Carbohydrate intake patterns and glycemic control of twenty one Illawarra subjects with IDDM: reasons for nonadherence to a carbohydrate exchange regimen

Elizabeth Hadfield

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CARBOHYDRATE INTAKE PATTERNS AND GLYCEMIC CONTROL OF TWENTY ONE ILLAWARRA SUBJECTS WITH IDDM: REASONS FOR NONADHERENCE TO A CARBOHYDRATE EXCHANGE REGIMEN.

A thesis submitted in partial fulfillment of the requirement for the award of the degree of:
MASTER OF SCIENCE (NUTRITION AND DIETETICS)
UNIVERSITY OF WOLLONGONG

by
Elizabeth Hadfield

DEPARTMENT OF PUBLIC HEALTH AND NUTRITION
UNIVERSITY OF WOLLONGONG
1995
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Abstract

The relationship between carbohydrate intake patterns (total carbohydrate and exchange patterns) and glycemic control was examined in twenty one Illawarra IDDM subjects aged 18 to 30 years. The adherence level of these subjects to their carbohydrate regimen and its relationship to glycemic control was also explored, together with the range of reasons given for nonadherence to their carbohydrate regimen.

The sample of Illawarra subjects with IDDM were taken from a patient list from the Illawarra Diabetes Education and Information Unit. Each subject’s dietary intake was assessed through a diet history using a modified version of the Burke method, and analysed by Diet - 1, from which subject’s carbohydrate exchange distribution and total carbohydrate intake was estimated. Nonfasting blood samples drawn from each subject were analysed for Glycosylated Haemoglobin (HbA1c) as the measure of glycemic control, and a one way ANOVA used to test for differences in glycemic control of subjects consuming different amounts of carbohydrate and having different levels of adherence. Adherence information was gained using set questions.

Twenty one IDDM subjects were recruited, representing 32% of the original study sample. Subjects consuming an even carbohydrate distribution achieved an average HbA1c level of 8.7%, compared to 10.5% in those consuming an uneven distribution. No significant relationship between total carbohydrate intake and HbA1c was observed, however average HbA1c increased slightly as carbohydrate intake increased. Glycemic control did not differ significantly with different adherence levels. Most frequently mentioned barriers to adherence to a carbohydrate exchange regimen were “I crave food I shouldn’t eat” and “my work life is too hectic”. The average age was higher in those subjects stating “craving food” and “family life” were obstacles to adherence.
These results suggest that in patients with IDDM aged 18 to 30 years, consuming a carbohydrate pattern which is even enhances glycemic control and that specific adherence barriers seem to be characteristic of this age group. Further studies with a larger sample size should confirm the trends observed here between carbohydrate intake and HbA1c, and the most prominent obstacles these people face in adhering to their carbohydrate regimen.
Chapter 1:
Introduction
Insulin Dependent Diabetes Mellitus (IDDM) is a chronic disease defined by absolute or relative insulin deficiency and is characterised by the presence of hyperglycemia (Brownlee and Cerami, 1981). With no known cure, management of the disease involves careful monitoring and regulation of diet, exercise and insulin administration to achieve optimal glycemic control. Dietary management of IDDM still remains an area of much interest, particularly the ideal amount and distribution of carbohydrate (Shimakawa et al, 1993). The individual regimen a patient follows will largely depend on the approach of the physician and dietitian consulted by the patient.

The exact prevalence of IDDM in the Illawarra region is unknown, however records of patients attending the Illawarra “Diabetes Education and Information Unit” (DEIU) have been used to give an approximate prevalence level of IDDM patients in the age group 18-30 years. From this list, 71 patients were identified in this age group. With the only two known local (Illawarra) Endocrinologists referring patients to the DEIU, these figures assume that nearly all Illawarra residents with IDDM have been to the DEIU at some stage after diagnosis. This however does not account for those who have moved away from the area since diagnosis, those who have moved to the Illawarra without attendance at the DEIU, and should be compared to prevalence figures in similar populations.

The issue of dietary adherence or compliance and its relationship to glycemic control in IDDM subjects has also been an area of considerable research in many populations worldwide (Harris and Linn, 1985; Okada et al, 1993; Hanestad and Albrektsen, 1991) with many authors investigating the reasons that people give for not following their recommended diet (Schlundt et al, 1994; Cotunga and Vickery, 1990 and Kurtz, 1990).

With problems and obstacles surrounding the measurement of actual adherence, some researchers have relied on patient reports of adherence and their stated reasons for not adhering to their diet, either through an open or closed questionnaire. Few authors however,
have specifically concentrated on studying adherence to a set carbohydrate exchange regimen and the reasons for not following the correct "exchanges", particularly in the age group 18-30. An exchange is equivalent to fifteen grams of carbohydrate and is used as a practical tool for people with IDDM to consume controlled amounts of carbohydrate. Meals can be expressed as a number of carbohydrate exchanges and foods containing similar exchanges of carbohydrate can be swapped or "exchanged".

One study has attempted to quantitatively assess the adherence of subjects to their carbohydrate exchange regimen but met with many problems and has dated in its (Christensen et al, 1983).

This particular age group is known to be subject to frequent change as job situation, location, marital status, residency etc is altered and frequently changing. With this in mind, it would be of particular interest and practical use to not only investigate the patterns of carbohydrate intake and the glycemic control of Illawarra people with IDDM in this age group, but the frequency with which adherence to their carbohydrate regimens are adhered to, and the specific reasons they have for not adhering as often as desired. Moreover, this information would be complemented by determining whether different levels of dietary adherence correspond to significantly different levels of glycemic control. This would raise the question and perhaps provide some answers on whether rigid adherence to a carbohydrate exchange regimen is worthwhile, and whether other dietary approaches are perhaps more worthwhile or offer other benefits.

Thus it would be of interest and practical use to Illawarra dietitians and diabetes health care workers to examine the variability of carbohydrate intake patterns and total carbohydrate intake amongst the 18-30 year old IDDM population and to examine the corresponding glycemic control that these people achieve. Results could help shape future approaches that
health workers take in terms of recommending amounts and distribution of carbohydrate foods as well as the method chosen to help promote dietary adherence.

The following project thus aims to:

1. Determine the variability of carbohydrate intake patterns in Illawarra subjects with IDDM aged 18-30 years, and to examine the glycemic control subjects achieve consuming each pattern of carbohydrate.

2. Find out the total amount of carbohydrate that these same subjects with IDDM are consuming and to compare the glycemic control between subjects consuming different levels of carbohydrate.

3. Elicit how often these subjects adhere to a set portion plan/exchange plan and to compare the glycemic control between subjects achieving different levels of adherence.

4. Find the range and frequency of reasons which people have for not adhering to or following a carbohydrate portion/exchange plan routinely.

5. Determine if there are any associations between different types of reasons people give for not adhering to a carbohydrate portion/exchange plan and subject characteristics such as age, sex, years since IDDM diagnosis, marital status, level of education, income, type of occupation etc.
Chapter 2:

Literature Review
2.1 Dietary Assessment Methodology

Medical research has become increasingly interested in the relationship between diet and several chronic diseases and has led to extensive investigation into the ways in which the nutritional status of individuals and groups can be assessed using valid and reliable methods which are standardised and cost effective (Slattery et al, 1994). Such investigations are not new, however. The work of Burke (1947) showed a growing awareness that evaluating nutritional status of patients with practical accuracy is of great public health importance. Dwyer (1988) reported that dietary assessment methods have been developed as far back as the ancient Chinese and Greeks. Not until this century however, has food composition data allowed for more refined methods of dietary assessment to be developed.

The objective of any dietary assessment method used in most epidemiological studies is to estimate the individual’s usual intake of foods and dietary components over a specific period of time and in a relatively inexpensive, practical way (Hankin and Wilkens, 1994; Kushi, 1994). The credibility of the dietary data and the conclusions drawn from the data depend on the validity and reproducibility of the measuring instrument (Hankin et al, 1991).

The validity of a dietary method refers to its ability to accurately estimate the dietary intake of the study population (Hankin and Wilkens, 1994). Hankin et al (1991) recognises the lack of a “gold standard” for validating a dietary method but discusses how many investigators have used detailed food records as a basis for comparison with a diet history.
The Food Frequency Questionnaire

A food frequency questionnaire is designed to obtain qualitative, descriptive information about usual food consumption patterns by assessing the frequency with which certain food items or food groups are consumed during a time period (daily, weekly, monthly etc) (Gibson, 1990).

Kushi (1994) and Krebs-Smith et al (1995) observe that it is increasingly common for analytical epidemiology studies of diet and disease to select food frequency questionnaires for dietary assessment for reasons such as low cost, low respondent burden and its focus on usual intake of subjects. However, it is well recognised that food frequency methods tend to yield great variance in nutrient intake in subjects of the same population which cannot be explained or accounted for (Kushi, 1994). Krebs-Smith et al (1995) in a study using a food frequency questionnaire to estimate fruit and vegetable intake revealed that frequency of intake of individual fruits and vegetables tended to be similar across surveys but estimates of total fruit and vegetable intake were very dissimilar and variable. Reasons for such wide variations are not clear but may be partially explained by the differential recall that people have when attempting to determine their intake over a specific period (Kushi, 1994).

Food frequency questionnaires, however may be very useful when trying to assess intake of one particular nutrient or food and its relationship to disease or disease control eg artificial sweetener intake, alcohol and condiments (Gibson, 1990). The method is quick, methodical and requires less respondent burden.

Given the problems of relying solely on food frequency data, it would seem that using food frequency questionnaires may be useful as a validating tool for other dietary intake assessment methods in some diet-disease research studies or used in combination with other
methods such as 24-hr recalls (Krebs-Smith et al, 1995) and diet histories (Kushi, 1994) to provide additional or confirmatory data (Gibson, 1990).

The Diet History

The diet history method first developed by Burke (1947), attempts to estimate the usual dietary intakes of individuals over several months or a year, relying on the subject’s recall. The subject is asked (in a personalised interview setting) to report the foods and beverages that he/she eats on a “typical” day starting from breakfast (Gibson, 1990). The interview adopts a combination of open and closed questions, becoming more closed as the interview progresses. Questions then begin to probe for specific quantities of foods mentioned, the frequency of their consumption and the amount of other foods eaten on weekends or from takeaway outlets, for example (Dwyer, 1988). Food models, pictures, non-directive probing and other supplementary dietary intake methods (Hankin et al, 1991) are usually employed in epidemiological studies to improve the accuracy and validity of the data recorded from the diet history (Dwyer, 1988; Gibson, 1990 and Maffeis et al, 1994).

As Burke (1947) states, it is the average dietary intake of the individual that is of interest for correlation with clinical and laboratory findings. The diet history, although used extensively in the therapeutic setting, can be modified to be suited to the research setting. It can be used for the purpose of comparing the average food intake of an essential nutrient or the average level of the diet as a whole with laboratory findings such as blood samples and anthropometric data.
Growing interest in the diet-disease relationships has prompted several studies to investigate the validity of the diet history as a method of determining diet intake (Herbert and Miller, 1988). Hankin and Wilkens (1994:198s) state that:

“the development and validation of appropriate dietary methods for use among culturally diverse groups are essential for identifying the role of diet in the aetiology of chronic diseases”.

The most common procedure for establishing the validity of the diet history in research is to compare recorded intakes (from the diet history) with data from another method that is assumed to be more accurate among a representative sample of the study population. These methods may be, for example, weighed food records (Hankin and Wilkens 1994; Maffeis et al, 1994), food frequency questionnaires (Gibson, 1990) and food records using photographs (Hankin et al, 1991). In general, the diet history produces higher estimates of group mean intakes than seven day food records when the history is taken over a long time period, such as one year (Gibson, 1990). However this variance is reduced as the time over which the diet history is taken is reduced. Other validation studies have shown reassuring results where quantitative diet histories have yielded reasonably accurate estimates of usual intake (Hankin et al, 1991). This emphasises the point that diet history instruments used in any study are usually population-specific and as such, any proposed dietary intake measuring instrument needs to be separately validated.
Diet History Analysis - Coding Rules

The information gained from a diet history is often analysed using a nutrient analysis computer program by many researchers. Thus there arises a need for rules to be developed whereby food types and quantities are entered in a standard way for reasons of experimental accuracy and validity.

As Gibson (1990) points out, coding errors arise from inadequate description of foods rather than weight errors when diet histories are recorded by the interviewer. Feskanich et al (1988) found that a lack of standardization in dietary data collection is a common problem in human nutrition research amongst other data collection protocol limitations. However, if coding rules are established prior to this to deal with incomplete or ambiguous descriptors of the foods, and if nutrient analysis packages which have a comprehensive range of food items are used, then such coding and recording errors can be significantly reduced (Gibson, 1990).

Bolland et al (1988) found that food models used in the diet history setting, can significantly increase the accuracy of coding and quantifying food items mentioned by the subject. Duplicate coding of diet history interviews by independent coder is also sometimes used in research as a quality control for coding (Gibson, 1990).

Other sources of error may occur at the analysis stage. Despite recommendations (Willett, 1989), some nutrient analysis programs such as Diet 1, do not allow data to be transferred automatically to other computers where the data can be ultimately used. Neither does the program allow totals to be calculated for each meal in the day. Only daily totals can be calculated. For some studies, these downfalls can be unfortunate since all data has to be manually translated to a computer statistical spreadsheet, which involves large amounts of time and also increases the chance for manual data entry error to occur.
2.2 Diabetes- Aetiology, Epidemiology and Present Management

Definitions

Diabetes Mellitus is a clinical expression of absolute or relative insulin deficiency, characterised by the presence of hyperglycemia.

There are two common types of diabetes, although other classes of glucose intolerance exist. These are:

1) Insulin Dependent Diabetes Mellitus (Type I)(IDDM)

and 2) Non- Insulin Dependent Diabetes Mellitus (Type II)(NIDDM)

The first type is the kind of diabetes typically developed by subjects under 30 years, although not always. The peak period of onset is from ages 8 to 14 years but may also occur in adults in their mid-twenties and older (Lyon and Vinci, 1993). In this disorder there is a total or almost a complete lack of insulin production by pancreatic cells and as such requires exogenous insulin treatment when onset (usually sudden) occurs. The worldwide incidence of type I diabetes is subject to much variation and reflects the distribution of ethnic populations and the importance of differential genetic susceptibility between populations (Bovonen et al, 1993). Australia which ranked 18th of more than 40 countries had an incidence rate of type I diabetes from 1985-1989 of 13.2 per 100,000 in the age group under 15 years (Bovonen et al, 1993). Other data sources suggest an incidence between 12-19 per 100,000 children (1984-89) and appears to be on the increase (Kelly et al, 1994). This compares to Finland which had the highest incidence in the world of 35.3 per 100,000 and the U.K having 32.5 per 100,000, North Dakota 18.9 per 100,000 (from 1978-1988), Austrian 7.7 per 100,000 (1989-90), Chile 2.5 per 100,000 (1990-91) and Korea 0.6 per 100,000 (1985-86) (Bovonen et al, 1993).
The second type is typically developed in subjects older than 30 years of age, though once again, this is not always the case. The degree of insulin deficiency is less severe and can be managed through diet with or without oral hypoglycemic drugs (Hartog, 1987).

**Aetiology**

There are three hypotheses for the development of type I diabetes. The first involves an autoimmune reaction where circulating antibodies progressively destroy the beta cells of the pancreas, thus inhibiting insulin production and secretion (Hartog, 1987). These circulating antibodies are found in the majority of newly diagnosed people with IDDM (Hartog, 1987; Kobberling and Tillil, 1988; Lyon and Vinci, 1993).

The second hypotheses postulates genetic factors as the main cause of diabetes. It has been well established that Caucasian subjects who possess HLA antigens DR3 and DR4 (located on the short arm of chromosome 6) are at increased risk of developing IDDM (Bottazzo et al, 1988). In this sense, type I diabetes has a genetically inherited factor in its causal pathway.

The third is the least common process and is related to a viral infection. Viruses such as Coxsackie and Mumps may have a part to play in the development of IDDM in some subjects but this is thought to be a precipitating factor in already predisposed individuals. (Hartog, 1987).

The actual aetiology of type 1 diabetes is still unknown but both genetic and environmental factors are involved in its development as described above. The role of the HLA genetics in the aetiology of type 1 diabetes is known, but neither the actual mode of inheritance nor how the environmental factors trigger beta cell production is known (Bovonen et al, 1993). A recent study (Kelly et al, 1994) has suggested that the incidence of IDDM may be increasing.
generally in Australia. The same authors suggested that a sharp increase in the incidence of IDDM in a population that does not appear to have altered (no apparent change in Australia’s at-risk population), provides further evidence that environmental antigens act as triggers of the disease process.

2.3 Insulin Dependent Diabetes Mellitus (IDDM)

Clinical Manifestations
In IDDM subjects, glycosuria is common and as such, many subjects experience polyuria and polydipsia caused by osmotic diuresis. The absence of insulin poses the risk of developing ketoacidosis from excessive ketone production by the liver. This occurs because the glucose present is not available to cells (due to the insulin deficiency), and as such, the fat in the adipose tissue is rapidly broken down to ketones (acetone, beta-hydroxybutyrate and acetoacetate) via lipolysis. Thus rapid weight loss is a common symptom of untreated IDDM (Lyon and Vinci, 1993).

Glycosylated Haemoglobin (HbA1c)- a Measure of Glycemic Control
In trying to optimise blood glucose control in diabetes, it is important to have a reliable and valid method of assessing blood glucose control in diabetic patients, particularly when research is involved. Since the 1970’s, glycosylated haemoglobin had been the best indicator available in indicating blood glucose concentration over the previous one to three months (Daneman et al, 1981). Most studies which require assessment of metabolic control in diabetics use HbA1c as the measure (Shimakawa et al, 1993).

Glycosylated haemoglobin is produced by a ketoamine reaction between glucose and the N-terminal amino acid of both beta chains of the haemoglobin molecule. A normal HbA1c level is in the range 5 to 8 percent and reflects good control in the preceding six to eight weeks,
whereas a level in the range of 12 to 15 percent would indicate poor control (Karam et al., 1991).

The relative ease with which HbA1c levels can be obtained make it a useful and feasible measurement of glycemic control. Simple blood glucose levels taken on the day of experimentation are open to many discrepancies since measurements are influenced by food, activity and stress (Home et al., 1989). However, as Karam et al (1991) points out, relying on HbA1c measurements as a sole indicator of glycemic control also has its limitations. An acceptable HbA1c level does not reflect whether a subject has had both high and low blood glucose readings, which have been “averaged out” and yield a HbA1c reading which appears to reflect acceptable blood glucose control (Karam et al, 1991).

In the long term, subjects with IDDM have greater risk of tissue damage particularly if the diabetes is complicated and difficult to manage, or if glycemic control is poor. Although any diabetes can be ameliorated by diet, insulin injection, or oral hypoglycemic agents, standard treatments has not been able to prevent the development of chronic complications affecting the eyes, kidneys, nerves arteries and capillaries (Hartog, 1987; Brownlee and Cerami, 1981).

The exact mechanism whereby these complications develop and progress is not known and there is continual controversy surrounding whether multiple insulin injections daily (intensive insulin therapy) is superior to conventional treatment in terms of trying to achieve optimal glycemic control, particularly when complications begin to arise (Lyon and Vinci, 1993).
2.4 Present Management of IDDM

Achieving and maintaining optimal glycemic control in IDDM involves a number of self-care activities including diet, insulin administration and exercise. Provision of a suitable diet is the mainstay of diabetes management in combination with each patient’s prescribed insulin regimen. Continuing education is seen as an integral part of diabetes treatment in order to maximise blood glucose control and hence reduce risk of long term complications.

Dietary Management of IDDM

Nutrition is perhaps the most important component of diabetes care and management. The amount, type and timing of food eaten will have a direct affect on the blood glucose level of a diabetic as will the exogenous insulin administered and the amount and timing of physical exercise (Lyon and Vinci, 1993).

Current literature and position statements regarding the nutrition management of diabetes have largely evolved from the recently completed landmark Diabetes Control and Complications Trial (DCCT) (DCCT Research Group, 1995; American Dietetic Assoc. 1995; Lyon and Vinci, 1993; Rubin and Peyrot, 1994). This was a prospective, randomised, multicenter trial sponsored by the National Institute of Health beginning in 1983 and followed more than 1400 adults and adolescent subjects with IDDM through to 1993. The subjects were split into two groups- one receiving conventional therapy, the other intensive insulin therapy. The trial provided ongoing ophthalmological, renal, neurologic and vascular assessment and monitoring to determine the effectiveness of intensive therapy in decreasing the severity of diabetic long term complications (Lyon and Vinci, 1993 and DCCT Research Group, 1993).

Subjects in the trial were found to adhere to their respective insulin regimens 97 percent of the time and those following intensive insulin therapy achieved HbA1c values between 6.7 and
7.3 percent, compared with 8.7 to 9.2 percent for conventional therapy (DCCT Research Group, 1995). The 2 percent difference in average HbA1c levels between the DCCT conventional and intensive groups was associated with a 60 percent reduction in risk for diabetic retinopathy, nephropathy and neuropathy (Rubin and Peyrot, 1994). Other complications were also reduced. In the intensive therapy group, the occurrence of microalbuminuria (urinary albumin excretion greater that 40mg / 24hrs) was reduced by 39 percent, and that of albuminuria (urinary albumin excretion greater than 300mg / 24 hrs) by 54 percent (DCCT Research Group, 1993). The DCCT Research Group’s dietary recommendation was:

“given the uniform, significant delay in onset and reduction in progression of the microvascular and neurological complications of IDDM, the DCCT research group recommended intensive therapy for most patients with IDDM”


**Conventional and Intensive Treatment.**

The ideal dietary approach for IDDM has been the subject of much debate recently, particularly with the mounting evidence supporting intensive insulin therapy from the DCCT. Conventional treatment (as in the DCCT) consists of those patients who receive up to two injections of insulin daily (including any mixture of short, intermediate and long acting insulin) and who do not usually adjust their insulin in accordance with blood or urine glucose monitoring results. Patients generally are taught to carry out at least one urine or capillary blood test per day with more intense monitoring encouraged on sick days and are instructed on how to take in a constant amount of carbohydrate at each meal (Davis and Gregory, 1933; DCCT Research Group, 1993).
In conventional therapy, the patient’s diet history is obtained and calories are prescribed to maintain 90 to 120 percent of ideal body weight or to provide normal growth and development (DCCT Research Group, 1995). The diet or meal plan taught is based on the subject’s usual eating pattern, as much as possible, but contains about 10 to 25 percent energy from protein, 30 to 35 percent energy from fat and 45 to 55 percent energy from carbohydrate with less than 25 percent of this coming from simple sugars (DCCT Research Group, 1995). The particular amount of carbohydrate planned at each meal or snack, depends on the insulin regimen prescribed by the subjects physician and on the subjects exercise routine (DCCT Research Group, 1995). Many dietitians translate this into carbohydrate portions or exchanges where one exchange equals 15 grams of carbohydrate. The patient is encouraged to follow this plan with the belief that this will promote optimal blood glucose control, without particular attention to adjusting his/her routine insulin injection on a day to day basis.

The above method has been the most common approach to dietary management of diabetes for many years. Many diabetes centres and dietitians still rely heavily on the exchange system for diabetes dietary management without particular attention to insulin adjustment, however, the move to more reliance on self monitoring blood glucose levels closely and adjusting insulin according to diet (intensive therapy) is becoming a prominent trend (Davis and Gregory, 1993). The DCCT trial has supported and promoted this change (Lyon and Vinci, 1993; Rubin and Peyrot, 1994; DCCT Research Group, 1995).

As suggested above, there is evidence to suggest that intensive treatment of diabetes yields benefits which go beyond those seen from previous insulin or dietary treatment regimens in terms of achieving optimal blood glucose control and reducing risks of long term complications. It has far reaching implications for both the person with diabetes and dietitians
and diabetes educators alike. With effective education, the individual can learn to follow trends in self-monitoring blood glucose and predict changes needed in insulin doses or dietary intake. The dietitian’s approach will no longer be solely educating on how to follow a prescribed carbohydrate controlled eating plan, but also teach the client about the nutrient content and metabolic effect of foods, insulin action, interpreting blood glucose results and how to cope with this through diet and insulin adjusting. Keeping rigidly to exchanges and meal timing will not be so crucial, thus allowing more patient flexibility (Lyon and Vinci, 1993; Franz et al, 1994; Rubin and Peyrot, 1994).

Despite the long term benefits documented for intensive therapy and the increased dietary flexibility offered to diabetics who manage their diabetes in this way, the practicalities of all diabetics adhering to an intensive insulin regimen, although desirable, would be problematic. The sort of intense treatment that subjects on the DCCT trial received would place an increased financial burden on the diabetic, increased regimen demands (with all its related problems), and increased risk of hypoglycemia (Rubin and Peyrot, 1994). Farkas-Hirsch and Hirsch (1994) elaborate on the practical difficulties of changing attitudes and education methods of physicians regarding diabetes treatment. The results of the DCCT trial would take years to translate to general practice through intensive inservicing and multidisciplinary team-forming between physicians, diabetes educators and dietitians (Farkas-Hirsch and Hirsch, 1994).

So what does the immediate future hold for effective diabetes management and what specific dietary approaches are able to achieve glycemic control similar, or as close as possible to that achieved in the DCCT trial? As Rubin and Peyrot (1994) point out, even though the DCCT intensive intervention may be seen as a “gold standard”, some alternative treatments offer some unique benefits that are acceptable to a large number of diabetics who are unwilling to
Carbohydrate- The Question of How Much?

Simple and complex carbohydrate have many and varied functional requirements in food. Simple carbohydrates include simple sugars (monosaccharides and disaccharides) and their derivatives (sugar alcohols such as sorbitol) and provide sweetness to food. Complex carbohydrates are more diverse and include starch, gums, structural polysaccharides, pectin and other oligosaccharides (Chinachoti, 1995).

In the late 1970’s and into the 80’s, diabetes associations began the well known dietary approach of reducing fat intake and increasing carbohydrate intake with a corresponding restriction of simple carbohydrate or sugars. As from 1986, diabetes associations began recommending that consumption of modest amounts of sugar was acceptable given that glycemic control was normal or near normal (Wolever and Miller, 1995). The use of glucose containing simple sugars and foods has traditionally been restricted in the diets of most diabetic patients on the premise that simple sugars, as opposed to complex carbohydrates, cause a rapid increase in blood glucose concentrations. However as Wolever and Miller (1995) discovered most studies supporting this theory have many limitations. Recent evidence has mounted which suggests that “isoenergetic exchange of sucrose and starch at moderate intakes has no significant effect on blood glucose responses in IDDM subjects” however more insulin is required when simple sugars are consumed instead of the complex carbohydrate or “low glycemic index carbohydrate” (Wolever and Miller, 1995:214s).

Loghmani et al (1991) reported findings where children with IDDM fed extra energy as sucrose in exchange for starch had no effect on blood glucose response which repeats similar findings by Bantle et al (1983) comparing IDDM subjects and normal subjects. Wolever and Miller (1995) conclude in their study that sugars added to food are no more likely to
compromise blood glucose control than naturally occurring sugars or most cooked starches. Moreover, the degree of glycemia after a meal depends on many factors including the source of the sugar or starch, the method of preparation (e.g., cooked or uncooked starch), and the composition of the total meal. Some starches are rapidly absorbed and produce a high glycemic response and a greater requirement for insulin than what has been traditionally thought—thus challenging the traditional teaching methods of carbohydrate distribution and exchange systems which have been heralded as the best teaching approaches over the last decade.

The need for appropriate carbohydrate intake to match insulin administration in IDDM subjects is essential in order to achieve normal glycemia and to avoid hyperglycemia, ketoacidosis, and hypoglycemia alike. However, the specific level and pattern of carbohydrate intake is controversial, and the method of teaching subjects with diabetes how to control their carbohydrate intake to match insulin administration is under continual revision and discussion.

However, given the increased need for insulin when consuming simple sugars and the high glycemic response of some simple sugar sources, the latest nutrition principle and recommendations formulated by the American Diabetes Association recommend 45-55 percent energy from carbohydrate with less than 25 percent of this coming from simple sugars. Consumption of concentrated sweets is generally discouraged, and use of a carbohydrate-based meal plan with snack system to match insulin regimen is recommended (American Diabetes Association, 1995).

Different studies examining the relationship between complex carbohydrate intake and glycemic control have produced varying results. Work by Simpson et al. (1981) and Shimakawa et al. (1993) suggest that a diet high in complex carbohydrate and fibre produces
similar or improved glycemic control compared with low carbohydrate diets. Findings by Anderson et al (1991), however, suggest that diets high in carbohydrate (70 percent of total energy), and high in fibre (70g / day), enhance peripheral glucose disposal and thus decrease insulin requirements, and also reduce total cholesterol but do not act to alter glycemic control. It should be noted that such diets are practically impossible to consume on a long term basis, and results of this study were based on a sample size of only ten subjects with IDDM.

But perhaps of considerable interest is the issue of adherence to any such dietary regimen. As Glasgow et al (1985:300) states:

“Given the presumed relationship between the diabetes treatment regimen, metabolic control of the disease, and the health consequences of diabetes, the extent to which diabetic individuals follow regimen prescriptions is an important area of study”.

2.5 Adherence to Carbohydrate Meal Plan in Subjects with IDDM.

Adherence - a definition.
Despite the recognition that adherence or compliance (these terms will be used interchangeably) to a diabetic dietary regimen by most patients is poor, there is little data to substantiate this due to a lack of adequate methods to describe dietary adherence (Christensen et al, 1983).

Kurtz (1990:50) describes adherence as the “extent to which a person’s behaviour coincides with medical or health advice”. Schlenk and Hart (1984) view compliance as both an attitude and a behaviour, consisting of both a willingness to follow a regimen and actually carrying out this regimen. In this sense non-adherence can then include any reluctance, disinterest,
refusal, or simple lack of sustained effort on the part of the diabetic subject and is seen as a major public health concern because it can play a role in the lack of success in clinical management (Cotunga and Vickery, 1990). Hindi - Alexander and Throm (1987) however, recognise that classing any deviation from a regimen as noncompliance is unacceptable and problematic. With an increase in emphasis on self management of diabetes and with recommendations from the DCCT (as previously described) promoting intensive insulin therapy, there now exists the notion that "educated nonadherence" is acceptable. For example, a person may deviate from their carbohydrate plan in accordance with the level of exercise that day or change the insulin dosage accordingly. As Cotunga and Vickery (1990:123) state, compliance can be viewed as...

"a continuum spanning from nonadherence at one extreme to blind adherence at the other, with intermediate points covering educated adherence and intelligent nonadherence".

Adhering to a meal plan involves making appropriate food choices in an ever-changing environment of work, family and peer commitments (Schlundt et al, 1994). Kurtz (1990), however, disagrees with this concept of adherence and the current approaches to dietary management of diabetes. In a report on adherence to diabetes regimens, Kurtz (1990) discusses the problematic current self management approaches which preclude the definition of the regimen in static terms. Kurtz (1990:50) describes ideal self-care as the "changing of the regimen to accommodate the situation rather than necessarily impinging on the lifestyle to meet the regimen".

Dietary adherence of the diabetic subject requires three separate sections to be addressed. The first is to measure the actual dietary intake of the diabetic subject and the issues involved in this have been discussed previously in this paper. The second is to measure how closely the
dietary intake recorded matches the diet plan for that individual. The third aspect involves presenting the measure of adherence in a meaningful, intelligent way (Christensen et al, 1983).

**Measuring Adherence to Carbohydrate Regimens- a Difficulty in Research**

To measure adherence to the carbohydrate regimen prescribed by each patient's dietitian or doctor, the number of deviations from the planned number of exchanges would have to be calculated (Christensen et al, 1983).

The first problem that arises is the availability of the original or current carbohydrate meal plan followed by the diabetic subject to act as the standard against which compliance is measured. As Glasgow et al (1985) points out, often this information is unavailable or no longer relevant to the subject's current management. If they are available, practical problems arise such as accessing patient's medical records.

There arises a second serious problem of validity when the study relies on patient recall of instructions. Christensen et al (1983), however, attempted to quantitatively assess the adherence of IDDM subjects to their diet which included their carbohydrate exchange regimen. Exchange deviation scores were calculated as the ratio of exchange deviations (additions and deletions) to the total number of exchanges in the carbohydrate exchange meal plan or regimen (also used by Cotugna and Vickery, 1990). Appropriate alterations from the carbohydrate meal plan were not counted as deviations eg in the case of exercise and hypoglycemic treatment. Twenty-four hour recalls were used to assess the usual intake of the subjects and then analysed for carbohydrate distribution (Christensen et al, 1983). The results of the study showed that the average patient added or deleted approximately one exchange for every four exchanges in the diet plan and only 10 percent of patients adhered to planned exchanges 90 percent of the time. Patients in good control reported significantly better dietary
adherence than those in poor control. Patients in poor control deviated from their diet plans approximately 50 percent more often than patients in good control.

Studies such as those by Christensen et al (1983) and Cotunga and Vickery (1990) support the reasoning that dietary adherence would be related to metabolic control. However, as noted by Brownlee-Duffeck et al (1987), metabolic control is multifactoral in its origin and the relationship might be expected to be mostly observed between subjects exhibiting the extremities of metabolic control rather than those lying towards the middle of the distribution (Christensen et al, 1983).

Another major difficulty in trying to capture the adherence or compliance level of diabetics to their carbohydrate exchange meal plan (and indeed many other aspects of diabetes self-care), is the fact that subjects will have different management prescriptions. Subsequently, comparing dietary adherence across so vast a group of people may prove to be problematic (Glasgow et al, 1985). For example, five different insulin regimens may emerge in the study and dietary intake and adherence would have to be studied and compared between subjects on the same insulin regimen.

Glasgow et al (1985) suggest reserving the study of adherence and compliance to cases where information is available and documented on the objective regimen prescriptions of each individual subject or patient.

**Dietary Adherence and Glycemic Control.**

Given the difficulties in measuring adherence, there has been much variance in the statistical results of those studying the relationship between general diabetes regimen adherence and metabolic control with many statistical relationships being weak and insignificant. Even multivariate analysis has failed to show that adherence summary scores constructed in many
studies predict metabolic control (Kurtz, 1990). However, as Brownlee-Duffeck et al (1987) and Kurtz (1990) found, most of the adherence items that did significantly predict metabolic / glycemic control (as measured by HbA1c) were dietary related. Hence there has emerged strong evidence to show that as adherence to one’s dietary regimen is enhanced, glycemic control is improved.

Despite all the problems in measuring and validating dietary adherence, it is a very important area for study, given the evidence of the relationship between blood glucose control and dietary intake, and in turn its effect on reducing the long term risks of cardiovascular and other complications.

Alternative approaches to studying diabetes dietary adherence may prove to be just as useful. Assuming a relationship between dietary adherence (more specifically, a carbohydrate exchange regimen or meal plan) and glycemic control, studying the reasons that diabetics give for non-adherence to their diet is of particular use to dietitians and diabetic educators alike, given their need to tailor education techniques to the needs of clients. This would promote optimal success and outcome.

**Reasons for Non-adherence to the Diabetic Diet.**

In a study by House et al (1986) a number of situational obstacles were found to prevent people with IDDM adhering to their diet including family factors, employment and economic conditions. Dunn et al (1984) identifies attitudes, beliefs and anxieties as factors which influence (positively or negatively) adherence to a dietary regimen and can also modify a person’s diabetes knowledge and thus their adherence behaviour in this way. House et al (1986) also identifies the fact that physical limitations also forms a category of “reasons for nonadherence” such as visual or ambulatory restrictions which may cause restrictions in food preparation etc.
As Schlundt et al (1994) point out, there is a lack of information or a practical guide to help dietitians and educators to make an assessment of an individual’s adherence obstacles. If dietitians and doctors perceive adherence problems differently to the actual patient, this can create an additional obstacle to the “already complicated task of dietary compliance” (House et al, 1986:434).

**Situational Obstacles**

A study by Ary et al (1986) studied the most frequently reported situations associated with nonadherence. Some of these could be specifically applied to dietary nonadherence discussed here. The most frequently cited reasons for nonadherence to diet was in the situation of “eating out” and specific “situations at home” such as “I eat when I am alone at home” (Ary et al, 1986). Closer inspection of these reasons showed that subjects found it hard to refuse inappropriate offers of food when eating out or when with others friends (Ary et al, 1986). Shlundt et al (1994) has also found that the most common situations in which dietary nonadherence prevailed were those related to negative emotional eating, social pressures, resisting temptation and forbidden foods, competing priorities, and a lack of social or family support.

Ary et al (1986) found that no single reason for nonadherence was given by the majority of subjects, suggesting that patient education should be tailored to each individual’s problems and adherence barriers. However, in a smaller age group, dealing specifically with dietary carbohydrate regimen adherence, there may be common reasons which emerge which could be addressed at multi-patient educational program developed specifically to address these problems.
Health Beliefs as a Predictor of Dietary Adherence.

Much literature has been written on the relationship between health behaviour and health beliefs. Most of these studies are based on the original Health Belief Model” which has grown out of the work of Lewin (Harris and Linn, 1985; Schlenk and Hart, 1984). This model hypothesises that individuals will not carry out a particular health- related behaviour (eg adhere to their carbohydrate regimen) unless they have at least a......

“minimal level of health motivation and knowledge, see themselves as vulnerable and the condition as threatening, are convinced of the health behaviour’s efficacy, and find few barriers to action”

(Schlenk and Hart, 1984:566).

Health beliefs that influence a person’s health behaviour are complex and defining those related to nonadherence to a carbohydrate “exchange” regimen would be further complicated given the fact that there is little known about the origins or conditions under which such health beliefs are formed (Harris and Linn, 1985). However identifying health beliefs which prevent adherence is an important area of study since if these beliefs can be changed by dietitians and educators, this would provide a feasible area of intervention.

Brownlee-Duffeck et al (1987) found that self reported adherence to general diabetic treatment regimens was predicted by factors such as perceived benefits of the treatment, cost, and perceived severity and susceptibility of the illness. The predicting factor differed amongst varying age groups. Despite the validity problems of the study where all questionnaires were newly developed and unvalidated, the results suggest that metabolic control in young people is more related to their perceived severity and susceptibility to the disease and it’s complications. If these result are replicated in the future, this may provide a helpful direction to dietitians aiming to target areas which influence adherence- whether on an individual
patient-counsellor situation or on a more group education level. As Schlenk and Hart (1984:537) found, examining health beliefs, establishing patient’s locus of control, may point to the need for more family involvement and social support in a patient’s therapeutic regimen and in educational programs related to that regimen which would aim to increase patient compliance levels through the use of “informed external control influences”. In other words, establishing the health beliefs and influences of patients regimen adherence can provide useful information for intervention directions and methods of increasing compliance.

**Psychosocial Variables and Dietary Adherence.**

Apart from those situation barriers to dietary adherence mentioned before, there are many other situations or psychological and social situations that influence a subject’s adherence to his / her dietary regimen. Supportive or nonsupportive family behaviours directed toward the diabetic person and other environmental factors such as personality, stress/ anxiety etc, were examined by Schäfer et al (1983) and Ruggiero et al (1993). Schäfer et al (1986) also examined the relationship between family behaviour and specific measures of diabetes regimen adherence. As Schäfer et al (1986) states, intuition tells us that regimen adherence should be related to family interactions because they either participate in implementing the regimen (eg in food preparation) and / or family routines are disrupted by the diabetes self-care regimen. Thus gauging each patient’s level of family support is an essential part of assessing dietary adherence and subsequent intervention of patients with type I diabetes.

Other factors which may influence the degree of adherence to a diabetic dietary regimen such as a carbohydrate “exchange” meal plan, is the individual’s satisfaction with life and their perceived difficulty in adhering to the actual dietary prescription. Hanestad and Albrektsen (1991) found that as an individuals perception of difficulty in adhering to their dietary regimen increased, their actual adherence fell. Moreover, as life satisfaction (as indicated by a quality of life questionnaire) increased, so did the ease of adherence to the diabetic regimen.
The results, however, like many adherence studies, relies heavily on patient self-report of adherence which is open to bias because of over or under-reporting and the effects of memory (Schlenk and Hart, 1984; Harris and Linn, 1985; Schafer et al, 1983).

**Knowledge and Dietary Adherence.**

Knowledge is a necessary part of self management of diabetes and, in the light of adhering to a carbohydrate exchange meal plan, a sound knowledge of the rationale and importance of adherence to the regimen is an important motivational factor in diabetes dietary adherence. If long term, positive dietary changes are to be made and sustained, an adequate knowledge base is required (Okada et al, 1993). In order to work out an appropriate education strategy for the management of diabetes (each adherence to carbohydrate exchanges), it is essential to know the extent of the patient’s knowledge, and to examine the factors involved in the development of this knowledge. Okada et al (1993) found in their study of the factors involved in the level of behaviour-changing diabetes knowledge amongst diabetics depended largely on socio-economic status, educational career, age, and years since onset of the illness. Sex and family history were not factors which significantly determined the level of behaviour-changing diabetes knowledge.

Despite this information, there remains a question of how this information is to be used in increasing the level of dietary adherence amongst patients in an individual and collective sense.

Price (1993) in his qualitative study to develop a learning model for diabetes self-management found that self management of diabetes is based on the practical knowledge which comes from actually living a diabetes regimen. Based on interview data from 18 adults with IDDM, this study suggests that people learn to self-manage diabetes by learning to recognise patterns of their own responses (biopsychosocial) to diabetes, and that they use this information to
formulate a plan that “works for me”. It is grounded in personal logic and experience - not necessarily solely on formal theoretical information received initially. Although Price (1993) was looking at general principles of diabetes management, the same ideas would be of value when assessing the dietary adherence of subjects with diabetes - and in particular, adherence to a specific carbohydrate exchange plan.

**Increasing Adherence to Dietary Regimen.**

In the light of all the studies mentioned above, it is not surprising that many reports have been published which discuss possible techniques to increase the dietary adherence of patients. Toobert and Glasgow (1991) suggest that problem solving skills is an important part of diabetes self-management and adherence and that problem solving training could be incorporated into diabetes education programs through identification of adherence barriers. Schäfer et al (1982) suggests goal setting and behavioural contracting procedures (based on a social learning theory approach) be used in the interview or counselling setting as a method of facilitating greater regimen adherence in adolescents.

Watts (1980:171) has suggested that traditional diabetes education programs have “little clinical value beyond improving knowledge about diabetes”. Watts (1980) points out the difficulty associated with developing methods to improve adherence since there are many factors which influence self-care and adherence. A multi-faceted education program is necessary to increase compliance. It should not only provide continued education about aspects of diabetes management such as diet, but ways to reduce stress, increase family support, improve general health, change health beliefs, and to improve the social support received by the individual. All these factors effect adherence to a diabetic regimen and as such, need to be directly addressed (Watts, 1980).
In reference to the current approaches to the dietary management of diabetes, there continues to be controversy regarding the best approach in terms of optimising glycemic control. Some continue to adopt the exchange approach, others a more intensive approach, others a Carbohydrate Counting technique and others still, a Glycemic Index approach. In the light of the above review, it becomes evident that this is not the sole concern of dietitians and educators. Other factors influencing adherence to any diabetic diet need to be addressed in combination with the methods chosen. Without adherence, research into which dietary approach is superior remains void and is rendered useless.
Chapter 3: Methods
3.1 Study Design and Sampling Technique.

This study used a variety of methods to obtain the data needed to address all of the objectives. As part of a larger PhD study conducted by Farideh Tahbez (Medical Research Unit), this MSc (Nutrition and Dietetics) project has used only some of the data collected in the overall IDDM study. However, it is important to consider the context of this study and the totality of procedures that subjects are exposed to since this may influence the way in which subjects respond to questions and thus influence results.

After approval by the Ethics Committee of the University of Wollongong, a sample of 71 IDDM subjects was obtained from a patient list constructed by the ‘Diabetes Education and Information Unit’ (DEIU) for the Illawarra Area and comprised of all known IDDM patients between the ages of 18 and 30, diagnosed between 1st of January, 1984 and 31st December 1994 in the Illawarra area. These potential subjects were approached through a letter outlining the purpose and procedure of the study, and were invited to participate through a follow-up phone call. Only IDDM subjects were used in this MSc study. Control subjects were recruited for the PhD study.

The subjects recruited attended an Illawarra Regional Hospital (IRH) residence where the study was being conducted and, upon signing of a consent form data was obtained from each subject over a time period of approximately one and a half hours. The subjects were asked to fill in six questionnaires before being interviewed for a Diet History. Several anthropometric measurements were then taken, before both urine and blood samples were obtained.

3.2 Data Collected

The following information was collected from each subject (both IDDM and control subjects) upon presentation at the IRH residence and information from the IDDM subjects formed the data used in this MSc study.
3.21 Questionnaires

A total of six questionnaires were filled in by each IDDM subject, of which the following are relevant to this study:

Introductory/Demographic Questionnaire

A general introductory questionnaire was completed which provided information on personal details such as age, sex, marital status, and nationality, diabetes history, insulin dosage, and medical history of each subject. This study used only some of this data which included age, sex, and the subject’s insulin regimen (see appendix 4.3).

Food Pattern Questionnaire

A Food Pattern Questionnaire was also used which was adapted (made suitable to Australian foods and terminology) from the Diabetes Control and Complications Trial Food Pattern Questionnaire by a MSc (Nutrition and Dietetics) student Effie Tsivis (1995) from the University of Wollongong. This Australian version of the DCCT “Food Pattern Questionnaire” asked general questions about eating habits and meal patterns of each subject and the frequency of consumption of certain foods (see appendix 4.4). Information collected from the diet history interview was validated or cross-checked using this questionnaire.

“Practical Aspects of IDDM” Questionnaire

Another questionnaire entitled “Practical Aspects of IDDM”, constructed by MSc (Nutrition and Dietetics) students, was also completed by subjects. The first two questions were constructed specifically for this research project and asked subjects how often they adhere to their carbohydrate exchange regimen and what specific factors prevent them from adhering to their regimen more frequently (refer to appendix 4.6 - question 1 and 2). Responses to these two questions formed the data to address objectives three and four of this study.
3.22 The Diet History Interview

A diet history was elicited from each subject. The interview followed a procedure as outlined by Burke (1947) but without the inclusion of a three day food record. Interviews were conducted by six Msc (Nutrition and Dietetics) students from the University of Wollongong who had been trained to conduct diet histories in a standard way.

The diet history interview took approximately twenty minutes to half an hour and was recorded on a standard form (see appendix 4.5). Food models were used by all interviewers to standardise food quantities and estimates.

3.23 Other measures

Although not used in this study, other measurements included taking the height and weight of each subject, waist and hip girth measurements, and skinfold thickness as a measurement of body fatness and total body fat. Blood pressure readings were also taken for all subjects.

3.3 Measurement of Diabetes Control

Following the diet history and anthropometric measurements, all subjects provided nonfasting blood and urine samples for analysis.

In this project, the blood sample was analysed for glycosylated hemoglobin C (HbA1c) as a measurement of blood glucose control over the previous six to eight weeks and provided data to address objectives one, two and three of this project. The blood sample was taken by an assistant from the Medical Research Unit at the IRH and analysed at the Biochemistry Department of the IRH. The HbA1c level of each sample was measured using High Performance Liquid Chromatography by a modified procedure adapted by the Biochemistry Department (IRH, Biochemistry Department 1995).
3.4 Dietary Analysis

Data from each subject’s diet history was analysed on Diet 1- a computer nutrient analysis package that is based on Australian and New Zealand food composition tables and the database NUTTAB (Xyrus software, 1989). This nutrient analysis program is able to calculate totals of each macro and micronutrients over the day of the diet history and express each as a percentage of Recommended Dietary Intakes. The macronutrients are expressed as a percentage of total energy intake.

Once the Diet-1 printout detailing total energy, macro and micronutrients was obtained, the required totals were then manually entered onto a master spreadsheet from which statistical tests were carried out.

For this MSc project, the total grams of carbohydrate from the Diet-1 analysis were manually translated into a carbohydrate regimen or exchange pattern and also expressed as a percentage of total energy intake.

Before foods from the diet histories of subjects were entered into Diet-1, coding rules were established. The nutrient content of food items not listed on the Diet-1 database were obtained from the manufacturer and information entered into the recipe section of the computer program. This was particularly necessary if the food item was eaten frequently (eg daily).
3.5 Analyzing the data - JMP Statistical Software.

The data collected in this study was analysed using the statistical software package “JMP” produced by DataViz Inc. (1989-94).

3.51 Statistical Analysis

Total Carbohydrate Intake and Glycemic Control

One-way Analysis of Variance (ANOVA) was used to compare the glycemic control of IDDM subjects consuming different quantities of carbohydrate. Subjects were grouped according to their carbohydrate intake and their corresponding HbA1c levels subsequently compared by ANOVA. The four groups were as follows: < 36 percent of total energy from carbohydrate, 36 to 45 percent, 46-55 percent, 56-65 percent, and >65 percent.

If results were significant, a post hoc comparison test “Tukey-Kramer HSD” was used to compare all pairs of data for significance differences in HbA1c levels. In this test, the lowest significant difference (LSD) possible between mean HbA1c levels of each carbohydrate group, is subtracted from the absolute difference between mean HbA1c levels. Thus, if the result is a positive figure, there is said to be a statistically significant difference between the HbA1c levels of the two carbohydrate groups being considered.

Adherence to a Carbohydrate exchange Regimen and Glycemic Control

A one way ANOVA was also used to test for any significant differences between the HbA1c levels of subjects assigned to one of five groups according to their stated adherence to their carbohydrate regimen. The adherence level of subjects was determined using responses to a question asking subjects to tick how often they followed their carbohydrate regimen (see appendix 4.6 - “Practical Aspects of IDDM” questionnaire, Q1).
Subjects were allocated to an adherence group on two separate occasions. The first grouping divided subjects into three groups, the second into two. This was done to determine whether comparing the two extreme groups enabled more sensitive detection of differences in HbA1c levels between varying levels of adherence. A one-way ANOVA test was used to test for any significant differences in glycemic control achieved between adherence groups.

3.52 Descriptive Analysis.

Differences in HbA1c levels between different carbohydrate exchange patterns were determined in the following way.

Subjects were firstly grouped into three groups according to their recorded HbA1c level, and secondly into two groups identifying their carbohydrate intake as being either even or uneven. An even carbohydrate distribution constitutes one in which the main meals have similar exchanges (within three exchanges) and where midmeals are not omitted. An uneven carbohydrate distribution is characterised by omission of midmeals and/or large differences between main meal exchanges (above five exchanges). Subjects who did not fall into either of these categories are omitted and only the two extreme groups compared. Comparisons were made subjectively.

An open-ended question was used to determine the reasons subjects gave for not adhering to their carbohydrate regimen and was developed from a similar question in the DCCT (DCCTRG, 1993), and modified with ideas from a similar question constructed by Schlundt et al (1994) (refer to appendix 4.6 Q 2).

Associations between reasons and subject characteristics were made subjectively. This involved comparing the average age, years since diagnosis and income level of subjects.
stating each type of reason. Information on the age, number of years since diagnosis and income level of subjects was obtained from the introductory questionnaire filled in by each participant (see appendix 4.3).
Chapter 4

Results
This chapter is divided into five parts. Each part presents the results from each of the five objectives stated in chapter one. Firstly, a brief profile of the subjects recruited is given before the summarised results are then presented. More detailed results are found in the appendices.

4.1 Subject Profile

Of the 71 IDDM subjects that made up the sample population from the DEIU lists, 21 were recruited. This represents 30% of the original sample population contacted. Four subjects were deemed ineligible after contact since three were non-insulin dependant diabetics, and one did not have diabetes at all. Three subjects could not participate due to Higher School Certificate studies, 12 people declined in participating, 10 people had moved away from the address listed, and 14 people were unable to be contacted on the phone number provided by the DEIU patient list. A further seven subjects with IDDM cancelled their appointments. One of the participating subjects refused to give a blood and urine specimen, and as such, was only used in some of the research objectives.

Of the 21 IDDM subjects recruited, 32% (n=7) were female and 78% male (n=14). Table 4.0 summarises the age and income level of the subjects, together with the average years since diagnosis and the types of insulin regimens adopted. The average income level of all subjects was in the category “$32,001 to $40,000”.

All 21 subjects who participated in the study were generally cooperative in providing information and blood and urine specimens. One participant, however, declined in giving a blood and urine specimen. As such, this subject is excluded from analyses which require HbA1c levels of subjects, thus giving a sample size of 20.
Table 4.0 Age, income, years since diagnosis, and insulin regimen of subjects with IDDM.

<table>
<thead>
<tr>
<th>Subject Characteristic</th>
<th>Number of subjects</th>
<th>Percent of total subjects</th>
<th>Average ± S.D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>21</td>
<td>100%</td>
<td>24.7 (± 3.4)</td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>less than 12,000</td>
<td>1</td>
<td>7%</td>
<td>-</td>
</tr>
<tr>
<td>12,000 - 22,000</td>
<td>0</td>
<td>0%</td>
<td>-</td>
</tr>
<tr>
<td>22,001 - 32,000</td>
<td>2</td>
<td>13%</td>
<td>-</td>
</tr>
<tr>
<td>32,001 - 50,000</td>
<td>7</td>
<td>47%</td>
<td>-</td>
</tr>
<tr>
<td>50,001 or more</td>
<td>5</td>
<td>33%</td>
<td>-</td>
</tr>
<tr>
<td>Years since diagnosis</td>
<td>21</td>
<td>100%</td>
<td>7.1 (± 3.8)</td>
</tr>
<tr>
<td>Insulin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 injections / day</td>
<td>10</td>
<td>50%</td>
<td>-</td>
</tr>
<tr>
<td>3 injections / day</td>
<td>9</td>
<td>45%</td>
<td>-</td>
</tr>
<tr>
<td>5 injections / day</td>
<td>1</td>
<td>5%</td>
<td>-</td>
</tr>
</tbody>
</table>
4.2 Variability of Carbohydrate Exchange Patterns and Glycemic Control.

The variability of exchange patterns that emerged from the study sample was great, particularly considering that the sample size was small. Table 4.1 summarises the results by separating subject’s exchange patterns into three groups according to the HbA1c level achieved by the subject. The first group lists the carbohydrate exchange patterns of those subjects having a HbA1c level between five and eight percent, the second lists the patterns of subjects having HbA1c levels between 8.1 and 9.9 percent, and the third group, of those between 10 and 12 percent. No subject has a HbA1c levels above this. Table 4.1 also states the number of insulin injections that each subject administers daily, and whether or not they adjust their insulin and diet routinely to suit their exercise pattern.

Table 4.2 displays some of the carbohydrate regimens which have been subjectively classed as being evenly or unevenly distributed. It also shows the average HbA1c achieved by these same subjects, the average number of insulin injections administered daily, and the proportion of subjects who routinely adjust their insulin to suit exercise.

One subject whose carbohydrate intake appeared fairly even, administered five insulin injections daily due to a very large carbohydrate intake. This subject was omitted from the analysis due to an unusually high carbohydrate intake.
Table 4.1 Carbohydrate exchange patterns and insulin administration of subjects grouped according to HbA1c levels.

<table>
<thead>
<tr>
<th>HbA1c group</th>
<th>Carbohydrate Pattern (exchanges)</th>
<th>No. insulin injections / day</th>
<th>*Adjust Insulin?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5% to 8%</strong></td>
<td>3, 1, 2, 1, 2, 1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>6, 0, 5, 3, 8, 3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>4, 3, 4, 2, 5, 2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>3, 2, 4, 1, 5, 2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>8.1% to 9.9%</strong></td>
<td>5, 1, 5, 1, 4, 1</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1, 2, 3, 0, 7, 3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2, 2, 3, 1, 7, 2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>7, 3, 4, 2, 3, 1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>4, 3, 4, 3, 5, 2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2, 3, 3, 3, 6, 1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3, 1, 7, 1, 5, 4</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>4, 0, 4, 0, 2, 0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>10% to 11.9%</strong></td>
<td>11, 0, 5, 0, 11, 0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>4, 3, 3, 0, 3, 0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>1, 2, 3, 2, 1, 6</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>11, 3, 8, 2, 10, 0</td>
<td>#5</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2, 2, 4, 1, 1, 2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>5, 8, 5, 3, 4, 5</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>6, 0, 5, 3, 4, 3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>12, 7, 10, 0, 5, 0</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

* Note: 1= the subject routinely adjusts insulin dosage and/or diet to accommodate for exercise
  2= the subject does not alter his/her insulin dosage.

# Outlier - not included in analysis.
Table 4.2 Average HbA1c level, average number of insulin injections and proportions of those adjusting insulin in IDDM subjects grouped according to whether carbohydrate distribution is even and uneven.

<table>
<thead>
<tr>
<th>Carbohydrate Distribution</th>
<th>Average HbA1c</th>
<th>No. of insulin injections/day</th>
<th>Percentage adjusting insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Even</td>
<td>8.7</td>
<td>2 to 3</td>
<td>89%</td>
</tr>
<tr>
<td>Uneven</td>
<td>10.5</td>
<td>2 to 3</td>
<td>25%</td>
</tr>
</tbody>
</table>

* Note: The carbohydrate patterns of subjects grouped even and uneven, are found in appendix 4.1.

4.3 Variability of Total Carbohydrate Intake and Glycemic Control

Table 4.3 shows the means and standard errors of the HbA1c levels of subjects according to their level of carbohydrate intake - indicated by the group that they are allocated to. No subjects consumed 66 percent or more carbohydrate from energy. The largest number of subjects (n=7) consumed between 36 and 45 percent of energy from carbohydrate.

The analysis of variance conducted (ANOVA) showed no significant difference between the mean HbA1c levels of subjects in different carbohydrate groups.
Table 4.3 Mean HbA1c levels of subjects grouped according to carbohydrate (CHO) intake.

<table>
<thead>
<tr>
<th>Group</th>
<th>Energy from Carbohydrate (%)</th>
<th>Number of Subjects</th>
<th>Mean HbA1c (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>≤ 35%</td>
<td>4</td>
<td>9.2 ± 0.7</td>
</tr>
<tr>
<td>2</td>
<td>36 - 45%</td>
<td>7</td>
<td>9.0 ± 0.6</td>
</tr>
<tr>
<td>3</td>
<td>46 - 55%</td>
<td>5</td>
<td>9.5 ± 0.6</td>
</tr>
<tr>
<td>4</td>
<td>56 - 65%</td>
<td>4</td>
<td>9.8 ± 0.7</td>
</tr>
<tr>
<td></td>
<td>Total:</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

4.4 Adherence to a Carbohydrate Exchange Regimen and Glycemic Control.

The mean HbA1c level of subjects in each adherence group and corresponding standard errors are given in table 4.4. As shown, differences between the means were minimal and the ANOVA test yielded statistically insignificant results. When subjects were grouped into two extreme groups of adherence, no significant differences in HbA1c were detected either.

Tables 4.4 Mean HbA1c levels of subjects grouped according to stated level of adherence to their carbohydrate exchange regimen.

<table>
<thead>
<tr>
<th>Group</th>
<th>Adherence level (days/week)</th>
<th>Number of subjects</th>
<th>Mean HbA1c (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 - 7</td>
<td>14</td>
<td>9.2 ± 0.4</td>
</tr>
<tr>
<td>2</td>
<td>3 - 4</td>
<td>2</td>
<td>9.7 ± 1.0</td>
</tr>
<tr>
<td>3</td>
<td>0 - 2</td>
<td>4</td>
<td>9.5 ± 0.7</td>
</tr>
</tbody>
</table>
Note that a large proportion of the study sample state that they adhere to their carbohydrate regimen “always” or “usually”, representing 70 percent (n=14) of the total sample. Of these 14, six subjects stated that they adhere “always” or “seven days a week” to their carbohydrate exchange regimen.

Despite results being statistically insignificant, Figure 4.1 illustrates the apparent increase in mean HbA1c levels as adherence to a carbohydrate regimen decreases from group one to three. The figure also shows the great within-group variation in HbA1c levels which is reflected in the large standard-errors indicated by the vertical error bars shown.

**Figure 4.1** HbA1c levels, and standard errors of IDDM subjects according to adherence to a carbohydrate exchange regimen.
4.5 Reasons for Nonadherence to a Set Carbohydrate exchange Regimen.

Table 4.5 lists the reasons subjects gave for nonadherence to their carbohydrate regimen, the number of subjects ticking each reason, and the percentage of total subjects that this number represents. The last three reasons are responses which subjects themselves provided apart from those stated in the question. It is important to note that subjects were able to “tick” more than one response.

Table 4.5 Range and frequency of reasons given for not adhering to a carbohydrate “exchange” regimen as often as they might otherwise.

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of subjects</th>
<th>*Percentage of total subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. “It didn’t give me good blood sugar control when I tried it before”</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>2. “I am tired of following a set plan”</td>
<td>4</td>
<td>24%</td>
</tr>
<tr>
<td>3. “My work is too hectic”</td>
<td>5</td>
<td>28%</td>
</tr>
<tr>
<td>4. “My family life makes it difficult”</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>5. “Family/friends are not supportive enough”</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>6. “I crave food I shouldn’t eat”</td>
<td>8</td>
<td>48%</td>
</tr>
<tr>
<td>7. “General interferences in life”</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>8. “Overtime or nightshift interferes”</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>9. “I don’t have any problems adhering”</td>
<td>1</td>
<td>6%</td>
</tr>
</tbody>
</table>

* Note that percentages do not add up to 100% since subjects were able to tick more than one response.
The sixth reason - "I crave food I shouldn’t eat", was the most commonly held reason for not adhering to a carbohydrate regimen as often as they might otherwise.

Response five ("family / friends are not supportive enough") was not a reason for nonadherence held by any of the participants. Four participants did not answer the question at all whilst five ticked more than one reason for nonadherence. Those four subjects not answering the question were not included in the category “I don’t have any problems adhering”.

4.6 Reasons for Nonadherence and Subject Characteristics.

Table 4.6 shows the average age, income level and the number of years since diagnosis of subjects, for each of the reason(s) given for nonadherence to their carbohydrate exchange regimen.

Table 4.6 Average age, years since diagnosis, and income level of subjects according to reason given for nonadherence.

<table>
<thead>
<tr>
<th>*Response category</th>
<th>Average age</th>
<th>Years since diagnosis</th>
<th>Average income category</th>
<th>Number of subjects responding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>24</td>
<td>7.6</td>
<td>$22,001-26,000</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>24</td>
<td>8</td>
<td>$40,001-50,000</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>24</td>
<td>7.5</td>
<td>$40,001-50,000</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>27</td>
<td>3</td>
<td>$40,001-50,000</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>26</td>
<td>9.1</td>
<td>$32,001-40,000</td>
<td>8</td>
</tr>
<tr>
<td>7</td>
<td>24</td>
<td>5</td>
<td>$40,001-50,000</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>24</td>
<td>8</td>
<td>$40,001-50,000</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>28</td>
<td>5</td>
<td>$40,001-50,000</td>
<td>1</td>
</tr>
</tbody>
</table>
* Reasons for nonadherence are as follows:

1. "It didn’t give me good blood sugar control when I tried it before”
2. “I am tired of following a set plan”
3. "My work is too hectic”
4. “My family life makes it difficult”
5. “Family / friends are not supportive enough”
6. “I crave food I shouldn’t eat”
7. “General interferences of life”
8. “Overtime or nightshift interferes”
9. “I don’t have any problems adhering”

Whilst no statistically significant associations were found, it is interesting to note that the average age of subjects was greater for those stating that “craving” food and family life made it difficult to adhere. The subject stating that “no problems” were encountered, had an age of 28 which is higher than the average age of 24.5 in the study sample. The average income level tended to be lower in those subjects stating that “craving” food and “it didn’t work before” were the main reasons for nonadherence. Years since diagnosis tended to be higher in subjects stating “craving” food was a barrier to adherence (9.1 years) and lower in those subjects stating family life made adherence difficult (3.0 years).

The observed differences in the average number of years since diagnosis of subjects giving various reasons for nonadherence are more clearly seen in Figure 4.2. It must be noted that
with a larger sample size, differences may become more detectable and as such, the conclusions drawn from these results should be treated with caution.

**Figure 4.2** Average number of years since diagnosis with IDDM in subjects grouped according to reasons given for nonadherence to a carbohydrate exchange regimen.
Chapter 5
Discussion
Findings from this study suggest that the design and sample size of a research study has a large impact on the results and the power of the conclusions that can be drawn. Although no statistically significant results were found in this study, the data may suggest the following: Firstly, more even carbohydrate exchange patterns tend to achieve better glycemic control than those who appear to have an unevenly distributed exchange pattern. Secondly, there is a need for a much larger sample size to determine any significant trends between total carbohydrate intake and glycemic control. Thirdly, although large within-group variation makes it difficult to draw conclusions, there appears to be an emerging trend where HbA1c levels of IDDM subjects increase as adherence to a set carbohydrate regimen decreases. Fourthly, some patterns appear to be evident in the types of reasons subjects gave for not adhering to their carbohydrate regimen as planned.

Each of these findings correspond to the research aims stated in chapter one and will be separately discussed here, together with the limitations of some of the results and the study design.

5.1 Subjects

The small sample size has contributed to the absence of statistically significant results, however this does not suggest that findings are not insignificant in themselves and is a problem common to many studies yielding useful results (Schafer et al, 1983; Schlundt et al 1994; Schlenk and Hart, 1984). The lack of data however, does limit the conclusions that can be drawn and as such, should be drawn to the attention of the reader. Nevertheless, general trends can be observed from the results and are discussed herein.

Larger scale studies with sufficient sample size to employ more sophisticated multiple regression analysis would yield more powerful results. Harris and Linn (1985), for example, recruited 93 diabetic subjects and achieved significant results when attempting to find an association between health beliefs and metabolic control. Christensen et al (1983) needed 97 subjects to find a significant relationship between diet exchange deviations and
metabolic control for the validation of the study's diet deviation scores. However, Schäfer et al (1983), found significant associations between some adherence measures (eg social learning measures) and HbA1c levels, with a sample size of only 34 adolescent IDDM subjects, although many associations were statistically insignificant.

It is also likely that a response bias has emerged in this study which is a weakness common to many studies involving medical compliance and disease control (Schlundt et al, 1990; Schlenk and Hart, 1984). It is likely that the subjects participating in this study have, on the whole, better disease control and/or regimen compliance than those that did not participate. Such a bias may mean that observing differences in glycemic control between differing levels of compliance may be more difficult and less significant than if a larger, more varied sample was used in the same age group.

The uneven sex distribution of subjects has limited the extent to which differences in adherence and glycemic control between males and females can be validly detected and, for this reason, could not be studied in this research project.

5.2 Variability of Carbohydrate Exchange Patterns and Glycemic Control.
As table 4.1 and 4.2 display, there appears to be better glycemic control amongst those having an apparently even distribution of carbohydrate across the day, irrespective of the total amount of carbohydrate. The average HbA1c level of subjects having a fairly even distribution of carbohydrate was 8.7 which, according to Karam et al (1991) is only slightly above the range for good control (5 to 8 percent) but well below the range for poor control (12 to 15 percent). This compares to subjects having more unevenly distributed exchange regimens who had an average HbA1c level of 10.5 percent (Karam et al, 1991).

Those in the uneven category in table 4.2, were classed as such because they tended to have greater variation in exchanges between main meals, and omitted midmeals more
frequently than those classed in the even group. The rationale for this grouping is based on subjective judgement of the researcher, and as such, it should be recognised that it has not been used by any of the researchers cited in chapter two. To the knowledge of the researcher, carbohydrate regimens have not been grouped or analysed in this way before and thus should be viewed as a method undergoing piloting.

The corresponding glycemic control of these two groups (even and uneven) would suggest that, adhering to a carbohydrate exchange plan with similar amounts of carbohydrate at each meal (within three exchanges), and including midmeals with smaller amounts of carbohydrate, would be an ideal carbohydrate regimen in terms of optimising glycemic control. However, table 4.1 shows that the percentage of subjects routinely adjusting their insulin or diet to suit their exercise, was greater in the two groups having better glycemic control than those having poorer glycemic control. This would suggest that the ability to adjust insulin and carbohydrate exchanges to suit circumstances such as exercise is also an important factor in achieving glycemic control. This observation would be supported by the recently completed DCCT study, which has recommended that consumption of carbohydrate should be based on individual blood glucose levels, and more emphasis be placed on insulin adjustment so that meal composition and timing can be more flexible (Lyon and Vinci, 1993).

It is widely recognised that the preferred carbohydrate intake pattern for people with diabetes is very individual and is largely dependent on the insulin and exercise regimen adopted by each person. However, when viewing the carbohydrate patterns of subjects in this study, it would seem that subjects consuming a more even carbohydrate pattern and who routinely adjust their diet and insulin for exercise, appear to have better glycemic control.

Despite findings from the DCCT Research Groups (1995) that more intensive, multiple injection insulin therapy achieves better glycemic control, such a pattern has not emerged
from these results. Both the even and uneven groups have subjects on insulin regimens of two and three injections daily (table 4.2) and subjects in all three groups in table 4.1 had a “mixed bag” of insulin therapy. One subject classed as having an even carbohydrate distribution in table 4.1, was on an insulin regimen of five daily injections. However, this subject was excluded because of an unusually high carbohydrate intake (34 exchanges per day), which would account for the need for large amounts of insulin. The lack of association between the frequency of insulin injections and glycemic control could be attributed to the fact that the sample size was relatively small, and variation in the types of insulin regimens observed here, limited.

There is an inherent problem in extending such findings to the wider Illawarra IDDM population because of the nature of the results collected. The carbohydrate patterns shown in table 4.1 are from the diets that subjects report to be a typical day’s intake. There is thus an underlying assumption that this “typical day” is representative of their routine carbohydrate intake every other day and their actual carbohydrate exchange plan. Moreover, combining data from each diet history and nutrient analysis recorded by six different interviewers, may introduce some error due to different food portion estimates and different interviewer techniques.

It is likely that the trends seen here could be strengthened, however, given a larger sample size, and allow for a more statistical approach. Subjects could then be grouped according to the same carbohydrate intake patterns and HbA1c levels statistically compared. The sample size of this study was too small to allow for such an approach.

5.3 Variability of Total Carbohydrate Intake and Glycemic Control

When subjects were grouped according to their carbohydrate intake as a percentage of their total energy intake and HbA1c levels compared, there appeared to be neither any statistical difference between the four groups, or any emerging trends. Table 4.3 shows the lack of a definite increase or decrease in glycemic control (HbA1c) as carbohydrate
intake increases. Although this contradicts findings by some authors (Simpson et al, 1981 and Anderson et al, 1991), others have had similar results in which no significant association between total carbohydrate intake and HbA1c was found (eg Shimakawa et al, 1993).

These results may be a true reflection of the possibility that glycemic control is not strongly influenced by total carbohydrate intake but rather, is dependent on other parameters. Glycemic control may be more dependent on the distribution of carbohydrate intake rather than the total amount of carbohydrate. Moreover, glycemic control may be influenced more by the amount and intensity of insulin therapy than the amount of carbohydrate consumed. This would support studies and literature reviews by Lyon and Vinci (1993), Rubin and Peyrot (1994) and the DCCT Research Group (1995).

The trends drawn from these results were somewhat limited by the small sample size. Given a larger number of subjects, it would be possible to make more definitive conclusions as to whether a true relationship between carbohydrate intake and glycemic control exists. Moreover, this would allow for multiple regression analysis to be performed which would control for other determinants of glycemic control such as insulin dosage, exercise level and weight.

Despite these limitations, if the mean HbA1c levels of the first and the fourth carbohydrate intake groups are compared, there seems to be an upward trend in HbA1c as carbohydrate intake increases. This would suggest that HbA1c may increase as a subject increases his or her carbohydrate intake from less than 35 percent of energy intake to 56 - 65 percent. The large within group variance, however, testifies to the lack of conclusive power that these apparent trends have.


5.4 Adherence to a Carbohydrate Exchange Regimen and Glycemic Control.

As Kurtz (1990) reviews, there has been very little statistically significant evidence to support the relationship between general diabetes regimen adherence and glycemic control. Glasgow et al (1987) found, that of 45 adherence - metabolic control correlations, only seven were statistically significant.

When subjects with IDDM were grouped according to stated adherence (table 4.4), the within group variation and standard errors were large. These results suggests the lack of a clear relationship between the adherence level of subjects to their carbohydrate regimen, as measured in this study, and glycemic control.

There may be reason to believe, however, that the validity of these results is tempered by three factors.

The first is to do with the way in which adherence is measured in this study. Relying on subject’s unverified, self-reported adherence may influence the validity of the result obtained, in that subjects may have stated an inflated adherence level that is more socially desirable. Seventy percent of subjects stated that they adhered to their carbohydrate intake regimen “always” or “usually”. High rates of adherence have been a widespread difficulty in compliance research (Schlenk et al, 1984; Harris and Linn, 1985; White and Santiago, 1988 and Kurtz, 1990) and has led to the development of a number of alternative approaches to measuring adherence to carbohydrate regimens, as discussed in chapter two.

Christensen’s et al (1983) use of exchange deviation scores was not able to be used in this study due to the lack of information on subject’s original carbohydrate regimens. It may have been more valid, though, to ask each subject the carbohydrate regimen that they
aspire to or routinely aim to follow, and then compare this with the actual carbohydrate distribution that they report from their diet history.

The second factor which may give reason for not accepting the apparent lack of relationship between adherence to a carbohydrate regimen and glycemic control, is the use of HbA1c as the sole indicator of glycemic control. As discussed in chapter two, the level of HbA1c does not reflect the high and low blood sugar readings that a subject may have had over the previous six to eight weeks, and so may not indicate the true glycemic control of the subject (Karam et al, 1991).

The third factor is the lack of sample size. A greater number of subjects would yield more valid results, and may (or may not) establish a clearer relationship between adherence to a carbohydrate regimen and glycemic control.

When the adherence levels of subjects with IDDM was compared from those in group one to those in group three, a slightly greater increase in the mean HbA1c level from was observed, as adherence decreased from “always” or “usually” to “not very often” and “never”. With a larger sample size, this trend may become stronger and provide evidence to suggest that adherence to the traditional carbohydrate exchange regimen is metabolically beneficial.

If significant results or clearer trends do not emerge from a larger sample size, it may be hypothesised that there may in fact be questionable benefit in promoting rigid adherence to a carbohydrate exchange regimen. This gives rise to some important questions about how Illawarra dietitians, diabetes educators and physicians alike are to approach dietetic management of IDDM. What other possible dietary approaches are being pursued in other areas, states, and countries which appear to be achieving better glycemic control and are within the reach of every IDDM patient? Should alternative methods such as carbohydrate counting (Davis and Gregory, 1993; Jenkins et al, 1987) and the Glycemic Index
(Jenkins et al, 1987) be considered? Is the increasing trend towards more insulin-adjustment and dietary flexibility a feasible option to consider?

These options would be supported by recent recommendations by the DCCT research group where more intensive insulin therapy and manipulation of insulin according to diet, yield superior glycemic responses compared to conventional treatment and rigid dietary adherence (DCCT Research Group, 1995; Lyon and Vinci, 1993).

5.5 Reasons for Nonadherence to a Set Carbohydrate exchange Regimen

The range and frequency of reasons people gave for nonadherence to their carbohydrate regimen were interesting. An emerging trend suggests that people aged 18 to 30 with IDDM, most often have difficulty adhering to their carbohydrate regimen because they “crave” food that they “shouldn’t eat” or because of their work life and shift work. The latter response, together with one other subject’s reason for nonadherence (“general interferences of life”), reflect the relatively hectic and demanding nature of the lifestyle that many people in this age group follow. It could be that the continual change in circumstances that this age group face may conflict with the demands of adhering to a carbohydrate regimen in the hope of optimal glycemic control. This may explain the fact that 48 percent of subjects admit to “craving” for inappropriate foods.

These findings may reflect a belief amongst the IDDM subjects interviewed that rigid adherence to a carbohydrate plan produces optimal blood glucose control and, as such, deviation from this leads to feelings of guilt. This seems to be a common finding by other authors where attitudes, beliefs and anxieties can influence adherence to a dietary regimen in a negative or a positive way (Dunn et al, 1984; Schlundt et al, 1994). As Brownlee-Duffeck et al (1987) found, adherence is largely related to whether a person believes that a regimen will be beneficial to his or her diabetic control. Twelve percent (n=2) of subjects indicated that adherence to their carbohydrate regimen “did not give me good blood sugar
control when I tried it before”, and as such, adherence would not seem beneficial to them. However, the larger percentage indicating feelings of guilt for craving inappropriate foods, may testify to a belief held by many of the subjects that the carbohydrate exchange regimen is an ideal and represents optimal control.

Keeping in mind the small sample size of this study, it would be of benefit to see these trends confirmed or contradicted in a larger study. If work life and “craving food” continue to be the main reasons that subjects do not adhere to their carbohydrate regimen as often as they might otherwise, it would benefit dietitians and patients alike to address the health beliefs behind their reasons and re-assess the present approaches to management of diabetes. For example, what are the foods which subjects believe are inappropriate and cause them to deviate from their carbohydrate plan? Are these food more permissible based on new evidence which suggests that sugars added to food are no more likely to compromise blood sugar control than naturally occurring sugars (Wolever and Miller, 1995; Loghami et al, 1991 and Bantle et al, 1983)? These authors found that the degree of glycemia after a meal depends on many factors such as the composition of the total meal and the individual glycemic response to the food.

It is recognised that an increase in the consumption of simple sugars increases the requirement of insulin (Loghami et al, 1991). However, given the results from this study and mounting evidence to suggest that flexibility in insulin administration and dietary adherence may be equally as beneficial, there may be an indication that traditional carbohydrate exchange teaching methods adopted in the Illawarra could be complemented or enhanced by more emphasis on insulin administration and other carbohydrate counting techniques.

It is interesting to note that no subject indicated that a lack of family and friend support made adherence to their carbohydrate plan difficult, which is different to findings Ary et al (1986) where this was a common reason for nonadherence. This may be specific to the
Illawarra or may simply be a reflection of the small sample size in this study. It is still important in the clinical setting, however, to gauge each subject’s level of family support as part of assessing the subsequent approach taken. This has been studied in detail by authors such as Schafer et al (1986) and Ruggerio et al (1993), and has been long recognised as an important part of the initial assessment of an IDDM patient before intervention is undertaken.

Given the short amount of time that a dietitian has with each patient, concentrating on issues or adherence problems most relevant to the patient’s age group, would be both time and cost effective, and ultimately benefit the patient. Examining what aspects of work life are problematic and the specific circumstances temptation to eat inappropriate food arises would allow the dietitian to plan ahead. This may involve developing teaching techniques to overcome these barriers, re-assess current management approaches, or consider alternative approaches such as more flexible insulin therapy. This does, of course, create new problems of coordinating diabetes educators, physicians and doctors alike to manage patients in a consistent manner and with uniform managerial principles and goals.

Responses by some participants, testify to the individual approach that subjects often command, as found by Ary et al (1986). For example, two subjects indicated that following a carbohydrate exchange regimen “did not work when I tried it before”, and as such, found it difficult to adhere as much as they would otherwise. For this group of people, a different approach which assesses their beliefs about diabetes and the benefits of medical and dietetic intervention, may be needed. This would require re-educating on the nature and long term complications of IDDM and perhaps call for a less rigid approach to dietetic intervention, should the individual lack incentive and motivation to follow a carbohydrate regimen or more intensive insulin therapy. This has been acknowledged by authors such as Schlenk and Hart (1984) and Harris and Linn (1985).
5.6 Reasons for Nonadherence and Subject Characteristics

As mentioned in chapter one, it would be of great practical use to dietitians should the main characteristics of subjects stating different reasons for nonadherence to their carbohydrate regimen be established. As shown in table 4.6, there appears to be some emerging trends in the age, income and number of years since diagnosis in subjects giving varying reasons for why adherence to their carbohydrate regimen may be difficult. It is to be noted, however, that drawing conclusions from these results about the wider Illawarra population should be discouraged until further recruitment of subjects can confirm apparent trends.

The fact that the average age of those finding family life a barrier to adherence was greater than the overall average may be simply due to the fact that more subjects in this older-young age group have children than those under say, 25, and thus have the demands and responsibilities of rearing children.

The greater average age (26) of those subjects stating that “craving inappropriate food” as a main reason for nonadherence, may be a trend worth following given a larger sample size, however could simply be due to the large within-group variation and have little significance. The greater age of the subject stating that “no problems” were experienced adhering to a carbohydrate regimen may reflect a trend whereby, as subjects get older and more experienced in managing their diabetes, adherence becomes easier and obstacles are overcome. It may also testify to a less-mobile lifestyle experienced as age increases.

In general, though, the small sample size of this study limits the extent to which trends can be clearly identified and hypotheses drawn. Trends may become more evident if a wider age group were to be examined. For example, comparing the different reasons for nonadherence between subjects 18 to 30 years old and those 45 and above.
The greater number of years since diagnosis with IDDM of subjects stating that “craving inappropriate food” was a problem compared to the average number of years since diagnosis, and the lower average number of years in subjects stating that family life made adherence difficult, is a result which would support other findings. Okada et al (1993) and Price (1993) have found that self management of diabetes is based on practical knowledge which comes from actually living a diabetes regimen (as discussed in chapter two). It may be that subjects in the first few years after diagnosis, find family life a practical obstacle to adherence to their carbohydrate regimen. This may involve trying to adjust family meal times and food types to suit his or her regimen, which could create some measure of inconvenience and frustration on the part of the person with IDDM or the family. However as time and experience pass, the diabetic learns to overcome these obstacles, to formulate a dietary plan that is suitable in practical terms, and finds that the remaining occasions in which adherence is difficult, is in the situations where foods offered are inappropriate and are “craved” for.

It would be useful, with a larger sample, to investigate whether this apparent trend between the number of years since diagnosis and specific adherence barriers is in fact justified and to investigate the ways in which subjects deal with these barriers. As addressed in chapter 2, the development of education programs to address such adherence obstacles must be multi-faceted- not only providing knowledge, but practical ways in which to increase adherence. This is made clear by other findings by Toobert and Glasgow (1991) and Watts (1980). Before this can be developed, clearly identifying the barriers specific to age groups, and the number of years a subject has had IDDM, is essential. The findings presented here are the beginnings of a worthwhile investigation into such adherence barriers experienced by people with IDDM in the Illawarra.

A lack of subject numbers in this study limits the conclusions that can be drawn about any apparent trend emerging from the comparison of nonadherence reasons and subject characteristics. Those stating that “it didn’t work when I tried it before” as a reason for
nonadherence to a carbohydrate regimen, appear to have a lower average income level than the sample average but the number of subjects in this group is only two. Given a larger sample size and findings from other research which suggests a relationship between adherence and socioeconomic indicators such as income (Okada et al, 1993), a relationship between income and the reasons given for nonadherence may be expected. It could be that subjects from lower income groups in the Illawarra find that a lack of family and friends support may be a barrier to adherence due to a weaker educational background and less understanding of the importance of present disease-management. The possibilities are many, however, and careful study design and adequate sample size is essential.

5.7 Other Limitations of the Study Design.

There remains two more areas of this study which need to be identified as possible weaknesses. They relate to the nature of the questionnaires used to gain information from subjects relevant to this study.

Questionnaire Design

As indicated in chapter three, only four questions out of the booklet of questionnaires filled in by each subject were used for this specific study. They related to: the reasons for nonadherence to a carbohydrate exchange regimen (Q2 of Practical Aspects of IDDM questionnaire), the actual frequency of adherence (Q1 of Practical Aspects of IDDM questionnaire), whether the subject changes his / her meal or insulin for exercise (Q6 of the Food Pattern Questionnaire) and the actual number of insulin injections used daily (Q8 of the Introductory Insulin Dependent Diabetes Study questionnaire).

The two questions relating to adherence to a carbohydrate regimen were situated at the very end of the questionnaire booklet. As such, they were filled in by participants after they had already completed approximately half an hour’s worth of intensive questions, including a lengthy food frequency questionnaire (see appendix 4.4). This may have led
to a greater respondent burden and an increased tendency for subjects to respond to questions with less thought or accuracy than if these questions were at the beginning of the questionnaire. Dunn et al (1984:37) found great difficulty in motivating patients to complete lengthy questionnaires and states that it only serves to compound the problem of “interpreting scores that are subject to the combined effects of boredom, fatigue, and intimidation”.

Only five of the 21 IDDM subjects used in this study gave more than one response to question two. The question stated that subjects could “tick more than one response”, however, if the question was not read in its entirety, subjects may have not realised that this was an option, and ticked only one response. This may have limited the range and comprehensiveness of possible “reasons for nonadherence” that could have been elicited from the subjects.

For this same question, the options or reasons provided for nonadherence were adapted from a DCCT questionnaire and from a study conducted by Schlundt et al (1994) which used a question similar to the one developed in this study. The reason for adapting these questions to suit this study, was to provide the most common reasons experienced by diabetic patients for nonadherence to diet, without wasting reasons or stating reasons which would be uncommon. The DCCT was a large longitudinal study where questionnaires were extensively piloted. Given this fact, it was assumed that the reasons given for nonadherence would approximate those that subjects would experience in this study. However, this question was not piloted on Illawarra residents in the age group 18 to 30 years, and as such, represents an area of weakness needing to be improved in future, similar studies.

The fifth response (“lack of support from family and friends”) was not ticked by any of the 21 IDDM subjects, suggesting that this may not be an important reason for dietary nonadherence in this age group and could have been omitted from the question. If a
similar study were to be done in the future using this same question, it would be of benefit to pilot the question on a readily available population.

**Dietary Intake Information**

The use of the diet history method as a tool for estimating a typical day’s macro and micronutrient intake, has its limitations. The difficulty in capturing a person’s typical day’s intake was experienced by interviewers in this study, particularly when subjects working shift work had very different carbohydrate patterns to those working normal hours. Moreover, a measure of error may have been introduced given the fact that six people were involved in entering data into Diet 1. As such, the information on the exchange regimens of each subject presented here should not be treated as exact amounts of carbohydrate, but rather a general indicator of the distribution of carbohydrate across the day.

It is also important to comment on the limitations of the way in which exchanges were calculated. Each exchange was rounded to the nearest whole number so that a subject consuming 20 grams of carbohydrate for breakfast would be documented as one exchange, whereas if a subject consumed 26 grams, this would be documented as two exchanges. This process of rounding numbers reduced the accuracy of the carbohydrate regimens presented in this study.
Chapter 6

Conclusions
Establishing conclusions about the glycemic control of subjects consuming varying exchange patterns of carbohydrate has been hampered by the small sample size of this study, and the subjective nature of the grouping methods adopted.

The large variability in the carbohydrate exchange patterns of subjects testifies to the need for individuality in approaching the dietetic management of people with IDDM. However, it would appear that consuming a diet which has similar amounts or exchanges of carbohydrate at main meals, and smaller amounts of carbohydrate at midmeals without omission of midmeals, is superior to consuming a more uneven carbohydrate distribution, in terms of achieving better glycemic control.

It would also appear that routine adjustment of insulin and diet to account for exercise, is conducive to achieving better glycemic control, in combination with an even carbohydrate distribution.

The apparent lack of association between the number of insulin injections per day and the level of glycemic control achieved in subjects with IDDM is likely to be a reflection of a lack of sample size. As such, the above conclusions must be viewed in the light of other studies with larger numbers of subjects before findings can be generalised to the larger Illawarra population of people with IDDM.

The lack of strength in the small, upward trend in HbA1c levels as total carbohydrate intake increases, together with contradictory findings by other studies, suggests the need for a greater sample size to establish a relationship that has a greater degree of power. It could be concluded from these findings, however, that glycemic control is additionally dependant on factors other than total carbohydrate intake. This does not mean that total carbohydrate intake is unimportant but simply must be considered in the context of other factors such as insulin dosage, exercise and weight.
It may be concluded that the apparent lack of association between carbohydrate regimen adherence and glycemic control is probably due to the study’s reliance on patient self-reports of adherence which is subject to response bias, and to external factors which influence HbA1c apart from carbohydrate intake. It is likely that, given a larger sample size, the small decline seen in the glycemic control of subjects decreasing their adherence, may become a stronger trend.

It could be concluded that the main reasons why subjects with IDDM in this study do not adhere to their carbohydrate exchange regimen as often as they would otherwise, surround the work life that subject’s follow and their “craving” for inappropriate foods. Lack of family and friend support does not appear to be an obstacle to adherence amongst these subjects. Extension of these findings beyond the study sample or development of education programs to increase the dietary adherence of people with IDDM in the Illawarra, requires validation of these results from an extended study with a larger sample size.

Furthermore, it could be concluded that family life and the desire to eat inappropriate foods is a barrier to adherence in subjects in this study having an average age between 26 and 30.

It may be hypothesised that, as the number of years since diagnosis with IDDM increases, reasons for nonadherence to a carbohydrate regimen change from issues of “hectic family life” to “craving” inappropriate foods. Such a conclusion should be kept within the study sample of this study and extended beyond this only when trends have been confirmed by future studies.
Despite the lack of significance in some of the results of this study, given that some of the emerging trends are likely to be confirmed by future research, the following chapter outlines some recommendations based on the findings of this MSc. project.
Chapter 7

Recommendations
Based on the findings and limitations of this study and its research methods, the following recommendations aim to increase the validity of the findings and enable more conclusive evidence to be established. This will allow for findings to be extended to the wider population of Illawarra people with IDDM and with a greater degree of power.

The limited power of the results of this study gives light to the need for a larger sample size to be recruited. The PhD study, of which this project has formed a part, is continuing to recruit more IDDM subjects. It is recommended that at least fifty subjects be recruited in total in order for the objectives of this study to be addressed adequately. This may require extending the age group to 40 or 45, and alternative recruitment methods sought. If the number of subjects gained from the DEIU’s patient list is limited, making networks with local General Practitioners through letters and phone calls may be a way in which to recruit subjects not listed with the DEIU or to update patient’s addresses and contact numbers. An advertisement in the local newspaper - the Illawarra Mercury, may give credit to the study and encourage participation by the target population.

Once a larger sample size is recruited, it is recommended that the objectives of this study be repeated in the following way:

1. With a greater sample size, there will be a greater number of carbohydrate exchange regimens elicited from participants, such that subjects can be allocated to a group having the same or similar carbohydrate patterns, and the HbA1c level of different groups compared using a one - way ANOVA and a Tukey Kramer HSD comparison test.

2. To compare the HbA1c levels of subjects consuming different amounts of carbohydrate as a percentage of their energy intake, it is recommended that the same method used in this study be repeated. However, it would be useful to also utilise Multiple Regression Analysis to
account for the factors which influence HbA1c apart from carbohydrate. These factors include the insulin dosage and pattern, the weight, and the exercise regimen of the subject. This information should continue to be elicited from participants, as in the present study.

3. To determine the adherence of subjects to their exchange regimen, it is recommended that an additional question to the one used here, be used. With a greater sample size, it would be possible to adopt an approach similar to that of Christensen et al (1983) where exchange deviations are calculated by comparing the carbohydrate exchange pattern elicited from the diet history (as in this study) with the original exchange regimen that a subject aims to follow. This would involve asking each subject to write down the carbohydrate regimen that they aim to follow or which their dietitian as recommended.

4. Based on the interesting trends beginning to emerge from the reasons subjects give for nonadherence to their carbohydrate regimen, it is recommended that the same question be used on subjects recruited for the PhD study currently being conducted or in similar studies in the future. Piloting the question on an accessible population such as patients with IDDM at the DEIU, would capture the most common reasons for nonadherence before it is finalised. Keeping the same format of the questionnaire is advisable to enable subjects to give more than one response. It is advised that such a question is asked nearer to the beginning of a questionnaire in order to reduce the effects of respondent burden and fatigue on the answers given.

5. The final objective of this study should be followed in a study of the similar nature to this one. Larger sample size would allow for each subject's characteristic to be observed independently and using statistical methods which account for confounding variables. It is recommended that more variables be used to identify socioeconomic status of subjects. It would be useful to investigate parameters such as the type of occupation that subjects have,
marital status, and gender. The larger sample size would allow for differences in the types of nonadherence reasons given to be detected between these variables.

If a similar study was to be conducted in the future, the use of other dietary intake methods to validate the diet history, is advisable. Although increasing respondent burden, it would be of benefit to the validity of results to use a three day food record to complement the diet history of participants. This would allow for a more typical day’s intake to be elicited more validly than if a food frequency questionnaire was used as a validation tool (as in this study). This may require creating greater participation incentives for potential subjects such as free literature about diabetes, a diabetic cookbook etc, which in turn, may require a small degree of sponsorship from a health organisation or local business.

It is strongly recommended that questionnaires in such a study, be kept to a minimum and the necessary information be clearly determined prior to questionnaire construction.

Finally, results from this study need to be confirmed or further investigated from a larger sample size. If results were to strongly suggest that there is little benefit involved in strict adherence to an even carbohydrate regimen, and that more intensive insulin therapy or alternative dietetic management approaches need to be considered, presentation of these findings to Illawarra dietitians, DEIU educators and relevant medical staff should be pursued. Discussion of these findings in the context of current managerial principles could lead to beneficial changes in current dietary intervention techniques.

If results suggested that adherence to a set carbohydrate regimen appears to be beneficial, presenting the most common reasons for nonadherence and the characteristics of subjects giving these reasons to Illawarra dietitians, would help create ways in which to overcome barriers to adherence. Developing a workshop designed at presenting these adherence
obstacles and appropriate methods of intervention and counselling to dietitians and diabetes educators, would be the most practically beneficial outcome of the study presented here.
References


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Krebs-Smith, S.M., Heimendinger, J., Subar, A.F., Patterson, P.H. and Pivonka, E. (1995), Using food frequency questionnaires to estimate fruit and vegetable intake:
Association between the number of questions and total intake. *Journal of Nutrition Education* 27(2), 80-85.


Appendices
Appendix 4.1 Carbohydrate “exchange” patterns of those subjects classed into “even” and “uneven” groups.

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Appendix 4.2

Subject Information Sheet & Consent Forms
CONSENT FORM
FOR PARTICIPANTS WITH DIABETES

ASSESSMENT OF INSULIN-DEPENDENT DIABETES MANAGEMENT

This research on the current management of diabetes in the Illawarra is being conducted by a group of clinicians and scientists supported by a steering committee with representatives from the Illawarra Area Health Service, the NSW Health Department, and the medical profession. Professor Dennis Calvert in the Medical Research Unit (Illawarra Area Health Service/University of Wollongong) heads the group, and Ms Farideh Tahbaz is coordinating.

Information relating to this study is detailed in the attached information sheet.

You are free to withdraw from all or part of this research program at any time without penalty, and without compromising in any way your treatment or access to services.

The ethical aspects of this study have been approved by the University of Wollongong Human Research Ethics Committee, which is responsible for the ethical aspects of research involving people in the Illawarra. If you have any enquiries regarding the conduct of the research please contact the Secretary of the University of Wollongong Human Research Ethics Committee on (042) 21 3079.

I understand that the information collected in this research will be used for the assessment of insulin-dependent diabetes management and I consent for the data to be used in that manner.

If you wish to take part in this research please sign below

Name ................................................ Signature ................................................ Date ...........................
ASSESSMENT OF INSULIN-DEPENDENT DIABETES MANAGEMENT

We plan to carry out an evaluation of the way in which people with insulin-dependent diabetes mellitus manage the diabetes. We hope as a result of this evaluation to be able to recommend ways in which management guidelines or services may be improved to provide the best possible outcomes for people with diabetes.

We have explained to you how we obtained your name, and we have reassured you that this information, and indeed any information we discover about you, is confidential and will not be released to anybody, unless you give us specific consent to pass information to your doctor. Any other information about this study that is published or passed to other bodies (for instance, the NSW Health Department) will be in such a form that no individuals can be identified. We shall, of course, send you a copy of your results, and (if you wish) the group results when they are available.

We will ask if we can interview you. Interviews will be conducted by Ms Farideh Tahbaz, who is a nutritionist with a Masters degree in nutrition or a graduate in nutrition who is studying for a Masters Degree. Ms Tahbaz, or a colleague will give you a standard questionnaire to fill out, which contains information on your own circumstances, on the way you manage your diabetes, on the way in which insulin is prescribed, and on the way you feel you manage your diabetes and your reactions to diabetes.

You will be asked if you can give a blood and urine specimen, to check the degree to which your diabetes is controlled, and have your height and weight and degree of fatness estimated. Blood would normally be taken from a vein in the arm. You will be asked for further information on the details of your usual diet.

It should be clear that there are no right or wrong answers on diet or diabetes management; we wish to obtain an accurate picture of current management, in its diversity, in the Illawarra.

Please feel free to ask Ms Tahbaz any questions that occur to you. We will ask you if we can write to your doctor and let him/her know the results of your blood test and if you wish, the dietary analysis.

If there are any outstanding questions, please ring Professor Dennis Calvert, phone (042) 266 594. If you have any queries regarding the conduct of the research, please contact the Secretary of the Human Research Ethics Committee on (042) 214 457.
Appendix 4.3

IDDM Introductory Questionnaire
Date:

Please indicate your answer by ticking the appropriate box ☐ or by writing your answer in the space provided. If you are uncertain about the answer to any of the questions leave them blank and ask the receptionist to help you.

**Characteristics of the subject:**

1. **Sex:**
   - Female ☐
   - Male ☐

2. **Marital Status:**
   - Single ☐
   - Married ☐
   - Separated/Divorced ☐
   - Widowed ☐

3. **Date of Birth:**
   - Day: ☐☐
   - Month: ☐☐
   - Year: 19☐☐

4. **Country of Birth:**
   - Australia ☐
   - Not Australia ☐

   If not Australia, what is your country of birth? ........................

5. **How long have you been resident in Australia?**
   - Months ☐
   - Years ☐

6. **Where were members of your family born?**
   - Your father ........................
   - Your father's father (paternal grandfather) ........................
   - Your father's mother (paternal grandmother) ........................
   - Your mother ........................
   - Your mother's father (maternal grandfather)
   - Your mother's mother (maternal grandmother)

7. **Are you of Aboriginal or Torres Strait Islander origin?**
   (If of mixed origin indicate the one to which you belong)
   - No ☐
   - Yes, Aboriginal ☐
   - Yes, Torres Strait Islander ☐
DIABETES HISTORY:

1. What date was diabetes diagnosed? Mo□/Yr□□

2. What is the name and address of your doctor who normally treats your diabetes?

3. Do you want us to send any results to your doctor (e.g., diet and blood test results)?
   - No □
   - Yes □

4. Have you ever taken oral drugs (tablets) for diabetes?
   - No □
   - Yes □
   a. If yes, are you currently taking oral drugs (tablets)?
      - No □
      - Yes □
   b. If no, how long ago did you stop taking oral drugs (tablets)?
      - Mo □  Yr □□
      - Unknown □

5. Are you currently taking insulin?
   - No □
   - Yes □

6. When did you begin permanent use of insulin?
   - Mo □  Yr □□
   - Unknown □

7. What is your current total daily dose of insulin: ------ ------ units

8. Are you currently taking oral drugs and insulin?
   - No □
   - Yes □

If yes to #5 or #8, what is your current insulin regimen? (answer one)
   - one injection daily □
   - two injections daily □
   - three or more injections daily □
   - pump □
   - other □
   - Specify:-------------------
9. Have you ever been hospitalized for diabetes ketoacidosis?

- No  
- Yes  
- Unknown  

**MEDICAL HISTORY:**

**A. Eye problems:**

Have you ever been told by a health care professional that you have or had:

1. Any diabetes related eye problems?

- No  
- Yes  
- Unknown  

If yes please specify: __________________________

2. Laser treatment?

- No  
- Yes  
- Unknown  

3. Impairment of vision?

- No  
- Yes  
- Unknown  

4. Cataracts?

- No  
- Yes  
- Unknown  

5. Detached retina?

- No  
- Yes  
- Unknown  

**B. Kidney problems:**

Have you ever been told by a health care professional that you have or had:

1. Diabetic kidney problem?

- No  
- Yes  
- Unknown  

2. Protein or albumin in the urine?

- No  
- Yes  
- Unknown
Have you ever had:

3. Kidney transplant?
   Yes □
   No □
   Unknown □

4. Kidney dialysis?
   Yes □
   No □
   Unknown □

C. Cardiovascular (heart or circulation) problems:

Have you ever been told by a health care professional that you have or had:

1. Any problems with heart or blood vessels?
   Yes □
   No □
   Unknown □

   If yes, please specify: ------------------------------

2. Abnormal Electrocardiogram?
   Yes □
   No □
   Unknown □

Have you ever had:

3. Heart pains or angina?
   Yes □
   No □
   Unknown □

4. Heart attack?
   Yes □
   No □
   Unknown □

5. Coronary bypass surgery?
   Yes □
   No □
   Unknown □
6. Stroke?
   No •
   Yes •
   Unknown •

7. High blood pressure?
   No •
   Yes •
   Unknown •

8. Drug treatment for high blood pressure?
   No •
   Yes •
   Unknown •

   If yes, are you currently receiving drug treatment?
   No •
   Yes •
   Unknown •

D. Peripheral vascular complications:

Have you ever been told by a health care professional that you have or had:

1. Any trouble with circulation in legs?
   No •
   Yes •
   Unknown •

2. Foot ulcers?
   No •
   Yes •
   Unknown •

3. Gangrene?
   No •
   Yes •
   Unknown •

Have you ever had:

4. Non-traumatic amputation?
   No •
   Yes •
   Unknown •
E. Other major medical disease?

1. Do you have any serious medical problems not mentioned yet?
   No  □
   Yes □
   Unknown □

   Specify: -----------------------------------------

F. Are there any people with diabetes in your family?

   No  □
   Yes □

If yes what is his/her relation with you? -------------------
Information on your background:

1. Education

What is the highest level of your education?
(Please tick and complete level if appropriate)

- commenced primary school
- finished primary school
- commenced high school
- finished high school
- university or other tertiary schooling (eg. TAFE) started
- university or other tertiary schooling (eg. TAFE) finished

Office use only

2. Economic data:

2.1 What is the total estimated family income before taxes?

- less than $12000
- $12000-$15000
- $15001-$18000
- $18001-$22000
- $22001-$26000
- $26001-$32000
- $32001-$40000
- $40001-$50000
- $50001 and over

Office use only

2.2 Occupation

What is your current occupation (if applicable)?

Office use only

Do you want a summary of the study results when available?

- No
- Yes

Contact address (to send you a summary of the results if you wish, and for future follow up):

Office use only

Tel:
Appendix 4.4

Food Pattern Questionnaire
Diabetes Control and Complications Trial (DCCT) - Australian Version*

This questionnaire asks general questions about your food choices and eating habits. Answer as best you can. If you have any questions about the form you can ask the researcher. More information will be collected during the clinic visit.

Thank you for your co-operation in providing this information.

1. Has your general pattern of eating changed in the last year?
   □ yes □ no  If yes, describe:

   _____________________________________________________________
   _____________________________________________________________
   _____________________________________________________________

2. Are you or have you in the past year been on any special diet in addition to a diabetic diet? (such as low salt, vegetarian, weight loss etc).
   □ yes □ no  If yes, describe this diet:

   _____________________________________________________________
   _____________________________________________________________
   _____________________________________________________________
   _____________________________________________________________
3. Are you currently increasing or decreasing your intake of any particular foods or beverages (such as foods high in fibre, caffeine, alcohol etc)?

☐ yes  ☐ no  
If yes, describe:

4. Does your meal pattern tend to vary from week to week? (due to shift work, sports activities, weekends etc).

☐ yes  ☐ no  
If yes, describe:

5. In the last year, have you taken any vitamin and/or mineral supplements?

☐ yes  ☐ no  
If yes, specify brand name, amount and how often taken
Do you change your meal pattern/insulin routine when you exercise? (e.g. do you eat additional carbohydrate before exercise or change your insulin dose, etc.)

[ ] yes  [ ] no  If yes, describe how:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

7. How do you treat hypos (low blood sugar)?

List food/beverages and amounts consumed:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

8. Do you use sugar or an artificial sweetener?

[ ] yes  [ ] no

If yes, specify which foods/beverages you add it to (such as cereal, fruit, coffee, tea, other):

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

If you use an artificial sweetener, specify brand name:
9. Do you add salt to your food at the table?
   □ always  □ occasionally  □ never, Go to Q11

10. How would you rate the amount of salt you add?
   □ light  □ moderate  □ heavy

11. Do you use a salt substitute at the table such as Lite, Co-salt, No-salt etc?
   □ always  □ occasionally  □ never
   If used, specify brand name: ________________________________________

12. Do you regularly use other salt seasonings at the table such as Chicken salt, onion salt, garlic salt?
   □ yes  □ no
   Specify kind(s):
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
13. **Indicate below your usual meal and snack patterns:**

For each meal state the usual time you eat it, for example breakfast at 7:30am and then state the number of times a week you would eat it at home, take from home etc.. Repeat this for each meal time.

<table>
<thead>
<tr>
<th>Usual Time of Meal</th>
<th>Eat at Home</th>
<th>Take from Home</th>
<th>Buy from Takeaway Outlet - Cafeteria, Cafe/Restaurant</th>
<th>Do not Eat</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morning meal (Breakfast)</td>
<td></td>
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<tr>
<td>Morning snack</td>
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<tr>
<td>Noon meal (Lunch)</td>
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<tr>
<td>Afternoon snack</td>
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<tr>
<td>Evening meal (Dinner)</td>
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<tr>
<td>Evening snack (Supper)</td>
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<tr>
<td>Additional snack</td>
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</tbody>
</table>

14. **Who prepares most of your home-cooked meals?**

- Self
- Parent
- Spouse
- Other Household Member

[ ] [ ] [ ] [ ]
Please estimate how often you eat the following foods by ticking the appropriate box. Include diet foods and other special products in the general food categories. For example include low calorie beer with beer. If they are diet/special products please indicate this in the comments section. You may also use the Comments Section for details such as seasonal variation or the brand/product name. Feel free to use the bottom of each page for any additional comments.

<table>
<thead>
<tr>
<th>BEVERAGES</th>
<th>Daily</th>
<th>4-6 times a week</th>
<th>1-3 times a week</th>
<th>1-3 times a month</th>
<th>1-3 times a year or never</th>
<th>Comments eg seasonal variation, low fat, product name etc...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coffee-regular or decaffeinated</td>
<td></td>
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<tr>
<td>Coffee substitute (eg Ecco, Caro)</td>
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<tr>
<td>Tea-regular, decaf, herbal</td>
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<tr>
<td>Drinking chocolate, Milo, Ovaltine etc</td>
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<tr>
<td>Beer, ale</td>
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<tr>
<td>Spirits, cocktails</td>
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<tr>
<td>Liqueur, Port, Brandy</td>
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<tr>
<td>Wine, dry or sweet</td>
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<tr>
<td>Soft drinks- cola and non-cola</td>
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<tr>
<td>Diet soft drinks-cola and non-cola</td>
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<tr>
<td>Cordial (regular or low joule)</td>
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</tbody>
</table>

<p>| DAIRY PRODUCTS              |       |                  |                  |                  |                          |                                                             |
| Milk-whole, skim, reduced fat, powdered UHT, buttermilk, etc |       |                  |                  |                  |                          |                                                             |
| Cottage/ricotta cheese      |       |                  |                  |                  |                          |                                                             |
| Cheese- block, slice, cheese spread |       |                  |                  |                  |                          |                                                             |
| Yoghurt, plain              |       |                  |                  |                  |                          |                                                             |
| Yoghurt, sweetened          |       |                  |                  |                  |                          |                                                             |
| Sour cream, dips            |       |                  |                  |                  |                          |                                                             |
| Ice cream regular           |       |                  |                  |                  |                          |                                                             |
| Ice confectionary/low calorie ice cream |       |                  |                  |                  |                          |                                                             |</p>
<table>
<thead>
<tr>
<th>DAIRY PRODUCTS (continued)</th>
<th>Daily</th>
<th>4-6 times a week</th>
<th>1-3 times a week</th>
<th>1-3 times a month</th>
<th>1-3 times a year or never</th>
<th>Comments eg seasonal variation, low fat, product name etc...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk shakes, smoothies</td>
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<tr>
<td>Eggs</td>
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<tr>
<td>Egg substitutes (eg Scramblers)</td>
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<tr>
<td>BREADS &amp; CEREALS</td>
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<tr>
<td>Bread and rolls-white</td>
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<tr>
<td>Bread and rolls-wholemeal, mixed grain</td>
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<tr>
<td>Fruit loaf/raisin bread</td>
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<tr>
<td>Plain Sweet Biscuits</td>
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<tr>
<td>Fancy Biscuits (eg cream, choc-coated etc)</td>
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<tr>
<td>Bagels, English muffins, crumpets</td>
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<tr>
<td>Sweet bun, Danish, doughnuts</td>
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<tr>
<td>Pancakes, pikelets, waffles</td>
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<tr>
<td>Cereals-Porridge/Oatmeal</td>
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<tr>
<td>Muesli</td>
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<tr>
<td>Other Breakfast Cereals</td>
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<tr>
<td>Pasta, Noodles</td>
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<tr>
<td>Rice-brown, white, rice mixes</td>
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<tr>
<td>Crackers/Crispbreads</td>
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<tr>
<td>Popcorn</td>
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<tr>
<td>Chips-potato, corn etc</td>
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<tr>
<td>Muesli/Health bars</td>
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<tr>
<td>DESSERTS</td>
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<tr>
<td>Puddings, custards</td>
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<tr>
<td>Bars, slices</td>
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<tr>
<td>Cakes</td>
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<tr>
<td>DESSERTS (continued)</td>
<td>Daily</td>
<td>4-6 times a week</td>
<td>1-3 times a week</td>
<td>1-3 times a month</td>
<td>1-3 times a year or never</td>
<td>Comments e.g seasonal variation, low fat, product name etc...</td>
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<tr>
<td>Pies, fruit crumbles</td>
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<tr>
<td>Gelatine desserts - Jelly etc</td>
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<tr>
<td>Other, specify:</td>
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</tbody>
</table>

**MEAT, POULTRY, FISH**

- Pork
- Lamb, Veal
- Beef
- Sausages/Continental Sausages
- Bacon
- Frankfurts, Saveloys
- Luncheon meats- ham, devon, salami, corned beef etc
- Variety/Organ meats- liver, tongue, kidney etc
- Chicken, turkey
- Duck, quail
- Fish, fresh or frozen- perch, salmon, hake, cod, sole etc
- Shellfish, fresh or canned - lobster, prawn, crab, mussels, scallops etc

**MEAT SUBSTITUTES**

- Peanut butter
- Nuts or seeds
- Canned or dried beans, lentils, split peas, lima beans, baked beans
- Soy protein foods such as tofu
<table>
<thead>
<tr>
<th>MIXED DISHES, SOUPS</th>
<th>Daily 4-6 times a week</th>
<th>1-3 times a week</th>
<th>1-3 times a month</th>
<th>1-3 times a year or never</th>
<th>Comments e.g seasonal variation, low fat, product name etc...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pizza, lasagne, macaroni &amp; cheese, ravioli, spaghetti bolognaise etc</td>
<td></td>
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<tr>
<td>Tacos, enchiladas, burritos, chilli etc</td>
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<tr>
<td>Hamburger</td>
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<tr>
<td>Stews/Casseroles/ Curry/Goulash</td>
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<tr>
<td>Meat Loaf</td>
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<tr>
<td>Quiche, soufle</td>
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<tr>
<td>Stir fry meat and vegetable dishes</td>
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<tr>
<td>TV/frozen dinners eg McCain, Findus</td>
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<tr>
<td>Soups, including cream soups, chowders</td>
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<tr>
<td>Sausage Roll, Pastie, Meat Pie</td>
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<tr>
<td>Canned meals eg Heinz, Kraft beef and vegetables</td>
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<tr>
<td>Other mixed dishes commonly eaten Specify:</td>
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</table>

<table>
<thead>
<tr>
<th>VEGETABLES</th>
<th>Daily 4-6 times a week</th>
<th>1-3 times a week</th>
<th>1-3 times a month</th>
<th>1-3 times a year or never</th>
<th>Comments e.g seasonal variation, low fat, product name etc...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potatoes-baked, boiled, mashed, hot chips etc</td>
<td></td>
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<tr>
<td>Sweet potatoes</td>
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<tr>
<td>Green vegetables-peas, broccoli, spinach, beans, cabbage etc</td>
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<tr>
<td>Other cooked vegetables-pumpkin, carrots, corn etc</td>
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<tr>
<td><strong>VEGETABLES (continued)</strong></td>
<td>Daily</td>
<td>4-6 times a week</td>
<td>1-3 times a week</td>
<td>1-3 times a month</td>
<td>1-3 times a year or never</td>
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<tr>
<td>Salads, raw vegetables</td>
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<tr>
<td>Vegetable juices-V8, tomato juice</td>
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<tr>
<td><strong>FRUIT AND FRUIT JUICES</strong></td>
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<tr>
<td>Fruit juice</td>
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<tr>
<td>Fruit-flavoured drinks-Tang etc</td>
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<tr>
<td>Citrus fruits-oranges, grapefruits</td>
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<tr>
<td>Canned fruits in natural juice/water</td>
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<td>Dried fruits-raisins, dates, prunes, apricots etc</td>
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<tr>
<td>Avocado</td>
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<tr>
<td><strong>SUGAR-FREE PRODUCTS</strong></td>
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<tr>
<td>Artificial sweeteners</td>
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<tr>
<td>Lollies, chewing gum</td>
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<tr>
<td>Chocolate</td>
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<tr>
<td>Syrups, jams</td>
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<tr>
<td>Ice cream</td>
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<tr>
<td>Biscuits, cake</td>
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<tr>
<td>Jelly</td>
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<tr>
<td>Puddings, custards</td>
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<tr>
<td><strong>MISCELLANEOUS</strong></td>
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<tr>
<td>Soy milk</td>
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<tr>
<td>Vegemite/marmite</td>
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<tr>
<td>Fish paste</td>
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<tr>
<td>Pickles, relish, chutneys</td>
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<tr>
<td>Olives</td>
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<tr>
<td>MISCELLANEOUS (continued)</td>
<td>Daily</td>
<td>4-6 times a week</td>
<td>1-3 times a week</td>
<td>1-3 times a month</td>
<td>1-3 times a year or never</td>
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<tr>
<td>Steak sauces, mustard</td>
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<tr>
<td>Tomato sauce, chilli sauce</td>
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<tr>
<td>Soy sauce, teriyaki sauce</td>
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<tr>
<td>Confectionary, gum, cough lozenges</td>
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<tr>
<td>Spreads- jam, honey, syrup, marmalade</td>
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<tr>
<td>Chocolate bars</td>
<td></td>
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<tr>
<td><strong>DIETARY SUPPLEMENTS</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins and/or minerals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bran</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheat germ</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malt</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other supplements</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OTHER COMMONLY CONSUMED FOODS OR BEVERAGES NOT INCLUDED IN PREVIOUS GROUPS**

Specify:


*ADAPTED FROM THE FOOD PATTERN QUESTIONNAIRE DEVELOPED BY:
The Nutrition Coordinating Centre
2829 University Avenue SW
MINNEAPOLIS, MN 55414
Appendix 4.5

Diet History Forms
1. AGE: ___  
2. SEX: M / F  
3. HEIGHT (cm): ___

4. WEIGHT (kg): ___  
5. PREGNANT ___

6. ACTIVITY: (sedentary) / (light) / (light- mod) / (moderate) / (mod-heavy) / (heavy) 
20 min sessions: nil / incidental / 1-2 / 7 / 3-4 / 7 / 5-6 / 7 / >6 / 7

MORNING MEAL
MIDDAY MEAL
EVENING MEAL

MORNING TEA
AFTERNOON TEA
SUPPER
**Diet History Coding Form**

**Energy Ratios**

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>307</td>
</tr>
<tr>
<td>Fat</td>
<td>308</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>309</td>
</tr>
<tr>
<td>Alcohol</td>
<td>310</td>
</tr>
</tbody>
</table>

**Fat Ratios**

<table>
<thead>
<tr>
<th>Fat Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyunsaturated</td>
<td>311</td>
</tr>
<tr>
<td>Monounsaturated</td>
<td>312</td>
</tr>
<tr>
<td>Saturated</td>
<td>313</td>
</tr>
</tbody>
</table>

**Macronutrients and micronutrients**

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (kJ)</td>
<td>314</td>
</tr>
<tr>
<td>Energy (cal)</td>
<td>315</td>
</tr>
<tr>
<td>Protein (g)</td>
<td>316</td>
</tr>
<tr>
<td>Fat (g)</td>
<td>317</td>
</tr>
<tr>
<td>Carbohydrate (g)</td>
<td>318</td>
</tr>
<tr>
<td>Alcohol (g)</td>
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</tr>
<tr>
<td>Fibre (g)</td>
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</tr>
<tr>
<td>Sugar (g)</td>
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<tr>
<td>Starch (g)</td>
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</tr>
<tr>
<td>Cholesterol (mg)</td>
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</tr>
<tr>
<td>Sat Fat (g)</td>
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<tr>
<td>Mono. Fat (g)</td>
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</tr>
<tr>
<td>Poly. Fat (g)</td>
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<tr>
<td>Ret-Eq (ug)</td>
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</tr>
<tr>
<td>Vitamin C (mg)</td>
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<td>Thiamin (mg)</td>
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<tr>
<td>Riboflavin (mg)</td>
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<tr>
<td>Niacin-Eq (mg)</td>
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<tr>
<td>Iron (mg)</td>
<td>335</td>
</tr>
<tr>
<td>Zinc (mg)</td>
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</tbody>
</table>
Appendix 4.6

“Practical Aspects of IDDM” Questionnaire
Practical Aspects of IDDM - Questionnaire

For the following questions please tick the response that best applies to yourself

**DIETARY ADHERENCE**

In Questions 1 - 3, we want to find out about your adherence to a diabetic diet, and the difficulties that you may experience keeping to a diabetic diet.

1. In general, how often do you routinely follow a carbohydrate portion plan on a typical day? For example do you have a pattern of carbohydrate “portions” you follow over the day, such as 3 portions for breakfast, 2 portions for morning tea, 4 for lunch, etc.
   I follow my carbohydrate portion plan:

   - Always (7 days a week) [ ]
   - Usually (5-6 days a week) [ ]
   - Sometimes (3-4 days a week) [ ]
   - Not very often (1-2 days a week) [ ]
   - No (0 days a week) [ ]
   - Don’t Know [ ]

2. We would like to know what specific factors prevent you from routinely following a carbohydrate “portion” meal plan or from following it as often as you might otherwise. You may tick more than one response or write your own down on the space provided.
   If don’t follow a set carbohydrate controlled meal plan it is because

   - It didn’t give me good blood sugar control when I tried it before [ ]
   - I am tired of following a set plan [ ]
   - My work is too hectic [ ]
   - My family life makes it difficult [ ]
   - Family/friends are not supportive enough [ ]
   - I crave food I shouldn’t eat [ ]
   - Other. Please Specify: [ ]

3. I generally find it....

   - Very difficult [ ]
   - Moderately difficult [ ]
   - Neither difficult or easy [ ]
   - Moderately easy [ ]
   - Very easy [ ]

   to adhere to my diabetic diet
WEIGHT CONTROL

In Questions 4 - 7 we want to find out about your weight maintenance.

4. Are you currently trying to reduce your weight (please indicate)
   No
   Yes
   If yes what measures are you taking?

5. Are you trying to maintain your current weight? (please indicate)
   No
   Yes
   If yes what measures are you taking?

6. Are you currently trying to increase your weight? (please indicate)
   No
   Yes
   If yes what measures are you taking?

7. Please indicate what you think is your ideal goal weight: _____kg
### ALCOHOL INTAKE

In Questions 8-9 we want to find out about the amount of alcohol you drink.

8. How often do you usually drink alcohol?

| Option                                      | 294
|---------------------------------------------|-----
| I don’t drink alcohol                      |     |
| Less than once a week                      |     |
| On 1 or 2 days a week                      |     |
| On 3 or 4 days a week                      |     |
| On 5 or 6 days a week                      |     |
| Every day                                  |     |

9. On a day when you drink alcohol, how many drinks do you usually have?

| Option                | 295
|-----------------------|-----
| 1 or 2 drinks         |     |
| 3 or 4 drinks         |     |
| 5 to 8 drinks         |     |
| 9 to 12 drinks        |     |
| 13 to 20 drinks       |     |
| more than 20 drinks   |     |

Office use only
EXERCISE

In questions 9-12, we want to find out about the exercise you had during the PAST 2 WEEKS
* For recreation, sport or health-fitness purposes
* As part of your tasks at work and around the house
Please distinguish between vigorous and exercise which made you breathe harder or puff and pant, and less vigorous exercise

RECREATION, SPORT OR HEALTH-FITNESS

9. In the PAST 2 WEEKS, did you engage in vigorous exercise - exercise which makes you breathe harder or puff or pant? (eg vigorous sports such as football, netball, tennis, squash, athletics: jogging or running: keep fit exercises: vigorous swimming: etc.)

   No  □
   Yes □

If yes, how many sessions of vigorous exercise did you have over the 2 week period? __________

Please estimate the TOTAL TIME spent exercising vigorously during the PAST 2 WEEKS.

        hours       minutes

296 □
297 □
298 □
299 □
300 □
301 □
302 □
303 □

10. In the PAST 2 WEEKS, did you engage in less vigorous exercise for recreation, sport or health-fitness purposes which did not make you breathe harder or puff and pant?

   No  □
   Yes □

If yes, how many sessions of less vigorous exercise did you have over the 2 week period? __________

Please estimate the TOTAL TIME spent exercising less vigorously each week.

        hours       minutes

11. In the PAST 2 WEEKS, did you walk for recreation or exercise for periods of 20 minutes or longer?

   No  □
   Yes □

If yes, how many times? __________
VIGOROUS TASKS AT WORK AND AROUND THE HOUSE (paid or unpaid work)

12. In the PAST 2 WEEKS, did you engage in vigorous activity, apart from exercise, which makes you breathe harder or puff and pant? (eg carrying loads, heavy gardening, chopping wood, labouring - at home, during employment or anywhere else).

   No □
   Yes □

If yes, how many sessions of these types of vigorous activity did you have over the 2 week period? _______________

Please estimate the TOTAL TIME spent in these types of vigorous activity during the past 2 weeks: ____________ hours___________minutes

Thank you for taking time to complete these questions 😊
Appendix 4.7

Blood Results
Blood Results:

- HbA1c -------------------- %
- Plasma cholesterol ----------- mmol/l
- HDL cholesterol ----------- mmol/l
- Apo A --------------- mmol/l
- Plasma triglyceride ----------- mmol/l
- Serum creatinine ----------- umol/l
- Serum albumin ----------- g/l
- Fibrinogen ----------- g/l

Urine Results:

- Albumin ----------- mg/l
- Creatinine ----------- mmol/l

Sugar:
- positive □
- negative □

Ketones:
- positive □
- negative □