hospital admissions. However, consistent with previous reports,<sup>(156)</sup> greater knowledge was recorded in females than male patients. This difference might be due to poorer dietary knowledge in males, who are frequently dependent on their spouse or mother to understand and adhere to dietary recommendations, although no evidence was found to support this.

The positive correlation between duration of diabetes and knowledge indicates that patients who had diabetes for a longer duration knew more about the condition. One might equally surmise that patients with a shorter duration would have a greater knowledge since diabetes instruction was provided at the time of diagnosis which would have been more recent in patients with a shorter duration. It is reasonable to expect these patients would also be more aware of the aspects of diabetes management which have been modified in recent years. Duration of diabetes was not associated with glycaemic control, attitudes or skills and it is therefore difficult to suggest reasons for the association between duration and knowledge found in this study. Indeed, previous reports concerning this relationship have been inconsistent and inconclusive.<sup>(304-306)</sup>

Body weight was also associated with knowledge, an inverse correlation being found between body weight and general diabetes knowledge and dietary knowledge, indicating increased weight with poorer knowledge. Initially it might be suggested that greater knowledge facilitates body weight control. However, such assumptions are difficult to substantiate because the % ideal body weight, which is the height:weight ratio adjusted for frame and sex, was not associated with knowledge. Since sex distribution was not accounted for, the association between weight and knowledge, as described, may only reflect the differences in patients' sex and knowledge as discussed previously.

As reported previously,<sup>(307)</sup> variation in knowledge was found among the socioeconomic groups (SEGs); higher SEGs demonstrated greater knowledge compared to lower groups. It has been suggested that increased knowledge in higher SEGs is due to better school education,<sup>(154)</sup> but details of patients' level of education were not considered in the present study. Possibly background and level of education are contributing factors for the association between knowledge and SEG. Greater knowledge was also positively correlated with favourable attitudes, and it is conceivable that patients' avidity to learn and know more about diabetes is influenced by their attitudes, thus accounting, in part, for the results observed in the present study.

Knowledge also varied depending on marital status; the divorced or separated patients attained higher scores than either the single or married patient subgroups. As stated earlier, these patients were also in better glycaemic control, possibly due to reduced emotional pressures and domestic problems. However, it is

conceivable that greater knowledge was associated with, and facilitated improved control in, the divorced or separated patients. It is possible that the divorced or separated patients had received a greater amount of attention and instruction than the single or married patients, although there is no evidence to support this. There were no other apparent reasons accounting for the differences in knowledge between these patients, and attitudes and skills were similar in the three groups.

#### Comparison of Diabetes Knowledge Between SG, CG, NG and NA Groups

Variations in diabetes knowledge were found at the 0 month assessment; the NA group demonstrated a poor understanding of diabetes compared to the other groups, and reiterates the necessity for effective recruitment procedures to encourage patient participation. The apparent similarity of the SG and CG concerning diabetes knowledge indicates comparability of these groups for further assessment and comparison. Although the NG did not obtain significantly greater knowledge scores than other groups, responses were consistently more accurate in all subject areas compared to all other groups. This is possibly due, in part, to the recent diagnosis of these patients and the comprehensive diabetes instruction, as provided in the Diabetic Unit.

The significantly greater level of knowledge demonstrated by the SG compared to the CG at 12 months, was presumably due to participation in the DE/MP. This was intended to increase knowledge and understanding, and demonstrated success of the programme in terms of this particular aim. However, a modified questionnaire was used in the 12 month assessment and it might be argued that the

content of the restructured questionnaire was responsible for the differences observed between the SG and CG. But indices of reliability and validity were increased in the 12 month questionnaire compared to that used at 0 month. It is therefore unlikely that these group differences are due to questionnaire design.

#### Maintenance of Improved Knowledge Skills

A further consideration is the retention and recall of knowledge acquired during an educational programme. In the follow-up assessment of SG and NG patients, 6 months after completion of the DE/MP, retention and recall of information was considered as excellent. It has been documented previously that increased knowledge was retained for as long as 22 months,<sup>(150)</sup> and is consistent with the results of the present study. The nature of the programme may determine the extent to which knowledge is retained and recalled. The 'psychology of learning'<sup>(228)</sup> should be considered if programmes are to be effective in increasing patients' level of understanding. Methods reported to enhance the learning process were adopted in the DE/MP, and included: repetition, summaries, primary principles and the organisation of information.<sup>(190)</sup> These techniques possibly contributed to the improvement and retention of diabetes knowledge shown in this study, and it is recommended that these be considered in other educational programmes.

Since improvement in diabetes knowledge was demonstrated following the DE/MP, and 6 months after the programme was completed, it is evident that the programme was effective in enhancing and maintaining increased patient knowledge and understanding.



## Attitudes Towards Diabetes

Patients' attitudes towards diabetes are recognised as a factor affecting compliance and motivation,<sup>(161)</sup> although very little has been reported concerning the association between attitudes, knowledge and glycaemic control in diabetes.<sup>(300)</sup> This may be partly due to the difficulties encountered in the measurement of attitudes and the methodological issues concerning the development of an accurate scale with which to assess attitudes (refer to section 2.5). Many educational studies to date have suggested that education alone is insufficient for the attainment of compliance and control, and that the patients' motivations, attitudes, beliefs and psychological status are also influencing factors. Therefore, an original feature of this study was the measurement of patients' attitudes towards diabetes and its association with glycaemic control, knowledge, management skills and other characteristics.

Methodological issues pertaining to the development of attitude scales was discussed in section 2.5. The requirement of a valid and reliable scale is emphasised, to confirm the accuracy of the measurement. Levels of reliability and validity demonstrated by attitudes scales used in the 0 and 12 month assessments were conservative compared to values reported in previous scales,<sup>(308)</sup> although the results compare favourable with other diabetes attitude scales which have been documented.<sup>(309)</sup> Such modest levels of reliability and validity recorded in the present study may be attributed to the small number of items or statements contained in the scale, since larger item pools usually achieve considerably greater validity and reliability measures.<sup>(269)</sup> However, for the purpose of this study, it was intended to develop a scale which was

short and concise, and which could be easily administered in the Outpatient Clinic. It is apparent that the benefits of a shorter scale are offset by the reduction in validity and reliability attained with fewer items.

Some authors have suggested that attitudes consist of three components - affection, cognition and behaviour<sup>(215)</sup> (section 1.7.1). Results of factor analysis in the present study do not support this multi-component theory, since DAS2m and DAS3m exhibited five factor or attitude areas (refer to section 2.5.8 and 12). Although these attitude areas were not very specific, this may be due to the modest reliability and validity of the scales, as described earlier. This has the effect of reducing the correlation among items which is responsible for increasing the specificity of the factors. In view of these results, it is suggested that a larger item pool than that of DAS2m or DAS3m should be used to increase the accuracy and precision of scales used in the measurement of attitudes in diabetes.

The assessment of attitudes at 0 months was undertaken using DAS2m, and demonstrated a significant variation in patients' attitude with socioeconomic group (SEG) and insulin type. More favourable attitudes were found in patients from SEG1 compared to SEG2 or SEG6, and it might be suggested that patients from a higher SEG develop a more favourable attitude towards diabetes. However, the association between SEG and attitudes was inconsistent since SEG2 did not have more favourable attitudes than SEG3, 4 or 6. A notable feature concerning attitudes and SEG was that patients in SEG6, all of whom were unemployed, held poorer attitudes than other SEGs. This may reflect their general attitudes as a result of unemployment, and

possibly indicates failure of the attitude scale to measure attitudes to diabetes accurately. This group of patients also demonstrated poor knowledge compared to SEG1. It is feasible that inappropriate beliefs and a poor understanding of diabetes have contributed to the development of less favourable attitudes, since these aspects are believed to have a significant role in attitude formation.<sup>(233)</sup>

Although patients using unmixed pork insulins attained higher attitude scores than patients using pre-mixed insulins, reasons accounting for this difference are difficult to identify, since patients using unmixed beef insulin were not significantly different than the pre-mixed group. It might be suggested that patients who appeared less enthusiastic towards diabetes and insulin treatment were considered more suitable for the use of pre-mixed insulin, which requires less preparation time than unmixed insulins. It is possible that the lack of enthusiasm in these patients is also reflected in their attitudes. Patients using pre-mixed insulin also achieved poorer glycaemic control compared to patients using alternative insulin preparations and may indicate an association between attitudes and glycaemic control in this group of patients. It is feasible that poor control influences the development of less favourable attitudes towards diabetes, or that adverse attitudes result in poorer compliance and glycaemic control. However, these are suggestions evolving from the present study, and further study is recommended to determine the interaction between attitudes, compliance and glycaemic control. Attitudes in the SG, CG and NG groups were similar, and indicated comparability of the SG and CG for further assessment and comparison. The NG, who attained higher attitude scores than the SG, may have expressed greater enthusiasm in

their attitudes due to their recent diagnosis. It is also conceivable that better glycaemic control, possibly achieved with less effort in this group, might facilitate improved attitudes towards diabetes. The attitudes of the total group (excluding NG) were positive. However, assumptions cannot be made concerning the favourability or unfavourability of the total group attitudes because the assessment was based on a newly developed scale with no previous criteria for comparison.

Reassessment of attitudes at 12 months was undertaken using a modified scale - DAS3m, which included several areas not considered in DAS2m. Although it was anticipated that validity and reliability of this scale would be greater than previous measures, psychometric analysis demonstrated that indices of validity and reliability were slightly lower than in DAS2M. The level of reliability and validity achieved, however, was adequate to reflect an accurate and consistent scale.<sup>(254)</sup>

The 12 month assessment demonstrated significantly improved attitudes in the SG compared to the CG, indicating that patients who had attended the DE/MP subsequently held more favourable attitudes regarding diabetes, compared to patients who continued with routine clinic care. Taking into account the concomitant increase in knowledge in this group, the improvement in attitudes may be accounted for by several theories of 'attitude change', as discussed in section 1.7.3. The 'learning theory' proposes that increased knowledge concerning a particular subject/object modifies the feelings and beliefs towards it, and subsequently provides acceptances and enhances attitude change.<sup>(233)</sup> It is possible that such events were responsible for the improvement of attitudes in the

SG. This change in attitude may also be attributed to the theory of 'cognitive-dissonance', which proposes that when knowledge and beliefs are inconsistent with attitudes, dissonance is produced which motivates the attitude change.<sup>(234)</sup> These theories argue that increased knowledge can effect a change in attitude towards diabetes, and were therefore applied in the present study. The positive correlation between attitudes and knowledge shown here, and reported previously,<sup>(291)</sup> would support those theories of attitude change described.

Attitudes are features in the Health Belief Model (HBM), a theory used to explain and predict compliance,<sup>(179)</sup> which suggest that compliance is influenced by attitudes and motivations. If glycaemic control indicates compliance, one might expect improved glycaemic control with more favourable attitudes. Indeed, improved glycaemic control was demonstrated at 12 months, with improved attitudes. However, these assessments were not correlated. This inconsistency between glycaemic control and attitudes, which was apparent in the 18 month assessment and which has also been reported previously,<sup>(291)</sup> does not however contradict the HBM theory. The HBM theory proposed that a number of factors interact to influence behaviour, only one category of which is attitude. These factors include motivation, beliefs, social and environmental factors and psychological status. It is recommended that these aspects, and the patients' health locus of control,<sup>(182)</sup> should be considered further to investigate the role of the HBM in compliance, as assessed by glycaemic control.

Attitudes remained similar in the SG and NG at the 6 month follow-up assessment, although glycaemic control deteriorated, and

would support the view that attitudes do not predict behaviour or compliance.<sup>(223)</sup> As recommended earlier, further study is required to investigate the influence of those factors inherent in the HBM theory,<sup>(179)</sup> to fully understand the area of compliance and diabetes.

The lack of association between attitudes and glycaemic control has been discussed. Although the relationship between these is unclear, the positive association between attitudes and knowledge at 12 months indicates the role of attitudes in learning motivation, possibly increasing patients' acceptance of new information. Thus, it is suggested that attitudes are an important aspect of education and that these be considered and developed in diabetes teaching programmes to promote learning and acceptance of information presented.

#### Self-Management Skills

Practical self-management skills, which indicate the behavioural aspects of knowledge, were assessed by observing patients performance in a number of routine practical skills. Since the test was short and concise consisting of only three areas (insulin injections, dietary exchanges and blood/urine glucose testing, as detailed in section 2.7), it offered a rapid, reproducible and appropriately relevant evaluation, which did not frighten or unduly burden the patients.

In many previous studies only the cognitive aspect of knowledge is reported,<sup>(150,154,155)</sup> despite the importance of the behavioural component, as recognised by a number of authors who have considered this parameter.<sup>(139,156,310)</sup> The practical skills test conducted in this study was based on observations made by the educator, and

provided valuable information without using written questionnaires. This type of assessment appeared to have a potential advantage for several patients who in the present study admitted that they felt 'uncomfortable' and 'under pressure' when completing written questionnaires. Also, patients appeared more relaxed during these assessment procedures, possibly due to their familiarity in actually performing the skills regularly rather than writing or answering questions about them. The information provided by the skills test was also used to restructure the content of selected parts of the DE/MP. In addition to these favourable aspects, the test also provided the criterion on which to measure the validity of the knowledge questionnaires, thus confirming accuracy and consistency of the knowledge assessments (refer to section 2.6.4). Competence in self-management skills was not associated with most of the patient variables, but a significant inverse correlation was found between self-management skills and body weight. Although it is conceivable that lower body weight could be related to increased competence, and particularly dietary skills, the % ideal body weight, which takes into account the patient's sex, height and frame, was not associated with overall skills or dietary skills. In view of this discrepancy, the association between self-management skills and body weight must be interpreted with caution.

Initially, self-management skills were similar in the SG, CG and NA groups and again indicated comparability of the SG and CG. The NG demonstrated greater competence in management skills compared to other groups, raising the possibility that recent education and supervision provided at diagnosis benefited their performance in the skills test. Also, this may indicate the success of the Diabetic

Unit, recently opened in the hospital, and the modified system of care which is provided for newly diagnosed patients.

Most patients demonstrated a reasonable level of competence in self-management skills. The most serious error was the incorrect identification of normal blood/urine glucose levels. Subsequently, increased attention was directed to the issue of 'blood/urine glucose control' during the DE/MP. The reassessment of skills on completion of the DE/MP, which demonstrated a significant improvement in the SG compared with the control group, is consistent with previous reports concerning education and behavioural skills.<sup>(117)</sup> Results of this assessment may reflect the effectiveness of the DE/MP in the development of behavioural skills, in addition to the cognitive elements as assessed by questionnaires.

Increased competence in management skills was positively correlated with increased knowledge, and may indicate the benefit of behaviourally-orientated education, as provided by the DE/MP. Examples of behavioural-orientation included use of model foods and provision of a buffet to consider diet, allowing patients to 'demonstrate' their skills in insulin administration and in blood glucose testing. Indeed, it is reported that behaviourally-orientated patient education is more effective than didactic types of instruction.<sup>(117,184)</sup> The association between improved knowledge and skills supports this view, and it is recommended that the development of self-care skills should be considered, in addition to the assimilation of knowledge during education programmes.

The SG and NG attained a high level of competence in management skills at 12 and 18 months, demonstrating the maintenance of



improved skills 6 months after completion of the programme, and inferring successful behaviour modification. However, the deterioration in glycaemic control in the follow-up assessment raises the possibility of a lack of compliance in related behaviours, contradicting the suggestion of behaviour modification. Clearly, distinction must be made between measures of behavioural skills and measures of compliance, since the performance of skills in the Outpatient Clinic may be very different than actual behaviour or compliance at home. It is essential that the skills test is not regarded as a measure of behavioural compliance, but rather for its use in assessing patients' 'ability' to perform behavioural skills and as a practical learning aid for the patient.

Although results of the skills assessment at 12 and 18 months were favourable, interpretation and recommendations are limited due to the lack of information concerning the reliability and validity of the test. Also, the test was short and simple and observed only a small number of skills. It is possible that more detailed observations would provide further information concerning patients' abilities in self-management. However, the skills test was a valuable tool for use in the present study, since it provided validity coefficients for knowledge questionnaires, and relevant information which enhanced the development of the DE/MP.

#### Inter-Relationship Between Assessment Parameters

Glycaemic control, knowledge, attitudes towards diabetes and self-management skills have been considered as separate components. The inter-relationship between these parameters was also investigated, as documented in section 3.7. The positive correlation

between knowledge and management skills, shown in all assessments, indicated that patients' knowledge 'was' associated with their performance of behavioural skills. This association also confirmed the external validity or accuracy of the diabetes knowledge questionnaires (DKQ). In view of the relationship between knowledge and behavioural skills, it might be feasible to consider a practical skills test as an alternative to written questionnaires in future studies. This would help to avoid embarrassment and intimidation which may be experienced by those patients who have difficulty reading and understanding questionnaires, and may provide a more accurate assessment of diabetes knowledge. The inverse correlation between knowledge and % HbA<sub>1c</sub> levels at 0 months inferred that better glycaemic control was associated with greater diabetic knowledge in this group of patients. This association would support the introduction and implementation of education programmes such as the DE/MP. These results are consistent with previous studies concerning the relationship between knowledge and control,<sup>(150-152)</sup> although it has been suggested that poor control is associated with greater knowledge of diabetes.<sup>(158)</sup> The lack of correlation between knowledge and control at 12 and 18 months may be attributed, in part, to the exclusion of the NA group who were not reassessed after 0 months. The NA group demonstrated significantly poorer control and knowledge at 0 months, and it is possible that increased variation provided by the NA group enhanced the discrimination of knowledge and control levels, which contributed to the disclosure of the inverse relationship in this assessment. The inconsistencies between the association of knowledge with control at 0, 12 and 18 months may also be attributed to the difference in knowledge

questionnaires used at 0 and 12 months. However, the accuracy and similarity of these questionnaires, as indicated by reliability and validity coefficients, do not support this suggestion.

Although attitudes and self-management skills were positively correlated at 0 months, this was not demonstrated in further assessments. Again, it is feasible that the different patient population, which was considerably reduced in the 12 and 18 month assessments, contributed to the observed inconsistencies. The positive correlation between knowledge and attitudes at 12 months was attributed to the improvement of both these qualities by the SG during the DE/MP, and supports the concept discussed earlier regarding the influence of attitudes in learning motivation.<sup>(163)</sup> This correlation was not observed at 18 months, possibly due to change in the population sample which comprised only 28 patients (SG) compared to 56 (CG + SG) at 12 months.

Although better glycaemic control was associated with increased competence in management skills at 12 months, the association between glycaemic control and knowledge was only weak. This may reflect the value of a behavioural skills test to demonstrate the association between control and knowledge. Also, it is possible that the skills test was more effective in reflecting those aspects of compliance relating to improved control, compared with cognitive knowledge assessments using questionnaires. To determine the feasibility of using a practical skills test as an alternative to written knowledge questionnaire, further study would be necessary using a developed skills test which demonstrated validity and reliability. This association between skills and control, however,

was not demonstrated at 18 months, and again was accounted for by the change and reduction in patient population in this assessment.

#### Evaluation of the DE/MP

The discussion so far has considered results concerning patient details and the assessment of various parameters before and after participation in the DE/MP. Evaluation of the patients' perceived benefits (likes, dislikes, preferences and opinions) is also vital in the development of more effective educational methods.<sup>(133,300)</sup> Thus, evaluation of the DE/MP and of the educator was conducted on completion of the 12 month programme.

Few patients had previously received a structured form of diabetes education. This highlighted the need to develop education and re-education services within the hospital and supported the introduction of the DE/MP. However, early during the course of the present study, a new Diabetic Unit was opened in the hospital which provided an on-going educational service for both in-patients and out-patients. An organised system of instruction and follow-up was developed for newly diagnosed patients, and professional advice, support and educational facilities were made available during the day and night.

Although patients' responses concerning the benefits of the programme were all commendable, it is probable that perceived impressions were biased due to the lack of previous organised education and supervision for comparison. It is reasonable to suggest that evaluation of the DE/MP was influenced, in part, by the novelty of participating in group teaching and receiving increased levels of attention and supervision. Results may reflect, to some

extent, the patients' subjective opinions concerning the DE/MP and educator.

The structure and length of the programme appeared adequate for most patients, which indicated acceptability of a long-term teaching programme. It is suggested that this type of programme (which consists of group teaching) is suitable for providing the in-depth education phase recommended for previously diagnosed patients.<sup>(164)</sup> It was apparent that patients preferred group teaching sessions compared to individual instruction, and supports the potential use of group therapy in diabetes education. The novelty of 'being part of a group' with which to share similar problems and anxieties was one aspect which tended to favour this preference, as indicated by patients' comments (refer to section 3.9.1).

#### Some Recommendations Emanating from the DE/MP

Experience of group teaching in the present study highlighted the need to consider the most suitable combination of individuals which can promote the success of group therapy. Consistent with previous reports,<sup>(274,311)</sup> it was observed that groups comprising patients of various ages were more effective in terms of communication and integration, compared to patient groups of similar age. Also, it was apparent that patients in the adolescent age groups, between 15 and 20 years, were less keen to integrate in the group or contribute in discussions. This may emphasise the need to consider adolescent patients as a distinct group, thus accommodating the additional emotional and psychological needs pertaining to these patients. Such a distinction has previously been identified and accommodated for, with the development of the Young Diabetic Leaders

Project, which provides innovative education specifically for young patients,<sup>(301)</sup> and by the provision of British Diabetic Association holidays specifically for adolescents. From observations and experience, it is recommended that diabetes teaching groups consist of patients of mixed ages, with the provision of additional attention and consideration for adolescent patients as required.

Various recommendations have been made regarding the ideal number of patients in educational groups, ranging from 6 to 10 patients,<sup>(274)</sup> 10 patients or less,<sup>(189)</sup> to 10 to 15 patients.<sup>(299)</sup> However, in the present study, groups consisted of between 3 and 7 patients only, due to the difficulties in recruiting sufficient patients at the same time. Despite the small number of patients included in the groups, successful personal interaction occurred between group members, and commitment and enthusiasm was established in all groups. This indicates that effective group therapy in diabetes can be achieved with a relatively small number of patients.

The role of the group leader (educator) has been described as a 'catalyst' for the communication and interaction within the group.<sup>(198)</sup> It is likely that success of group teaching is dependent, to some extent, on the qualities and skills of the leader in facilitating group interaction and to moderate group discussions. On the basis of subjective evaluation and patients' comments (section 3.9.1), it is suggested that the personal qualities and communication skills of the educator (GMC) contributed to the development of effective group teaching in this study.

Evaluation in this study indicated the benefits of group teaching in terms of providing peer reinforcement and motivation, reducing the amount of teaching time per patient and enhancing the

motivation of the educator with increased patient feedback. It is recommended that increased attention be given to the development and integration of group teaching in diabetes education.

Topics considered in the programme were presented using various teaching aids, both lectures and demonstrations were provided and care was taken to avoid technical or medical terms. This aspect was commented on by several patients (section 3.9.1), and illustrates the importance of using appropriate vocabulary to suite all individuals in the group. Comments were also made concerning the educator (GMC), who is herself diabetic. This appeared to be an asset since several patients said they felt they had 'something in common' with the educator who could identify with their problems. This aspect of 'peer identity' had also been used successfully in the Young Diabetic (YD) programme called 'Sharing a Way of Life'.<sup>(301)</sup> This involves the participation of young patients in the diabetic community, by meeting with other young newly diagnosed patients, providing moral support and reassurance, and enhancing the practical aspects of diabetes education. Using an experienced diabetic subject as a health education resource has been suggested previously,<sup>(312)</sup> the successful response in the present study and that of the YD project would support this view.

Several patients also drew attention to those aspects of the programme they considered not to be ideal. These included the difficulty in obtaining time off from work, insufficient time allocated to sessions and problems understanding the information presented. Regarding the issue of work and times of sessions, every effort was made to accommodate the patients' work commitments and patients were given the option of attending the sessions at the most

convenient time for them. Subsequently, many patients attended sessions late in the afternoon after work. Also, an evening group was formed and several patients attended on Saturday mornings. However, for some patients, who did not live close to the hospital, these appointment times did not appeal, and these patients preferred to attend during working hours, despite the difficulties imposed. This emphasises one of the possible reasons accounting for poor attendance in educational programmes, and highlights the need for a convenient and flexible appointment system, thereby encouraging attendance.

Although teaching sessions lasted for approximately three-quarters to one-and-a-quarter hours, one patient felt that more time was needed. It is reported that the optimum teaching time, to facilitate learning, is half-an-hour, after which time concentration and attention are considerably reduced.<sup>(277)</sup> Therefore it was felt that the duration of the teaching sessions was more than adequate. Difficulty in understanding the information was mentioned by one patient, and draws to attention the need to identify the requirements and abilities of individual patients within the group and to tailor the teaching appropriately.

Concerning glycaemic control, all patients perceived an improvement during the course of the DE/MP, and this was attributed to a variety of reasons, mainly reflecting increased diabetic knowledge. Some patients, however, had not achieved improved glycaemic control. It is possible that these patients experienced increased personal reassurance and confidence, due to a greater understanding of the condition, and which was misconceived as



improved glycaemic control. Inappropriate responses may also indicate ambiguity of this particular question, and reiterates the problems regarding questionnaire design as discussed earlier. (300,303)

Regarding aspects of self-management, most patients described several changes they had made to the management of their diabetes (refer to section 3.9.1). These changes reflect the more recent recommendations in diabetes management, and emphasise the need for re-education and follow-up of patients with a longer duration of diabetes.

Evaluation of the DE/MP demonstrated that patients 'wanted' to know more about diabetes and were keen to learn. This was also reflected in the assessment of knowledge and skills undertaken at 12 months. The patients expressed their appreciation for the attention and supervision provided during the programme, and probably contributed to the favourable evaluation. It is possible, however, that patients who did not wish to participate in the DE/MP - the NA group, would not have enjoyed this type of attention and therefore evaluation would perhaps present a different view of the programme. It might then be suggested that evaluation of the DE/MP was biased by the patient sample who participated and did not include NA patients. However, it can be argued that diabetes education programmes and their evaluation are dependent on patient co-operation and willingness to participate, which was not shown by the NA group.

#### Evaluation of the Diabetes Educator and Recommendations

The importance of the doctor-patient relationship in

influencing compliance was considered earlier, and it is reasonable to suggest that this also applies to the educator-patient relationship regarding motivation to learn and comply with instructions. Therefore patients' satisfaction with the educator was also considered in this study.

Most patients agreed that the quality of teaching was very good, possibly indicating acceptance of the innovative educational methods used. As indicated by patients' responses (section 3.9.2), the educator demonstrated effective communication skills and empathy during the DE/MP. Indeed, it is recommended that the educator should have particular qualities, including: a non-authoritarian approach to patients, the capacity to relate to others and increase confidence, and the ability to teach. It is conceivable that the effectiveness of a diabetes education programme is dependent, in part, on the personal attributes of the educator as described. It is suggested that such qualities were responsible for increasing patient interaction and participation in the teaching groups in the DE/MP, and which enhanced the success of this programme.

Assessment of the educator, however, does not feature in the evaluation of education programmes to-date.<sup>(300)</sup> It is possible that this is an important factor accounting for some of the inconsistencies concerning the effectiveness of diabetes education described earlier.<sup>(139,150,154,155,156, 310)</sup>

The age of the educator, who was younger than 75% of patients, was irrelevant to all patients except one, who would have preferred someone older. The age of this patient was unknown due to the confidential questionnaire administration, therefore this response cannot be commented on. The general opinion, that age is not

important, may indicate that other qualities, such as those described previously, are more important to the patient and supports the recommendations cited earlier concerning the personal attributes of the educator. Additional comments were provided by several patients, often illustrating their approval of a diabetic educator, and which support the earlier suggestions of using peer diabetics as a health education resource.<sup>(312)</sup>

Although most of the responses were complementary to the educator, these evaluation questionnaires were mailed to the patients who were asked not to identify themselves. Hence it was considered that honest and reliable responses had been encouraged as much as possible. However, it is also possible that the questionnaire design and wording influenced evaluation responses.

This subjective evaluation, although of limited value, did demonstrate patients' satisfaction with the educator and reiterated the potential for using motivated diabetic patients as an educational resource. It is recommended that further consideration be given to the integration of peer orientated support and instruction in diabetes education.

#### Follow-Up Evaluation

To assess patients' coping skills and well-being following the DE/MP, a 6 month follow-up evaluation was conducted. Patients frequently perceived their glycaemic control as better than their actual glycaemic control, as assessed by % HbA<sub>1c</sub> levels. Such inconsistency may be due to a misinterpretation of the question, and it is possible that patients' responses reflect 'how they feel' rather than their level of glycaemic control. It is conceivable

that patients were aware that glycaemic control had deteriorated but were too embarrassed or disappointed to admit this. Also, it is possible that patients were genuinely unsure about their control levels due to infrequent monitoring of blood glucose at home.

Although most patients had not experienced any particular problems in the 6 months following the DE/MP, several patients (18%) reported problems concerning hypos, foot problems and injection times. However, the relative increase or decrease in such problems cannot be commented on since the incidence of these was not assessed prior to the DE/MP.

A considerable number of patients (79%) had undertaken adjustments in insulin dose on occasions, without instruction from medical or nursing staff. Reasons for these alterations included: recurrent hypos, illness, exercise, high blood glucose levels and Christmas. Most of these patients were not familiar with insulin adjustments prior to the DE/MP, and therefore these results indicated a significant change in the management of insulin. This may have also reflected an increase in patients' confidence and self-responsibility in the management of their diabetes. Despite these modifications and patients' apparent behavioural change towards insulin treatment, glycaemic control had deteriorated. This raises the question whether adjustments in insulin dose, as initiated by the patient, can benefit glycaemic control. It might be argued that this group of patients did not have an adequate understanding of insulin regimes and control to carry out appropriate adjustments in insulin treatment, but knowledge concerning insulin and control was very good in this group of patients, as indicated by the 12 month

knowledge assessment (section 3.3.5), and does not support the suggestion that inappropriate adjustments were made.

Admission to hospital had been required for 3 (9%) patients, all of which were due to unsuspected hypoglycaemia. Although this is a small number of patients, it might indicate that the subject of hypoglycaemia requires more detailed consideration in the DE/MP. Also, it is conceivable that these patients were over ambitious concerning their achievements in glycaemic control, which subsequently resulted in hypoglycaemia. This is further supported by the % HbA<sub>1c</sub> levels recorded for these patients, all of which were below 10%. The risks of achieving good glycaemic control have been detailed elsewhere,<sup>(101)</sup> and it is possible that results described in this study support these considerations.

Since most patients (94%) thought they would benefit from a yearly refresher session in diabetes education, it might reflect the patients' personal need for a follow-up review, and supports previous recommendations for continued education.<sup>(164)</sup> However, an efficient follow-up system is difficult to organise for such large numbers of patients currently attending most diabetic clinics. It is suggested that further consideration should be given to the design of an effective follow-up service which would cater for the larger population of diabetic patients attending many hospitals.

The follow-up evaluation was useful in identifying particular aspects of diabetes education which may require further consideration or revision, including hypoglycaemia and insulin adjustments. This evaluation was only undertaken with the SG patients after the completion of the DE/MP. No comparison was made with either CG patients or with responses recorded prior to the programme, and

therefore evaluation was of limited value. It is recommended that in future studies of this kind, more quantitative and objective evaluation methods be used in order to investigate and describe the benefits of educational programmes.

This study had demonstrated an improvement in glycaemic control, knowledge of and attitudes to diabetes, and self-management skills following a long-term, non-intensive outpatient education programme. The DE/MP has been described in detail and represents a unique attempt to improve the motivations and attitudes of the patients. The content and structure of this type of programme appeared to be acceptable, and patients expressed their enjoyment at having participated. It was evident that patients 'were' keen to know more about diabetes, and subsequently demonstrated increased confidence, responsibility and motivation towards their condition.

#### Conclusions and Recommendations

Results of this study strongly support the role of organised and structured education in the treatment and management of diabetic patients. However, it was reported earlier that many patients were unwilling to participate in such a programme and it is recommended that more effective recruitment procedures be designed to persuade patients of the benefits of diabetes education. Educational methods and assessment procedures for variables such as glycaemic control, knowledge, attitudes and skills can vary considerably in different studies. Therefore, the design and development of standardised methods of education and assessment is recommended. This may help to explain previous inconsistencies concerning diabetic knowledge

and control, and may further support the benefits of improved education services for diabetic patients.

Maintenance of glycaemic control in the long-term was not demonstrated at 18 months follow-up, although attitudes were favourable, and knowledge and self-management skills were considered excellent. It was suggested that the reduced amount of attention and supervision received by the patients after the completion of the programme, had contributed to reduced patient motivation and the subsequent deterioration in glycaemic control. Thus, the need for continued follow-up care in order to obtain maximum benefit from educational programmes was emphasised.

A major consideration in the present study was the development of motivation. Indeed, results indicated an improvement in patients' extrinsic motivation, although this appeared insufficient for the maintenance of improved glycaemic control. It was proposed that 'intrinsic motivation' is a significant factor determining the maintenance of particular behaviours or compliance.<sup>(299)</sup> Therefore, it is recommended that increased attention be given to the development of patients' intrinsic motivation to maximise the long-term benefits of diabetes education.

Following discussion of the patients' Health Locus of Control (HLC),<sup>(179)</sup> it was suggested that this was a contributory factor accounting for the deterioration in compliance and control at the follow-up assessment. However, since the patients' HLC was not measured in the present study, the influence of the HLC in compliance and control in diabetes cannot be elaborated on. The Health Belief Model (HBM) which predicts and explains compliance, indicates that social and environmental factors influence

compliance. Although such parameters were not assessed in the present study, it is likely that deterioration in glycaemic control was attributed, at least in part, to these aspects.

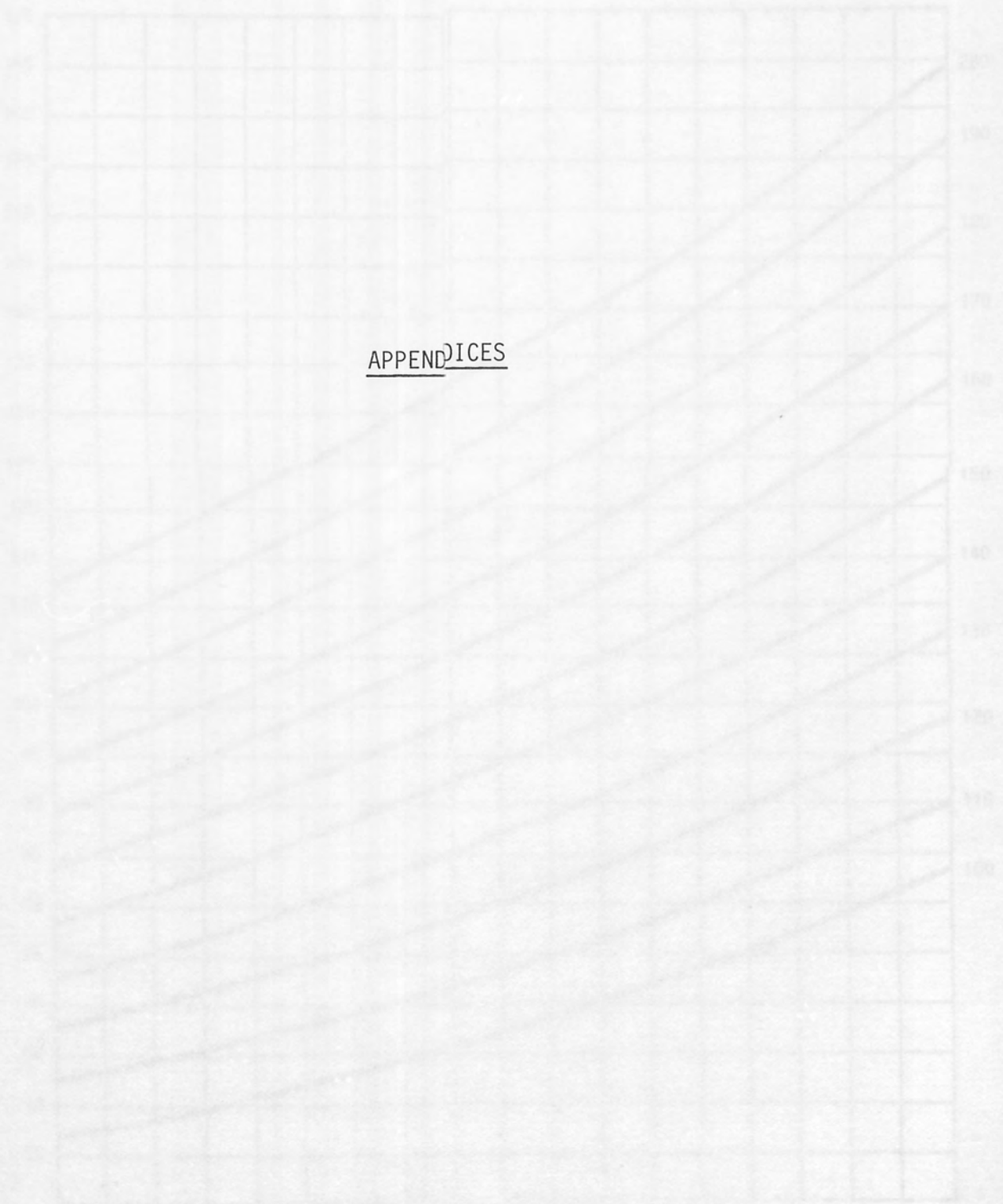
Patients' attitudes are recognised as an important component affecting compliance and motivations in diabetes. Although many studies have reported the effects of knowledge on glycaemic control, very little has been documented regarding the relationship between attitudes, knowledge and glycaemic control. This may be due, in part, to the difficulties encountered concerning the measurement of attitudes, as described in section 2.5. A unique feature of the present study was the measurement of attitudes to diabetes and to investigate the association with glycaemic control, knowledge, skills and other patient characteristics. Indeed, more favourable attitudes were associated with increased knowledge and, to a lesser extent, with improved glycaemic control. It is recommended that further study is required to investigate the influence on compliance in diabetes, attributed to the Health Locus of Control, the Health Belief Model theory and attitudes to diabetes. This would help to determine the most relevant aspects to be considered and enhanced in future diabetes educational programmes which aim to increase compliance.



# IDEAL WEIGHT CHART FOR MEN

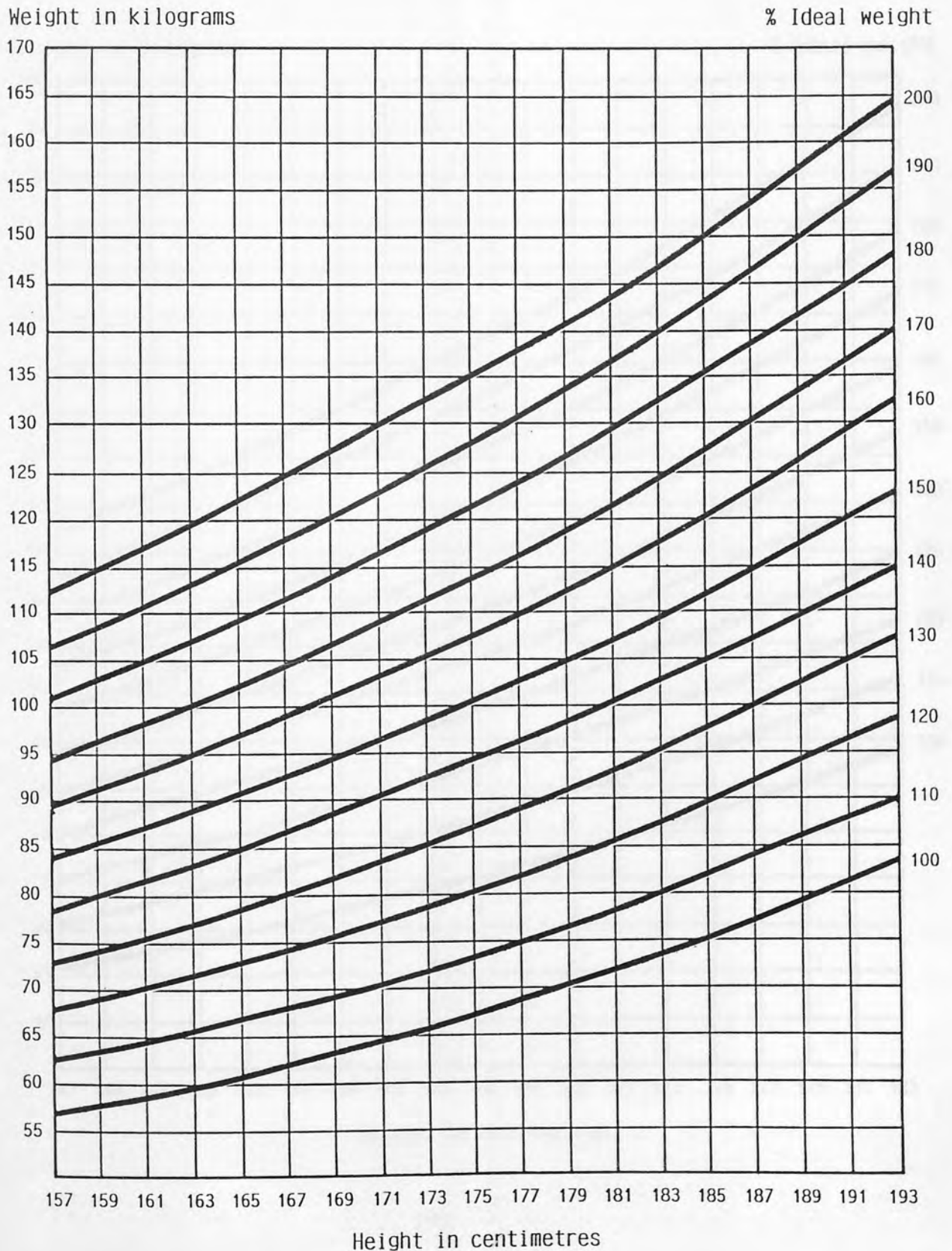
Weight in kilograms

2 Ideal weight

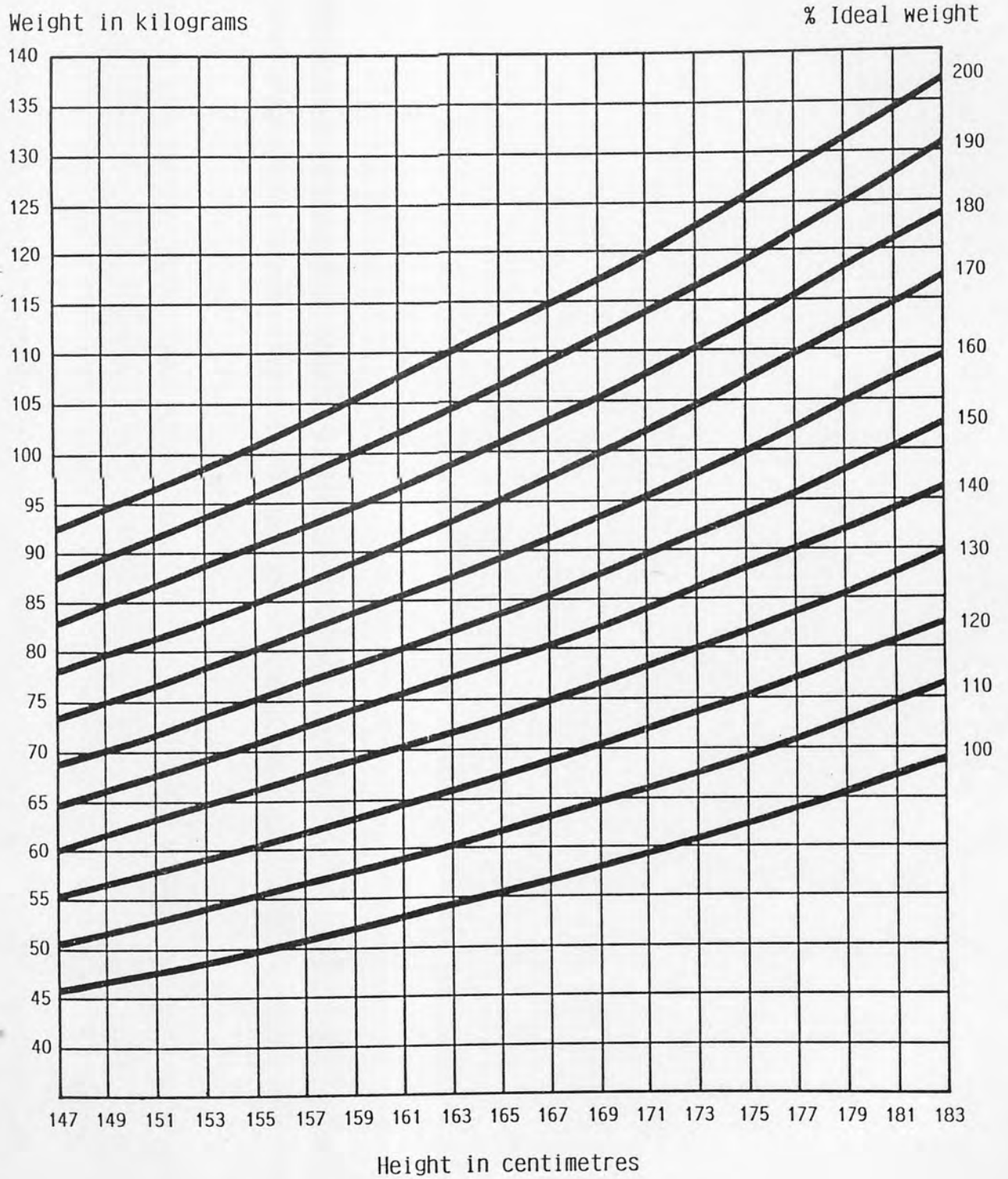


APPENDICES

## IDEAL WEIGHT CHART FOR MEN



## IDEAL WEIGHT CHART FOR WOMEN



Glytrac™ Electrophoresis Method for Determination of HbA<sub>1</sub>





Aston University

Illustration removed for copyright restrictions



Aston University

Illustration removed for copyright restrictions

(071, 072, 073, 074)

APPENDIX 3.1

It would be very grateful if you could complete this short questionnaire. Your answers will be treated with strict confidentiality and will be used only for the purpose stated. Please do not write your name on any statements.

APPENDIX 3

This includes attitude scales used in the development of DAS2m and DAS3m, and results of psychometric tests

Use the space below each statement to indicate your level of agreement.

(ATT. QUE. PRE-TEST)

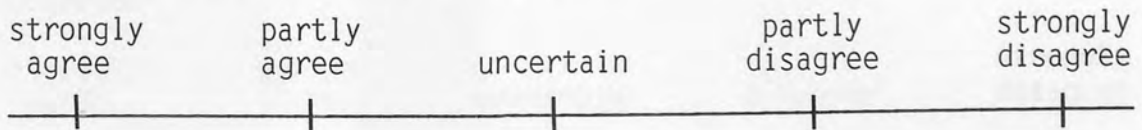
INSULIN DEPENDENT DIABETES QUESTIONNAIRE

We would be very grateful if you would complete this short questionnaire. Your answers will be treated with strict confidence and you do not need to give your name. Please be HONEST about your response to each statement.

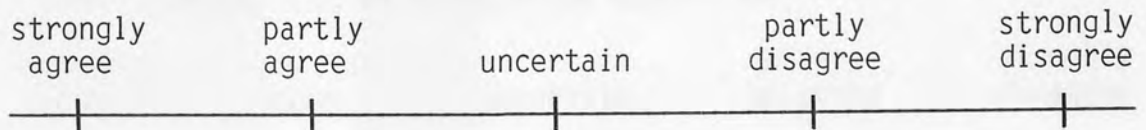
INSTRUCTIONS

1. Please read each statement carefully.
2. Decide to what extent you agree or disagree with the statement.
3. Mark an 'X' at that point along the scale below each statement.

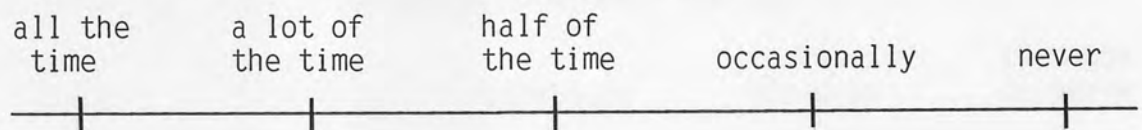
1. Having diabetes makes life difficult



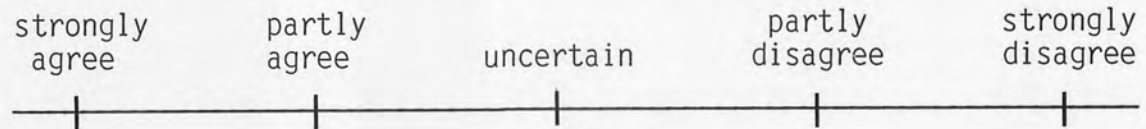
2. It will be necessary for me to take insulin for the rest of my life



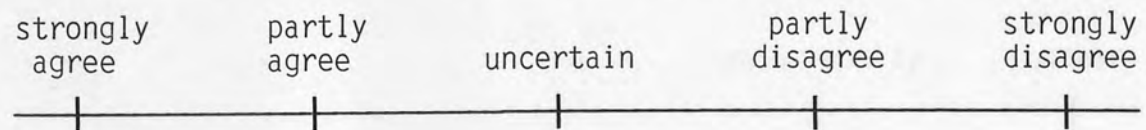
3. How often do you follow the doctor's advice?



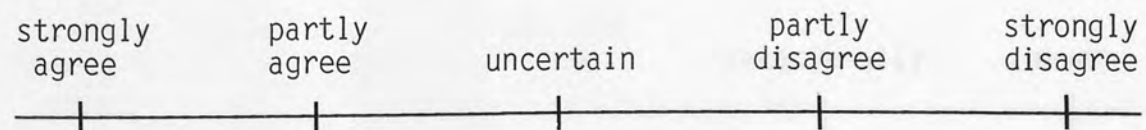
4. There is very little I can do now to prevent any diabetic complications which might occur later in life



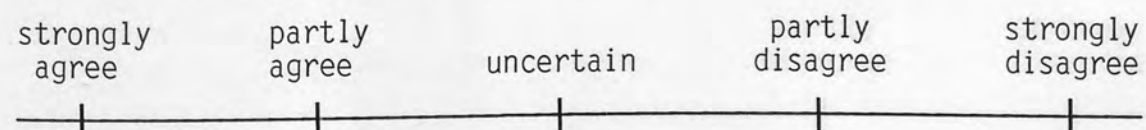
5. I find it hard to do all the things I have to do for my diabetes



6. I would never miss my insulin

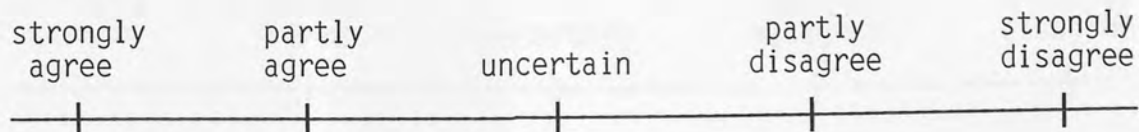


7. The diabetic diet does not really help me

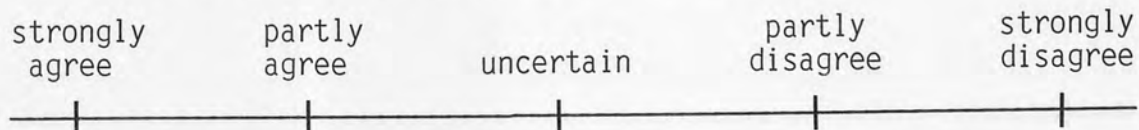




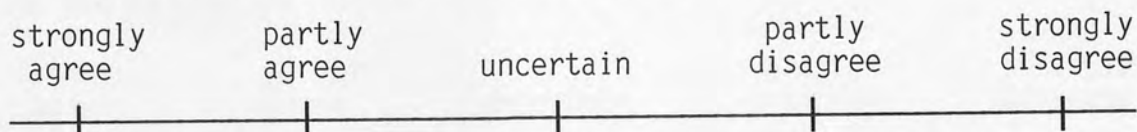
8. Testing my blood/urine helps me to achieve better control of my diabetes



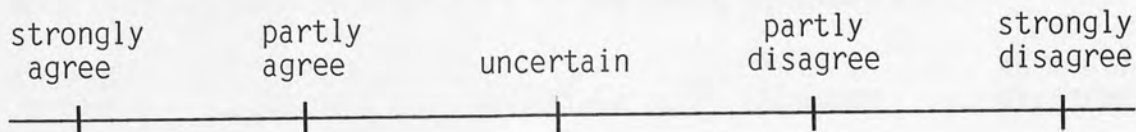
9. I know I should test my blood/urine more often



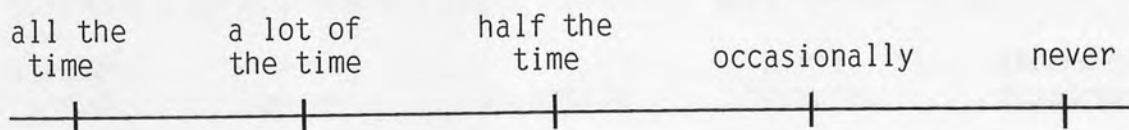
10. I very much want my diabetes to be well controlled



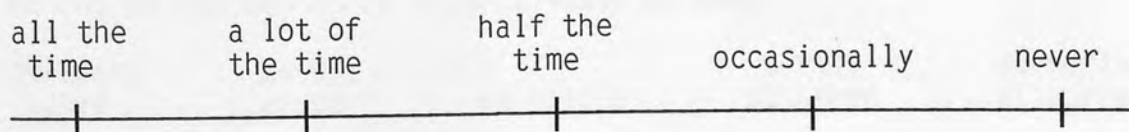
11. I think it is important to test for ketones when feeling ill



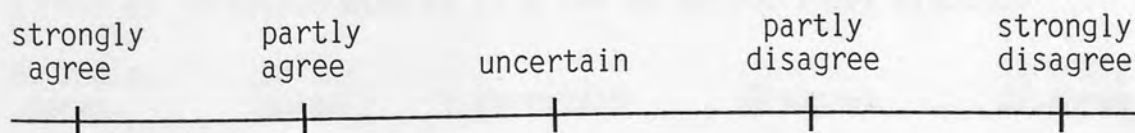
12. I carry glucose sweets or some carbohydrate with me



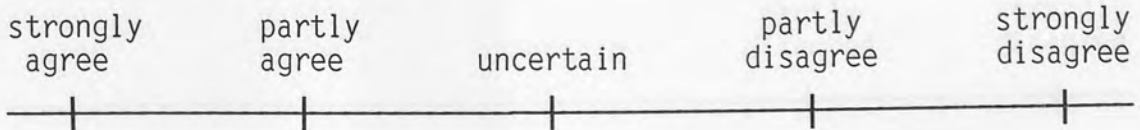
13. I carry identification that I am diabetic



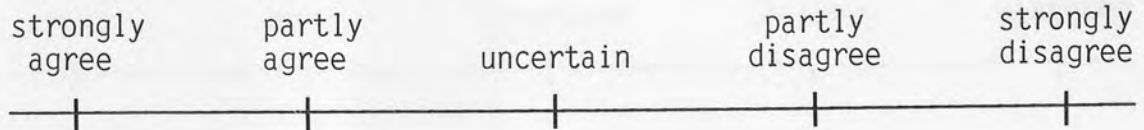
14. I do not have the time to look after my diabetes as I should



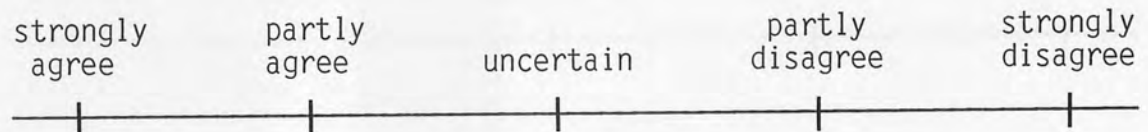
15. I always stick to my diet



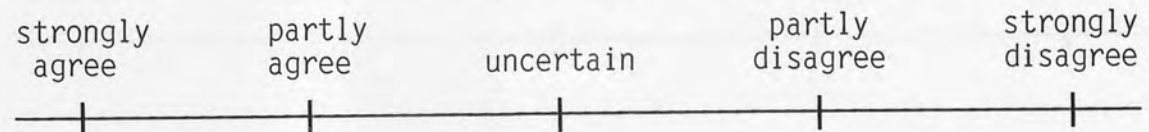
16. It is difficult for me to have regular meals because of my lifestyle (e.g. work, social life, family)



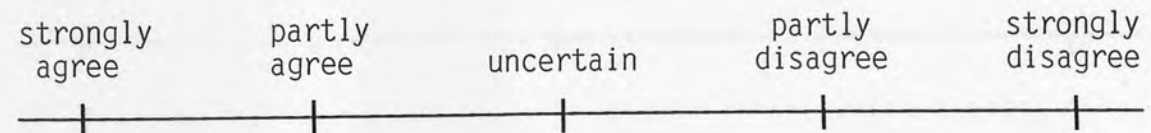
17. I live for today and do not think much about what can happen to me in the future



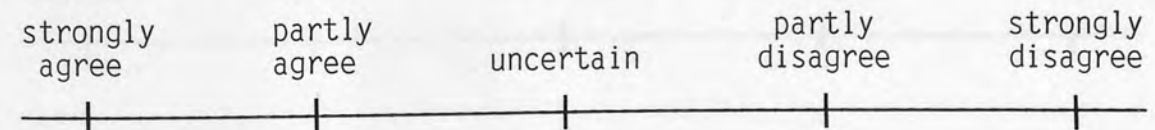
18. When I am on holiday I tend to forget about my diabetes



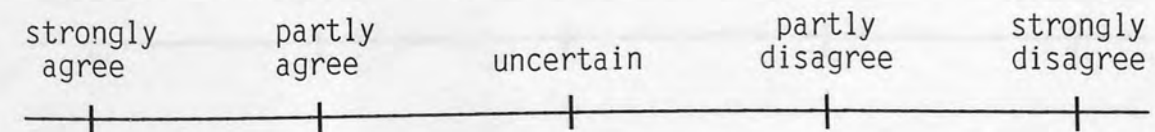
19. Having a high urine/blood sugar (glucose) does not worry me



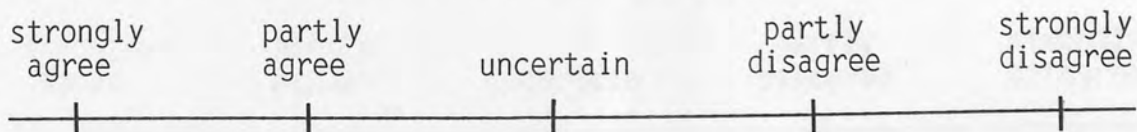
20. Coming to the clinic is often a waste of time



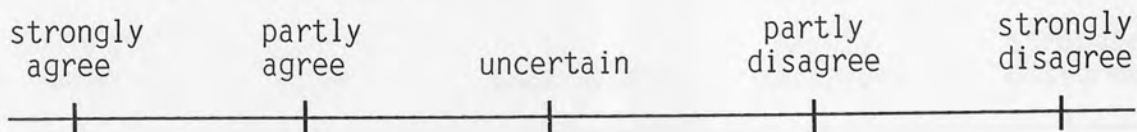
21. I feel as satisfied with my life now as before I got diabetes



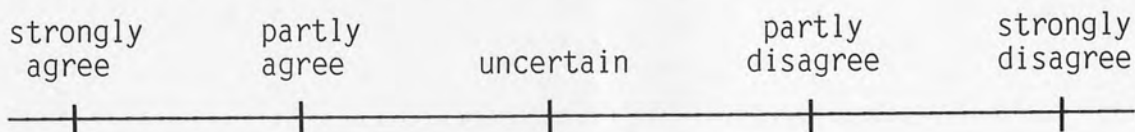
22. I try and control my diabetes as much as possible



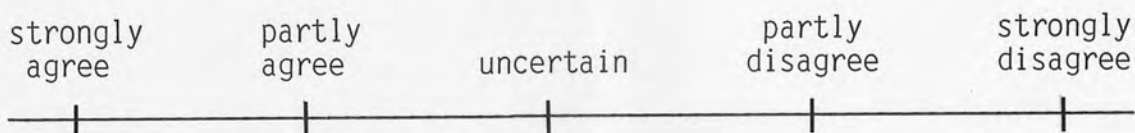
23. Exercise can help my diabetes



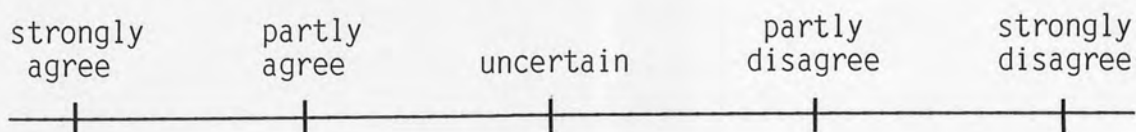
24. I can do just about anything I set out to do



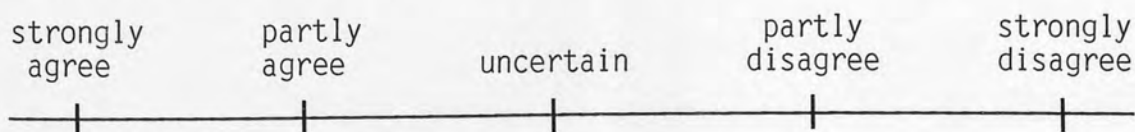
25. I would increase my insulinn dose if I had 'flu



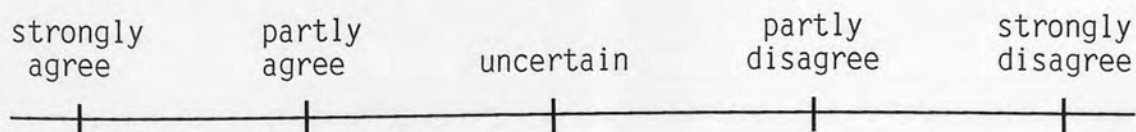
26. Your diabetes is not usually well controlled



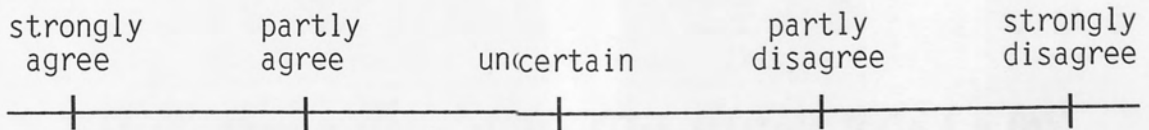
27. I do not think it matters what your urine/blood sugar (glucose) is



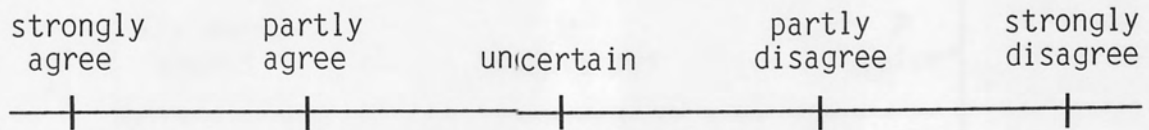
28. I do not mind complying with my diet and insulin



29. I eat more carbohydrate than is allowed in my diet



30. My diabetes is well controlled



THANK YOU FOR YOUR HELP

Discriminatory Analysis of the Pilot Attitude Scale 1 - DAS1

Statement Number	W Statistic*	P Value*
1	28.5	0.10
2	33.5	0.42
3	37.5	0.87
4	25.0	0.03
5	25.0	0.03
6	39.0	1.00
7	30.0	0.17
8	33.0	0.37
9	33.0	0.30
10	39.0	1.00
11	27.0	0.06
12	33.0	0.37
13	33.0	0.37
14	27.0	0.06
15	28.5	0.10
16	27.0	0.06
17	38.5	1.00
18	30.5	0.17
19	27.0	0.06
20	42.0	0.60
21	29.0	0.12
22	34.0	0.52
23	40.5	0.80
24	24.0	0.02
25	25.0	0.03
26	22.5	0.01
27	32.0	0.29
28	24.0	0.02
29	24.5	0.02
30	36.5	0.74

\* Derivative of Mann-Whitney statistic and appropriate significance levels computed by Minitab Statistics programme

APPENDIX 3.3

Statements selected from Pilot Test (DAS1)

Discriminating Power p<0.05 Statement Numbers	Discriminating Power p<0.1 Statement Numbers	Additional Statement
4	7	12
5	14	15*
24	16	16*
25	18	
26	19	
28	21	
29		

Statement numbers as indicated on DAS1 (Appendix 3.1)

\* Additional statements refer to numbers on DAS2 (Appendix 3.4)

(ATT. SCA. No. 2)

Group A

A= B= C= Total=

Group B

NAME \_\_\_\_\_ UNIT NO. \_\_\_\_\_

INSULIN DEPENDENT DIABETES QUESTIONNAIRE (B)

We would be very grateful if you would complete this short questionnaire. Your answers will be treated in strict confidence. Please be HONEST

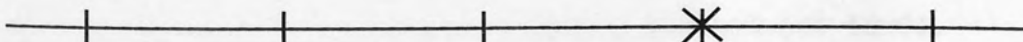
INSTRUCTIONS

1. Please read each sentence carefully.
2. Decide how much you agree or do not agree with each sentence.
3. Make an 'X' at that point along the scale under the sentence.

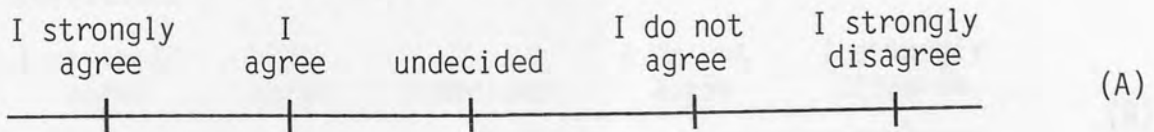
EXAMPLE

Coming to the diabetic clinic is a waste of time!

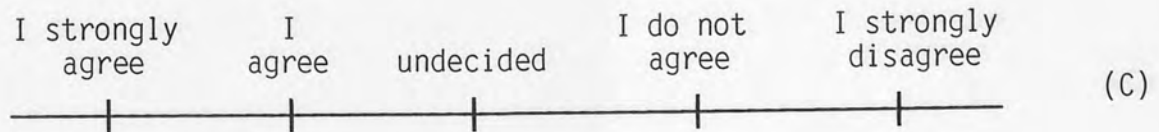
I strongly agree	I agree	undecided	I do not agree	I strongly disagree
------------------	---------	-----------	----------------	---------------------



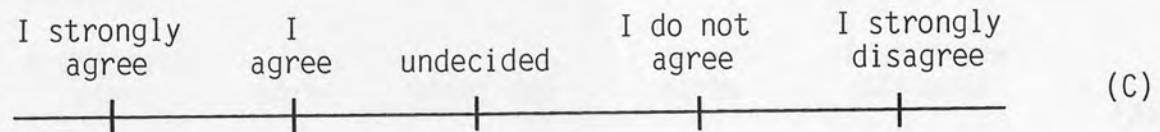
1. You are as happy with your life now as before you got diabetes.



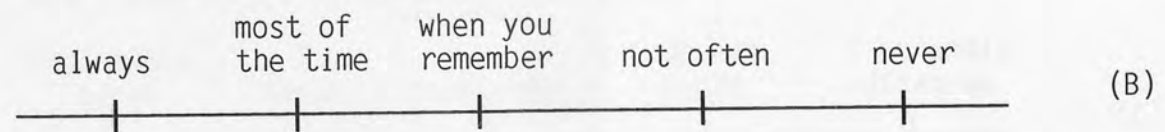
2. There is nothing you can do now to prevent some of the complications of diabetes.



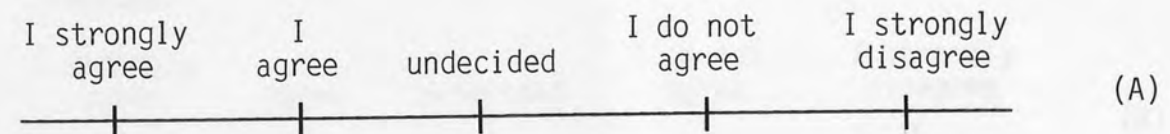
3. The diabetic diet does not really help 'you'.



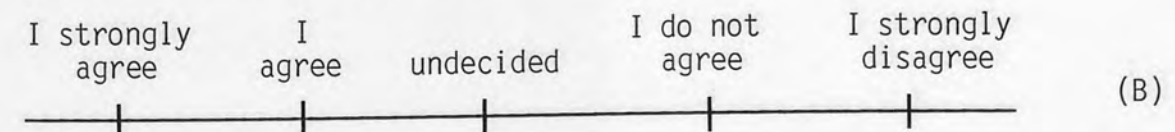
4. You carry glucose sweets or other carbohydrates with you:



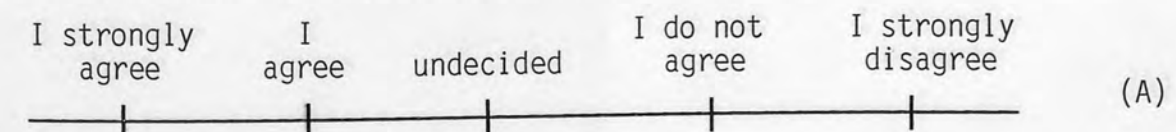
5. You feel it is unfair having to always be careful about your diabetes.



6. When you are on holiday or away from home you are less careful about your diabetes.

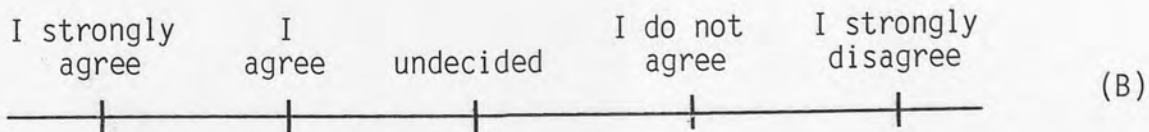


7. You feel able to do just anything you set out to do.

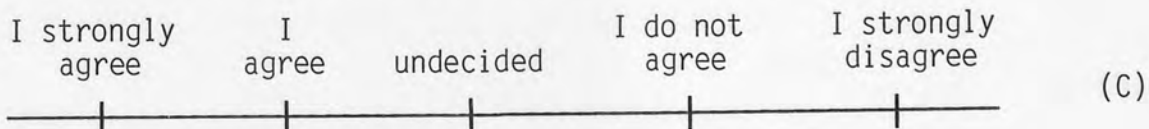




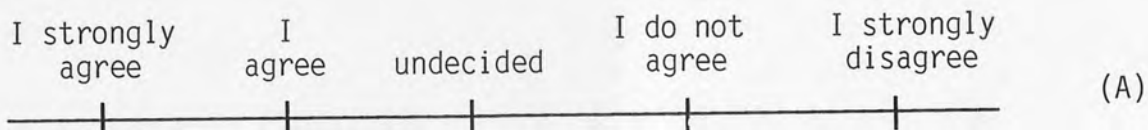
8. You would increase your insulin if you had the flu or an infection.



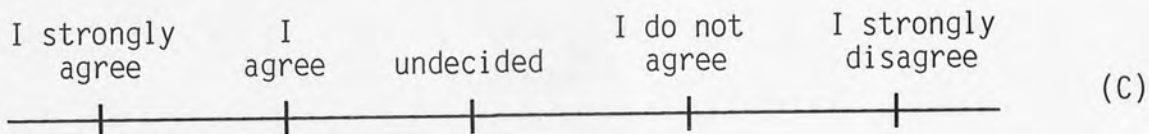
9. Looking after your diabetes properly takes up too much time.



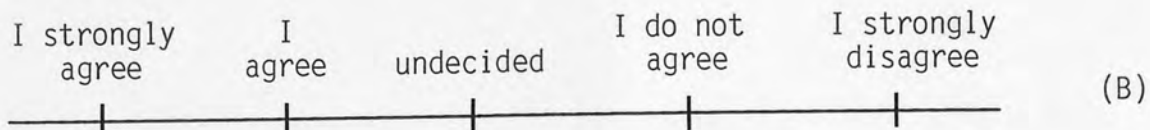
10. You like to know what your urine or blood glucose (sugar) level is.



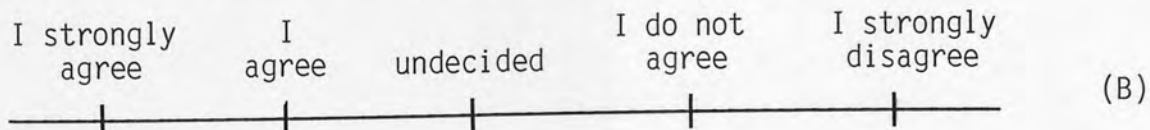
11. Your diabetes is always well controlled.



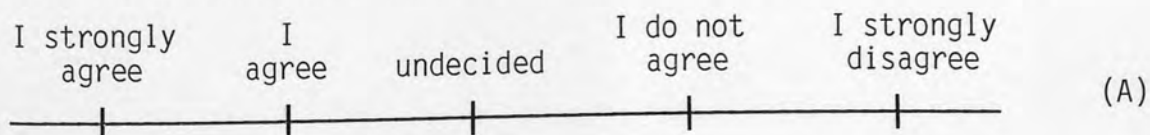
12. You often find it hard to have regular meals because of your lifestyle.



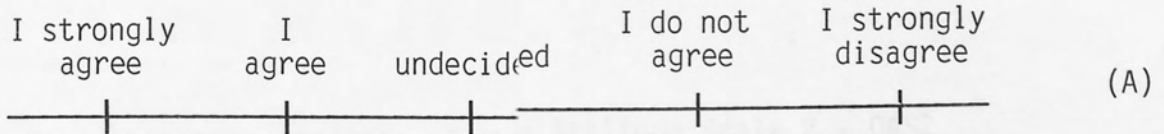
13. You often eat more carbohydrate than is allowed in your diet.



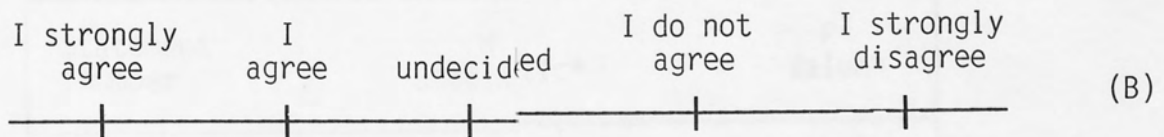
14. You really don't like having to keep to a diet and take insulin



15. Your family understand your diet.



16. Your family helps you to keep to your diet.



Discriminatory Analysis of the Attitude Scale 2 - DAS2

Statement Number	W Statistic*	P Value*
1	808.0	0.003
2	702.0	0.1
3	825.0	0.001
4	827.5	0.001
5	847.0	0.001
6	851.5	1.001
7	740.0	0.02
8	778.0	0.002
9	771.0	0.003
10	828.0	1.001
11	825.0	0.001
12	810.0	0.001
13	727.0	0.04
14	776.0	0.002
15	861.0	0.001
16	852.0	0.001

\* Derivative of Mann-Whitney statistic and appropriate significance levels computed by Minitab Statistics programme

(ATT. SCA. No. 2)

Group A

A= B= C= Total=

Group B

NAME \_\_\_\_\_ UNIT NO. \_\_\_\_\_

INSULIN DEPENDENT DIABETES QUESTIONNAIRE (B)

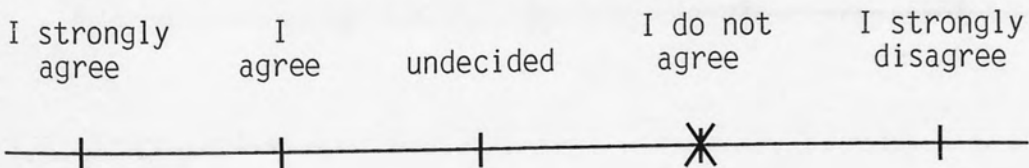
We would be very grateful if you would complete this short questionnaire. Your answers will be treated in strict confidence. Please be HONEST

INSTRUCTIONS

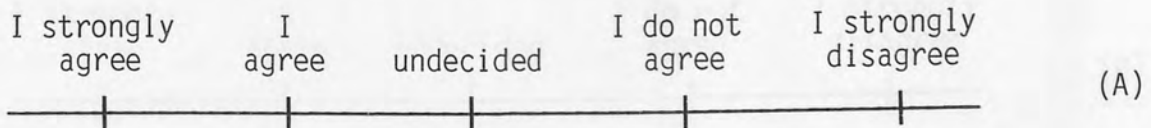
1. Please read each sentence carefully.
2. Decide how much you agree or do not agree with each sentence.
3. Make an 'X' at that point along the scale under the sentence.

EXAMPLE

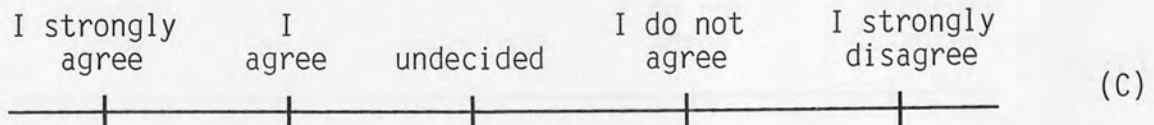
Coming to the diabetic clinic is a waste of time!



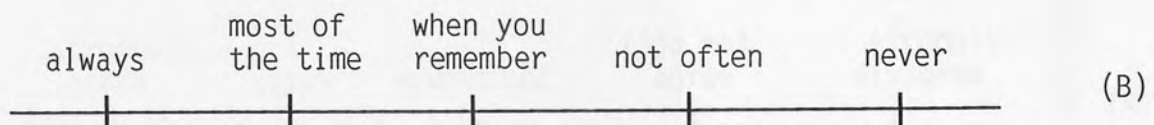
1. You are as happy with your life now as before you got diabetes.



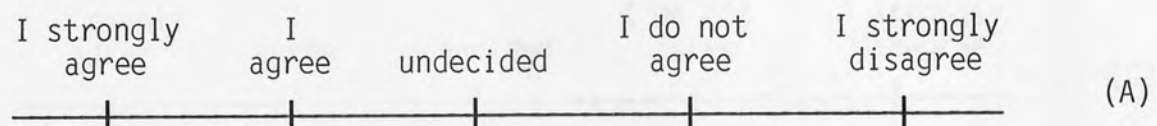
2. The diabetic diet does not really help 'you'.



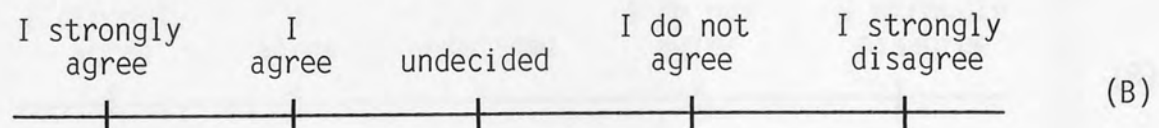
3. You carry glucose sweets or other carbohydrates with you:



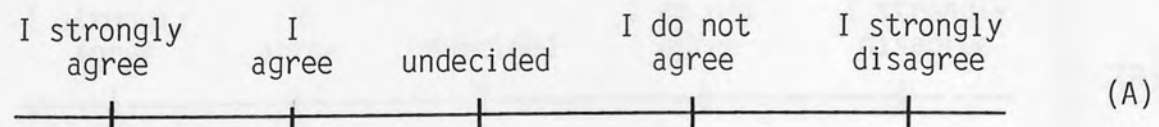
4. You feel it is unfair having to always be careful about your diabetes.



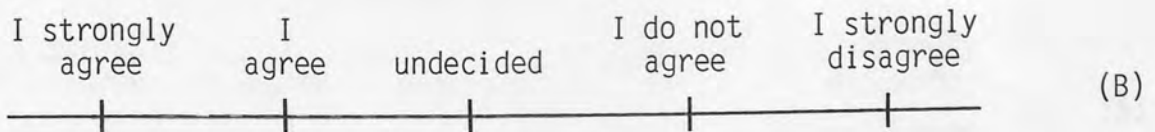
5. When you are on holiday or away from home you are less careful about your diabetes.



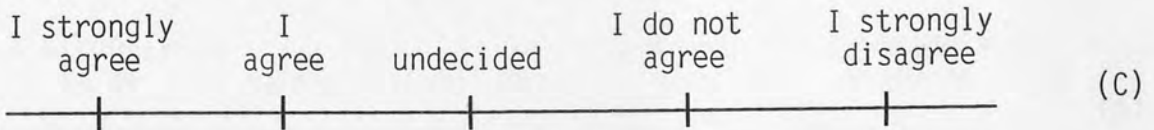
6. You feel able to do just anything you set out to do.



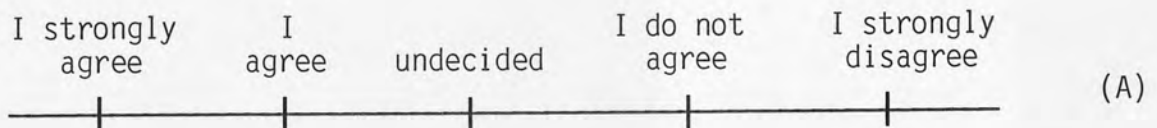
7. You would increase your insulin if you had the flu or an infection.



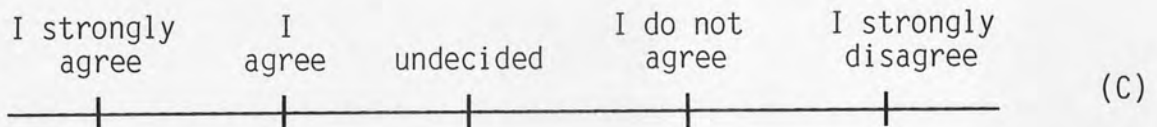
8. Looking after your diabetes properly takes up too much time.



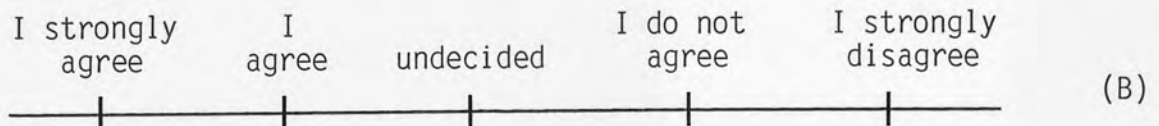
9. You like to know what your urine or blood glucose (sugar) level is.



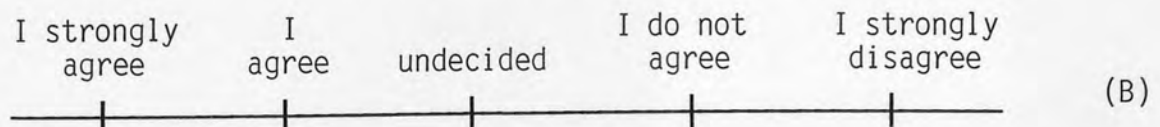
10. Your diabetes is always well controlled.



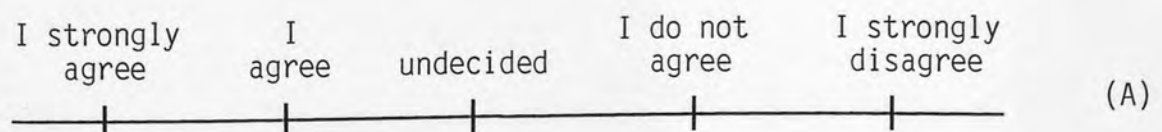
11. You often find it hard to have regular meals because of your lifestyle.



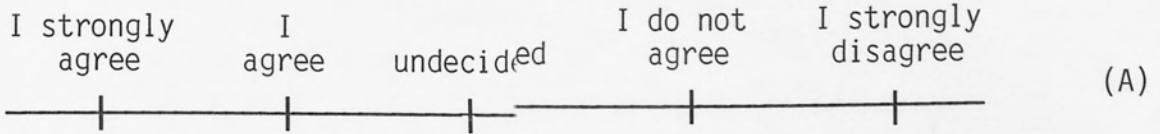
12. You often eat more carbohydrate than is allowed in your diet.



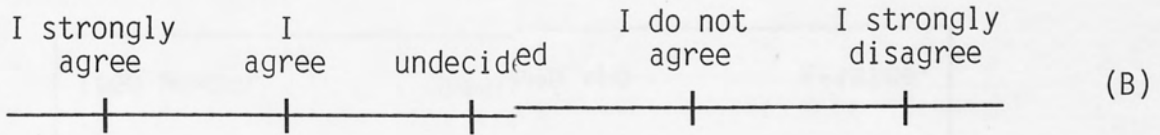
13. You really don't like having to keep to a diet and take insulin



14. Your family understand your diet.



15. Your family helps you to keep to your diet.



Item-total score rank correlation coefficients of DAS2m

Item Number	Spearman rho rs	P-value*
1	0.47	0.01
2	0.44	0.02
3	0.48	0.01
4	0.58	0.01
5	0.57	0.01
6	0.31	0.05
7	0.33	0.05
8	0.45	0.02
9	0.48	0.01
10	0.50	0.01
11	0.43	0.02
12	0.29	0.05
13	0.41	0.05
14	0.60	0.05
15	0.53	0.01

\* P-values indicate level of significance by a two-tailed test



Factor Pattern Matrix for DAS2m

	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
ATT1	0.19742	-0.37435	-0.16508	-0.19486	-0.66438
ATT2	0.49885	0.01163	0.01023	-0.10839	0.20828
ATT3	-0.06001	-0.04428	-0.10578	-0.45682	0.12107
ATT4	0.34923	-0.08961	-0.10586	-0.21195	0.07387
ATT5	0.04998	-0.28639	-0.23549	-0.12678	0.35228
ATT6	0.65796	-0.01966	0.01437	0.17215	-0.08229
ATT7	-0.21951	-0.28652	0.04082	-0.35663	-0.08357
ATT8	0.37037	-0.04570	-0.09682	-0.19034	-0.01560
ATT9	0.25631	0.25115	0.00544	-0.84166	0.03223
ATT10	0.28894	-0.34247	-0.12821	-0.03237	-0.01222
ATT11	0.11471	-0.57713	0.16100	-0.02244	0.03791
ATT12	0.07546	-0.09804	-0.00290	-0.09707	0.44757
ATT13	-0.09393	-0.45645	-0.28703	0.12173	-0.03592
ATT14	0.09188	-0.04825	-0.86142	0.08965	0.08784
ATT15	-0.00966	0.16867	-0.78366	-0.11670	-0.09919

APPENDIX 3.9

Distribution of DAS2m items among underlying factors

Factor Number	Item Number
1	2, 4, 6, 8
2	1, 10, 11, 13
3	14, 15
4	3, 7, 9
5	5, 12

Ref

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1-3

Charing Cross Hospital (Fulham)

DEPARTMENT OF ENDOCRINOLOGY

DIABETIC PATIENT

QUESTIONNAIRE

Q. No.	Q. Text	Yes	No	Don't Know
1	1. I feel very well most of the time			
2	2. I feel a constant tiredness			
3	3. I feel nervous and shaky			
4	4. I feel thirsty and I drink a lot of water			
5	5. I have a constant hunger			
6	6. I feel a constant itching of the skin			
7	7. People seem to notice when I am nervous			
8	8. It is quite hard to keep my weight			
9	9. It is a relief to be able to eat what I like			
10	10. I feel a constant thirst			
11	11. As a diabetic you feel different to other people			

1984



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(ATT. SCA. 2)

GROUP A

GROUP B

NAME \_\_\_\_\_

UNIT NO. \_\_\_\_\_

INSULIN DEPENDENT DIABETES QUESTIONNAIRE (B)

I would be very grateful if you would complete this short questionnaire. Your answers will be treated in strict confidence. Please be honest about your answers.

INSTRUCTIONS

1. Please read each statement carefully.
2. Look at the choice of answers at the top of the page and decide how much you agree or disagree.
3. Put a tick in the box which best describes how you feel about it.

THANK YOU



	I strongly agree	I agree	un-decided	I disagree	I strongly disagree
1. Being diabetic is a disadvantage in life.					
2. You feel you are able to take part in everything you want, even though you have diabetes.					
3. You could be more careful about your diabetes if you tried.					
4. Your diabetes can be a nuisance for your family.					
5. It is better to know as much as possible about diabetes.					
6. You feel that you can control your own diabetes.					
7. Having a 'hypo' is embarrassing when other people are around.					
8. Doctors and nurses make too much fuss about diabetic control.					
9. Attending the Diabetic Clinic is <u>very</u> important.					
10. When you are on holiday or away from home you are just as careful about your diabetes.					
11. Blood and urine tests are very important to you					
12. The public could be more helpful towards diabetics.					



APPENDIX 3.12

Discriminatory Analysis of the Attitude Scale 3 - DAS3

Statement Number	W Statistic*	P Value*
1 +	286.5	0.001
2 +	305.0	0.001
3	239.0	0.21
4 +	281.5	0.001
5 +	265.5	0.01
6 +	279.0	1.002
7	246.5	0.1
8 +	262.0	0.02
9 +	271.5	0.07
10 +	263.5	1.02
11 +	259.0	0.03
12	219.0	0.71
13 +	290.0	0.001
14 +	257.0	0.004
15 +	265.0	0.01
16	241.5	0.17
17	236.0	0.26
18 +	279.0	0.002
19 +	256.0	0.04
20	225.5	0.60

\* Derivative of Mann-Whitney statistic and appropriate significance levels computed by Minitab Statistics programme

+ Indicates statement number used in DAS3

APPENDIX 3.13

(ATT. SCA. 2)

GROUP A

GROUP B

NAME \_\_\_\_\_

UNIT NO. \_\_\_\_\_

INSULIN DEPENDENT DIABETES QUESTIONNAIRE (B)

I would be very grateful if you would complete this short questionnaire. Your answers will be treated in strict confidence. Please be honest about your answers.

INSTRUCTIONS

1. Please read each statement carefully.
2. Look at the choice of answers at the top of the page and decide how much you agree or disagree.
3. Put a tick in the box which best describes how you feel about it.

THANK YOU

1. Being diabetic is a disadvantage in life.
2. You feel you are able to take part in everything you want, even though you have diabetes.
3. Your diabetes can be a nuisance for your family.
4. It is better to know as much as possible about diabetes.
5. You feel that you can control your own diabetes.
6. Doctors and nurses make too much fuss about diabetic control.
7. Attending the Diabetic Clinic is very important.
8. When you are on holiday or away from home you are just as careful about your diabetes.
9. Blood and urine tests are very important to you
10. You would increase your insulin if you had an infection and your blood or urine sugar level was high.
11. Doctors make too much fuss about diabetic complications.

	I strongly agree	I agree	un-decided	I disagree	I strongly disagree
1. Being diabetic is a disadvantage in life.					
2. You feel you are able to take part in everything you want, even though you have diabetes.					
3. Your diabetes can be a nuisance for your family.					
4. It is better to know as much as possible about diabetes.					
5. You feel that you can control your own diabetes.					
6. Doctors and nurses make too much fuss about diabetic control.					
7. Attending the Diabetic Clinic is <u>very</u> important.					
8. When you are on holiday or away from home you are just as careful about your diabetes.					
9. Blood and urine tests are very important to you					
10. You would increase your insulin if you had an infection and your blood or urine sugar level was high.					
11. Doctors make too much fuss about diabetic complications.					

12. You often eat more carbohydrate than you actually need.

13. You feel that your diabetic diet is too difficult to keep to.

14. The thought of insulin injections for the rest of your life does not bother you.

	I strongly agree	I agree	un-decided	I disagree	I strongly disagree

\*\*\*\*\* THANK YOU \*\*\*\*\*

APPENDIX 3.14

Item-total score rank correlation coefficients of DAS3m

Item Number	Spearman rho rs	P-value*
1	0.49	0.01
2	0.59	0.01
3	0.35	0.05
4	0.57	0.01
5	0.47	0.01
6	0.46	0.01
7	0.55	0.01
8	0.56	0.01
9	0.45	0.01
10	0.65	0.01
11	0.43	0.01
12	0.27	0.05
13	0.56	0.01
14	0.37	0.05

\* P-values indicate level of significance by a two-tailed test

Factor Pattern Matrix for DAS3m

	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
ATT1	0.56118	0.06709	-0.04537	-0.07811	0.13454
ATT2	0.67141	-0.15458	-0.02648	0.04597	-0.10218
ATT3	0.58963	0.07908	-0.00265	0.11931	-0.18655
ATT4	0.09234	-0.65711	0.03182	-0.10867	-0.22813
ATT5	0.51283	-0.14119	-0.00142	-0.08620	0.09490
ATT6	0.09819	-0.56048	-0.00936	0.00439	0.11328
ATT7	-0.02331	-0.81881	-0.03755	-0.05658	-0.18027
ATT8	-0.00065	-0.20271	-0.57516	0.22678	-0.02438
ATT9	-0.08440	-0.23564	-0.15114	-0.04102	-0.68104
ATT10	0.12592	-0.04239	-0.11061	-0.93493	-0.13106
ATT11	-0.07147	-0.37324	0.06329	-0.42251	0.09024
ATT12	-0.00667	0.10608	-0.44836	-0.14113	0.03349
ATT13	0.11366	0.05185	-0.90167	-0.05972	-0.13500
ATT14	0.24883	0.28680	-0.05015	-0.03868	-0.34110



APPENDIX 3.16

Distribution of DAS3m items among underlying factors

Factor Number	Item Number
1	1, 2, 3, 5
2	4, 6, 7
3	8, 12, 13
4	10, 11
5	9, 14

APPENDIX 4

This includes the objectives and questionnaires used in the assessment of diabetic knowledge, and results of psychometric tests used in development procedures

TEACHING PLAN FOR INSULIN DEPENDENT DIABETICS

	Taught by	Outcome	Date
Basic knowledge of diabetes mellitus			
URINE TESTING: How/why recording When to test Various test strips			
Introduction to basic equipment on N.H.S.  Care of equipment			
INJECTIONS: Sites Technique Family or friend to learn			
INSULIN: What it is Action Storage Times of injection Dose Altering dose Illness and insulin			
"HYPO'S": Causes Signs and symptoms Treatment Experience Relatives aware			
Importance of carrying diabetic identity			

	Taught by	Outcome	Date
Diet Diet and illness			
Importance of diet in Diabetic control			
Weight			
Hyperglycaemia			
Causes			
Signs and symptoms			
Treatment			
Ketoacidosis			
Home monitoring of blood glucose levels			
Normal levels			
BM stix - how to use			
Recording results			
Various meters			
Care of feet			
Pregnancy			
Importance of control			
Breast feeding			
Smoking			
Exercise			
Insurance			
Car driving			
Shift work			
Holidays/travel			
Alcohol			
British Diabetic Association			

DATE	PROGRESS AND FOLLOW-UP	WARD/OPD

DIABETIC QUESTIONNAIRE

Patient's Name \_\_\_\_\_ DRH No. \_\_\_\_\_

Please tick the answer which you consider is most appropriate.

1. The usual cause of diabetes is
  - (a) not eating enough food
  - (b) failure of the pancreas to make enough insulin
  - (c) failure of the kidneys to control glucose in the urine
  - (d) I do not know
  
- 2i. You test your urine
  - (a) for practice
  - (b) to make sure you are passing enough urine
  - (c) to check that your blood glucose is not too high
  - (d) I do not know
  
- 2ii. A normal blood glucose level should be between
  - (a) 10-17 mmol/l
  - (b) 17-25 mmol/l
  - (c) 3.5-8 mmol/l
  - (d) I do not know
  
- 3i. When you test your urine there should be
  - (a) no sugar or only a trace of sugar
  - (b) more than 2% sugar
  - (c) 1% sugar or more
  - (d) I do not know

- 3iii. When testing your blood glucose using test strips (BM-test Glycemie 20-800), the colours should be
- (a) white and very light blue
  - (b) fawn and medium blue
  - (c) dark green and dark blue
  - (d) I don't know
- 4i. When testing your urine with Diastix which colour tells you that your glucose level is satisfactory
- (a) dark brown
  - (b) medium brown
  - (c) light blue/green
  - (d) I do not know
- 4ii. When your blood glucose is more than 10 mmol/l it tells you that
- (a) you may need more insulin
  - (b) you may need less insulin
  - (c) it doesn't matter
  - (d) I don't know
5. Insulin causes the level of blood glucose
- (a) to increase
  - (b) to decrease
  - (c) to stay the same
  - (d) I do not know
6. Do you normally store your insulin
- (a) in the freezer
  - (b) in the refrigerator
  - (c) in a warm room
  - (d) nowhere in particular

7. The morning injection of insulin should be given
  - (a) 1 hour before breakfast
  - (b) 20 minutes before breakfast
  - (c) 30 minutes after breakfast
  - (d) I do not know
  
8. Your insulin injections should be given
  - (a) at the same place all the time
  - (b) using arms, legs and abdomen
  - (c) on a different part of the thigh each time
  - (d) I do not know
  
9. When you give your insulin injection you should hold the syringe and needle
  - (a) at  $45^{\circ}$  to the skin
  - (b) at  $90^{\circ}$  to the skin
  - (c) almost parallel to the skin
  - (d) I don't know
  
10. Your injection(s) of insulin needs to last
  - (a) during the day only
  - (b) all day and all night
  - (c) only during the main meals
  - (d) I do not know
  
11. You can safely miss your insulin for
  - (a) one injection
  - (b) one whole day
  - (c) not at all
  - (d) I do not know



12. If you become ill with a cold, sore throat or 'flu, would you expect your blood glucose (or urine glucose test) to
- (a) get worse
  - (b) stay the same
  - (c) get better
  - (d) I do not know
13. If you were going to take a lot of exercise (e.g playing sport) you would be best advised to keep your insulin the same and
- (a) increase your carbohydrates
  - (b) decrease your carbohydrates
  - (c) keep your carbohydrates unchanged
  - (d) I do not know
14. A hypoglycaemic/insulin reaction is brought about because
- (a) you have had too much insulin and not enough rations
  - (b) you have had not enough insulin and too many rations
  - (c) you haven't taken enough exercise
  - (d) I do not know
15. When you know that a hypoglycaemic/insulin reaction is coming on, do you normally
- (a) have another injection of insulin
  - (b) try and forget it
  - (c) eat something containing sugar or glucose
  - (d) I do not know
16. What symptoms tell you that your glucose level is too high
- (a) sweating and trembling
  - (b) you pass more urine and feel thirsty
  - (c) You feel more energetic than usual
  - (d) I do not know

17. If your urine contains ketones, which you can identify with Ketostix test strips or Acetest tablet, you should
- (a) stop your insulin
  - (b) decrease your insulin
  - (c) increase your insulin
  - (d) I do not know
18. Good control of your glucose level will cut down the risk of other medical conditions associated with diabetics, such as
- (a) disorders of bones and joints, like arthritis
  - (b) disorders of eyesight, blood vessels and kidneys
  - (c) contagious diseases, like mumps and German measles
  - (d) I do not know
19. It is important to take good care of your feet because
- (a) flat feet is associated with diabetes
  - (b) diabetics can have a poor circulation in their feet and legs
  - (c) insulin injections into the legs may cause swelling of the feet
  - (d) I do not know
20. In your diet should you
- (a) eat every kind of food, including sweets and puddings
  - (b) avoid foods which are high in sugar
  - (c) avoid all proteins
  - (d) I do not know
21. Which of the following is counted as carbohydrate
- (a) roast beef
  - (b) brussel sprouts
  - (c) potatoes
  - (d) I do not know

22. It is better to eat

- (a) the same number of carbohydrate rations at lunch each day
- (b) a different number of carbohydrate rations at lunch each day
- (c) extra carbohydrate rations at lunch on weekends
- (d) I do not know

Thank you very much for taking the time to answer these questions.  
We are very pleased to answer any queries you may have.

Dudley Road Hospital  
and Aston University

GC/CJB/KGT 1/83

(G.M. COWAN - D.R.H.)

PRETEST (1)

INSULIN DEPENDENT DIABETIC QUESTIONNAIRE

1. Please choose the option(s) which you think complete the statement or answer the question.
2. Mark an 'X' in the box next to your choice.
3. Remember you may choose more than one option if you think it is correct.

NAME \_\_\_\_\_

ARE YOU A PATIENT OR HOSPITAL STAFF?

A PATIENT

HOSPITAL STAFF

1. Diabetes is a condition which

- (a) can be controlled with treatment
- (b) you will have for the rest of your life
- (c) occurs when you eat too much sugar
- (d) occurs when there is not enough insulin
- (e) I do not know

2. Insulin causes the amount of glucose in the blood to

- (a) increase
- (b) decrease
- (c) stay the same
- (d) I do not know

3. You should have your insulin injection

- (a) 5 - 10 minutes before a meal
- (b) 15 - 30 minutes before a meal
- (c) 35 - 40 minutes before a meal
- (d) 10 - 15 minutes after a meal
- (e) I do not know

4. You should store your insulin in

- (a) a warm, dark place
- (b) a freezer
- (c) a fridge
- (d) in some other cool place
- (e) I do not know

5. Where do you inject your insulin?

- (a) on different part of the thigh each time
- (b) either the thighs, arms or stomach
- (c) in the arms only
- (d) I do not know

6. Clear insulins act

- (a) quicker than cloudy ones
- (b) slower than cloudy ones
- (c) just the same as cloudy ones
- (d) I do not know

7 i) When you test your urine there should be

- (a) no sugar
- (b) a trace of sugar
- (c) 1% sugar
- (d) I do not know

7 ii) What do you think a normal blood glucose (sugar) is?

- (a) 4 to 7 mmol/l
- (b) 10 to 17 mmol/l
- (c) 17 to 25 mmol/l
- (d) 1 to 4 mmol/l
- (e) I do not know

8. Testing your urine or blood for glucose (sugar) should be done

- (a) only once a week
- (b) only when you feel ill
- (c) once or twice a day
- (d) only when you feel like it
- (e) I do not know

9. You should test your urine for ketones

- (a) when you have a high blood or urine glucose (sugar level)
- (b) when you feel ill
- (c) when your blood or urine glucose (sugar) level is low
- (d) I do not know

10. If you have a high blood or urine glucose (sugar) level and ketones were present would you

- (a) contact the hospital or see your own doctor
- (b) take more insulin
- (c) take less insulin
- (d) keep your insulin and diet the same and test your blood/urine the next day
- (e) I do not know

11. Some of the common symptoms of a hypoglycaemic or insulin reaction are

- (a) feeling hungry and sweaty
- (b) blurred vision
- (c) feeling sick and thirsty
- (d) feeling weak and trembling
- (e) passing a lot of urine
- (f) I do not know

12. If you feel a 'hypo' or insulin reaction coming on you should

- (a) take some exercise
- (b) have 4 units of insulin immediately
- (c) rest for half an hour or until you feel better
- (d) eat a wholemeal bread sandwich
- (e) take some glucose sweets or sugar
- (f) I do not know

13. A hypo or insulin reaction might be caused by

- (a) being less active than usual
- (b) taking too much insulin
- (c) missing a meal
- (d) missing your insulin injection
- (e) being more active than usual
- (f) I do not know

14. Some signs of a very high blood glucose (sugar) levels are

- (a) passing a lot of urine
- (b) feeling hungry
- (c) feeling thirsty
- (d) feeling sick
- (e) I do not know



15. High blood glucose (sugar) levels can be caused by

- (a) eating too much food (carbohydrates)
- (b) forgetting to have your insulin
- (c) having too much insulin
- (d) doing too much exercise
- (e) getting an infection
- (f) being upset and worried
- (g) I do not know

16. Before doing extra exercise like gardening or sport you should

- (a) cut down your insulin
- (b) take more insulin
- (c) have the same insulin dose and take more carbohydrate
- (d) cut down your insulin and take more carbohydrate
- (e) I do not know

17. If you have a cold or flu and do not want to eat, you should

- (a) stop taking your insulin
- (b) take less insulin than usual
- (c) take the same or more insulin
- (d) I do not know

18. Do you carry with you or wear some form of identification that you are a diabetic?

- (a) always
- (b) sometimes, when you remember
- (c) never

19 i) Do you carry some sweets or other form of carbohydrates with you?

(a) YES

(b) NO  → GO TO QUESTION 20.

19 ii) What do you usually carry with you?

(a) dextrose sweets

(b) biscuits

(c) some kind of sweets

(d) bread

(e) any other - specify  \_\_\_\_\_

20. Cuts or sores on diabetic's feet may be slow to heal or become infected because

(a) diabetics have been born that way

(b) diabetics can have a poor circulation in their feet and legs

(c) diabetics may not feel the cuts and sores

(d) taking insulin slows down the healing of the wounds

(e) I do not know

21. To check for any long term complications due to your diabetes, your doctor may examine

(a) your hearing

(b) your blood pressure

(c) your feet

(d) your kidneys

(e) your eyes

(f) I do not know

22. Smoking by a diabetic

- (a) increases the risk of damage to the blood vessels
- (b) can cause poor blood circulation in the legs
- (c) increases the risk of heart disease
- (d) has no particular effect different than in a non-diabetic person
- (e) I do not know

23. A portion in your diet is

- (a) an amount of food that weighs 10 grams
- (b) an amount of food that contains 10 grams of carbohydrate
- (c) all protein foods that weigh 10 grams
- (d) I do not know

24. Which of the following foods would you count in your diet?

- (a) brussel sprouts
- (b) potatoes
- (c) carrots
- (d) apples
- (e) grapefruits
- (f) bread
- (g) chicken
- (h) sausages

25. Which of the following foods are high in fibre?

- (a) brown bread
- (b) green beans
- (c) baked beans
- (d) cornflakes
- (e) all bran
- (f) I do not know

26. A healthy diabetic diet contains

- (a) foods high in fat
- (b) foods low in fat
- (c) foods high in fibre
- (d) foods high in protein
- (e) I do not know

27. Being diabetic you should eat foods containing carbohydrates

- (a) at regular intervals throughout the day
- (b) only when you are feeling 'hypo'
- (c) when you are feeling hungry
- (d) after you have had an insulin injection
- (e) I do not know

I would be grateful if you would answer the following questions concerning the questionnaire you have just completed.

1. Did you find the length of the questionnaire

(a) very long

(b) an acceptable length (reasonable)

(c) fairly short

(d) undecided

2. Were there any questions which you did not understand or that could have been explained better?

(a) NO

(b) YES

Please write the question numbers here

ANY OTHER COMMENTS \_\_\_\_\_

'THANK YOU SO MUCH FOR YOUR HELP'

INSULIN DEPENDENT DIABETIC QUESTIONNAIRE

1. Please read each statement or question and choose the option(s) which complete the statement or answer the question.
2. Mark an 'X' in the box next to your choice.
3. Remember you may choose more than one option.

NAME \_\_\_\_\_

UNIT NO. \_\_\_\_\_

On this copy of the questionnaire the symbol ● has been added to denote an acceptable correct option.

1. Insulin causes the amount of glucose in the blood to

- (a) increase
- (b) decrease
- (c) stay the same
- (d) I do not know

2. You should have your insulin injection

- (a) 5 to 10 minutes before a meal
- (b) 15 to 30 minutes before a meal
- (c) 35 to 40 minutes before a meal
- (d) 10 to 15 minutes after a meal
- (e) I do not know

3 i) When you test your urine there should be

- (a) no sugar
- (b) a trace of sugar
- (c) 1% sugar
- (d) I do not know

3 ii) What do you think a normal blood glucose (sugar) is?

- (a) 4 to 7 mmol/l
- (b) 10 to 17 mmol/l
- (c) 17 to 25 mmol/l
- (d) 1 to 4 mmol/l
- (e) I do not know

4. If you feel a 'hypo' or insulin reaction coming on you should

- (a) sit down and rest for half an hour or until you feel better
- (b) eat something sweet immediately
- (c) keep eating until it goes away
- (d) I do not know

5. A hypo or insulin reaction might be caused by

- (a) being less active than usual
- (b) taking too much insulin
- (c) missing a meal
- (d) missing your insulin injection
- (e) being more active than usual
- (f) I do not know

6. Some signs of a very high blood glucose (sugar) level are

- (a) passing a lot of urine
- (b) feeling hungry
- (c) feeling thirsty
- (d) feeling sick
- (e) I do not know

7. If you have a cold or flu and do not want to eat, you should

- (a) stop taking your insulin
- (b) take less insulin than usual
- (c) take the same or more insulin
- (d) I do not know



8. Before doing extra exercise like gardening or sport you could

- (a) cut down your insulin  ●
- (b) take more insulin
- (c) have the same insulin dose and take more carbohydrates
- (d) keep your insulin and diet the same  ●
- (e) I do not know

9. Cuts or sores on diabetic's feet may be slow to heal or become infected because

- (a) diabetics have been born that way
- (b) diabetics can have a poor circulation in their feet and legs  ●
- (c) taking insulin slows down the healing of the wounds
- (d) I do not know

10. Which of the following foods would you count as carbohydrate in your diet?

- (a) brussel sprouts
- (b) potatoes  ●
- (c) apples  ●
- (d) half a grapefruit
- (e) bread  ●
- (f) chicken
- (g) sausages  ●
- (h) beefburgers  ●
- (i) I do not know

11. Which of the following foods are high in fibre?

- (a) wholemeal bread  ●
- (b) green beans  ●
- (c) baked beans  ●
- (d) cornflakes
- (e) weetabix  ●
- (f) jacket potatoes  ●
- (g) crisps
- (h) I do not know

Thank you very much for completing the questionnaire - you have helped us to carry out a survey in the Diabetic Clinic - Thanks

Discriminatory Analysis of DKQ1

Statement Number in DKQ1	W Statistic*	P Value*
1	858	0.002
2	780	0.09
3	862	0.001
4	682	0.9
5	696	0.001
6	856	1.002
7	842	0.005
8	833	0.008
9	884	0.001
10	845	1.004
11	942	0.001

\* Derivative of Mann-Whitney statistic and significance levels as computed by Minitab Statistics programme

INSULIN DEPENDENT DIABETIC QUESTIONNAIRE

1. Please read each statement or question and choose the option(s) which complete the statement or answer the question.
2. Mark an 'X' in the box next to your choice.
3. Remember you may choose more than one option.

NAME \_\_\_\_\_

UNIT NO. \_\_\_\_\_

On this copy of the questionnaire the symbol ● has been added to denote an acceptable correct option.

1. I am sure that I will be able to control my diabetes.	<input type="checkbox"/>
2. I am sure that I will be able to control my diabetes.	<input type="checkbox"/>
3. I am sure that I will be able to control my diabetes.	<input type="checkbox"/>
4. I am sure that I will be able to control my diabetes.	<input type="checkbox"/>
5. I am sure that I will be able to control my diabetes.	<input type="checkbox"/>
6. I am sure that I will be able to control my diabetes.	<input type="checkbox"/>
7. I am sure that I will be able to control my diabetes.	<input type="checkbox"/>

1. Insulin causes the amount of glucose in the blood to

- (a) increase
- (b) decrease
- (c) stay the same
- (d) I do not know

2 i) When you test your urine there should be

- (a) no sugar
- (b) a trace of sugar
- (c) 1% sugar
- (d) I do not know

2 ii) What do you think a normal blood glucose (sugar) is?

- (a) 4 to 7 mmol/l
- (b) 10 to 17 mmol/l
- (c) 17 to 25 mmol/l
- (d) 1 to 4 mmol/l
- (e) I do not know

3. A hypo or insulin reaction might be caused by

- (a) being less active than usual
- (b) taking too much insulin
- (c) missing a meal
- (d) missing your insulin injection
- (e) being more active than usual
- (f) I do not know

4. Some signs of a very high blood glucose (sugar) level are

- (a) passing a lot of urine  ●
- (b) feeling hungry
- (c) feeling thirsty  ●
- (d) feeling sick  ●
- (e) I do not know

5. If you have a cold or flu and do not want to eat, you should

- (a) stop taking your insulin
- (b) take less insulin than usual
- (c) take the same or more insulin  ●
- (d) I do not know

6. Before doing extra exercise like gardening or sport you could

- (a) cut down your insulin  ●
- (b) take more insulin
- (c) have the same insulin dose and take more carbohydrates
- (d) keep your insulin and diet the same  ●
- (e) I do not know

7. Cuts or sores on diabetic's feet may be slow to heal or become infected because

- (a) diabetics have been born that way
- (b) diabetics can have a poor circulation in their feet and legs  ●
- (c) taking insulin slows down the healing of the wounds
- (d) I do not know

8. Which of the following foods would you count as carbohydrate in your diet?

- (a) brussel sprouts
- (b) potatoes  ●
- (c) apples  ●
- (d) half a grapefruit
- (e) bread  ●
- (f) chicken
- (g) sausages  ●
- (h) beefburgers  ●
- (i) I do not know

9. Which of the following foods are high in fibre?

- (a) wholemeal bread  ●
- (b) green beans  ●
- (c) baked beans  ●
- (d) cornflakes
- (e) weetabix  ●
- (f) jacket potatoes  ●
- (g) crisps
- (h) I do not know

Thank you very much for completing the questionnaire - you have helped us to carry out a survey in the Diabetic Clinic - Thanks

APPENDIX 4.7

Item-total score correlation for DKQ1m

Item Number	Spearman rho rs	P-value*
1	0.50	0.01
2	0.36	0.05
3	0.64	0.001
4	0.39	0.05
5	0.29	0.05
6	0.41	0.01
7	0.55	0.01
8	0.30	0.05
9	0.53	0.01

\* P-values indicate level of significance by a two-tailed test



APPENDIX 4.8

Item Difficulty, P, of DKQ1m, using 96 subjects

Item Number	P-Item difficulty
1	0.81
2	0.68
3	0.48
4	0.22
5	0.67
6	0.14
7	0.79
8	0.29
9	0.06

P - Proportion of patients responding correctly

Average item difficulty  $p = 0.46$

Ref 

--	--	--	--	--

  
1 - 4

Charing Cross Hospital (Fulham)

DEPARTMENT OF ENDOCRINOLOGY

supported by the British Diabetic Association

INSULIN DEPENDENT

patient  
questionnaire



Date to patient 

--	--	--	--	--	--

PTST.I/B Pretch, K



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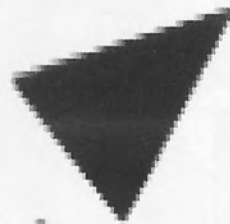
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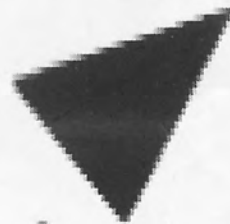
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11. (ii) What do you think a normal blood sugar is?



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INSULIN DEPENDENT DIABETIC QUESTIONNAIRE

1. On the following pages there are some questions or statements about diabetes.
2. There are a number of choices which follow each question or statement.
3. Please read each statement or question carefully and decide which choice(s) answer the questions or completes the statement correctly.
4. When you have made your choice, mark an 'X' in the box beside it.
5. Remember you may choose more than one answer.

NAME \_\_\_\_\_

UNIT NUMBER \_\_\_\_\_

\*\*\*\*\* THANKYOU \*\*\*\*\*

On this copy of the questionnaire the symbol ● has been added to denote an acceptable correct option.



1. Insulin causes the amount of glucose in the blood to

- (a) increase
- (b) decrease
- (c) stay the same
- (d) I do not know

2. Where do you inject your insulin?

- (a) into the muscle
- (b) into the fat
- (c) into blood vessels
- (d) I do not know

3. Clear insulins act

- (a) quicker than cloudy ones
- (b) slower than cloudy ones
- (c) just the same as cloudy ones
- (d) I do not know

4. A portion in your diet is ....

- (a) an amount of food that weighs 10g
- (b) an amount of food that contains 10g of carbohydrate
- (c) all protein foods that weigh 10 g
- (d) I do not know

5. Which of the following foods should you count as carbohydrate in your diet?

- (a) brussel sprouts
- (b) potatoes  ●
- (c) apples  ●
- (d) oranges  ●
- (e) bread  ●
- (f) bacon
- (g) I do not know

6. Which of the following foods are high in fibre?

- (a) wholemeal bread  ●
- (b) green beans  ●
- (c) baked beans  ●
- (d) cornflakes
- (e) weetabix  ●
- (f) jacket potatoes  ●
- (g) crisps
- (h) I do not know

7. A good, healthy diabetic diet contains .....

- (a) foods high in fat
- (b) foods low in fat  ●
- (c) foods high in fibre  ●
- (d) foods low in salt  ●
- (e) I do not know

8. High fibre foods can ....

- (a) allow the blood sugar to rise slowly  ●
- (b) allow the blood sugar to rise quickly
- (c) help blood sugar control  ●
- (d) I do not know

9. Alcoholic drinks can ....

- (a) increase your blood sugar
- (b) lower your blood sugar  ●
- (c) I do not know

10. High blood sugar (glucose) levels can be caused by ....

- (a) eating too much carbohydrate  ●
- (b) forgetting to have your insulin  ●
- (c) having too much insulin
- (d) doing too much exercise
- (e) getting an infection  ●
- (f) being upset and worried  ●
- (g) I do not know

11. If you found you had a large amount of ketones in your urine you would think ....

- (a) fats in your body had broken down  ●
- (b) you need more insulin  ●
- (c) you need less insulin
- (d) I do not know

12. If you have a high blood or urine sugar level and ketones were present, you should do the following .....

- (a) take more insulin
- (b) take less insulin
- (c) keep your insulin and diet the same and test your blood/urine later
- (d) I do not know

13. A hypo or insulin reaction might be caused by .....

- (a) being less active than usual
- (b) taking too much insulin
- (c) missing a meal
- (d) missing your insulin injection
- (e) being more active than usual
- (d) I do not know

14. Before doing extra exercise like shopping or sport, you could do the following .....

- (a) reduce your insulin slightly
- (b) increase your insulin slightly
- (c) have the same insulin dose and take extra carbohydrate
- (d) I do not know

15. If you have a cold or flu and do not want to eat, you should .....

- (a) stop taking your insulin
- (b) take less insulin than usual
- (c) take the same or more insulin
- (d) I do not know

16. Which parts of your body can be affected by diabetic complications?

- (a) your stomach
- (b) your feet
- (c) your kidneys
- (d) your eyes
- (e) your ears
- (f) I do not know

Response	Specificity	P-value*
(a) your stomach	0.46	0.01
(b) your feet	0.19	NS
(c) your kidneys	0.35	0.05
(d) your eyes	0.49	0.01
(e) your ears	0.32	0.05
(f) I do not know	0.42	0.01
	0.72	0.001
	0.75	0.001
	0.61	0.01
	0.66	0.01
	0.66	0.01
	0.60	0.01
	0.58	0.01
	0.61	0.01
	0.44	0.01
	0.49	0.01
	0.54	0.01

\* P-value indicates level of significance by a statistical test.

NS = Not significant, evaluated on the basis of poor agreement with total test score.

Item-total score correlation for DKQ2m

Item Number	Spearman rho rs	P-value*
1	0.48	0.01
2 +	0.19	NS
3	0.35	0.05
4	0.49	0.01
5	0.32	0.05
6	0.42	0.01
7	0.72	0.001
8	0.75	0.001
9	0.61	0.01
10	0.66	0.01
11	0.66	0.01
12	0.60	0.01
13	0.55	0.01
14	0.61	0.01
15	0.44	0.01
16	0.49	0.01
17	0.54	0.01

\* P-values indicate level of significance by a two-tailed test

+ Item number 2 excluded on the basis of poor correlation with total test score

APPENDIX 3  
APPENDIX 4.14

Item Difficulty, P, of DKQ2m, using 60 subjects

Item Number	P-Item difficulty
1	0.85
2	0.85
3	0.80
4	0.78
5	0.63
6	0.28
7	0.58
8	0.43
9	0.61
10	0.45
11	0.40
12	0.65
13	0.63
14	0.46
15	0.73
16	0.73

P - Proportion of patients responding correctly

Average item difficulty  $p = 0.61$

NAME \_\_\_\_\_ UNIT NO. \_\_\_\_\_

PRACTICAL ASSESSMENT (1)

INSULIN	COMMENT	SCORE
<p>DRAWING-UP:</p> <p>(a) adds air (b) no air bubbles (c) accurate dosage</p> <p>INJECTION TECHNIQUE:</p> <p>(a) angle</p>		
DIET	COMMENT	SCORE
<p>(a) can identify 10g portions from a selection of model foods.</p>		
BLOOD/URINE TESTS	COMMENT	SCORE
<p>(a) can identify the normal urine/blood glucose concentrations on test stick bottles.</p>		

TOTAL SCORE = \_\_\_\_\_



Diabetes and Endocrine Unit  
Dudley Road Hospital  
Birmingham B18 7QH  
Telephone 021 624 3001  
Dr A. P. Mowbray MD FRCP - Ext 4204  
Dr N. A. Taylor MD FRCP - Ext 4202  
Diabetes Unit - Ext 4207

APPENDIX 6

This includes letters and questionnaires used in the evaluation of the DE/MP. Results of the evaluation are shown in the questionnaires contained in this Appendix.



Diabetes and Endocrine Unit  
Dudley Road Hospital  
Birmingham B18 7QH

Telephone: 021-554 3801

Dr. R. F. Fletcher MD FRCP - Ext: 4591

Dr. K. G. Taylor MD MRCP - Ext: 4592

Diabetic Unit - Ext: 4126-7

Dear

Hope you are keeping well since I last saw you and having no problems with your diabetic control - you will be an expert soon!

I probably told you about the next group session which will concern 'HYPOS', we will discuss (a) what they are, (b) why they occur, (c) the effects on your body and diabetic control, and, most important, (d) how to prevent them and treat them.

I would like you to come to the hospital

on

at

Please come to the \_\_\_\_\_  
\_\_\_\_\_

Look forward to seeing you,

Yours sincerely,

G.M. Cowan, B.Sc.  
Diabetic Educator

NAME \_\_\_\_\_ UNIT NO. \_\_\_\_\_

DIABETES PROGRAMME EVALUATION QUESTIONNAIRE

You have attended a diabetes educational programme for 12 months and I would be very grateful if you would answer some questions concerning this programme.

INSTRUCTIONS

1. Please read each question carefully and decide which answer from the list below is most suitable.
2. Mark a tick in the box next to your choice. If more than one answer is correct you may want to tick more than one box.
3. Please do be honest and tick the answer you really agree with.

\*\*\*\*\* THANK YOU \*\*\*\*\*

(1)

(1) Have you previously had any organised instruction about diabetes since you were first diabetic?

yes

7 (21%)

no

27 (79%)

(1a) Where was this provided?

in a diabetic unit

3 (9%)

in a hospital ward

4 (12%)

in a diabetic clinic

if 'other', where was this? \_\_\_\_\_

(2) In what way was this presented?

talk(s)

7 (21%)

books and pamphlets

4 (12%)

slides

1 (3%)

demonstration

1 (3%)

video or film

1 (3%)

others - please specify \_\_\_\_\_

(3) You have been attending the sessions on diabetes for 12 months now.

How useful do you think they have been?

very useful

29 (85%)

useful

5 (15%)

not very useful

no use at all

(2)

- (4) Do you think you have learnt anything from the programme?

a great deal

18(53%)

quite a lot

16(47%)

not much

nothing

- (5) Are you glad you joined in the study?

yes

34(100%)

no

not sure

- (6) Do you feel that this programme has helped you to cope with events such as parties, weddings, exercise etc.

yes

32(94%)

no

undecided

2 (6%)

- (7) The group sessions were held at monthly intervals. Do you think the time interval between sessions was:

too long

1 (3%)

too short

about right

33(97%)

- (8) Each session lasted approximately 1 hour. Do you think this was

too long

too short

7 (21%)

about right

27(79%)

(3)

(9) You have attended 11 sessions in the diabetes programme. Do you think 11 sessions was:

too many

not enough

about right

not sure

6 (17%)

23 (68%)

5 (15%)

(10) Which of the following did you prefer?

group meetings

individual meeting

some of each type

14 (41%)

2 (6%)

18 (53%)

(11) Was there anything you particularly liked about the sessions you attended? - Please specify.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

(12) Was there anything you did not like about the sessions you attended? - Please specify.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

(13) Do you think that you have more control of your diabetes since taking part in the programme?

yes

no

not sure

34 (100%)

(4)

(13a) What do you think is the reason for this?

---



---



---

(14) Are you more careful about your diabetes since you attended the programme?

yes

just the same

less careful

29 (85%)

5 (15%)

(15) Has your attendance at the diabetes sessions made you do anything different in the way you manage your diabetes?

yes

no

30 (88%)

4 (12%)

(15a) If yes, please give some examples.

---



---

(16) Were you a member of the British Diabetic Association before starting these diabetes sessions?

yes

no

12 (35%)

22 (65%)

(17) If no, was there any particular reason? Please specify.

---



---

(5)

RESULTS

(18) Did you learn to test your blood glucose:

before the programme

22(65%)

as part of the programme

12(35%)

(19) Is there anything else you wish to say about the programme - if so, please write below.

---



---



---



---

----- THANK YOU -----

21(31%)

3 (9%)

27(79%)

7 (21%)

50(88%)

4 (12%)

33(97%)

1 (3%)

1 (3%)

33(97%)



Tick the box which you feel answers the question.

		RESULTS
(1)	Did you feel that Gerry Cowan was a good teacher?	
	a. very good <input type="checkbox"/>	31(91%)
	b. satisfactory <input type="checkbox"/>	3 (9%)
	c. could have been better <input type="checkbox"/>	—
	d. not very good <input type="checkbox"/>	—
(2)	Did you find it easy to talk to Gerry Cowan?	
	a. yes - very easy <input type="checkbox"/>	27(79%)
	b. yes <input type="checkbox"/>	7 (21%)
	c. just alright <input type="checkbox"/>	—
	d. not really <input type="checkbox"/>	—
(3)	Was she able to answer all your questions?	
	a. yes, all of them <input type="checkbox"/>	30(88%)
	b. most of them <input type="checkbox"/>	4 (12%)
	c. some of them <input type="checkbox"/>	—
	d. no <input type="checkbox"/>	—
(4)	Did you understand all the topics Gerry talked about?	
	a. yes -it was well explained <input type="checkbox"/>	33(97%)
	b. yes - but could have been explained better. <input type="checkbox"/>	1 (3%)
	c. no - but I understood some of it <input type="checkbox"/>	—
	d. no - I didn't understand a lot of it <input type="checkbox"/>	—
(5)	Concerning the age of the person teaching you, would you prefer someone:	
	a. older than Gerry Cowan <input type="checkbox"/>	1 (3%)
	b. it does not really matter <input type="checkbox"/>	33(97%)

Our Ref:



Diabetes and Endocrine Unit  
Dudley Road Hospital  
Birmingham B18 7QH

Telephone: 021-554 3801

Dr. R. F. Fletcher MD FRCP - Ext: 4591

Dr. K. G. Taylor MD MRCP - Ext: 4592

Diabetic Unit - Ext: 4126-7

Dear

You recently took part in a programme to learn more about diabetes and help you with your control. It would be very helpful to me if I could have your opinions on the educator (Gerry Cowan) and about the programme itself.

Please could you answer the questions shown on the enclosed sheet and send it back to me in the stamped addressed envelope provided.

Please do be honest, your answers will be treated in strictest confidence.

Thank you for your help.

Yours sincerely,

Dr. K.G. Taylor  
Consultant Physician



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Comparison of original groups with patient groups who completed  
the study

Variable	SG n = 42	SG n = 31	CG n = 28	CG n = 25
Sex: Male	18	16	20	18
Female	24	15	8	7
Age (yrs)	30.9 $\pm$ 1.9	32.0 $\pm$ 2.3	39.4 $\pm$ 2.4	40.2 $\pm$ 2.5
Duration (yrs)	11.3 $\pm$ 1.0	11.7 $\pm$ 1.2	15.8 $\pm$ 2.1	15.8 $\pm$ 2.3
DNA %*	12.3 $\pm$ 2.1	11.5 $\pm$ 2.4	10.4 $\pm$ 2.8	8.0 $\pm$ 2.8
Hospital admissions (patient/yr duration)	0.21 $\pm$ 0.07	0.13 $\pm$ 0.03	0.31 $\pm$ 0.20	0.33 $\pm$ 0.23
Race: Caucasian	35	26	24	22
Asian	3	2	2	1
West Indian	4	3	2	2
Socio-economic Group**				
1	1	0	5	3
2	4	2	4	4
3	13	13	12	11
4	5	4	6	6
5	1	0	0	0
6	12	8	1	1
Marital Status:				
Single	20	15	7	5
Married	18	12	21	20
Divorced/separated	4	4	0	0

Values expressed as mean  $\pm$  SEM

\* DNA % indicates percentage clinic non-attendance in previous 4 years

\*\* Socio-economic Group according to the Office and Populations Survey Index (238)

Comparison of original groups with patient groups who completed  
the study

Variable	SG n = 42	SG n = 31	CG n = 28	CG n = 25
Weight (kg)	68.0 $\pm$ 1.9	67.9 $\pm$ 2.4	73.6 $\pm$ 2.3	73.6 $\pm$ 2.5
Ideal body weight (%)	113.4 $\pm$ 2.1	112.0 $\pm$ 2.5	113.6 $\pm$ 1.83	113.7 $\pm$ 1.9
Insulin type*				
1	15	10	8	8
2	16	12	9	6
3	6	5	5	5
4	2	2	6	6
5	3	2	0	0
Insulin dose ( $\mu$ /kg)	0.80 $\pm$ 0.04	0.80 $\pm$ 0.05	0.68 $\pm$ 0.04	0.69 $\pm$ 0.05

Values expressed as mean  $\pm$  SEM

\* Insulin type: 1 = pre-mixed  
 2 = medium plus short-acting pork insulin  
 3 = medium plus short-acting beef insulin  
 4 = long or medium acting only  
 5 = human insulin

APPENDIX 7.2

0 month assessment of glycaemic control of original patients groups  
compared with groups participating in study

Glycaemic Control	SG n = 42	SG n = 31	CG n = 28	CG n = 25
HbA <sub>1c</sub> (%)	11.9 $\pm$ 0.35	11.8 $\pm$ 0.45	11.7 $\pm$ 0.43	11.8 $\pm$ 0.46
Scale:* 1	9	8	3	3
2	17	11	17	15
3	13	10	7	7
Blood glucose (mmol/l)	8.2 $\pm$ 0.41	8.5 $\pm$ 0.49	7.7 $\pm$ 0.55	7.7 $\pm$ 0.56

Results expressed as mean  $\pm$  SEM

\* Scale of glycaemic control: 1 = good  
 2 = moderate  
 3 = poor



APPENDIX 7.3

0 month assessment of attitudes in original patient groups  
compared with the SG + CG participating in the study

SG n = 42	SG n = 31	CG n = 28	CG n = 25
50.1 $\pm$ 1.3	50.5 $\pm$ 1.7	55.1 $\pm$ 1.7	55.9 $\pm$ 1.8

Results expressed as mean  $\pm$  SEM

0 month assessment of diabetes knowledge in original patient groups  
compared with the SG + CG participating in the study

Subject Area	SG n = 42	SG n = 31	CG n = 28	CG n = 25
Overall	60.8 $\pm$ 3.8	62.7 $\pm$ 3.4	60.3 $\pm$ 4.1	60.1 $\pm$ 4.6
Blood glucose	65.1 $\pm$ 5.1	65.7 $\pm$ 5.6	57.5 $\pm$ 6.3	60.1 $\pm$ 6.6
Insulin	73.8 $\pm$ 8.0	75.8 $\pm$ 9.5	83.9 $\pm$ 8.9	82.0 $\pm$ 9.9
Diet	55.3 $\pm$ 4.4	57.8 $\pm$ 4.9	45.8 $\pm$ 5.5	48.9 $\pm$ 5.6
Hypoglycaemia	74.0 $\pm$ 5.7	72.4 $\pm$ 6.9	64.7 $\pm$ 9.2	60.4 $\pm$ 9.9
Basic care	52.8 $\pm$ 4.1	56.4 $\pm$ 4.8	62.5 $\pm$ 6.2	60.0 $\pm$ 6.5

Results expressed as mean  $\pm$  SEM

0 month assessment of self-management skills in original SG and CG  
compared with the SG and CG completing the study

	SG n = 42	SG n = 31	CG n = 28	CG n = 25
Management skills (total)	7.87 $\pm$ 0.32	7.93 $\pm$ 0.3	7.55 $\pm$ 0.29	7.56 $\pm$ 0.31
Insulin	4.18 $\pm$ 0.09	4.14 $\pm$ 0.11	3.98 $\pm$ 0.13	4.0 $\pm$ 0.12
Diet	3.08 $\pm$ 0.17	2.96 $\pm$ 0.59	2.90 $\pm$ 0.22	2.88 $\pm$ 0.24
Blood/urine testing	0.84 $\pm$ 0.06	0.82 $\pm$ 0.07	0.67 $\pm$ 0.08	0.68 $\pm$ 0.09

Results expressed as mean  $\pm$  SEM

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2. ... N. Engl. J. Med. 306: ...

3. ... secretion of the pancreas. ...

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