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Nutritional Intake and Physical Activity of an Adult Population with Diabetes Mellitus Using the Continuous Subcutaneous Insulin Infusion Pump

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NUTRITIONAL INTAKE AND PHYSICAL ACTIVITY OF AN ADULT POPULATION WITH DIABETES MELLITUS USING THE CONTINUOUS SUBCUTANEOUS INSULIN INFUSION PUMP

by

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ABSTRACT

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by

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This study described three days of dietary intake, physical activity, and glycemic control in 14 female and eight male adult diabetics using Continuous Subcutaneous Insulin Infusion (CSII). Changes in weight after initiation of CSII were also described.

Dietary intakes were analyzed using the NUTREDFO computer program then compared to established standards. Both sexes had mean intakes of zinc, folate, vitamin B_6, and magnesium below the Recommended Dietary Allowances (RDA, 1980) for age and sex. Female consumption of iron and total calories consumed were also below recommendations. When dietary intakes were analyzed on a nutrient per 1,000 kcal basis men had intakes of zinc and folate below recommended levels, but met suggested allowances for other nutrients. Women still had suboptimal intakes of zinc, folate, iron, and, to a lesser extent, vitamin B_6 and magnesium.

Mean protein intake was within the recommendation range outlined by the American Diabetes Association (ADA, 1979), but above levels

suggested in a 1987 (ADA) update. Intake of total fat, saturated fat, monounsaturated fat, and cholesterol were above and carbohydrate intake was below recommended levels (ADA, 1987).

No significant differences between the mean dietary intake of an age and sex matched group of females from this study and the second National Health and Nutrition Examination Survey (NHANES II, 1983) were noted.

When variability in caloric and carbohydrate intake was examined no significant differences between days were found.

Mean energy expenditures were higher than estimated levels for the general population. Activities were often reported in fairly large blocks of time, thus changes in activity on a minute to minute basis may not have been accurately described.

Mean blood glucose was near normal on all three days of the study. However, glycosylated hemoglobin levels, done within two months of the study period, were elevated in seven out of 18 subjects.

Weight gain is often reported after initiation of CSII. The women in this study showed a net increase of 3.13 lbs after changing to CSII. However, men lost an average of 1.79 lbs after starting pump therapy.

To the extent that this population is indicative of CSII users as a whole it was concluded that education, directed at increasing dietary intake of foods rich in zinc, folate, magnesium, and vitamin B_6 for both sexes and iron intake for females, would be beneficial. Information on appropriate ways to comply with the dietary

recommendations of the ADA (1987) and to offset the weight gain often associated with CSII may also be useful to the pump wearer.

(195 pages)

CHAPTER I

INTRODUCTION

Background of the Problem

The 1922 discovery of insulin by Drs. Banting and Best made Insulin Dependent Diabetes Mellitus (IDDM) a viably treatable disease (Banting and Best, 1922). Yet, despite 60 years of research the incidence of complications and the prevalence of IDDM have increased (Peterson, 1982). Conventional treatment of IDDM preserves life, but is frequently associated with large variations in blood glucose and prevailing hyperglycemia (Skyler, 1979a). The need for insulin delivery closely resembling the bodies own actions has long been identified. Dr. Best himself viewed insulin as a drug and expected more physiological methods of giving insulin to be developed (Best, 1974).

New methods in insulin delivery have been and are continuing to be studied and evaluated, along with new forms of insulin. Most investigations have focused upon the effect of insulin delivery on glycemic control and on treating or preventing the pathologic sequela often associated with IDDM.

The Continuous Subcutaneous Insulin Infusion (CSII) pump was developed to simulate the physiological release of endogenous insulin (Brink and Stewart, 1986; Champion et al., 1980; Kragen and Chisholm, 1985).

The pump provides continuous subcutaneous infusion of rapid acting (regular) insulin in basal amounts plus patient-activated bolus doses of insulin delivered by the pump before meals. Adjustments in

the bolus doses of insulin are usually made on the basis of carbohydrate content of meals and on capillary blood glucose measurements performed by the patient on blood samples obtained from pricking the finger several times per day (Felig and Bergman, 1982).

Research on these devices suggests that improved regulation of blood glucose levels can occur, approaching euglycemia (Falko et al., 1982; Tamborlane et al., 1981; Rudolf et al., 1981; Pickup et al., 1980; Pietri et al., 1980a; Thorp, 1986; Raskin, 1982; Brink and Stewart, 1986). Several studies have suggested that the improved glycemic control associated with CSII therapy may decrease or reverse some of the metabolic abnormalities associated with IDDM (Lawson et al., 1985; Hamet et al., 1982; Peterson et al., 1980; Schiffrin and Belmonte, 1981a). Kragen and Chisholm (1985) conclude that it is also possible to simulate the major physiological fluctuations in blood insulin levels when CSII therapy is used.

Despite the continuing research with CSII therapy and the growing use of CSII pumps in community-based practices it remains a relatively new procedure (Macey, 1982; Felig and Bergman, 1983). Controversy surrounding the pump's efficacy and to a lesser extent its safety continues. Several investigators suggest that further investigation is necessary before it may be advised as a general treatment modality for the majority of persons with IDDM (Marliss et al., 1981; Salans, 1982; Felig and Bergman, 1983; Thorp, 1986; Watkins, 1985; Teutsch et al., 1984). Brink and Stewart (1986) feel that the use of CSII has "not been proved for extended periods of time" (p. 617). The American Diabetes Association (ADA) (1982) has made a policy statement

regarding situations and patients that may require or be likely candidates for CSII.

Current treatment of IDDM involves a multifaceted approach utilizing insulin, physical activity, and diet. Successful control of IDDM requires the balancing of these three components and the careful monitoring of that balance. Tight metabolic control in pump therapy involves accurately predicting insulin requirements. Predictions are based on dietary intake, physical activity, and self-blood glucose monitoring (Grinvalsky and Nathan, 1983).

Despite the importance of dietary intake and physical activity in CSII therapy there are no publications of the complete nutritional analysis of daily dietary intakes of CSII pump users, nor have descriptions of their daily physical activities been reported. Chantelau et al. (1982) and Capper et al. (1985) both describe dietary practices of persons with IDDM treated by CSII. However, both studies concentrate on the variability in the number and timing of meals and the carbohydrate content of those meals. Neither gives a complete nutritional analysis of the subject's intake. Information on the actual dietary intake, physical activity, and glycemic control of pump wearers would provide a pool of data to draw on in determining nutritional requirements for these patients. Descriptive data on blood glucose levels, concomitant with daily physical activity and nutritional intake, would provide valuable information for health care professionals involved in CSII management.

Problem Statement

Management of IDDM requires a thorough understanding of dietary intake, physical activity, and insulin action and the effect of each individually and interactively on diabetic control. This is especially true for CSII regimens where tighter glycemic control is desired. To date, there have only been two reported studies on the actual dietary intake of individuals on CSII (Chantelau et al., 1982; Capper et al., 1985). Data on the actual daily physical activity of pump wearers is nonexistent. Information describing dietary intake, physical activity, and assessment of control during the same time period has not been reported. Such descriptive information would benefit members of health care teams treating patients on CSII by providing information from pump wearers on their intake and activity, two of the primary controllable components in diabetes management.

Purpose

The purpose of this study was to obtain and describe three consecutive days of dietary intake, physical activity and glycemic control, as measured by a self-monitoring procedure, of persons with IDDM who use CSII pumps. Long term glycemic control was described using hemoglobin A_1 s ($HgbA_1$ s) and hemoglobin A_1C s ($HgbA_1C$ s).

Dietary intake data was compared to established recommendations of the Recommended Dietary Allowances (RDA) (Food and Nutrition Board, 1980, hereafter cited as RDA (1980) and ADA (1979, 1987)). This data was also compared to the second National Health and Nutrition Examination Survey (1976-80) (United States Dept. of Health and Human Resources, 1983, hereafter cited as NHANES II (1983)). Subject's

weight at initiation of pump therapy and during the three day intake period was obtained to determine weight changes following initiation of CSII therapy. Additional descriptive data was obtained from the patient questionnaire.

Objectives

Objective I

Obtain and describe the nutrient intake of the study population by:

A) Analyzing three day dietary intake records using a computerized nutrient analysis program which provides a description of 26 nutrients (Nutredfo).

B) Comparing nutrient intake information with:

1) The RDA (1980) for sex and age matched groups.
2) Nutrient allowances per 1,000 calories (Hansen and Wyse, 1980) for sex and age matched groups.
3) Dietary intake data of sex and age matched groups from NHANES II (1983).
4) The ADA's (1979, 1987) recommendations for diet in diabetes.

C) Describing variability of the:

1) number of meals
2) daily carbohydrate intake
3) daily caloric intake

Objective II

Describe the physical activity of the study population by analyzing a three-day activity record using a computerized energy expenditure program (ENERGY).

Objective III

Describe the glycemic control of the study population by:

A) Describing a $HgbA_1$ or $HgbA_1C$ level within two months of the dietary intake study.

B) Describing blood glucose levels as determined by the subject's self blood glucose monitoring during the study period.

Objective IV

Describe changes in weight since initiation of CSII therapy.

Objective V

Further describe the population using additional data gathered from the survey questionnaire.

Limitations

1) The sample size was statistically small (n = 22) and was primarily gathered from a single geographic region of the United States.

2) Food intake and physical activity records reflect self-reported data and may be subject to error.

3) The study period extended from October to March. This may have influenced dietary intake due to availability of certain foods.

The variation in weather and sports seasons over the time period may have affected the physical activity records.

4) The data base used did not always include the exact food items specified on the food-intake records. The researcher's professional judgment was used to extrapolate data for an approximation of the food from the existing data base or for a new food to be added.

5) The data base did not include values on dietary fiber due to inadequate available information. Therefore dietary fiber intake was not analyzed.

6) Weights reflected the typical amount of error found in a clinic setting including differences in techniques used by individuals taking weights, amount and type of clothing worn by subjects, and differences in scales.

7) Factors that may alter $HgbA_1$ and $HgbA_1C$ values, including use of certain medications, were not studied within the framework of this investigation.

Definition of Terms

Diabetes Mellitus

Diabetes Mellitus (DM) is an hereditary disease of metabolism associated with an inadequate supply or impaired effectiveness of insulin. It is characterized by disturbances of carbohydrate, fat and protein homeostasis.

Diagnosis is primarily based on elevated blood-glucose levels. Two classic criteria used to establish the presence of DM include a

fasting plasma glucose level greater than or equal to 140 mg/dl and an abnormal oral glucose tolerance test with a venous plasma glucose level greater than or equal to 200 mg/dl two hours after intake of 75 grams of oral glucose (Harrison, 1983).

Associated pathological findings include microangiopathy, neuropathy, retinopathy, and macroangiopathy (Goodhart and Shils, 1980). Approximately 5.8 million people in the United States have been diagnosed as being diabetic, and there are an estimated additional four to five million people who have diabetes but who have not yet been diagnosed. In 1982, 34,583 deaths were attributed to diabetes. DM is ranked as the seventh leading underlying cause of death in the U.S. (National Institute of Health, 1985). Due to its chronicity and complications it remains one of the most crippling of all diseases.

Insulin Dependent Diabetes Mellitus

Insulin Dependent Diabetes Mellitus (IDDM) is one of four major diabetic classifications and accounts for five to ten percent of the total diabetic population (Hadden and Harris, 1985; Rifkin and Raskin, 1981). Criteria for the classification of IDDM were outlined by the National Diabetes Data Groups (NDDG) of the National Institute of Health (1979) and by the World Health Organizations (WHO) Expert Committee on Diabetes (1980). Primary characteristics of IDDM include:

1) Low or absent levels of circulating endogenous insulin secondary to permanent functional loss of the β islet cells of the pancreas.

2) Usually abrupt symptomatic onset before age 35.

3) Dependence on injected insulin to prevent ketosis and sustain life.

4) Abnormal immune response and islet cell antibodies generally present at diagnosis.

5) Association with human leukocyte antigens (HLA) D3 and D4.

6) Etiology probably only partly genetic, as only 35% of monozygotic twins are concordant.

Continuous Subcutaneous Insulin Infusion

Continuous Subcutaneous Insulin Infusion (CSII) is a relatively new method of insulin delivery. The technique uses small portable pumps attached to subcutaneous needles by a small plastic catheter. The pumps automatically deliver a continuous infusion of regular insulin at a basal rate designed to hold the plasma concentrations of glucose in the normal range during the overnight fasting period and before meals. Additional boluses of regular insulin are given by the wearer via the pump to compensate for glycemic excursions, primarily associated with meals (Brink and Stewart, 1986; Champion et al., 1980; Kragen and Chisholm, 1985).

Glycosylated Hemoglobin

Hemoglobin A_1 ($HgbA_1$) is formed by a slow nonreversible nonenzymatic glycosylation process between hemoglobin A and sugar or sugar phosphates. $HgbA_1$ is composed of three smaller components which include hemoglobin A_1A, hemoglobin A_1B and hemoglobin A_1C ($HgbA_1C$). They are collectively known as the fast hemoglobins due to their

charge negativity and rapid migration when subjected to cation exchange chromatography compared with hemoglobin A. $HgbA_1C$ represents the greatest fraction of the three and is specifically composed of the adduct of glucose attached to the B chain terminal valine residue by a ketoamine linkage (Goldstein et al., 1982; Baynes et al., 1984). A direct relationship exists between the degree of hemoglobin glycosylation and the degree of hyperglycemia overtime (Gabbay et al., 1977). Glycosylated hemoglobin is the major objective indicator of chronic diabetes control currently available for use. It is widely acknowledged that $HgbA_1$ and $HgbA_1C$ levels obtained from a single blood sample provide an index of the mean glucose level during the preceding two to four months (Goldstein, 1984; Nathan et al., 1984).

CHAPTER II

REVIEW OF THE LITERATURE

Morbidity and Mortality on CSII

CSII pumps are now widely available for general clinical use in private medical practice. The number of diabetics using CSII and the number of physicians prescribing it as a treatment modality is on the rise (ADA, 1985). Although the exact number of insulin pumps currently in use is unknown, 5880 pumps had been sold in the United States by 1982 (National Institute of Health, 1985). Information on morbidity and mortality associated with CSII is still being investigated. Complications involving severe loss of glycemic control and diabetic ketoacidosis have been reported (Peden et al., 1984). A study by the Center for Disease Control (CDC) found most failures of insulin delivery systems are precipitated by infection, and that the number of deaths reported for persons on CSII therapy does not exceed that to be expected in a diabetic population of a similar age (Teutsch et al., 1984).

The three unique risks associated with pump therapy include pump slowing with resultant ketoacidosis, pump runaway associated with severe hypoglycemia, and catheter site infection. In a study of 1060 CSII users Teutsch et al. (1984) reported that hypoglycemic reactions increased in 9.3% and decreased in 34.9% after initiation of pump use. Diabetic ketoacidosis (DKA) increased in 4.4% and decreased in 30.6%. Local reactions or abscesses at the infusion site were noted in 25% of the subjects, but subsided readily with minimal treatment. Bending et

al. (1985) found no significant increase in DKA or hypoglycemic coma among the 121 CSII users studied when compared to a matched population of subjects with IDDM treated with conventional insulin therapy (CIT). In a similar study Mulhauser et al. (1985) reported no increase in DKA or severe hypoglycemia with CSII despite normalization or near normalization of $HgbA_1C$ values. Pickup et al. (1985) found no increase in severe hypoglycemia in patients treated with CSII vs CIT, but did report a significantly increased evidence of DKA.

Metabolic and Hormonal Control

Metabolic Abnormalities Associated with IDDM

Diabetes is associated with a very high incidence of arteriosclerotic heart disease and hypertension (Wahlquist et al., 1984; Steiner, 1981). This has been correlated with depressed high density lipoprotein (HDL) levels and increased cholesterol, triglyceride (TG), and low density lipoprotein (LDL) levels (Falko et al., 1982; Heyningen, 1986; Lopez-Virella et al., 1983). Current research on lipid metabolism suggests that even minimal alterations in glucose tolerance may raise the risk of atherosclerosis (Chantelau et al., 1982). In the diabetic individual insulin does not inhibit hormone sensitive lipase which releases fatty acids and glycerol to form triglycerides (TG). There is also no promotion of glucose transport into the fat cells so fat storage is greatly inhibited or blocked. The resultant elevated level of circulating fatty acids and glycerol is not stored as adipose tissue but is deposited in the liver as TGs and causes fatty liver. The excess of fatty acids in the liver

promotes conversion of fatty acids to phospholipids and cholesterol, sometimes increasing plasma lipoproteins three-fold. These increased lipid profiles have been linked to the heart disease seen in DM. Fatty acids in the liver stimulate the carnitine transport mechanism, and extreme amounts of acetyl coenzyme A is formed. This excess is broken down into ketone bodies, i.e. acetoacetic acid, B-hydroxybutyric acid and acetone, and causes diabetic ketoacidosis (Berne and Levy, 1983).

Normalization of blood glucose control is associated with normalized serum lipid levels. In an 8-month study of 68 diabetics using CSII vs. CIT Lawson et al. (1985) confirmed the reduction or normalization of serum cholesterol and TG concentration with improved blood glucose levels. There was also a significant decrease in venous blood lactate and 3 hydroxybutyrate levels on CSII. This reduction was not demonstrated with CIT. Earlier studies have also reported improved lipid profiles with significantly improved glucose control (Tamborlane et al., 1979a; Pietri et al., 1980a). Overall findings indicate that to the extent that hyper-cholesterolemia, hyper-triglyceridemia, and hyper-lipoproteinemia contribute to accelerated atherosclerosis in diabetes, CSII treatment may reduce the prevalence of this complication.

Using CIT, diabetics generally have diminished uptakes of amino acids by muscle tissue and elevated blood levels of branched chain amino acids. In the nondiabetic person insulin affects protein by increasing active transport of amino acids into the cell, increasing translation of Messenger RNA to form new protein, increasing

transcription of DNA, decreasing catabolism of protein, and decreasing gluconeogenesis to conserve amino acids and protein stores (Berne and Levy, 1983). Metabolic aberrations in protein, associated with inappropriate utilization of insulin or inappropriate insulin levels, can lead to muscle atrophy and degeneration, which is especially harmful to persons with IDDM, or to diabetics with illness or chronic debilitation. CSII therapy has been shown to normalize levels of branched chain amino acids. Research suggests that net amino acid flux across muscle tissue may be returned to normal with the use of CSII (Tamborlane et al., 1979a).

Hormonal Control

The hormonal abnormalities associated with diabetes, ie. aberrant levels of growth hormone, glucagon, somatomedin, and catecholamines, have been brought to normal or near normal levels by use of CSII (Hamet et al., 1982). Impaired growth is a well-recognized complication of diabetes poorly controlled in childhood. Juvenile-onset diabetics are often shorter than their non-diabetic peers. This is most often noted when the onset of IDDM is prior to puberty (Tattersal and Pyke, 1973; Mella, 1981). Generally, growth hormone levels of diabetics are higher than normal and somatomedin levels are within normal limits on CIT. Therefore, attention has focused on relative somatomedin deficiency in diabetes in comparison to growth hormone levels. In a study of adolescents both somatomedin and somatomedin C increased 70-75% with a simultaneous decrease in growth hormone levels after initiation of CSII therapy. In the growing

adolescents, growth velocity doubled in 13-15 months on the pump (Tamborlane et al., 1981).

Relative hyperglucagonemia and A-cell dysfunction persists in diabetic patients despite conventional therapy. This potentiates the hyperglycemia and ketonuria associated with DM. The use of CSII therapy has been demonstrated to reduce glucagon levels to the middle of the nondiabetic range. This decrease in glucagon may be secondary to increased somatomedin levels since it is a known glucagon suppressing agent (Raskin et al., 1979).

Microvascular Complications

The role of hyperglycemia in the pathogenesis of diabetic microvascular disease has not yet been established (Raskin et al., 1983). Research presents conflicting data on the importance of glycemic control on these complications. When near-normal glucoregulation was maintained for 6 weeks on CSII a statistically significant increase in motor nerve conduction velocity (MCV) in the median and peroneal nerves was identified. However, no significant MCV changes were noted in the ulnar nerve or in sensory nerve conduction studies. During this study all patients with diabetic neuropathy noted a marked improvement in their symptoms (Pietri et al., 1980b). The most probable explanation for these findings is the decrease in postsynthetic glycosylation of many proteins, including hemoglobin, albumin, and the proteins of the lens, when normoglycemia is achieved (Boulton et al., 1982; Raskin, 1982). In contrast, a 1-2 year study of diabetic microangiopathy reported an initial decrease in proteinuria but found that all subjects remained proteinuric after 18

months. Further evidence that CSII treatment failed to reverse severe diabetic nephropathy in this study was established by an increase in the subject's serum creatinine and a decrease in creatinine clearance (Tamborlane et al., 1982).

Diabetes is one of the leading causes of blindness in the U.S. (National Institute of Health, 1985). CSII may help diminish this severe complication, but studies are inconclusive and conflicting. In one study restoration (with the insulin pump) of near normal glucose levels was accompanied by reduced retinol flourescin leakage in diabetics showing the typical picture of preproliferative retinopathy, i.e. marked capillary dilation and leakage areas of nonperfusion and capillary looping. After three months on CSII there was a large improvement in vision and a reduction of retinovascular permeability to dye. Revascularization of previously nonperfused areas was also noted. Such a reversal is usually seen only after hypophysectomy. This study suggests that even in late stages of diabetes retinopathy will respond to improved glycemic control (Pickup et al., 1980). Reported results from a similar study did not show any detectable regression of microvascular changes. Retinopathy either remained stable or worsened while on the pump despite maintenance of glucose and HgA_1C within normal limits (Tamborlane et al., 1982).

Glycemic Control

Glycemic Control in Adults with IDDM

There is significant alteration of glycemic control with IDDM due to inappropriate insulin response to fluctuating glucose levels. This

lack of control with its resultant hyperglycemia and extreme glucose fluctuations may be the underlying cause of diabetic complications. In nondiabetic humans, insulin is delivered at essentially two rates; a slow basal rate between meals and a postprandial rate which disposes of absorbed nutrients. Normal plasma glucose rises to 250 mg/dl after ingestion of a carbohydrate load, but secondary to the increased insulin infusion rate, normal fasting levels of 80-90 mg/dl are usually achieved within two-three hours. Insulin response to glucose changes is normally rapid and postprandial glucose levels seldom exceed 120-140 mg/dl one hour after eating. If glucose levels reach 300-400 mg/dl insulin will respond at 10-20 times the normal basal rate (Guyton, 1981). In the diabetic this precise control is lost and the exceedingly low insulin-to-glucose ratio may be responsible for the markedly distorted metabolic state. In diabetes, glucose production is augmented and peripheral glucose utilization is reduced until a new equilibrium is reached at a very high plasma glucose level of 300-2000 mg/dl (Berne and Levy, 1983). In nonpregnant subjects with IDDM fasting, preprandial blood glucose levels of 70-120 mg/dl, 2-hour postprandial levels of <180 mg/dl, and 3-hour postprandial levels of >60 mg/dl are considered reasonable goals for tight control. Only rarely have patients on CIT consistently met these goals. Such levels are generally attained only with subjects who are willing to comply to treatment regimens which require measurement of blood glucose several times daily and adjustment of insulin accordingly (Coustan et al., 1986; American College of Physicians, 1984).

Glycemic Control in Adults with IDDM who use CSII Pumps

The benefits of pump therapy in preventing or retarding long-term complications of IDDM have not been proven (Barbosa et al., 1981). However, there is increasing evidence that the degree of prevailing hyperglycemia in persons with IDDM is sufficient to contribute to the development of long-term complications associated with the disease (Thorp, 1986).

Research indicates that CSII use corrects glucose profile aberrations to normal or near normal levels and that its effect on glycemic variations and hyperglycemia is greater than CIT or optimized conventional therapy (OCT) (Falko et al., 1982; Home et al., 1982; Schiffrin and Belmonte, 1981a; Tamborlane et al., 1979b). CIT rarely brings glucose control within normal range. Studies repeatedly demonstrate mean capillary blood glucose levels in excess of 175 mg/dl using conventional treatment (Tamborlane et al., 1979a; Schiffrin and Belmonte, 1981a; Falko et al., 1982; Pietri et al., 1980a and Tamborlane et al., 1981). Large glycemic excursions with conventional therapy have also been reported (Champion et al., 1980; Sherwin et al., 1980; Calabrese et al., 1982). OCT with four insulin doses per day and close blood glucose monitoring decreases mean capillary blood glucose to the 135-165 mg/dl range, but does not bring it within normal limits. In two studies comparing OCT with CSII both concluded that a better glucose profile was established with CSII (Calabrese et al., 1982; Schiffrin and Belmonte, 1981b). There is little disagreement regarding the effectiveness of CSII in achieving normoglycemia or near normoglycemia even for long time periods.

Other studies, up to two years in length, both in the hospital and at home, show mean capillary blood glucose and $HgbA_1C$ levels at normal or near normal levels (Mulhauser et al., 1985; Leichter et al., 1985; Schiffrin and Belmonte, 1981a; Falko et al., 1982; Tamborlane et al., 1981). These values were usually attained on approximately 80% of the patients usual insulin dosage on CIT and with few incidents of severe hypoglycemia (Tamborlane et al., 1982; Calabrese et al., 1982; Boulton et al., 1982).

Glycemic control is more difficult to attain at certain time periods, during physiologic changes, and with specific individuals. CSII has been effective in normalizing glucose profiles in most of these cases. Fasting blood glucose levels are known to rise between 0300-0800 hours. The exact cause of this "dawn phenomenon" is not known, but a plausible explanation is the cortisol surge observed in many diabetics in the early morning hours. CSII has been shown to achieve normoglycemia during the dawn phenomenon if a carefully determined nocturnal infusion rate is used (Schmidt et al., 1981; Geffner et al., 1983; Bending et al., 1985).

Pregnancy has long been known to cause large glycemic variations in diabetics. Data suggest that prevention of maternal hyperglycemia may be of critical importance in reducing the risks for the infant born to a diabetic mother (Roverski et al., 1979; Coustan et al., 1980). The use of CSII in pregnancy improves metabolic control. Rudolf et al. (1981) and Coustan et al. (1986) found that glycosylated hemoglobin levels were normalized and glycemic excursions were strikingly diminished when CSII therapy was used with diabetic

mothers. Favorable pregnancy outcomes were achieved in all subjects. However, Coustan et al. (1986) has demonstrated that OCT may be just as effective in improving metabolic control as CSII if it is combined with frequent blood testing, stringent treatment goals, and continuous readjustment of insulin doses. In the nonpregnant diabetic subject Schiffrin and Belmonte (1982) and Reeves et al. (1982) found no differences in metabolic control with CSII and OCT although OCT generally required significantly higher insulin doses to achieve the same result. Conversely Nathan et al. (1982) and Home et al. (1982) report better control with CSII therapy.

The effects of CSII observed on twelve very brittle diabetic patients, i.e., metabolically unstable, ketosis-prone, and post-kidney transplantation, provided less conclusive results. One-half of the patients studied showed significant and consistent improvement of blood glucose concentrations with concomitant reduction in $HgbA_1Cs$. The other six patients demonstrated fluctuating glucose levels and elevated $HgbA_1Cs$. In all cases control remained far from normal (Barbosa et al., 1981). Other studies on brittle diabetics have shown minimal improvement of metabolic control with CSII (Pickup et al., 1980). In contrast Noto et al. (1985) reported case studies of two very brittle diabetics who failed to respond to all other therapies but who improved dramatically after CSII therapy.

Self Blood Glucose Monitoring

Self blood glucose monitoring (SBGM) is one means by which control can be assessed and decisions made about changes in treatment and insulin adjustment (Moses and Balint, 1984). Clinical trials have

demonstrated improvement in glycemic control with appropriate use of SBGM and subsequent adjustment of insulin based on obtained blood glucose levels (Cohen and Zimmet, 1980; Grayman et al., 1984). Other recognized advantages of SBGM include a decreased number of hospitalizations for severe hypoglycemia and DKA, increased active involvement of patients in their own care and diabetic management, and the ability of patients to modify treatment to conform to daily changes in diet and activity (Brecher and Birrer, 1984). The primary disadvantage of SBGM is noncompliance. Moses and Balint (1984) report that 49% of 134 patients surveyed did not use their glucometers at all or performed fewer than ten tests per month. Bell and Walshe (1984) found that 52% of 84 patients with IDDM decreased their use of testing by one half within three to six months of starting SBGM and that only 27% made regular insulin adjustments based on blood glucose levels obtained.

Although there is general agreement that subjects can accurately measure blood glucose level in supervised or training situations, only two studies have addressed the accuracy of SBGM in a home situation. Schiffrin et al. (1983) compared the blood glucose readings done at home by 20 adolescents with those done on simultaneously collected blood samples in a laboratory and found a high correlation between the two sets of readings. The authors suggest that subjects can easily learn to accurately monitor their blood glucose. Most et al. (1986) did a similar study using 33 adult subjects, but found that in 53.8% of the cases laboratory values differed from patient-determined values by more than 20%. The authors reported the correlation coefficient of

.74 was lower than the .86 - .98 that has been reported in clinical studies.

Two basic methods are available for SBGM. In the first method a drop of blood is placed on a test strip. After a specific period of time the color change on the strip is compared to a color chart. The second method is newer and more accurate. After a drop of blood has been placed on the test strip and a specified amount of time is allowed to elapse, the test strip is placed in a glucometer. A glucometer is a reflectance photometer which, by reflecting a beam of light from the strip, produces a digital readout of the patients blood glucose. Most glucometers have an accuracy rate of 90% (Brecher and Birrer, 1984).

Recommendations for timing and frequency of SBGM vary from seven to eight tests in one day every seven to ten days to three or more tests in one day several times per week (Mountier et al., 1982). Beebe (1987) suggests a daily blood glucose profile of seven test results per day while the subject is attempting to establish good blood glucose control, decreasing to one or two tests per day once reasonable control is achieved. Optimal testing may include four preprandial tests per day with periodic spot checking, especially before bed, and daily adjustment of insulin based on test results. Consistent use of SBGM may increase the subjects awareness of internal and external cues regarding their own blood glucose levels. It has been demonstrated that patients who are very experienced with SBGM have a high correlation between their perception of their blood glucose levels and actual blood glucose levels. However, rates of

clinically unacceptable estimation errors were still high enough within this experienced group to indicate that subjects should always confirm perceived blood glucose with blood testing before modifying therapy or administering insulin (Cox et al., 1985).

Glycosylated Hemoglobin

Reports of HbA_1C reduction associated with CSII (Falko et al., 1982; Leichter et al., 1985) are especially significant since this parameter is considered to be an objective measurement of long-term glycemic control in DM. Unlike blood glucose levels, glycosylated hemoglobin values are independent of the time of day, blood glucose or insulin levels, illness, and the fed or fasted state of the patient when the blood sugars are drawn (Nathan et al, 1984; Gabbay et al., 1977).

Nathan et al. (1984) concludes that the $HgbA_1C$ assay provides a measurement of long-term glycemic control that would not otherwise be obtainable in a clinical setting utilizing only blood glucose testing, urine testing, or the patient's report of symptoms. Goldstein (1984) suggests that glycosylated hemoglobin may be a revolutionary advance in the clinical management of DM.

The level of $HgbA_1$ or HgA_1C is generally thought to reflect the average blood glucose concentration over the prior two to four month period (American College of Physicians, 1984; Goldstein et al., 1980; Gabbay et al., 1977; Nathan et al., 1984; Compagnucci et al., 1981).

The interpretation of glycosylated hemoglobin values must take into account this averaging of blood glucose concentration. They may be successfully used to compare the average level of glycemic control

in an individual or a group over long time intervals. They are good indicators of the summated effects of prior therapy and other factors influencing glycemic control but do not convey any information about the stability of glycemic control or whether the direction of any change is toward improvement or deterioration (Pecoraro et al., 1982).

Peacock (1984) and Goodwill and Stewart (1984) suggest that interpretation of glycosylated hemoglobin values should be based on the same individual over time and that an important clinical application is the verification of the patient's own home blood glucose monitoring with the $HgbA_1$ or $HgbA_1C$ values.

The American College of Physicians (1984) concludes that although glycosylated hemoglobin may provide clinically useful information regarding the management of IDDM, its usefulness is hindered by the lack of a well-accepted standard method that is precise and repeatable. Reference values are not standardized and comparison of values between labs, even using the same method, is not recommended.

Sources of error in determining $HgbA_1$ and $HgbA_1C$ values include excessive levels of the labile aldamine intermediate associated with a short period of hypoglycemia immediately before the blood draw, possible denaturation by a pH buffer, excessive incubation or temperature flux, and disease states or medical problems which may effect glycosylated hemoglobin levels. These include elevated TG levels, high levels of blood alcohol, acute or chronic anemia, lead toxicity, iron-deficiency anemia, splenectomy, and renal failure (Peacock, 1984). To avoid as many sources of error as possible only assays that remove labile portions via dialysis or the use of isotonic

saline, or that do not measure labile components of glycosylated hemoglobin should be used (Ditzel et al., 1981). Close monitoring of temperature and pH must be done to avoid denaturation and attention directed to the subject's particular factors which are known to affect measurements.

Measurements of $HgbA_1$ and HbA_1C are generally done with high performance liquid chromatography, colorimetric assay, or standard micro-column techniques (Goldstein et al., 1980; Pecoraro et al., 1982). Values that are considered normal vary not only between techniques but between individual labs. Guidelines for interpreting glycosylated hemoglobin values differ but individuals with DM usually have values between five and ten percent. Subjects with IDDM have values ranging from 8-23%. Values exceeding 11.0% may show poor glycemic control and may be indicative of noncompliance with therapy or problems with the treatment regimen. Peacock (1984) suggests that, for column chromatography methods, levels from five to nine percent are normal for the nondiabetic and that levels less than ten percent indicate good control of DM. Levels from 10-14% demonstrate fair control, but indicate a need for the patient to be more compliant or for the treatment regimen to be modified. Values greater than 15% indicate poor control and a need for remedial therapy.

Diet and Nutritional Recommendations for Persons with Diabetes Mellitus

In the preinsulin era low carbohydrate, high fat, calorically restricted diets were the cornerstone of diabetes therapy (Arky et al., 1982). Nuttall (1983) outlines the history of diet therapy for

DM. In 1797, John Rollo, a surgeon general in the British Army, initiated the complete avoidance of carbohydrate in the dietary treatment of diabetes. His prescription called for a diet of animal products with the complete elimination of every kind of vegetable matter. Nearly a century passed before Bourchard modified this diet to include a few green vegetables that had been boiled sufficiently to remove the starch. Bourchard also prescribed long fasts and tight calorie restrictions to avoid glycosuria in his patients. In the early 1900s Bernard Naynyn advised protein and carbohydrate restriction for therapy, since he found that protein could also cause glycosuria. In 1914, Frederick Allen introduced the Allen starvation treatment. This involved caloric restriction and carbohydrate intake of 10 gms/day or less. Although a small minority of physicians treated patients with high carbohydrate diets of oatmeal or rice and reported some success, until the discovery of insulin by Banting and Best (1922) DM was usually treated with dietary regimens of restricted carbohydrate and/or restricted caloric intake.

Today diet is still a principal component in clinical management of DM. It has been shown that dietary management plays a primary role in control of blood glucose concentration (ADA, 1979), but data on the metabolic consequences of various dietary regimens is still incomplete (Nuttall, 1983).

According to the ADA (1979, p. 520) "The dietary recommendations for diabetic persons are, in most respects, the same as for non-diabetic persons." Crapo (1983) recommends that diets for diabetic

subjects without marked loss of control should meet the 1980 RDAs for the individual's age and sex.

The ADA (1979) outlined seven goals of diet therapy for individuals with DM. These include:

1) attain and maintain optimum nutrition to improve overall health.
2) attain and/or maintain ideal body weight.
3) provide for normal physical growth in children and pregnant and lactating women.
4) maintain plasma glucose as near physiologic range as possible.
5) prevent or delay diabetic complications (i.e. retinopathy, neuropathy, atherosclerosis, etc.) insofar as these are related to metabolic control.
6) modify the diet as needed for complications and for associated diseases.
7) individualize the diet making it as attractive and realistic as possible and give appropriate education and follow-up.

In 1987 the ADA updated their nutritional recommendations for persons with DM. The new goals are similar, but include the need for greater consistency in meal timing for persons using exogenous insulin and for the use of blood glucose monitoring results as an aide in the integration of insulin therapy with eating and exercise.

Recommendations for diet composition in DM have changed considerably from the traditional low carbohydrate regimen once advocated. The ADA (1979) recommended increasing complex carbohydrates in the diets of patients with DM to 50-60% of total kilocalories. In economically depressed areas of Asia and Africa many

persons with DM consume 70-80% of their total calories as carbohydrate without problems. Evidence suggests that diets with 60-85% of total calories as carbohydrate are well-tolerated and may lead to a reduction in exogenous insulin requirements, providing the total caloric intake does not increase (Burgess, 1982; Rayner, 1982). Although high carbohydrate diets have sometimes been associated with poor tolerance, poor compliance, and worsening of control in diabetics already in poor control, Crapo (1983) and Nuttall (1983) suggest that increasing complex carbohydrates can potentially provide clinical benefits if used wisely by motivated subjects who have been properly instructed in the diet.

The ADA (1979) suggests that the preponderance of carbohydrate intake should be from starches and foods high in fiber. Increasing fiber intake has been recommended by the Canadian Diabetes Association (CDA) (1981), the British Diabetes Association (BDA) (1982) and the ADA (1979) as a means of reducing postprandial blood glucose rises. Dietary fiber, especially viscous fibers like guar and pectin, may slow gastric emptying time or limit diffusion of digested products to the absorptive surfaces of the small intestine. Thus they seem to cause flatter, more sustained elevations of blood glucose (Crapo, 1983). The recent update by the ADA (1987) suggested a gradual increase in dietary fiber intake to approximately 40 gms/day or 25 gms/1000 kcal of food intake for most individuals with DM.

Carbohydrates that are slowly digested, release their products of digestion slowly into circulation, and cause flatter, more sustained elevations of the blood glucose are commonly referred to as "lente" or

sustained-release carbohydrates. Jenkins (1982) suggests that information on the effect on blood glucose of lente carbohydrates, dietary fiber, and nutritional interaction between foods in a mixed meal will be used in the practical dietary management of diabetes in the future.

Despite reports of improved glucose tolerance, controversy still surrounds the use of high-fiber diets. There is concern that high-fiber diets may cause malabsorption of certain trace minerals, be unpalatable, be poorly tolerated in some subjects, and result in increased stool bulk and flatulence (Nuttall, 1983).

Current research indicates that large differences exist in the glycemic response to different carbohydrate foods. In order to quantify these differences and to initiate a uniform method for classifying the glycemic effect of foods, the glycemic index (GI) has been developed. The GI is defined as the area under the curve for a test food divided by the area under the curve for glucose for a reference food, commonly white bread or glucose, where the available carbohydrate content of both the test and reference foods is the same. That number is multiplied by 100 and reported as a percentage (Jenkins et al., 1981).

Jenkins et al. (1981) reported blood glucose responses to different foods ranging from 10-105% of an equivalent amount of pure glucose. Great variation in the glycemic index between food groups was noted. The group mean percentages went from a low for lentils of 31 $\pm$ 3% to a high for root vegetables of 72 $\pm$ 6%. A high degree of variation was also noted within food groups. Fructose had a GI of 20

± 5% compared to sucrose with a GI of 59 ± 10%. (The mean and standard deviation are expressed throughout the text as mean ± standard deviation.)

There is a wide range of factors which affect glycemic response when eating a meal, including hydration of the starch, particle size, type of fiber present, presence of phytates or saponins, and the amount of protein and fat available. Despite these variations Wolever et al. (1985) suggest that the glycemic index concept is still useful as an aid in the determination of blood glucose response to the mixed meal. Dorchy et al. (1981) suggest that if daily food intake is divided into five or six meals and the rate of absorption of foods is taken into account, a fixed pattern of carbohydrate intake is unnecessary in order to obtain the best diabetic control.

Further research on the GI of individual foods and on mixed meals should be undertaken and thoroughly evaluated before any modification in diabetic diet therapy, based upon the GI, is appropriate.

In general, it is still recommended that glucose and glucose-containing disaccharides such as sucrose and lactose be limited in the diabetic diet (Arky et al., 1982; Crapo, 1983). However, the need for tight control of simple sugars is being reevaluated. The ADA (1987, p. 126) states that "modest amounts of refined sugars may be acceptable, contingent on metabolic control and body weight". Bantle et al. (1983) found no significant difference in blood glucose levels when diabetic subjects were fed mixed meals containing 25% sucrose, glucose, potato starch or wheat starch and conclude that dietary sucrose, when consumed as part of a meal, does not aggravate

postprandial hyperglycemia. Crapo and Olefsky (1983) suggest that diabetics need not be overly concerned about moderate amounts of sucrose in a mixed meal since it does not seem to have a deleterious effect on glycemic control. Nuttall (1983) states that since sucrose has not been proven to adversely affect the health or longevity of persons with DM, less restriction should be placed on concentrated sweets in diabetic diets. Ruderman et al. (1984) concludes that the addition of moderate amounts of simple sugars seems to be tolerated by most diabetic individuals, and that the addition of simple sugars to the diet, evaluated on an individual basis, may improve compliance thus improving glycemic control.

The ADA (1979) recommends lowering fat intake for persons with DM from the typical 40-45% of caloric intake to 30-38%. The ADA (1987) suggests fat intake be further reduced to 30% or less of total caloric intake. The CDA (1981) and the BDA (1982) suggest that a maximum of 35% of total calories comes from fat. Limited intakes of saturated fat and cholesterol have been recommended because diets high in these substances have been implicated in the etiology of atherosclerosis (Arky et al., 1982). There is strong evidence that diabetics have increased plasma cholesterol. Saudek and Young (1981) hypothesize that diet may play a key role in diabetics cholesterol homeostasis. The CDA (1981) and the ADA (1979) recommend limiting cholesterol intake. The ADA (1987) suggests limiting cholesterol to 300 mg/day or less. The limiting of saturated fats is also advised. The ADA (1979, 1987) states that the level of saturated fatty acids should not exceed 10% of total calories, that polyunsaturated fatty acids should supply

up to 10%, and that the remainder of fat intake should be derived from monounsaturated fats. Ruderman et al. (1984) recommends that 50-70% of the fat ingested be unsaturated.

"Modest restriction of salt intake should be considered in well controlled diabetic persons without medical problems," according to the ADA (1979, p. 521) recommendations. It should also be considered in the estimated 40-80% of the diabetic population with hypertension (Arky et al., 1982).

Although not necessarily recommended, if approved by their physician, alcoholic beverages may be included in limited amounts in the diets of patients with DM. The type and quantity of calories present should be included in the diet plan (ADA, 1979; CDA, 1981). The ADA (1987) suggests that intake should not exceed 2 oz. of alcohol one to two times a week. Ruderman et al. (1984) stresses that alcohol should not exceed 6% of the total caloric intake in the diabetic individual.

Table 1 gives a synopsis of the ADA (1979), BDA (1982), CDA (1981), and the ADA (1987) recommendations for diabetic individuals.

Diet and Nutritional Recommendations for Persons with Diabetes Mellitus who use CSII pumps

Synchronizing diet, insulin, and exercise is the main emphasis of therapy in IDDM. Under conventional treatment, a standardized daily regimen of food intake and physical activity is required to match the peaks of intermediate or long-acting insulin. The need for regularity of food intake matched to the insulin pattern is particularly important (ADA, 1979; Crapo, 1983). Thus, under conventional

Table 1. Summary of dietary recommendations of the American, British and Canadian Diabetes Associations

Source	*ADA (1987)	ADA (1979)	**BDA (1982)	***CDA (1981)
Protein	0.8 gm/kg of body wt	12-20% calories	Exact amount not specified (up to 20% calories	Exact amount not specified (up to 20% calories)
Fat	< 30% calories cholesterol < 300 mg/day	30-38% calories	Maximum 35% calories modified	30-35% calories modified fat
Carbo-hydrate	55-60% calories Emphasis of complex CHO (use of modest amount of simple sugars may be acceptable depending on metabolic control of individual	50-60% calories. Emphasis on complex CHO (restriction of simple CHO)	50-55% calories. Emphasis on complex CHO (restriction of simple CHO)	Minium 45% calories. Emphasis on complex CHO (restriction of simple CHO)
Sodium	1,000 mg/1,000 calories (not to exceed 3,000 mg)	Moderation	Moderation	Moderation
Fiber	40 gm/day or 25 gm/ 1,000 calories (maximum intake 50 gm/day)	Encouraged from food sources	Encouraged from food sources	Encouraged from food sources
Alcohol	Limited use with physician approval	Limited use with physician approval	No specific recommendation	Limited use with physician approval
Nutritive sweeteners	Acceptable in management of DM	Advisability of use varies with control	Considered to be of little benefit	Moderation advised
Non-nutritive	Acceptable in management of DM	Currently considered acceptable in diabetic dietary patterns	Currently considered acceptable in diabetic dietary patterns	Moderation advised

*American Diabetes Association
**British Diabetes Association
***Canadian Diabetes Association

management, the timing of meals and snacks is determined by insulin action and not by the individual.

The major difference between CSII pump therapy and CIT is the elimination of insulin peaks with CSII (Savesky, 1983). With pump therapy insulin is delivered at a constant basal rate and insulin boluses are adjusted to meal size and timing, to intensity and duration of physical activity, and to blood glucose levels. The wearer adjusts the insulin dose rather than being forced to adjust meals, activity, and life style on the basis of the action of intermediate-acting insulin.

CSII allows for greater dietary flexibility, but dietary management remains a primary component of therapy under this regimen. According to the ADA (1982, p. 140) the "use of continuous insulin delivery in no way allows for discarding diet or the daily scheduling of events necessary for total diabetic management".

Although the exact role of diet in CSII therapy is still unclear some guidelines have been described. According to Grinvalsky and Nathan (1983) successful dietary patterns have the same basic elements as successful CIT dietary patterns with a few exceptions. Similarities include:

1) Low-fat diet with 50-60% of total calories as carbohydrate, 30-38% as fat and 10-20% as protein; complex carbohydrates are advised.
2) Achieve and maintain ideal body weight and/or promote growth and development.
3) Three meals per day at reasonably regular times and with similar total caloric and carbohydrate content. Snacks may be more

flexible. If meal timing is not fairly consistent previous meal boluses may effect the next meal. Meal sizes that vary widely in calorie or carbohydrate content have been shown to make the adjustment of preprandial boluses more difficult.

4) Avoidance of concentrated sweets. Although blood glucose can be controlled more effectively on the pump, ingestion of large amounts of concentrated sweets still causes glucose fluctuations.

Differences include:

1) Matching of insulin boluses to preprandial blood glucose concentration, meal size, and carbohydrate content of meals. For this reason CSII is usually recommended for subjects willing to do frequent SBGM and who are highly diet-educable.

2) Careful attention to weight maintenance diets. Many diabetics using CSII note a tendency to gain weight. This may be attributable to more efficient utilization of caloric intake on this regimen.

3) Increased flexibility of meal and snack timing with the pump. However, this does not mean complete freedom in meal timing. It has been observed that nearly all successful diet regimens for pump patients followed a fairly successful structured meal pattern. Since insulin peaks are generally eliminated on CSII snacks are not necessarily required. Night-time snacks are usually recommended to avoid nocturnal hypoglycemia.

4) Immediate treatment of the pump patient at the first symptoms of hypoglycemia. Ten to 15 gm of sample carbohydrate is generally enough to normalize blood glucose in ten to 15 minutes. Pump

wearers may tolerate lower blood glucose levels so symptoms of hypoglycemia may occur at lower blood glucose levels than on CIT.

Although the guidelines suggested above by Grinvalsky and Nathan (1983) have had three years of successful clinical trial, they are not universally accepted, and other diet protocols are in use. Chantelau et al. (1984) suggest that lean CSII users do not need to follow structured meal patterns. They report that 90% of 70 pump-treated patients had normal $HgbA_1C$'s for several years without following a structured meal pattern. Chantelau et al. (1985) report that a moderate intake of sucrose (approximately ten percent of their total carbohydrate intake) is well tolerated by pump-treated diabetics and encourage a more liberal diet in the treatment of persons with IDDM who use CSII. Savesky (1983) reports five diet protocols that are being used by CSII wearers. These include the traditional ADA Exchange Lists for Meal Planning (ADA, 1976), calorie counting, carbohydrate counting, a liberalized diabetic diet where the composition or quantity of food is not regulated but concentrated sweets are avoided, and a totally free diet which does not restrict concentrated sweets.

Dietary Studies of Persons with IDDM

Few studies have been done on the actual dietary intake of persons with IDDM. Although intakes of various nutrients have been reported there have been no reports of the complete micronutrient intake of persons with IDDM.

Sterky (1962) studied the dietary intake of diabetic and nondiabetic school children from seven to 20 years of age. Dietary

intakes were gathered using the 24-hour recall method. Two hundred fifty-four children, 130 with IDDM and 124 without IDDM, took part in the investigation of food habits. The study revealed that protein intakes were generally higher and that carbohydrate and calorie intakes were lower in diabetics than in nondiabetics. The average intakes of carbohydrates, proteins, and fats by diabetic children were 41.55%, 14.3%, and 44.15% respectively. Children with DM were also significantly lower than their counterparts in intakes of calcium, iron, vitamin A, thiamin, and riboflavin. Over 50% of all children studied were below the 1958 RDA for the vitamins and minerals specified.

Seppanen and Reunanen (1979) studied the dietary intake of 185 subjects with IDDM and Non-Insulin Dependent Diabetes Mellitus (NIDDM) and compared them to a group of healthy non-diabetic subjects. Comparisons of the percentages of total caloric intake from carbohydrate and protein revealed that diabetics consumed more protein and less carbohydrate than their non-diabetic counterparts, 16-18% vs. 13-14% protein and 41-46% vs. 47-51% carbohydrate for the respective populations. Both groups consumed 38-40% of their total energy intake from fat. Diabetics ate 12-21 gms of sugar daily compared to an average of 70 gm/day for subjects without DM. Over 66% of the participants with IDDM ate six or more meals per day.

Dietary Studies of Persons with IDDM who use CSII

Chantelau et al. (1982) described the dietary intake of seven subjects on CSII. Subjects adhered to diets following ADA (1979)

guidelines for the first three days of the study and then switched to a liberalized diet. The less restricted diet offered free choice of number, timing, and carbohydrate content of meals, but simple sugars were still avoided. On the liberalized diet, carbohydrate content varied from 40 ± 12 gm carbohydrate at breakfast to 53 ± 24 gm carbohydrate at supper. The average daily carbohydrate intake was 156 ± 4 gm/day. The percent of total calories derived from carbohydrate was 34 ± 5%, from protein 15 ± 2%, and from fat 51 ± 5%. Timing of meals varied up to 94 ± 55 minutes from one day to the next. On the less restricted regimen the average number of daily meals fell from five or six per day to three or four per day. Mean glucose levels were within normal limits on the conventional and on the less restricted diet. Mean $HgbA_1C$ value fell from 9.7 ± 1.9% before initiation of CSII and a relatively unrestricted diet to 7.3 ± 0.5%, 4-6 months after installation of this regimen. Further evaluation of the dietary intake was not presented.

Eating behaviors and diet composition of 15 individuals with IDDM treated with CSII were investigated by Capper et al. (1985). Diet composition was evaluated on the basis of a 24-hour recall. Mean diet composition as a percent of calories was 38% ± 1.8% carbohydrate, 20% ± 0.9% protein, and 42% ± 1.2% fat. Food-frequency comparisons of diet while on conventional vs. pump therapy revealed statistically significant increases in the number of snacks and the delaying of meals for more than one hour while using CSII. The amount of refined carbohydrate consumed did not change significantly after initiation of CSII.

Average meal-time variations on the pump were: breakfast, 126 ± 20 minutes; lunch, 84 ± 15 minutes; dinner, 122 ± 14 minutes, and snack, 101 ± 17 minutes. Maximal mealtime variations were 126 ± 20 minutes. Variations in the size of meals also increased on pump therapy. Mean $HgbA_1C$ levels went from 10.4 ± .3% on CIT to 8.6 ± .3% after a mean of 16.2 ± 2.3 months of CSII therapy.

The number of subjects who did not adhere to a structured meal plan or directly use the exchange system, but tried to keep meal composition, proportions, and timing reasonably consistent, increased from 67% on CIT to 85% on CSII. Micronutrient composition of the meals was not reported.

Weight Changes in Subjects Using Continuous Subcutaneous Insulin Infusion

The tendency for diabetics on CSII therapy to gain weight has been consistently reported in the literature (Hamet et al., 1982; Leichter et al., 1985; Home et al., 1982; Capper et al., 1985). Modest weight gains of one-and-one-half to two kilograms (kg) after six to 52 weeks of CSII pump use were commonly described (Hamet et al., 1982; Home et al., 1982). Capper et al. (1985) noted a mean peak weight gain of 4.76 kg after two to 15 months of pump therapy in 12 of the 15 subjects studied. This represents a 7.9% increase in body weight. Subjects believed weight gain was caused by improved glucose control, with the body's use of calories previously lost in urine and increased food consumption secondary to the convenience of adding more insulin to compensate for larger meals and additional snacks.

Leichter et al. (1985) reported an increase in percent of desirable weight from 104 ± 3% to 112 ± 4% in ten patients two years after initiation of CSII. The authors speculate that weight gain may be secondary to improved glycemic control in the face of long-term caloric excess or the overzealous use of insulin to cover larger or more frequent meals.

Hamet et al. (1982) noted a weight increase in seven of eight subjects studied. Mean weight increased from 60 kg after three weeks of pump therapy to 62 kg after five months on the pump. The authors state that weight gain may be a significant problem with CSII therapy and suggest that patients decrease their caloric intake by an amount equivalent to observed pre-CSII glycosuria. The amount of glucose lost in the urine before initiation of CSII is now available for use by the body. If the subject does not decrease caloric intake by an amount equal to that previously lost or compensate for the extra calories now available to the system by increased physical activity, weight gain may result.

Physical Activity in Persons with Insulin Dependent Diabetes Mellitus

The basic principle in control of IDDM is the balance among energy expenditure (physical activity), energy availability (food intake), and insulin action (Skyler, 1979b). Thorough understanding and appropriate implementation of each of these components is essential in successful management of IDDM.

Because of its glucose-lowering effect, exercise or increased physical activity has traditionally been recommended to patients with

DM. Therapeutic use of exercise was advocated as early as 600 BC. The enhancement of glucose uptake following physical activity was described in the 1880s. Improved tolerance to carbohydrate load with exercise has been repeatedly reported since the 1920s (Vranic and Berger, 1979). Studies indicate increased sensitivity to insulin and increased insulin binding to receptors with physical training. Conversely, inactivity has been shown to increase insulin resistance and cause deterioration of glucose tolerance (Skyler, 1979b; Caron et al., 1982). Reduced insulin requirements have been reported after implementation of a regular exercise program in subjects with IDDM (Sachdeo et al., 1983; Vranic and Berger, 1979).

The overall metabolic response to exercise is complex and involves a combination of hormonal, enzymatic, neural, and substrate control. In the nondiabetic individual the rate of glucose utilization and glucose production are precisely matched. This regulation is so good that unless activity is severe or prolonged, blood glucose concentration remains stable. Normal hormonal alterations that occur with increased physical activity include a decrease in insulin secretion and increased blood levels of catecholamines, growth hormone, cortisol, and glucagon. Cortisol and glucagon are increased significantly only with prolonged activity (Skyler, 1979b). The regulation of insulin levels is vital since it must be high enough to enhance peripheral glucose utilization, and to sensitize the liver to the action of gluconeogenic and glycogenoltyic hormones like catecholamines, but low enough not to prevent glucose production (Vranic and Berger, 1979).

The individual with IDDM lacks this sensitive insulin response to variations in the level of physical activity. Thus, glucose homeostasis is jeopardized. This is further complicated by inappropriate responses of other circulating hormones during exercise. Epinephrine, norepinephrine, and growth hormone response to exercise is exaggerated in the conventionally treated diabetic (Tamborlane et al., 1979b).

Screening of metabolic control with SBGM and urine testing are recommended before strenuous or prolonged activity to prevent hypoglycemia or hyperglycemia. In nondiabetic individuals insulin secretion decreases during exercise, increasing hepatic glucose production to compensate for increased glucose utilization by the muscle. This down regulation does not occur in persons with IDDM and a relative hyperinsulinemia and hypoglycemia may occur (Sachdeo et al., 1983).

Nathan et al. (1985) suggest using a "lente" carbohydrate such as whole milk 30 minutes before starting moderate activity. Such a snack has been shown to cause a delayed increase in plasma glucose concentration without causing increased plasma glucose values during exercise. Alternatively, subjects may snack on rapid-acting carbohydrate after the completion of exercise. Fifteen to 30 grams of carbohydrate for 30 minutes of exercise are commonly recommended. If strenuous exercise is to be prolonged for more than one or two hours a reduction in insulin administration may decrease the risk of hypoglycemia, and additional carbohydrate may need to be consumed to replete muscle glycogen stores (Kemmer and Berger, 1984).

Insulin plays a permissive role in the increase of glucose uptake by the muscle during exercise. Subjects with insulin deficiency may experience a worsening of hyperglycemia since their hepatic glucose production may still increase with exercise, but peripheral utilization of glucose will be limited. It is suggested that persons with marked acetonuria (3 plus acetone in urine) or with blood glucose in the 250-350 mg/dl or greater range limit exercise or strenuous physical activity until improved metabolic control is achieved (Caron et al., 1982; Kemmer and Berger, 1984; Schumann, 1983).

Exercise and physical activity have not been commonly used as treatment modalities in IDDM due to the lack of precise data on predicted metabolic effects (Nuttall, 1983; Kemmer and Berger, 1984).

Zinman et al. (1984) studied 13 subjects with IDDM for 12 weeks to assess acute and long-term glucose responses to exercise. They found that the acute glucose lowering effect of exercise extended over the entire 13-week period, but that long-term control, assessed by $HgbA_1C$'s, did not improve. A significant increase in caloric intake on exercise days (2849 $\pm$ 330 kcals) vs. nonexercise days (2569 $\pm$ 273 kcals) was also noted. The authors conclude that therapeutic use of exercise training in diabetic management may require more research on, and precise guidelines for, exercise timing and nutrient intake based on SBGM.

Caron et al. (1982) studied the effect of 45 minutes of exercise performed 30 minutes after meals in eight subjects with IDDM and report that the majority demonstrated a marked improvement in the abnormal glycemic excursions often seen in diabetics postprandially.

Improved glycemic response to the subsequent meal was also noted. The authors suggest that although this information may be useful in prescribing exercise timing for persons with IDDM, long-term studies on the metabolic control of IDDM with respect to exercise requires further study.

The duration and intensity of physical activity has been demonstrated to affect glucose levels in the subject with IDDM. Hubinger et al. (1985) reports that short-term exhaustive exercise, two minutes 15 seconds to four minutes 15 seconds in length, did not affect the level of blood glucose in the nine individuals studied. Both continuous exercise for 30 minutes and three ten-minute exercise periods at half the maximal work load of each subject, interrupted by two three-minute rest periods, caused significant decreases in blood glucose levels. Other authors have reported that physical activity may have a prolonged effect on diabetic control and that, depending on duration and intensity, it may influence intake requirements for up to 48 hours after cessation of the activity (Skyler, 1979b; Caron et al., 1982). Consideration of the intensity and duration of physical activity must be considered in advising its use in the management of IDDM

Physical Activity in Persons with IDDM who use CSII

CSII is reported to be a safe and adequate method for treating individuals with IDDM during exercise and to aide in the normalization of deviate hormonal and metabolic responses associated with physical

activity in diabetics treated with CIT (Gooch et al., 1983; Viberti et al., 1984).

The primary concern with CSII therapy during strenuous physical activity is the possibility of developing hypoglycemia. Postprandial blood glucose levels are lower on CSII therapy and the risk of hypoglycemia induced by post-meal exercise may be increased. Hyperinsulinemia accelerates exercise-stimulated glucose utilization while decreasing hepatic glucose production which normally meets the needs of exercising muscle. Boluses of rapid-acting insulin may peak at a higher level than on conventional treatment regimens and thus lower blood glucose more quickly (Koivisto and Tronier, 1983; Gooch et al., 1983).

Despite these concerns most authors do not report an increased risk of hypoglycemia following postprandial exercise in pump users, even when mild hyperinsulinemia is observed (Trovati et al., 1984; Yki-Jarvinen et al., 1984).

Koivisto and Tronier (1983) studied 11 subjects treated with CSII or CIT and reported that plasma insulin levels were 50% higher at the beginning of postprandial exercise in pump wearers than in their conventionally-treated counterparts. Blood glucose levels fell 60% more during exercise in subjects on CSII therapy, but in contrast to subjects on CIT, did not continue to fall during the recovery period. Total decreases in blood glucose levels were similar in both groups and there were no reports of hypoglycemia.

In contrast, Schiffrin et al. (1984) reports that six subjects treated with CSII therapy had a marked increase in hypoglycemia

following moderate exercise in the post-absorptive state when compared to six subjects treated with OCT. Schiffrin and Parikh (1985) found that a 30-50% reduction of the premeal insulin bolus in anticipation of postprandial exercise of moderate intensity (45 minutes of cycle ergometer exercise at 55% VO_2) resulted in near-normal glycemic values and prevented hypoglycemia. Intake of 15 gm of glucose before and 15-30 gms of glucose after 45 minutes of moderate postprandial exercise was recommended to prevent hypoglycemia in the case of unplanned physical activity.

Individuals using CSII are generally highly motivated people striving for improved diabetic control. Their insulin administration is primarily based on blood glucose levels and dietary intake which have both been shown to be affected by physical activity. The absorption and utilization of insulin may also be affected by physical training. Information on the actual daily physical activity of pump wearers would be of use in treating these patients and in educating them on insulin bolusing. To date the actual daily physical activity of subjects on CSII has not been documented.

Dietary Assessment Methods

Comparative studies of different dietary assessment methods have been done for over four decades, but results remain inconclusive. Each method used has advantages and disadvantages (Karvetti and Knuts, 1981).

Stuff et al. (1983) points out two major limitations found in all assessment methods. First, as the accuracy of dietary intake assessment increases, there is increased interference with normal

lifestyles and usual intakes. Second, unless the method uses direct chemical analysis it is dependent on food composition tables that only approximate the actual nutrient content of foods consumed.

Block (1982) summarizes studies on the validity and reliability of various dietary assessment methods and concludes that validation of dietary intake methods is very difficult since the true or actual intake should be known as a comparison value and that the intake reported needs to be established as the usual or typical intake for the subject. Since these criteria are extremely difficult to establish, validations are usually comparisons of one dietary assessment method with another or are based on the reproducibility of nutrient intake data in repeated studies.

According to Beaton et al. (1983) there is no ideal dietary collection method, but depending on the scope of the study and information sought, different methods may be preferred.

Methods used to assess nutrient intake include the food record, the dietary recall, and the dietary history. Food-frequency questionnaires are excluded from this group since they are primarily used as a method to measure typical food consumption rather than actual dietary intake for a specific period (Mullen et al., 1984).

Food intake records involve recording all food consumed over a specified period of time. Subjects weigh, measure, or estimate food eaten depending upon the guideline specified. This method does not require skilled interviewers since records are filled out by the subjects themselves throughout the intake period.

Research has primarily addressed the issues of validity of the food record, the number of days the records should be kept, and for which days of the week records should be kept.

Gersovitz et al. (1978) found good agreement with actual known intake and mean values obtained by the seven-day food record. Good correlation was also found between individual values during the first few days of the recorded week. Validity reportedly declined by the fifth, sixth, and seventh days of the food record. Block (1982) concludes that good agreement has been established between mean values obtained by the seven-day food record and by actual weighing, but that the validity of this method may be limited to group mean values since individual records may become unreliable, especially toward the end of the record keeping period.

Gutherie and Crocetti (1985) assessed the magnitude of variation in nutrient intake of individuals over a three-day period. They report that 85% of the 21,569 people surveyed had intakes of a specific nutrient on any one day that varied by more than 25% from the average for the three-day period. Therefore intake on any one day cannot be considered a sensitive indicator of the usual intake of that nutrient for an individual. They concluded that information provided by a one-day intake is inadequate and inappropriate for accurate assessment of the intake of an individual and questionable as a good representation of the usual intake of groups. This is supported by the conclusions of Beaton et al. (1983).

Stuff et al. (1983) proposes the three-day food record as a reasonable method for obtaining nutrient intake data and for assessing

the general quality of the diet but feels it may not be as precise in predicting individual intake as the seven-day record. The use of the three-day food record for establishing nutrient intake is also supported by Young and Trulson (1960). Jackson et al. (1986) concluded that four consecutive days of records are needed to provide an acceptable tool for assessing dietary intake.

Significant differences in nutrient intake between weekend days and week days have been reported in a group of pregnant women and a group of industrial workers by Chalmers et al. (1952) and in 30 adult women by Beaton et al. (1983). Since there is a documented difference in the quantity and type of food selected on weekend days compared to week days, exclusion of weekend days in intake records may distort assessment of actual mean dietary intake.

Other concerns with the use of food records include the need for a high degree of cooperation on the part of the subject, the possibility that subjects may change their usual eating behavior because they are writing down their intake, and the likelihood that portion sizes may vary as a result of attention paid to scrutinizing quantities (Chalmers et al., 1952; Block, 1982; Gersovitz et al., 1978). Jackson et al. (1986) suggest that respondents often report what they thought was expected of them, commonly over-reporting low intakes and under-reporting high intakes.

The 24-hour recall requires the subject to remember everything that was eaten over the previous 24 hours. It is preferable to have a trained interviewer administer the 24-hour recall. This method is more open to direct validation since the time and intake are limited,

making direct observation and measurement of intake possible and practical (Block, 1982).

Madden et al. (1976) compared the 24-hour recall with weighed duplicate meals for 76 elderly persons. Mean values of the two methods were found to be similar for all nutrients except calories.

When Pao et al. (1985) compared the intakes of 8,779 individuals, divided into 22 age-sex groups, using a 24-hour recall and a two-day dietary record, mean intakes for most nutrients and age groups were not significantly different. Exceptions that were noted, primarily among males, for caloric intake, fat, and carbohydrate were so few that they could be due to chance alone.

Gersovitz et al. (1978) compared the dietary intake of 31 elderly subjects, obtained by 24-hour recall, with the observed actual weighed amounts of foods eaten. Mean reported intake values were not significantly different for nine out of ten nutrients. Mean recalled protein intake was the only nutrient which differed significantly from mean actual intake.

Despite good correlations with actual weighed intake the 24-hour recall only reflects one day and may be a poor indicator of usual intakes so is not considered an appropriate tool for assessing the usual diet of an individual. When assessing 24-hour recall Madden et al. (1976) and Stunkard and Waxman (1981) found subjects often over-reported low intakes and under-reported high intakes and suggest that, to the degree that subjects tend to report the mean or perceived expected intake, there may be an underestimation of extremes in intake and a false negative difference between groups.

The dietary history includes any method which consists of an extensive interview designed to elicit the usual diet. Diet histories have been reported to yield higher values than the seven-day record or 24-hour recall (Young et al., 1952; Lepper and Phelan, 1963). However, Jain et al. (1980) concluded that although the diet history does not give a picture of total nutrient intake identical to diet records it is useful as an estimate of dietary patterns among groups and is sufficiently reliable to be used for epidemiological studies.

Since no one food intake assessment method has been established as the most reliable for all conditions, the researcher must decide the most effective method to use within the constraints of the research environment and depending on the objectives of the research.

Physical Activity Assessment Methods

Assessing the habitual activity of people is probably the most difficult parameter measured in energy-balance studies. Assessment of dietary intake requires measurement only when the subject consumes food. Body fat or weight can be measured at periodic intervals, but energy expenditure is a continuous function. It is also highly variable with occupational and leisure activities, changing greatly with many people throughout any given day, from day to day, and from season to season. Energy output is dependent on the nature and intensity of the activity, environmental conditions, previous exercise, and the amount of time elapsed since ingestion of a meal (Montoye, 1971; Acheson et al., 1980).

Several methods have been used to determine energy expenditure including analysis of heart rate variations during daily activities,

retrospective questionnaires of habitual activity patterns, and calculations of energy output based on formulas that determine metabolic rate with a percentage of this basal rate used to establish physical activity (Reiff et al., 1967; Mahalko and Johnson, 1980; Acheson et al., 1980).

Indirect calorimetry is based on the calculation of heat production from gaseous exchange: oxygen consumed, carbon dioxide expired, or both. The agreement in caloric values obtained by calculation from either oxygen consumption or carbon dioxide production is quite good. Indirect calorimetry appears to be the most accurate method to assess the energy cost of daily activities (Bouchard et al., 1983). The use of various devices such as the Planck respirometer, which consists of a small dry gas meter worn on the back and a face mask which the subject breathes through, has been used to establish values of caloric expenditure for various activities (Wirths, 1974; Durnin and Passmore, 1967).

Although indirect calorimetry is considered very accurate it is difficult to use since it requires considerable time, expense, and a highly motivated population of subjects. The physical encumbrance involved with even the lightest of respirometers may introduce bias into an estimation of daily physical activity by altering the subject's typical activity pattern (Acheson et al., 1980; Bouchard et al., 1983).

The factorial or diary method involves the recording, by the subject or a direct observer, of all activities and their duration over a specified time period. The energy costs of the different

activities are generally obtained from the literature (Durnin and Passmore, 1967), and the energy cost of each activity is multiplied by the total time spent in that activity over the time frame specified, typically 24 hours. Validation of this method is generally based on its correlation with retest experiments, oxygen consumption studies, and intake balance studies and is generally considered to be a reliable summary of mean energy expenditure for the group (Taylor et al., 1978; Acheson et al., 1980).

Bouchard et al. (1983) developed a three-day activity record to estimate the amount and pattern of daily energy expenditure. Energy expenditure was qualified on a scale from one to nine. The categories were based on the energy, expressed in METs, required to perform the particular activity. MET is defined as a multiple of the resting metabolism with one MET equaling the average resting energy expenditure or oxygen consumption of a reference individual. Twenty-four-hour time periods were divided into 96 fifteen-minute activity units. This instrument was then used by 300 subjects on two week days and one weekend day to record their physical activities. Results indicated that daily patterns of energy expenditure tended to fluctuate a great deal. The highest weekly variations were noted between week days and weekend days. When a retest experiment was performed daily energy expenditure for any of the days activities was closely reproducible. Reliability correlations ranged from .86 to .95. Mean calorie energy expenditure for the three days was highly reliable with a coefficient of 0.96. High-intensity activities are reported with somewhat greater accuracy than activities requiring less

effort. The authors conclude that the use of a three-day diet record can be very useful in quantifying mean energy expended per day, but that the diary method may be inappropriate for energy-balance studies since it does not assess change in activities from minute to minute.

Reiff et al. (1967) confirm the importance of assessing very small increments of activity in energy balance studies since many activities like tennis or shopping involve short periods of high activity intermixed with periods of comparative rest. Thus, unless this type of information can be obtained, diet records should be used only for approximation of energy expenditure.

Acheson et al. (1980) studied the physical activity of 12 individuals for six to 12 months. Each subject filled out a diary divided into five-minute periods, but which could be further subdivided by the individual. Energy costs of each activity were evaluated from the literature and by actual measured energy cost of each activity for each person obtained over the course of the study. Compared to the intake/balance technique, which evaluated changes in individual body fat over six to 12 months, the diary, based on the literature reports of energy costs of various activities, overestimated energy output by 0.3%. Using measured energy cost for each individual the diary overestimated energy output by six percent. Neither of these differences was statistically significant. The authors conclude that although the record method is tedious and makes great demands on the subject it probably "represents quite an accurate summary of their activity over the periods of investigation" (p. 1161) but that individual errors were too large and random to allow a

prediction of fat gain or loss. Blaxter (1956) suggests that to account for changes in body energy using energy consumed vs. energy expended requires measuring each of these parameters within 0.5%. This has not been achieved in man outside of a metabolic unit.

Overall, the literature supports the use of the diary records, using an evaluation of the energy cost of activities based on the literature, as a reasonably accurate assessment of individual energy expenditure over time. It does not support its use for energy balance studies or as an exact account of a person's minute to minute activities.

CHAPTER III

METHODOLOGY

Subjects

The study population consisted of 22 subjects, seven males and 15 females, with IDDM, ranging in age from 22 to 55 years. Participants had used subcutaneous insulin infusion pumps for from eight to 52 months. Basis for exclusion of subjects from the study included: lactation, pregnancy, severe heart disease, and renal failure. Persons with diabetic complications such as mild neuropathy, retinopathy, and nephropathy were included in the subject population. Participants were all patients of Dana H. Clarke, M.D., and his associate, Kathleen Ford, M.D., endocrinologists who subspecialize in diabetology in Salt Lake City, Utah. At the time of the study (1984), approximately 100 patients using CSII attended their Diabetes Health Care Clinic for medical care.

Research Approach

This study utilized a descriptive research approach and was designed to describe the study population in terms of average dietary intake, physical activity, glycemic control, and weight change since initiation of CSII. Other descriptive data were gathered by questionnaire or from the subject's medical record. Nutrient intake information was analyzed by computer and compared with the 1980 RDA, the ADA (1979) dietary recommendations for persons with DM, and with nutritional information for age and sex matched groups from NHANES II (1983).

Materials and Instrumentation

Materials Folder

Each subject was provided with a materials folder with all study material, instructions, and examples needed to complete the participant part of the study including:

1) A cover letter outlining the purpose of the study and the participant's responsibilities (Appendix A).

2) A consent form to be signed by each subject participating in the study. The form gave written consent to the investigator to review the patient's medical record, providing the subject's name remained confidential, and to report findings from those records, the three-day diet record, the three-day physical activity record, and the subject questionnaire (Appendix A).

3) A questionnaire with 43 questions designed to obtain descriptive information regarding the subjects diabetes, use of CSII, diet, and diabetes control. Question types consisted primarily of multiple choice and fill in the blank. Two short essay questions concerning the patients feelings about the pump were also included (Appendix B).

4) Written instructions for describing foods eaten and recording amounts. Specific instructions were given for certain food groups including cereals, cheese and yogurt, fruits and vegetables, soups, desserts, beverages, breads, meats, eggs, and fats (Appendix C).

5) A portion size guide for estimating weights of meats and cheese was provided for subjects to use when reporting quantities (Appendix C).

6) Subjects were asked to keep a written record of blood glucose values obtained by SBGM during the three-day food intake period. A record of the time of day the blood was taken was also requested. An example of the type of record asked for and space for recording the blood glucose value and the time of day were provided (Appendix D).

7) Study participants were asked to complete food intake records on three consecutive days including one weekend day. A separate sheet for each day was included along with an example record sheet. If food was being eaten to cover an insulin reaction subjects were asked to indicate this on the food intake sheet. Space was provided to specify the amount of the pre-meal insulin bolus and the time it was given (Appendix E).

8) Two addressed (to the researcher) postage-paid envelopes were included to facilitate return of study material.

Physical Activity Record

Each subject was requested to keep a record of his or her activities over the same three-day period as the food intake record. Activities were categorized into eight groups adapted from Durnin and Passmore (1967), Bouchard et al. (1983), and Katch and McArdle (1983). Instructions stressed the need to account for every minute of each day from midnight to midnight. If subjects were unable to categorize an activity based on the examples given in the instructions and example sheet, the activity was to be written at the top of the day's record and was categorized by the researcher. Only one participant utilized this option. Although subjects were conscientious about accounting for the entire 1440 minutes in a day, it was noted that a large

majority tended to group activities into time frames of 15, 30, or 60 minutes, making the accuracy of the exact minutes spent at a particular activity questionable (Appendix F).

Follow Up Material

Each participant was sent a summary of his or her average intake and average caloric expenditure for the three-day period (Appendix G). Average intake of 12 specific nutrients, the recommended dietary allowances of these nutrients, and the percent of the RDA the subject's average intake represented were included on the sheet. Average intake of potassium and sodium and the percent of daily calories from protein, carbohydrate, and fat were also noted. Caloric expenditure was broken down into an average for the three-day physical activity record and estimated caloric expenditure for basic metabolic function. A copy of this summary was sent to Dr. Dana Clarke's office. The summary was briefly explained in an accompanying cover letter (Appendix G). Subjects were advised to increase intake of good food sources of those nutrients which showed an intake of less than 75% of the RDA (1980).

Procedures

Consent and Approval

All study participants were patients of Dana Clarke, M.D., and Kathleen Ford, M.D., two affiliated diabetologists in Salt Lake City, Utah. Permission to approach their patients being treated with CSII and to review those patient's medical records, with consent of the individual, was obtained from them. Subjects were first notified of

the study by a letter outlining the study's purpose and requirements of participants (Appendix A). This letter and a pre-addressed postage-paid envelope were enclosed with a regular mailing by Dr. Clarke's office to notify all CSII patients of a pump meeting. An invitation to participate in the study, regardless of attendance at the meeting, was extended in the letter.

During the meeting the researcher outlined the reason for the study and gave a detailed description of what each participant would be expected to do. Emphasis on recording accuracy and completeness was stressed. The importance of prompt return of study materials was also discussed. Each person in attendance was given a materials folder and each of the enclosed forms was briefly reviewed by the researcher. Eight participants were gleaned from the pump meeting.

Contact with potential subjects not in attendance at the pump meeting was done by phone. In Utah, 12 subjects who met the research criteria were willing to participate. Two additional participants, one from Wyoming and one from California, were also contacted by phone. Two of the individuals reached by phone had already returned the enclosure from the original mailing expressing interest in the study. Materials folders were mailed to these participants. Participants were contacted a second time by phone to ensure receipt of the materials folder, to review the packet contents, and to receive instructions similar to those given at the pump meetings.

Thirteen of the participants completed their packets within two months of the original contact. One subject did not return his materials to the researcher for four months after completion. Despite

repeated telephone contacts, it took four additional months to get eight more participants to return their materials. One subject finally completed the study eight months after the original contact. Overall the study lasted from September 1984 to April 1985.

Glycosylated Hemoglobin

Free $HgbA_1$ determinations were offered to subjects to aide in evaluation of glucose control and as an incentive to participate in the study. Eight of the subjects already had $HgbA_1$Cs or $HgbA_1$s taken within two months of their record-keeping days. Ten participants accepted our offer and had $HgbA_1$s taken at Holy Cross Hospital within two months of the completion of the study. Weights were taken at the same time. Four others did not have current glycosylated hemoglobin levels, but declined our offer because it required travel to reach Holy Cross Hospital or presented scheduling difficulties.

Glycosylated hemoglobins taken from the medical chart were done at Holy Cross Laboratory or Smith-Kline Laboratory. Both labs use column separation techniques on washed whole blood. Holy Cross Hospital uses the BioRad hemoglobin A_1 by column test. Smith Kline uses BioRad hemoglobin A_1C from Bio-Rad, Richmond, California 94804. Standards used by Smith-Kline Laboratory are 1) normal - 4.4-8.2%, 2) fair or borderline 8.3-9.2%, 3) less than optimal > 9.2%. Standards used by Holy Cross are less defined with values over 9.0% considered abnormal. The health professionals at Dr. Clarke's clinic use these values as guidelines for intervention. When glycosylated hemoglobin values exceed 8.2% from Smith-Kline lab or 9.0% from Holy

Cross lab, steps may be taken to promote improved regulation of glucose in the individual.

Weight

Subject's weight histories were obtained from their medical charts. Weights were taken and recorded by the staff of Dr. Clarke's office using a platform beam scale. Weights within one month of the initiation of CSII were available for 15 subjects. Other participants were not patients of Dr. Clarke's at the initiation of CSII therapy. One subject was pregnant when she began pump treatment so her initial weight was not used in the study. Weights, within one month of the study record, were taken from the medical record or done at the Holy Cross Hospital lab. The lab also uses a standard beam scale. Three participants did not have available weights within the specified time frame so subject's stated weights were used. The stated weights were checked against previous weights available in the medical record and found to be consistent. Ideal body weights (IBW) were derived from the 1983 Metropolitan Life Height and Weight Tables for Adults (Appendix K). Percent IBW was calculated using the formula:

$$\% \text{ IBW} = \frac{\text{current weight}}{\text{ideal weight}} \times 100$$

taken from Grant and DeHoog (1985). Weights were compared against the midpoint of the range given for medium frame builds for a person of the same height as the individual subject.

Weights were taken in indoor clothing at varying times throughout the day. No attempt was made to adjust weights for these variables. Time between weights was calculated to the nearest number of months.

Height

The subject's height in inches was taken from the medical record when available. These were often recorded from the subject's hospital stay when CSII pump use was initiated and were usually taken in stocking feet. If a height was not recorded in the medical record the subjects stated height in inches was used in determining energy expenditure.

Duration of Diabetes and CSII Therapy

Participants recorded the year their diabetes was diagnosed and the year and month they began CSII. The latter was confirmed in the subject's medical record. The number of years with diabetes was determined by subtracting the year of diagnosis from the year the study materials were completed. Duration of CSII pump use was recorded in months and determined by counting the number of months from initiation of CSII up to and including the month the records were kept.

Patients Age

Age was specified in years and determined by subtracting the year of birth from the year the study records were kept.

Vitamin and Mineral Supplements

Subjects were asked if they took vitamin or mineral supplements and if so to specify the name brand. These were noted and tallied, but were not included in the assessment of subject's nutrient intake.

Pre-Meal Insulin Bolus and Ratio of Insulin to Carbohydrate

When describing the number of minutes before a meal the subject gave his or her insulin bolus and the ratio of insulin to carbohydrate the participant used to determine the size of the pre-meal bolus, ranges were often given. If ranges were used to answer these questions then the mid-point was used in analyzing these data.

Clarification of Physical Activity

If any day on the physical activity assessment sheet did not total 1440 minutes the researcher contacted the subject by telephone so the subject could account for the discrepancy.

Evaluation of Nutrient Intake

Raw data. Raw data from the three-day food record was coded, using a separate five-digit code for each item, for entry into the NUTREDFO program.

Amounts of food consumed by the subjects were converted from household measurements to grams. Agriculture Handbook No. 456 (Adams, 1975) provided the reference for conversion of cups, teaspoons, etc. of specific foods to grams. Product information was used to convert items such as a McDonald's Big Mac to grams.

Data base. The Nutrition Education Information System or NUTREDFO is a nutrient data base and analysis program developed as a tool for nutrition guidance research and development of nutrition guidance information by Utah State University and the Nutrition Guidance and Education Research Division of the Human Nutrition Information Service, United States Department of Agriculture. The

data base contains three major files: 1) a permanent file of 460 foods and 26 nutrients or constituents. No zero values are used in the permanent file. Foods were chosen from items that are commonly eaten and that have standard accepted compositions. The 26 are:

calories
protein
fat
total saturated fat
total monounsaturated fat
total polyunsaturated fat
cholesterol
carbohydrate
added sugar
alcohol
calcium
iron
magnesium
phosphorus
zinc
potassium
sodium
vitamin A
thiamin
riboflavin
pre-niacin
vitamin B_6
vitamin B_{12}
ascorbic acid
folacin
pantothenic acid

2) A temporary nutrient file for user-stored nutrient values for foods not in the permanent file. 3) A documentation file for on-line identification of the original source of each nutrient and constituent value (DeLeeuw, E. et al., 1984).

The NUTREDFO software provides a number of functions that can store, retrieve, or analyze data in a variety of ways. Six of these were used by this researcher. These include:

1) a printed listing of the nutrient levels and serving size given foods stored in the permanent and temporary files

2) calculation of the calorie and carbohydrate intake for individual meals

3) calculation of the mean and minimum and maximum range for each nutrient consumed over three days

4) calculation of the percent of standard for mean nutrient intake over three days. The selected standard was the 1980 RDA's based on age and sex. Percents of standard for sodium, potassium, and pantothenic acid were not given since only safe and adequate daily dietary intakes have been estimated for these nutrients and RDA has not been established.

5) calculation of the percent of calories from protein, fat, carbohydrate, and alcohol. Based on the mean intake over three days. The percentage of fat was subdivided into total saturated fat, total polyunsaturated fat, and total monounsaturated fat. The percentage of added sugar was separated out of the total percent of carbohydrate.

6) calculation of each nutrient per 1,000 kilocalories based on the mean intake over three days.

Nutrient data for the NUTREDFO data base was primarily obtained from the USDA Agricultural Handbook No. 8 "Composition of Foods... Raw, Processed and Prepared" (Watt and Merrill, 1963) or from revised sections of that handbook.

Information for some nutrients was taken from research articles from the Journal of the American Dietetic Association or from the USDA provisional tables. When other data were unavailable information from

the National Food Consumption Survey (USDA, 1980) was used or values were imputed.

Although the NUTREDFO Database contains the most up-to-date information obtainable, it is still restricted to available data and by the accuracy of the methods extant for determining the values used.

In the NUTREDFO data base most values for added sugar were imputed and represent the amount of carbohydrate in a product added during the processing. This was calculated by subtracting the grams of carbohydrate found in the naturally-occurring food from the grams of carbohydrate in the processed product. The added sugar in ready-to-eat cereals was determined analytically.

Pre-niacin values in the NUTREDFO data base represent preformed niacins in food and do not take into account the conversion of tryptophan to niacin. The RDA (1980) recognizes that the conversion of tryptophan to niacin may be a significant source of niacin in the diet and takes it into consideration in its recommendations.

The number of foods on the data base is limited and excludes mixed foods such as chili or pot pies. Thus foods that closely approximated the item actually consumed had to be used or foods had to be added to or temporarily altered on the data base.

All three of these alternatives were used in this research. Over 30 foods were added to the data base using USDA Handbook 8 (Watt and Merrill, 1963), revised portions of Handbook 8 and product information. Some values were unavailable and a zero was placed in that slot. Added sugar values were often imputed by subtracting the amount of sugar in the naturally-occurring product from the grams of

sugar in the processed product. Temporary changes in the amount of added sugar were made in certain products such as gelatin or jelly to make them reflect their diet or sugar-free counterparts.

Evaluation of Physical Activity

Raw data. The number of minutes spent per day in each one of the eight energy levels was totaled and entered into the PUBLIC ENERGY computer program. The sums of minutes spent in all energy levels were added together to ensure that they accounted for all the minutes (1440) in the midnight-to-midnight time period.

The subject's sex, height in inches, weight in pounds, and age in years were also entered into the program.

Data base. PUBLIC ENERGY is a computer program developed at Utah State University and available on the VAX system. It can be used as part of a larger format which combines the ENERGY and NUTRAN programs, but for the purposes of this study, it was used separately.

PUBLIC ENERGY allows the user to record the minutes of physical activity performed per day in each of eight separate categories for up to seven days. Each day's caloric output, based on the amount of time spent at each energy level, is totaled. The average number of minutes spent at each energy level and the average caloric output for the entire day are also calculated by the program.

Each energy level is assigned different number of calories burned per minute based on the work of Durnin and Passmore (1967) and summarized by Whitney and Hamilton (1981). The number of calories utilized per minute at each level varies depending on the subject's age, weight, height, and sex.

The program also calculates the subject's basal energy expenditure (BEE) based on the Harrison Benedict equation (Mahalko and Johnson, 1980).

Statistical Analysis

SPSS-X and MINITAB, statistical computer packages available on the VAX system at Utah State University, were used for statistical analysis of the data. T tests and, where possible, Fisher's Exact Test were used to determine significant differences between groups. Variability in carbohydrate and caloric intake between days was analyzed using a randomized complete block design. Means $\pm$ standard deviations were used for reporting data.

CHAPTER IV

RESULTS AND DISCUSSION

Restatement of the Problem

Management of persons with IDDM who use CSII would be facilitated by a greater body of knowledge regarding their dietary intake, physical activity, and level of control. The primary purpose of this study was to describe adult subjects using CSII in terms of their dietary intake, physical activity, glycemic control, and weight changes following initiation of CSII. Dietary intake was compared with established standards of the RDA (1980), nutrient allowances per 1,000 calories (Hansen and Wyse, 1980) and the ADA's (1979, 1987) stated principles of nutrition in diabetes. Comparison with a sex and age matched group from NHANES II (1983) was also made.

Responses to Questionnaire

Demographic

Twenty-two subjects, four married males, four single males, eight married females, and six single females, made up the study sample. The mean age was 34 years $\pm$ ten years with a range of 22 years to 55 years.

Education levels ranged from four subjects with high school degrees to three subjects with advanced college degrees. Eleven other subjects had completed bachelor's degrees and the remaining four subjects had attended trade school or attained two-year associate degrees.

Duration of IDDM ranged from five to 40 years with a mean of 14.6 ± 8.0 years. Use of CSII ranged from eight to 52 months with a mean of 29.0 ± 11.1 months (Table 2).

The sample included a variety of occupations including professional, managerial, nonprofessional, homemaker, student, and other.

Diets

Fifty percent of the subjects, four males and seven females, were trying to follow modified diets which increased or decreased one or more nutrients. Nine individuals were on low fat diets, four of whom were also trying to lower their salt intake. One subject was trying a high carbohydrate, low sugar diet, and another a low simple carbohydrate, low fat diet. Only one subject reported trying to adhere to a low calorie diet secondary to weight gain. The basic goals of these diets are in line with recommendations for nutrition in diabetes outlined by the ADA (1979, 1987). None of the subjects studied reported current use of fad or unusual diets that would be considered extremely inappropriate for the person with DM.

Traditionally, persons with IDDM follow specific meal plans with set calorie, carbohydrate, and protein levels. Only 54.5% of the group sampled responded affirmatively to following a specific calorie level in their diet. Four males used caloric levels ranging from 1700-2600 kilocalories (kcals)/day. Eight females used caloric levels ranging from 1000-1400 kcals/day. These caloric levels are generally below the RDA (1980) for energy intake of 2700 ± 400 kcals for men and 2000 ± 400 kcals for women age 23-50 years. These reduced calorie

Table 2. Descriptive Data (CSII)

Subject #	Age years	Sex[1]	Duration[2] of D.M.* years	Duration[3] of Pump Therapy months	Marital[4] Status	Education[5]
01	29	M	06	22	S	C
02	32	F	09	40	M	HS
03	34	F	10	41	S	ADV
04	53	M	26	32	M	ADV
05	25	M	11	08	M	HS
06	28	F	20	20	M	C
07	50	M	16	26	M	O
08	24	F	22	09	S	C
09	23	F	05	22	S	C
10	32	M	10	26	S	C
11	37	M	13	52	S	O
12	22	F	14	17	M	C
13	29	F	05	48	M	C
14	47	M	40	22	M	ADV
15	30	F	09	35	M	C
16	28	F	14	34	S	O
17	55	M	15	39	S	C
18	24	F	10	25	S	C
19	27	F	07	10	M	HS
20	39	F	19	36	M	HS
21	43	F	22	27	M	O
22	38	F	21	29	S	C
Mean ± SD+	34.0 ± 10.0		14.6 ± 8.0	29.0 ± 11.1		
Range	22 - 55		5 - 40	8 - 52		

[1]M=male, F=female
[2]Duration of Diabetes Mellitus from year of onset to year of subjects completion of study material
[3]Duration of pump therapy from month of initiation to month of subjects completion of study material
[4]M=married, S=single
[5]HS=high school, C=college degree, ADV=advanced degree and O=other degree or certificate
*D.M.=Diabetes Mellitus
+SD = standard deviation

levels may be used to offset the tendency to gain weight after initiation of CSII (Leichter et al., 1985; Hamet et al., 1982). Nine people or 40.9% of the sample studied reported that snacks were included in their meal plan. Eleven out of 19 subjects responding answered positively to eating snacks between meals even when not following a meal plan. Using Fisher's Exact Test, no significant difference ($p = .05$) was found between the reported use of snacks between males and females. Grinvalsky and Nathan (1983) conclude that successful dietary management of CSII users usually involves a fairly structured meal plan and suggest an evening snack. Chantelau et al. (1985) encourage a more liberalized diet for pump users, and report (Chantelau et al, 1984) that, for several years, 63 subjects had good glycemic control without adhering to a specific meal plan or calorie level. Since insulin peaks may be eliminated by CSII (Savesky, 1983) it seems reasonable to allow somewhat greater flexibility in meal planning for pump users. However, care must be taken to educate the patient regarding SBGM; the possible effect of a bolus from the previous meal affecting the next if the meals are timed too closely, and the difficulty that large variation in carbohydrate or caloric content of meals may add to adjustment of preprandial boluses.

Use of Food Grouping System

Exchange-list diets are generally prescribed for persons with IDDM, and, of 20 respondents, 80% reported using either the Exchange List for Meal Planning (American Diabetes Association, 1976) or another exchange system, Food and You (Prater et al., 1982). Twenty

percent indicated that they read labels and counted carbohydrates, but did not adhere to a particular exchange system.

Systems used to count carbohydrates often overlapped. Forty-five and one-half percent utilized the Exchange List for Meal Planning (American Diabetes Association, 1976). An additional 18.1% reported they use it in conjunction with other methods to count carbohydrates, such as reading labels or using books which are designed for that purpose. Thirteen and six-tenths percent report using carbohydrate-counting books exclusively. Two subjects specified that they use the Barbara Krause Guide to Carbohydrates (Krause, 1983). Food and You (Prater et al., 1982) was used by 22.7% of the respondents.

Diet Changes After Switching to CSII

The use of the CSII pump allows for greater lifestyle flexibility for the person with IDDM. When asked if diet plans had changed since initiation of CSII, 81.8% answered affirmatively. Ninety-five and one-half percent reported eating differently after switching to the pump. Types of changes reported and combinations of changes varied widely. Eight subjects reported that the timing of meals had changed. Five of the eight also indicated a change in the type of food eaten. Differences in the number of snacks per day and the amount of food eaten were each noted by five subjects. Four subjects reported changes in the amount of simple sugars consumed. Other changes noted include changes in the number of meals per day and in the overall flexibility of the diet. With the exception of variations in refined carbohydrate intake, Capper et al. (1985) reported similar changes,

i.e. increased flexibility regarding the number, timing, and size of meals in the diets of 15 subjects when they switched from CIT to CSII.

Diet Instruction

Management of IDDM generally includes diet instructions for the patient and at initiation of CSII diet, instruction is usually reviewed and augmented. In this sample, 86.4% were given instruction on dietary management when their diabetes was diagnosed, 40.9% of these received instruction exclusively from a dietitian, and an additional 22.7% received this instruction from a dietitian in conjunction with another health professional, i.e. a physician or nurse. Ninety-five and one-half percent of the subjects received dietary instruction at initiation of CSII with 54.5% being instructed by a dietitian in combination with a physician or nurse. Another 27.3% received instruction exclusively from a dietitian and 13.6% received instruction from a physician or nurse.

Specific instruction on carbohydrate counting was reported by 90.9% of the sample, with 40.9% instructed by a dietitian in conjunction with a nurse or physician. Approximately 31% were instructed by a physician or nurse and 18.2% were taught by a dietitian (Table 3). Ten out of 21 subjects responding felt that they needed further dietary instructions. The most common teaching requests included review and update of general diabetic diet, counting carbohydrates, and information on legumes as protein exchanges. Further information on counting carbohydrates would be of importance to this group since their preprandial insulin boluses are calculated

Table 3. Dietary instructions given to subjects (CSII)

Instructor	Instruction		
	At Diagnosis IDDM[X]	At Initiation CSII[XX]	On Counting Carbohydrates
Physician or nurse	5	3	7
Dietitian	9	6	4
Dietitian in combination with physician or nurse	5	12	9
No instruction	3	1	2

[X]IDDM = Insulin dependent diabetes mellitus
[XX]CSII = Continuous subcutaneous insulin infusion

on a unit of insulin to grams of carbohydrate ratio in conjunction with blood glucose levels.

Dietetic Foods and Sugar Substitutes

Special low carbohydrate products are on the market which allow the person with IDDM a wide variety of food choices without the rapid rise in blood sugar associated with large quantities of simple carbohydrates. Five males and ten females, or 68% of the subjects, indicated that they use special dietetic foods. The two most commonly reported items were diet soft drinks and food products sweetened with Nutrasweet (aspartame), ie. gelatin, puddings, etc. Other items that were often listed include low calorie or reduced sugar products such as jellies, syrup, juice-packed fruit, and reduced calorie salad dressings, and margarine. Only two people reported using sorbitol candy or special low calorie baked goods.

Sugar substitutes were used by 77.3% of the subjects, six males and 11 females. Thirteen persons reported using Equal^{R} (aspartame), eight of which used it exclusively while five others used it in conjunction with a saccharin-based sweetener such as Sucaryl^{R} or Sugar Twin^{R}. Three subjects indicated that they only used sweeteners made with saccharin. Fructose was used by one respondent. The use of both noncaloric (aspartame and saccharin) and caloric (fructose and sorbitol) alternative sweeteners are appropriate for persons with D.M. (ADA, 1987). However, fructose, xylitol, and sorbitol do add calories to the diet and the person with D.M. must be aware that they may affect blood glucose levels. These extra calories may also add to the weight gain already noted with CSII. Although not documented, it is

likely that diabetics may consume larger amounts of artificial sweeteners than the population as a whole, thus increasing any potential risks. Further research into artificial sweeteners and their use by persons with diabetes is needed.

Supplements

Unless other medical problems or deficiencies exist the person with IDDM does not have any special need for extra vitamin or mineral intake compared with the population as a whole. A nutritionally adequate varied diet should meet the vitamin and mineral requirements of most individuals (ADA, 1987). Despite such statements, the use of vitamin mineral supplements is widespread. In this study, four males and seven females of the 21 subjects answering, reported that they do use vitamin or mineral supplements. No significant difference in the number of males vs females using supplements was noted ($p = .05$). Although the type of supplement varied considerably, the majority, five persons, used over-the-counter multi-vitamins or multi-vitamin mineral pills such as One-A-Day or Centrum. One or two people specified using calcium, vitamin C, vitamin E, and B complex vitamins. Supplementation at or near nutrient levels outlined by the RDA (1980) may not be needed if nutritional intake is adequate, but has not been shown to be detrimental. Supplementation of vitamins or minerals at very high levels, i.e. megadosing, may be potentially harmful. Two males used vitamin or mineral supplements exceeding three times the RDA (1980) for fat-soluble vitamins and ten times the RDA (1980) for water-soluble vitamins.

Insulin Bolus and Carbohydrate to Insulin Ratio

Persons on CSII receive a basal dose of regular insulin throughout the day and give themselves a bolus dose of regular insulin to cover food intakes. Five males and 14 females answered the question regarding the timing of the pre-meal insulin bolus. Males gave their insulin bolus from five to 30 minutes before the meal and women gave their insulin bolus from five to 45 minutes before the meal. For the entire sample, insulin was given a mean time of 21 $\pm$ 12 minutes before eating.

Only 16 subjects responded to the question regarding the ratio of insulin to the anticipated carbohydrate intake for the pre-meal insulin bolus. The mean units of insulin to grams of carbohydrate ratio was one unit of insulin to 10 $\pm$ 3 grams of carbohydrate with a range of one unit of insulin to 5 grams of carbohydrate to one unit of insulin to 18 grams of carbohydrate.

When ranges of values were given the mid-point was used. Several subjects gave different insulin to carbohydrate levels for breakfast than for other meals. In these instances the ratio used most frequently throughout the day was taken.

Judging the appropriateness of this group's timing of insulin boluses, and especially their carbohydrate to insulin ratio, is difficult because exact parameters have not been set and a high degree of individualization is necessary. Generally, subjects were given guidelines initially, i.e. insulin boluses approximately 20-30 minutes before meals, one unit of regular insulin for every ten grams of carbohydrate to be eaten and were encouraged to establish what worked

best for them by SBGM. Carbohydrate to insulin ratios are particularly hard to standardize since they may be affected by several variables including blood glucose level, background insulin, timing of previous meal and bolus, and, in some subjects, time of day. Mean values for both insulin bolus and carbohydrate to insulin ratio fell within the guidelines specified but ranged widely among individuals.

Alcohol Use

Both the Canadian (1981) and American (1979, 1987) Diabetes Associations approve limited use of alcohol with physician approval. Eight of the 21 subjects responding indicated they do use alcohol in their diets. Alcohol was added into the diets of six subjects as a fat or a combination of fat, carbohydrate, and calories. One subject counted alcohol exclusively as a carbohydrate, and another considered its caloric value only when adding it to the diet.

Reactions

Concerns regarding the use of CSII as a treatment modality include the likelihood of increased incidences of hypoglycemia and the risk of severe hypoglycemia resulting from pump runaway, or extreme miscalculation of the insulin bolus requirement.

Twenty-one subjects responded to questions regarding changes in insulin reactions since switching to pump therapy. Approximately 57% of those indicated that the number of reactions had decreased, 38% had had more reactions since changing from conventional therapy, and 5% didn't identify any change in reaction frequency. The number of reactions reported per month ranged from 0.5 to 45.0 with a mean of

13.2 ± 12.6. When a range was reported for number of reactions the midpoint was used. Severity of reactions was reportedly decreased by 57% and unchanged by 19% of the sample studied. Approximately 24% noticed an increase in the severity of reactions. Although this study did not attempt to qualify or grade the severity of reactions it is interesting to note that nearly a quarter of the subjects did report some increase in the severity of their reactions. The frequency of severe reactions (i.e. requiring intravenous glucose or intramuscular glucagon injections) has generally not been reported to increase significantly after initiation of CSII (Bending et al., 1985; Mulhauser et al., 1985; and Pickup et al., 1985). If reaction severity can be quantified on a scale, a comparison may be made between the relative severity of reactions between CSII users and those persons on CIT.

Self Rating of Diabetes Control

Subjects were asked to rate their diabetes control as excellent, good, fair, or poor. To faciliate statistical analysis these responses were assigned numerical values of four, three, two, and one, respectively. The majority, 73%, felt their control was excellent or good since initiation of CSII, 23% rated their control as fair, and only one subject classified her control as poor (Table 4). This high rating of diabetes control is well supported by reports in the literature of improved glycemic control on CSII (Calabrese et al., 1982; Boulton et al., 1982). A negative correlation ($r = -0.67$) was found between subject's self-rating of diabetes control and their individual glycosylated hemoglobin values (values from lab #1, $n = 13$)

Table 4. Self report of changes in insulin reactions and diabetes control since initiation of CSII

Subject #	Number of reactions			Severity of reactions			Number of reactions per month[x]	Rating of diabetes control			
	increased	no change	decreased	increased	no change	decreased		excellent	good	fair	poor
01	x					x	11.0	x			
02		x		x			12.0			x	
03	x					x	30.0	x			
04			x			x	11.0		x		
05			x			x	9.0			x	
06			x			x	8.0			x	
07			x		x		12.0		x		
08			x	x			0.5		x		
09			x			x	5.0		x		
10			x			x	1.0		x		
11			x			x	30.0		x		
12	x			x			45.0		x		
13			x			x	30.0		x		
14	x					x	7.0		x		
15			x		x		2.0				x
16	x				x		17.0		x		
17			x	x			1.5		x		
18	x					x	23.0			x	
19			x			x	0.5		x		
20	x			x			21.0			x	
21	—	—	—	—	—	—	—	x			
22	x				x		1.0		x		
Totals	8	1	12	5	4	12	13.2±12.6[+]	3	13	5	1

[x]If ranges of values were reported a midpoint was used
[+]Mean ± standard deviation
-Data unavailable

(Table 7). Thus, subjects who rated their control as good or excellent had generally lower glycosylated hemoglobin values than subjects who rated their control as poor or fair. Although this is not an extremely high correlation it does indicate some degree of accuracy in the subject's ability to assess his or her own level of control.

SBGM

Persons on CSII adjust their own insulin based on intake, blood glucose level and, to a lesser degree, on planned physical activity. SBGM is an important tool in the self-management of pump users. Eighty five percent of the 20 subjects responding indicated they test their blood three to five times a day. Other answers varied from one to eight tests per day. This level of compliance to a testing regimen by subjects with IDDM is higher than that reported by Moses and Balint (1984) or by Bell and Walshe (1984). CSII users are a very motivated group and this may account for the relatively high level of SBGM reported.

Twenty subjects primarily used glucometers to test their blood. Two subjects reported using chemstrips or dextrostixs as their principal means of assessing their glucose levels.

Foods That Affect Blood Glucose

Various foods have been reported to raise blood glucose levels precipitously in some individuals with IDDM. Seventeen subjects noted specific foods which caused rapid rises in their blood sugar. Most commonly reported food items included candy, sugar, grape or orange

juice, desserts, frosting or sweets, and ice cream. Such items as popcorn, bagels, potatoes, white bread, pizza, and graham crackers were each identified as raising blood sugar levels by at least one subject. It is interesting to note that wide variations exist in the GI of these foods. Sugar (GI of sucrose = 59%) and candy bars (GI 68%) could be expected to increase blood glucose. However, ice cream (GI = 36%) and orange juice (GI = 46%) were more commonly reported to rapidly increase blood sugar than potatoes (GI = 70%) or white bread (GI = 69%) (Jenkins et al., 1981). Although further research is needed to determine the blood glucose response of large groups to various foods, by using SBGM individual subjects can become aware of certain foods which alter their blood glucose precipitously. Once these are determined the subject can then alter intake, insulin, or exercise accordingly.

Concerns and Attitudes About CSII

Cumbersome, restrictive, and costly were the three words used most frequently to express subject's concerns regarding pump therapy. Many subjects felt that being hooked up to the pump all the time and continually finding a place to attach it to clothing became tedious. Worry about price and insurance coverage for the pump and testing equipment was mentioned by numerous subjects. Less frequently mentioned concerns included running out of good injection sites, weight gain, breaking the pump during exercise, getting it wet, and forgetting to adjust basal rates.

Despite legitimate concerns, the vast majority of subjects "loved" the pump or felt "great" about it and stated that it allowed

them greater flexibility in their lives. This is consistent with the findings of Nathan et al. (1982). Repeatedly, subjects indicated that they would never go back to conventional therapy. Only three comments with a negative connotation were made. One subject indicated that although she intended to stay with pump therapy it was not the ultimate answer. Two others indicated that pump treatment could occasionally cause a roller coaster change of blood glucose levels.

Weight Changes

Weights for seven male subjects at the initiation of CSII ranged from 153.0 pounds (lbs) - 197.0 lbs with a mean of 169.0 ± 20.6 lbs. Percent ideal body weight (IBW), derived from the Metropolitan Life Height and Weight Tables for Adults (Grant and DeHoog, 1985) (Appendix K), ranged from 87.5% to 115.0% with a mean of 104.7 ± 10.3%. At the time of this study, seven to 40 months after individuals had begun pump therapy, weights averaged 167.2 ± 15.3 lbs and IBW ranged from 91.7% to 112.5% with a mean of 103.4 ± 8.6%. Although actual mean weight decreased there was an average monthly increase in weight of 0.3 ± 1.2 lbs per month based on a time-weighted average (Table 5).

Only eight women had weights recorded in their medical charts at initiation of CSII. These ranged from 135.5 lbs to 163.0 lbs and averaged 147.5 ± 11.3 lbs. IBWs ranged from 93.2% to 113.3% with a mean of 106.3 ± 6.1%. By the time of this study three of the women had lost from four and one-half to 17 lbs. Over the same ten-to-41 month period five women had gained from 1.0 to 25.5 lbs. Mean IBWs had increased 2.6%. However, based on a time-weighted average women showed a monthly decrease in weight of 0.02 ± 0.63 lbs/month

Table 5. Weight changes for men since initiation of CSII

Subject #	Weight at initiation of CSII	% IBW+ at initiation of CSII	Weight at time of study	% IBW at time of study	Unweighted weight change from initiation of CSII to time of study	Time in months between weight at initiation of CSII and weight at time of study	Overall weight change per month since initiation of CSII
	lbs		lbs		lbs		lbs/month
01	153.0	93.6	150.0	91.7	-3.0	22	-0.14
04	175.0	113.6	179.5	116.6	+4.5	32	+0.14
05	140.0	87.5	160.0	97.9	+20.0	07	+2.86
07	184.0	115.0	180.0	112.5	-4.0	25	-0.16
10	181.0	105.8	176.0	102.9	-5.0	26	-0.19
14	153.0	107.4	145.0	101.8	-8.0	22	-0.36
17	197.0	110.1	180.0	100.6	-17.0	40	-0.43
Mean ± SD+	169.0±20.6	104.7±10.3	167.2+15.3	103.4±8.5	-1.8±11.6	23.8 ± 9.9	+0.3±1.2

n = 7 information unavailable on 1 male subject

+IBW, Ideal Body Weight based on the Metropolitan Life Tables (Grant and DeHoog, 1985)

+SD, Standard Deviation

When subject #05 is omitted overall weight change per month since initiation of CSII becomes −0.2 ± 0.2 lbs/month

(Table 6). All 14 female subjects had weights available at the time of this study. These ranged from 123.0 lbs to 173.0 lbs with an average of 149.4 ± 12.4 lbs. IBWs ranged from 93.9% to 126.3%. Women appeared to be slightly more accurate at estimating their weight changes than men although both groups had wide divergences in their estimations vs. their actual weight changes.

Contrary to most reports in the literature (Hamet et al., 1982; Leichter et al., 1985; Capper et al., 1985) male subjects lost an average of 1.8 lbs per person over an average of 23.8 ± 9.9 months of CSII therapy. Although monthly weight change increased slightly, when subject #05, who gained 20 lbs in seven months, is omitted, the mean monthly weight change showed a decease of 0.2 ± 0.2 lbs/month. Monthly weight changes throughout pump treatment were unavailable. Monthly records may have indicated greater weight gains that were compensated for as subjects adjusted to decreased calorie needs with the improved glucose control associated with CSII. Capper et al. (1985) reported that seven out of nine subjects who were discontented with their weight gain on CSII had lost at least part of the excess by an average of 16.2 ± 2.3 months on the pump, and that peak weights were reached two to 15 months after CSII. In contrast, Leichter et al. (1985) found weights in ten subjects still increased by 8.1% IBW after two years. Comparison between studies is difficult since information on a large sample of subjects regarding total caloric intake, output, and weight history both before and after pump treatment is necessary for a complete evaluation.

Table 6. Weight changes for women since initiation of CSII

Subject #	Weight at initiation of CSII	% IBW+ at initiation of CSII	Weight at time of study	% IBW+ at time of study	Unweighted weight change from initiation of CSII to time of study	Time in months between weight at initiation of CSII and weight at time of study	Time weighted weight change from initiation of CSII to time of study
	lbs		lbs		lbs		lbs
02	142.5	106.3	149.0	111.9	+6.5	40	+0.16
03	136.0	93.2	150.0	102.7	+14.0	41	+0.34
09	162.0	113.3	145.0	101.4	-17	22	-0.77
12	146.5	106.9	142.0	103.6	-4.5	17	-0.26
18	135.5	105.9	161.0	125.8	+25.5	26	+0.98
19	163.0	109.4	153.5	103.0	-9.5	10	-0.95
20	139.0	103.7	140.0	104.5	+1.0	36	+0.03
21	156.0	111.4	165.0	117.9	+9.0	29	+0.31
Mean ± SD++	147.5±11.4	106.3±6.1	150.7±8.8	108.9±8.9	3.1±13.6	27.6±11.1	-0.02±0.63

n = 8 Information unavailable on 6 female subjects

+IBW = Ideal Body Weight based on 1983 Metropolitan Life Tables (Grant and DeHoog, 1985)

++SD = Standard Deviation

After an average of 27.6 months overall weight increased an average of 3.1 lbs for female subjects, which is consistent with the two kg increase noted by Home et al. (1982) and Hamet et al. (1982). Percent IBW increased by 2.6%. Although the increase in percent IBW is somewhat less than noted by others (Leichter et al., 1985; Capper et al., 1985) the overall increase and maintenance of several pounds after many months on CSII is consistent with the body of reported research.

Both men and women in this study had overall mean intakes several hundred calories below levels suggested by the RDA (1980) and mean caloric expenditures in excess of reported averages (Food and Nutrition Board, 1980). To the extent that these are accurate evaluations and can be projected over long time periods, these figures would account for weight loss or for less of a weight gain than previously reported.

Weight gain may be a significant problem with CSII and since attainment and maintenance of IBW is an important goal of diabetic management, education of the pump wearer is necessary to offset this tendency. Avoidance of consistently larger meals and snacks should be stressed and subjects should be informed that they may actually need somewhat fewer calories depending on their level of control prior to CSII use.

Measures of Control: Glycosylated Hemoglobin and Blood Glucose

Glycosylated hemoglobin values were obtained from two laboratories. All $HgbA_1$s done in conjunction with this study (n=10)

were obtained at Holy Cross Hospital, but five of the eight subjects who had preexisting glycosylated hemoglobin levels had $HgbA_1Cs$ done at Smith-Kline Laboratory. Mean lab values from Holy Cross were 9.5 ± 1.5% and ranged from 7.4% ± 13.1%. Lab values from Smith-Kline were significantly lower ($p = .05$) with a mean of 6.1 ± 1.1% and range from 4.6% - 7.1% (Table 7).

Glucose values obtained by SBGM were recorded by subjects during the three-day intake period. Mean levels for days one, two, and three were 121.0 ± 29.4 mg/dl, 123.2 ± 32.2 mg/dl, and 123.4 ± 45.3 mg/dl, respectively. Single glucose values ranged from 27 mg/dl to 402 mg/dl over the three days. No significant differences between days or between sexes ($p = .05$) were found. Overviewing the data, no trends were noted regarding time of day and blood glucose levels, i.e. subjects did not have consistently high or low blood glucose levels at any given time period throughout the day (Table 8).

Mean fasting preprandial blood glucose levels for all three days are slightly above the 70-120 mg/dl used as a guidelines for tight control (American College of Physicians, 1984). Although higher than the majority, these means are within the range of capillary blood glucose levels found by other researchers evaluating CSII use (Falko et al., 1982; Tamborlane et al., 1981; Pietri et al., 1980a). These somewhat elevated values may not be high enough to explain why seven out of 18 glycosylated hemoglobin levels obtained for this group exceeded normal limits. No significant degree of correlation was found ($r = 0.156$) between individual glycosylated hemoglobins (values from lab #1, $n = 13$) (Table 7) and individual mean glucose levels.

Table 7. Glycosylated hemoglobin values (CSII)

Lab*		Lab**	
Subject #	Value % Hemoglobin A_1	Subject #	Value % Hemoglobin A_1C
01	10.3	04	6.6
02	10.0	14	7.1
03	8.0	18	5.4
07	11.0	19	4.6
08	8.5	20	6.9
09	9.0		
10	10.7		
12	9.6		
13	7.4		
15	13.1		
16	8.5		
17	9.4		
22	8.5		
Mean $\pm$ SD+	9.5 $\pm$ 1.5		6.1 $\pm$ 1.1

+SD, standard deviation
*Lab 1 - Holy Cross Laboratory - Normal values $\leq$ 9.0 mg/dl
**Lab 2 - Smith-Kline Laboratory - Normal values 4.4 - 8.2 mg/dl

Current glycosylated hemoglobins were unavailable for subjects 05, 06, 11 and 21

Table 8. Glucose values obtained by self blood glucose monitoring (CSII)

Subject #	Mean Glucose Value mg/dl Day 1	# of Glucose Values Obtained Day 1	Mean Glucose Value mg/dl Day 2	# of Glucose Values Obtained Day 2	Mean Glucose Values mg/dl Day 3	# of Glucose Values Obtained Day 3	Range of Glucose Values Over 3 Days mg/dl
01	99	4	125	4	137	4	36-297
02	134	4	127	5	109	4	76-196
03	117	6	111	9	89	5	40-239
04	127	3	150	2	150	3	95-180
05	146	3	124	3	74	3	56-210
06	103	5	125	6	178	4	45-271
07	150	5	94	6	108	4	32-262
08	146	3	191	4	249	5	93-402
09	113	4	134	4	95	4	72-184
10	90	2	151	3	92	3	45-290
11	140	6	80	5	124	8	35-233
12	150	4	131	4	138	3	38-314
13	80	5	75	5	143	4	29-264
14	95	5	115	5	89	4	41-183
15	196	4	158	4	108	4	89-213
16	103	5	108	4	108	5	67-145
17	103	4	109	4	123	5	49-180
18	88	2	105	2	76	4	42-125
19	92	4	52	4	46	4	27-130
20	126	6	127	7	117	6	51-214
21	163	4	142	4	164	4	82-242
22	100	3	176	5	197	3	68-224
Mean ± SD+	121.0±29.4		123.2±32.2		123.4±45.3		
Range	80-196	2-6	52-191	2-9	46-249	3-8	27-402

+SD=standard deviation

Therefore subjects with a mean three-day glucose level within normal limits did not necessarily have a glycosylated hemoglobin level in the normal range. Since glycosylated hemoglobin is an indicator of mean blood glucose over the preceding two months and gives a more accurate picture of control over time, this may suggest greater compliance to various parameters affecting blood glucose over the three-day study period than would normally take place, at least for those subjects whose mean glucose level and glycosylated hemoglobin level are widely disparate.

Mean Nutrient Intake Compared to Established Standards and Recommendations

Nutrient intakes for individuals were analyzed using the NUTREDFO computer program at Utah State University. Vitamin and mineral supplements were not included in the analysis. Average nutrient intakes for men and women were compared with the RDA (1980) (Appendix H), the ADA dietary recommendations for diabetes (1979), and nutrient allowances per 1,000 calories (Hansen and Wyse, 1980) (Appendix I). Female subjects age 25-34 years also had their intakes compared with an age and sex matched group from NHANES II (1983).

Mean Nutrient Intake of Males Compared with the RDA (1980)

Mean intakes for all nutrients for the eight male subjects were compared with the RDA (1980) for age and sex. Two males age 53 and 55 years were included in the 23-50 year old RDA (1980) group. Recommendations for thiamin, riboflavin, niacin, and calories are

slightly lower for the 51 years and over age category than they are for the 23-50 year old age group.

Average nutrient intake exceeded 75% for all nutrients. Consumption of three nutrients was ≤ 90% of the RDA (1980). These included folate 78.9%, zinc 88.4%, and calories 87.0%. However, mean caloric intake was within the range given for energy needs. Vitamin B_6 (92.5%) and magnesium (96.1%) were the only other nutrients consumed in quantities less than 100% of the RDA.

Intakes of potassium and sodium were 90% and 156.7% respectively. Using the midpoint of the range of estimated safe and adequate daily dietary intakes (ESADDI) (Food and Nutrition Board, 1980) (Appendix J) as a comparison, mean potassium intake remained within the range estimated as safe but mean sodium intake exceeded the upper limits of the range given (Table 9).

On an individual basis, folate intake for one subject was < 50% of the RDA, between 50 and 67% for three others and between 68 and 75% for yet another. Intake levels for zinc and B_{12} at < 50% of the RDA were each found in two separate individuals. Table 10 represents individual mean intakes of men compared to the RDA (1980).

Overall, men had significantly higher intakes of nutrients than women with the exception of calcium, vitamin A, and vitamin C ($p = .05$).

The RDA (1980) is a guideline for the average daily intake of nutrients required for a healthy population group. They will not necessarily meet the requirements of all individuals. Specific subjects may require higher or lower amounts than the guidelines

Table 9. Nutrient intake and percent RDA for men (CSII)

Nutrient	Mean ± SD[+]	Range	RDA[++]	% RDA
Kcals	2348 ± 532	1617 - 3046	2700 ± 400	87.0
Protein (gm)	97.6 ± 24.7	48.5 - 124.6	56	174.2
Fat (gm)	110.1 ± 32.6	63.4 - 140.1		
Saturated fat (gm)	39.8 ± 12.7	26.6 - 63.4		
Polyunsaturated fat (gm)	19.8 ± 7.8	8.4 - 32.1		
Monounsaturated fat (gm)	39.8 ± 11.3	21.5 - 49.3		
Cholesterol (mg)	366.3 ± 164.9	88 - 626		
Carbohydrate (gm)	251.0 ± 81.3	130.6 - 347.4		
Added sugar (gm)	34.4 ± 29.3	4.6 - 81.5		
Alcohol (gm)	0.4 ± 1.1	0 - 3.1		
Calcium (mg)	1062 ± 410	556.0 - 177.20	800	132.7
Iron (mg)	16.1 ± 4.2	12.2 - 23.0	10	160.6
Magnesium (mg)	336 ± 96	246.0 - 549.0	350	96.1
Phosphorus (mg)	1596 ± 421	958.0 - 2243.0	800	199.5
*Zinc (mg)	13.3 ± 3.5	6.18 - 17.96	15	88.4
Potassium (mg)	3375 ± 910	2335 - 5321	1875 - 5625[+++]	90.0
Sodium (mg)	3448 ± 1131	2349 - 5263	1100 - 3300[+++]	156.7
Vitamin A (I.U.)	7332 ± 2735	4379 - 11797	5000 IU	146.6
Thiamine (mg)	1.70 ± 0.50	1.18 - 2.75	1.4	121.4
Riboflavin (mg)	2.23 ± 0.71	1.36 - 3.41	1.6	139.4
**Pre-Niacin (mg)	27.4 ± 10.1	18.5 - 50.6	18	152.0
Vitamin B_6 (mg)	2.04 ± 0.66	1.62 - 3.57	2.2	92.5
***Vitamin B_{12} (mcg)	4.95 ± 1.72	1.39 - 7.13	3.0	165.0
Ascorbic Acid (mg)	143 ± 81	65 - 280	60	237.9
Folate (mcg)	316 ± 151	189 - 606	400	78.9
Pantothenic Acid (mg)	6.11 ± 1.33	4.56 - 8.19	4 - 7[+++]	82.9

n = 8 Two men age 55 and 53 were included in the 23-50 year old age grouping of RDA's

*When zinc is recalculated using median % RDA = 86.6.

**Pre-niacin - represents only pre-formed niacin and does not include the conversion of tryptophan to niacin. When recalculated using median % RDA = 146.7.

***When vitamin B_{12} is recalculated using median % RDA = 182.0.

[+++]Based on Estimated Safe and Adequate Daily Dietary Intake. Midpoint used in calculations.

Table 10 . Individual mean nutrient intake of males compared with the RDA* for age and sex

Nutrient	No. of Subjects with Intakes < 50% of the RDA	No. of Subjects with Intakes 50-67% of the RDA	No. of Subjects with Intakes 68-75% of the RDA	No. of Subjects with Intakes 75-100% of the RDA	No. of Subjects with Intakes 100-125% of the RDA	No. of Subjects with Intakes 125-170% of the RDA	No. of Subjects with Intakes > 175% of the RDA	% Range
Protein (gm)				1		3	4	85.7-217.9
Calcium (mg)			1	2		3	2	69.3-237.1
Iron (mg)	1				3	3	2	115.0-227.0
Zinc (mg)				5	2			40.7-108.0
Vitamin A (IU)				2	2	2	2	87.6-248.2
Thiamin (mg)			1	2	3	1	1	68.7-195.7
Riboflavin (mg)				2	1	3	2	76.3-210.6
Niacin (mg)					5	2	1	111.1-274.4
B_6 (mg)			2	5		1		69.4-155.0
B_{12} (mcg)	1			1		1	5	40.0-208.0
Ascorbic Acid (mg)				2		1	5	80.0-467.7
Folacin (mcg)	1	3	1	1	1	1		36.2-149.0

n = 8

*RDA, Recommended Dietary Allowances (1980)

given. However, the RDA (1980) increases the average requirement by an amount sufficient to meet the needs of nearly all members of the population. In the clinical situation these recommendations are often used as a screening tool to evaluate individual intakes. Although persons with IDDM are not members of this healthy population group the ADA (1987) states that "the need for essential basic nutrients is the same for all people of equivalent age, sex and size, diabetic or not" (p. 132). "There is no evidence unique to the patient with diabetes to warrant special vitamin or mineral supplementation" (p. 127).

Mean intakes for folacin and zinc were low. Suboptimal intakes have been identified in segments of the United States' population, especially with regard to zinc (RDA, 1980). Zinc deficiency may be of even greater concern in the person with IDDM since it may further impair normal tissue regeneration. Animal meats and seafood are the best sources of available zinc. Folacin intake may be increased by further addition of fresh green leafy vegetables to the diet. These additions would also increase the fiber content of the diet in accordance with ADA (1987) guidelines.

Individuals with nutrient intakes below 75% of the RDA (1980) were advised to increase their consumption of foods rich in that nutrient.

Sodium intake for males exceeded the ESADDI (Food and Nutrition Board, 1980) without considering salt added by the subject during food preparation or at the table. Mean sodium intake of this sample is also in excess of the maximum 3000 mg a day suggested by the ADA (1987).

Mean Nutrient Intake of Females
Compared with the RDA (1980)

When mean nutrient intakes for 14 female subjects were averaged and compared to the RDA (1980) for age and sex, consumption of nine nutrients met or exceeded 100% of the recommended levels. Iron (64.9%), zinc (58.1%), and folate (50.7%) were consumed in amounts less than two-thirds of the RDA (1980). Other nutrients that had mean nutrient intakes under recommended levels include: vitamin B_6 (69.0%), magnesium (75.1%), and caloric intake (77.0%).

Average intakes of potassium, pantothenic acid, and sodium were compared with the midpoints of the ranges for ESADDI (Food and Nutrition Board, 1980). Although low, mean intakes of potassium (62.9%) and pantothenic acid (74.0%) were still within the lower limits of the range given as safe and adequate. Sodium (104.2%) intake, exclusive of salt added to food by the subject, unless specifically noted on the intake records, was near the midpoint of the range specified (Table 11).

Average mean nutrient intakes were compared with the RDAs for 23-50 year old females. One subject, age 22 years, did not fall in this category but was included in the overall average. Requirements for calories, vitamin D, thiamin, riboflavin, and niacin are slightly higher for the 19-22 year age category.

Mean nutrient intake of individual subjects revealed significant intake of specific nutrients in quantities less than two-thirds the age and sex matched RDA (1980). The largest number of individuals had low intakes of zinc, folate, B_6, and iron, which is consistent with the findings for average mean intakes. However, despite average mean

Table 11. Nutrient intake and percent RDA for women (CSII)

Nutrient	Mean ± SD[+]	Range	RDA[++]	% RDA
Kcals	1541 ± 340	986 - 2206	2000 ± 400	77.0
Protein (gm)	68.3 ± 13.7	46.4 - 82.4	44	155.2
Fat (gm)	67.0 ± 23.9	35.0 - 122.4		
Saturated fat (gm)	21.6 ± 8.5	11.7 - 44.2		
Polyunsaturated fat (gm)	13.4 ± 5.5	4.5 - 21.1		
Monounsaturated fat (gm)	23.2 ± 9.6	9.2 - 39.6		
Cholesterol (mg)	228.9 ± 120.9	84 - 459		
Carbohydrate (gm)	172.8 ± 45.5	94.3 - 256.2		
Added sugar (gm)	30.3 ± 27.2	1.8 - 91.8		
Alcohol (gm)	0.0	0		
Calcium (mg)	819 ± 197	471 - 1236	800	102.4
Iron (mg)	11.7 ± 2.7	6.3 - 15.6	18	64.9
Magnesium (mg)	225 ± 38	115 - 270	300	75.1
Phosphorus (mg)	1181 ± 207	802 - 1577	800	147.7
Zinc (mg)	8.7 ± 2.3	5.19 - 11.51	15	58.1
Potassium (mg)	2358 ± 647	1198 - 3197	1875 - 5625[+++]	62.9
Sodium (mg)	2293 ± 1043	1548 - 4587	1100 - 3300[+++]	104.2
Vitamin A (IU)	6062 ± 4383	1631 - 14818	4000 IU	151.6
Thiamin (mg)	1.19 ± 0.26	0.79 - 1.43	1.0	119.0
Riboflavin (mg)	1.52 ± 0.32	0.81 - 2.21	1.2	126.7
Pre-niacin (mg)*	18.2 ± 4.0	10.1 - 27.9	13	140.1
Vitamin B_6 (mg)	1.38 ± 0.39	0.76 - 2.09	2.0	69.0
Vitamin B_{12} (mcg)	3.38 ± 1.24	1.45 - 6.23	3.0	112.7
Ascorbic acid (mg)	101 ± 57	25 - 237	60	168.1
Folate (mcg)	203 ± 63	80 - 293	400	50.7
Pantothenic acid (mg)	4.07 ± 0.98	2.03 - 5.0	4 - 7[+++]	74.0

[+]SD, standard deviation

[++]RDA Recommended Dietary Allowances (1980) for women 23-50 years of age - 55 kg reference women

[+++]Based on Estimated Safe and Adequate Daily Dietary Intakes (1980). Midpoint used in calculations.

n = 14 One woman age 22 was included in the 23-50 year old age grouping of RDA's

Preniacin represents only pre-formed niacin and does not include the conversion of tryptophan to niacin

intakes exceeding 100%, low intake of calcium, riboflavin, and ascorbic acid were also noted in one or more subjects (Table 12).

Women had low intakes of folacin and zinc. Additionally, females had a mean intake of iron well below recommended levels. It is difficult for women to ingest sufficient iron without exceeding caloric or protein requirements. Increasing the availability of iron by eating ascorbic acid-containing fruits or juices with meats at least twice a day and avoiding substances, which reduce iron absorption when eaten with an iron containing meal (such as phosphate, phytates, and oxalates,) can aide the individual in increasing iron stores (Williams, 1981). Some women with heavy menstrual flow or clinically low hematocrits may require iron supplementation.

Intake of vitamin B_6 and magnesium was low in females and marginal in males. Although low in comparison with set RDA (1980) standards the need for vitamin B_6 is influenced by the amount of protein consumed. When intake is evaluated on the basis of a suggested ratio of 0.02 mg of vitamin B_6 per gram of protein eaten (RDA, 1980) mean requirements for females studied become 1.37 mg vitamin B_6 and for males, 1.95 mg vitamin B_6. Mean intake of vitamin B_6, for both sexes, exceeded these values. If protein intake were decreased to meet ADA (1987) guidelines the need for vitamin B_6 might also decrease.

Magnesium is available in a wide variety of foods. Low intakes of magnesium can easily be countered with an increase in foods high in this mineral.

Table 12. Individual mean nutrient intake of females compared with the RDA* for age and sex

Nutrient	Number of subjects with intake < 50% of the RDA	Number of subjects with intake 50-67% of the RDA	Number of subjects with intake 68-75% of the RDA	Number of subjects with intake 76-100% of the RDA	Number of subjects with intake 101-125% of the RDA	Number of subjects with intake 126-175% of the RDA	Number of subjects with intake > 175% of the RDA	% Range
Protein (gm)					2	8	4	105.5-208.0
Calcium (mg)		2		7	4	1		54.1-129.3
Iron (mg)	3	4	3	4				35.0-90.0
Zinc (mg)	3	6	1	4				34.6-89.7
Vitamin A (IU)	2		2	1	3	2	4	40.1-374.1
Thiamin (mg)				3	7	4		79.0-182.6
Riboflavin (mg)		1		2	1	10		65.0-181.6
Niacin (mg)				1	2	11		77.7-200.8
B_6 (mg)	2	3	1	8				39.0-100.0
B_{12} (mcg)	1	1		3	4	4	1	23.7-214.0
Ascorbic acid (mg)	2	1			2	4	5	39.5-396.7
Folacin (mcg)	4	8	1	1				20.0-96.8

n = 14

*RDA, Recommended Dietary Allowances (1980)

Caloric intake was below the range given by the RDA (1980) for women. This may partially account for some of the low intake levels observed. When percent IBW at the time of the study, weight change, and the discrepancy between caloric intake and output is evaluated, the question of some alteration of intake for the study period arises. Maintenance of 108.9% of IBW, if female subjects are both as active as assessed and have intakes at the level evaluated, would be difficult. Since the instrumentation for establishing physical activity is the least proven it is the most suspect, but a slight decrease in food consumption to increase perceived compliance during the intake period must also be considered.

Mean Nutrient Intake Compared with Nutrient Allowances per 1000 Calories

Nutrient allowances per 1,000 calories are obtained by dividing each RDA by the average calorie allowance and multiplying by 1,000. Values for nutrient allowances per 1,000 calories were established by Hansen and Wyse (1980) and based upon the 1980 RDAs and ESADDIs.

When compared to the 23-50 year age group of nutrient allowance per 1,000 kcal, men had intakes only slightly below recommended levels in two nutrients: folate and zinc. Magnesium and vitamin B_6 met or exceeded their recommended levels although average mean intake of these nutrients was less than 100% of the RDA (1980) (Table 13).

Intake per 1,000 kcals close to or at established allowances indicates that subjects were consuming foods rich in these nutrients and, if total caloric levels had been higher may have met or exceeded the RDA (1980).

Table 13. Nutrients of males expressed as nutrients per 1,000 kcals (CSII)

Nutrient	Men	Nutrient Allowances[+] per 1,000 kcals
Protein (gm)	43.7 ± 11.2	21
Calcium (mg)	456 ± 112	296
Iron (mg)	73.4 ± 2.0	3.7
Magnesium (mg)	150 ± 23	130
Phosphorus (mg)	693 ± 108	296
Zinc (mg)	5.9 ± 1.8	6.0***
Potassium (mg)	1451 ± 190	2500***
Sodium (mg)	1451 ± 265	1500***
Vitamin A (IU)	3202 ± 1611	370 ug R.E.[++]
Thiamin (mg)	0.75 ± 0.13	0.5
Riboflavin (mg)	0.95 ± 0.13	0.6
*Pre-niacin (mg)	12.4 ± 3.1	7.0 NE**
Vitamin B_6 (mg)	0.90 ± 0.28	0.8
Vitamin B_{12} (mcg)	2.21 ± 0.73	1.1
Ascorbic acid (mg)	65 ± 44	22
Folate (mcg)	135 ± 53	148
Pantothenic acid (mg)	2.66 ± 0.30	2.0***

n = 8 Two men age 55 and 53 were included in the 23-50 year old grouping of nutrients per 1,000 kcals

*Pre-niacin = represents only preformed niacin and does not include the conversion of tryptophan to niacin.

**NE = niacin equivalent includes preformed niacin and the conversion of tryptophan to niacin

***Based on Estimated Safe and Adequate Daily Dietary Intakes (1980)

+From Hansen and Wyse (1980)

++R.E., vitamin A expressed as retinol equivalents

On a nutrient per 1000 kcal basis women still had low intakes of iron, zinc, folate, and, to a lesser extent, vitamin B_6 and magnesium (Table 14). The intake of at least the first three of these nutrients would probably have been less than the RDA (1980) even if caloric intake had been higher. Foods more nutrient dense in these vitamins and minerals need to be consumed for these diets to meet recommended levels.

Based on ESADDI (RDA, 1980) potassium intake for both men and women was below the recommended allowance per 1,000 kcals. However, the 2500 mg per 1,000 kcal recommended would put intake near the upper limit set by the RDA (1980) if total caloric intake was at or near suggested levels.

Mean Nutrient Intake Compared with Nutrient Intake from NHANES II

Only one subset of the sample was large enough to compare with an age and sex matched group from NHANES II (1983). Dietary intakes of seven women ages 25 to 34 years were compared to 1,170 females in the same age category and spanning all income ranges from NHANES II (1983). Mean values for several nutrients including calcium, polyunsaturated fat, and vitamin A appear much greater in the study sample than those from NHANES II (1983). However, using a t test ($p=.05$) with a pooled standard deviation, there was not enough evidence to prove a significant difference between any of the mean values tested. The small sample with its high degree of variability, may be too small for realistic comparison. Although not statistically reliable, mean intakes for most nutrients appear similar, including

Table 14. Nutrient intake of females expressed as nutrients per 1,000 kcals (CSII)

Nutrient	Women	Nutrient Allowances[+] per 1,000 kcals
Protein (gm)	45.5 ± 7.9	22
Calcium (mg)	553 ± 152	400
Iron (mg)	7.7 ± 2.0	9.0
Magnesium (mg)	149 ± 29	150
Phosphorus (mg)	790 ± 135	400
Zinc (mg)	5.8 ± 1.2	8.0***
Potassium (mg)	1552 ± 506	2500***
Sodium (mg)	1737 ± 666	1500***
Vitamin A (IU)	3852 ± 2629	400 Ug R.E.[++]
Thiamin (mg)	0.80 ± 0.17	0.5
Riboflavin (mg)	1.01 ± 0.20	0.6
*Pre-niacin (mg)	12.0 ± 2.1	7.0 NE**
Vitamin B_6 (mg)	0.89 ± 0.28	1.0
Vitamin B_{12} (mcg)	2.15 ± 0.67	1.5
Ascorbic acid (mg)	66.43 ± 42.31	30
Folate (mcg)	134 ± 54	200
Pantothenic acid (mg)	2.68 ± 0.60	2.0***

n = 14 One woman age 22 was included in the 23-50 year old age grouping of nutrients per 1,000

*Pre-niacin = represents only preformed niacin and does not include the conversion of tryptophan to niacin.

**NE = niacin equivalent includes preformed niacin and the conversion of tryptophan to niacin

***Based on Estimated Safe and Adequate Daily Dietary Intakes (1980)

[+]From Hansen and Wyse (1980)

[++]R.E., vitamin A expressed as retinol equivalents

total caloric intake which was over 350 calories less than the mean caloric level established by the RDA (1980) for both groups (Table 15).

Mean Nutrient Intake Compared with ADA Recommendations

The ADA (1979, 1987) has given recommendations for persons with DM, of percent of total calories from protein, fat, and carbohydrate (Table 16). Both sexes were within the range recommended for protein by the 1979 recommendations but exceeded those for the 1987 update. The ADA (1987) recommendations for protein were changed to those of the RDA (1980) or 0.8 gm protein/kg adult body weight. Depending on intake and weight, this would generally place protein intake near the lower end of the range given by the 1979 recommendations of 12-20% of total calories. Based on mean body weight at the time of this study, the guideline suggests an optimal mean intake for females in this sample of 54.7 gm and for males of 60.7 gm. Actual mean intakes were 68.3 gm and 97.6 gm respectively. If caloric intake had been higher it is reasonable to assume that protein intake would have exceeded recommended levels by an even greater margin. The average American grows up consuming excessive amounts of protein. This cultural influence coupled with the suggestion that diabetics consume a protein source at every meal makes it imperative that portion control be strict and that meats and other protein sources be lean or low fat if ADA guidelines are to be adhered to.

Mean intake of fat, 41.9 $\pm$ 6.9% for males and 38.5 $\pm$ 7.5% for females, exceeded both sets of ADA (1979, 1987) recommendations. The

Table 15. Comparison of mean nutrient intake of 25-34 year old females with age and sex matched subjects from NHANES II[+]

Nutrient	Study n=7 Mean ± SD[++]	NHANES II[+] n=1,170 Mean ± SD[++]
Kilocalories	1629 ± 328.21	1,643 ± 855.00
Carbohydrate (gms)	194 ± 45.06	187 ± 109.44
Protein (gms)	68 ± 11.18	64 ± 37.62
Fat (gms)	67 ± 19.60	68 ± 41.04
Saturated fat (gms)	20 ± 6.89	24 ± 17.10
Monounsaturated fat (gms)	24 ± 8.51	25 ± 17.10
Polyunsaturated fat (gms)	15 ± 4.26	10 ± 10.26
Cholesterol (mg)	272 ± 133.17	278 ± 242.82
Calcium	906 ± 216.23	636 ± 718.20
Phosphorus (mg)	1191 ± 186.21	1021 ± 718.20
Iron (mg)	11.9 ± 2.72	10.9 ± 6.16
Sodium (mg)	2287 ± 719.41	2401 ± 1744.2
Potassium (mg)	2716 ± 326.33	2088 ± 1573.20
Vitamin A (IU)	7706 ± 5208.65	4665 ± 10294.2
Thiamine (mg)	1.29 ± 0.30	1.08 ± 1.03
Riboflavin (mg)	1.71 ± 0.23	1.48 ± 1.37
Preformed Niacin (mg)	17.83 ± 2.55	16.48 ± 12.65
Vitamin C (mg)	121 ± 53.75	92 ± 133.38

[+]NHANES II, Second National Health and Nutrition Examination Survey (1976-80)
[++]SD, Standard Deviation

Table 16. Percent of calories from protein, fat, carbohydrate, added sugar and alcohol (CSII)

Nutrient	Men	Range	Women	Range	ADA* Recommendations (1979)	ADA Recommendations (1987)
Protein	17.0 ± 4.6	9.4 - 24.0	18.0 ± 3.1	12.7 - 23.7	12 - 20%	0.8 g/kg body wt
Fat	41.9 ± 6.9	27.7 - 50.7	38.5 ± 7.5	25.3 - 56.6	30 - 38%	< 30%
Saturated fat	15.1 ± 2.8	11.2 - 20.1	12.5 ± 3.4	6.8 - 20.5	< 10%	< 10%
Polyunsaturated fat	7.4 ± 1.9	4.2 - 9.5	7.7 ± 2.5	3.2 - 10.4	≤ 10%	< 10% (prefer 6-8%)
Monounsaturated fat	15.2 ± 2.7	9.4 - 17.7	13.1 ± 3.5	6.6 - 18.3	≤ 10	30-(PUS + S)
Carbohydrate	42.7 ± 11.0	32.3 - 65.7	45.3 ± 8.6	25.6 - 60.0	50 - 60%	55 - 60%
Added sugar	5.8 ± 4.9	1.1 - 15.3	7.2 ± 5.9	0.6 - 22.5		
Alcohol	0.088 ± 0.25	0.0 - 0.7	0.0	0.0 - 0.0	Limited use	Limited use

n = 8 men, n = 14 women
American Diabetes Association
Saturated fat (S), Polyunsaturated fat (PUS) and Monounsaturated fat (MS) are part of total fat intake
Added sugar is part of the total carbohydrate intake

intake of saturated fat and monosaturated fat was also in excess of suggested guidelines. Polyunsaturated fat was ingested at recommended levels, but was disproportionately low in relation to other types of fat intake. Fat intake of this sample did not distinguish between grades of meat consumed or attempt to evaluate how well fat was trimmed from the meat. Since mean fat intake exceeded 1987 ADA recommendations by over 25% in some cases, it seems reasonable to assume fat intake would still be higher than suggested levels even if only lean cuts were eaten. Diabetes is associated with a high degree of hypertension, arteriosclerosis, and alterations in circulating lipoproteins and cholesterol (Wahlquist et al., 1984; Heyningen 1986). There is sufficient evidence that fat modified diets decrease this risk that the ADA (1987) has lowered its recommendations for total fat intake to under 30% of total calories. Only two subjects studied met this goal. The new recommendations also suggest limiting cholesterol to < 300 mg/day. Females in this study had a mean cholesterol intake of 228.93 mg meeting this goal. Males exceeded this level with a mean intake of 366.25 mg. The use of CSII has been demonstrated to improve serum lipid levels via improved glucose regulation (Lawson et al., 1985). However, there is insufficient evidence to suggest that lipid levels are completely normalized or that pump wearers should necessarily be less restricted in fat intake than other diabetics. To the extent that this sample represents CSII users as a whole it would suggest that pump wearers might benefit from more emphasis and education on limiting fats in the diet.

The percent of total calories consumed as carbohydrate, 42.7 ± 11.0% for men and 45.3 ± 8.6% for women, was below suggested levels. In an observation of actual food intake of subjects the researcher found the intake of fruits and vegetables to be adequate. However, there was a wide degree of variation among individuals, substantiated by the range of carbohydrate intake as a percent of total calories from 32.3% to 65.7%. Carbohydrate intake could not meet suggested levels with such high mean intakes of both protein and fat. Concomitant decreases in intake of these with an elevated intake of complex carbohydrate would be needed to meet recommendations.

Although fat intake was slightly lower and carbohydrate intake slightly higher mean diet composition as a percentage of calories was similar to that reported by Capper et al. (1985).

The ADA has not given recommendations regarding the amount of added sugar in the diabetic diet but suggests that modest amounts may be acceptable in some individuals if metabolic control and weight are well maintained. Grimvalsky and Nathan (1983) suggest avoidance of concentrated sweets with CSII since, despite the ability to counter elevations in blood glucose with regular insulin, glucose fluctuations are still increased after ingestion of refined sugar. Capper et al. (1985) did not find an increase in the use of refined sugars after initiation of pump therapy. The amount of total calories from added sugar varied widely in this sample ranging from 0.6% to 22.5%. Overall the mean for added sugar was 6.7 ± 1.2% and did not vary significantly between men and women ($p = .05$). As used here added sugar refers to sugar added during processing of foods and drinks or

sugar added by the subjects and noted on the food records. Only one subject ingested alcohol during the study period.

Variability in Carbohydrate Intake, Calorie Intake and Number of Meals

Variability of carbohydrate and calorie intake between days was analyzed using a randomized complete block design. Subjects were split into two groups depending on which three-day intake period they chose, i.e. days, 1, 2, and 3 (Sunday, Monday, and Tuesday) or days 5, 6, and 7 (Thursday, Friday, and Saturday). Carbohydrate and caloric intakes for each group were analyzed separately resulting in four separate blocks. Analysis revealed insufficient evidence to reject the hypothesis that carbohydrate intake was equal between days 1, 2, and 3. The same conclusion was reached regarding equality of carbohydrate intake between days 5, 6, and 7 (Tables 17 and 18). Statistical evaluation of the variability of caloric intake also showed insufficient evidence to reject the hypothesis that caloric intake for days 1, 2, and 3 were equal. This same conclusion was obtained for caloric intake between days 5, 6, and 7 (Tables 19 and 20).

The mean number of separate meals and snacks consumed each day ranged from 3.9 ± 1.4 to 4.2 ± 1.4. Chantelau et al. (1982) found that when subjects on CSII were offered free choice of the number, timing, and carbohydrate content of their meals the average number of daily meals fell from 5-6/day to 3-4/day. Although mean values for the three days did not differ significantly ($p = .05$) the number of meals and snacks consumed by individuals showed considerable

Table 17. Variability of carbohydrate intake between days 1[+], 2 and 3

Source	Degrees of Freedom	Mean Square	Variance Ratio (F)	Table Value of F (α=0.05)
Subjects	9	19032.1		
Days	2	583.8	0.268[*]	3.55
Error	18	2174.5		
Total	29			

[+]Days 1, 2 and 3 are Sunday, Monday and Tuesday, respectively
[*]Insufficient to conclude that significant variance exists between days

Table 18. Variability of carbohydrate intake between days 5[+], 6 and 7

Source	Degrees of Freedom	Mean Square	Variance Ratio (F)	Table Value of F (α=0.05)
Subjects	11	7231.5		
Days	2	2119.9	0.041*	3.44
Error	22	2693.5		
Total	35			

[+]Days 5, 6 and 7 are Thursday, Friday and Saturday, respectively.
*Insufficient to conclude that significant variance exists between days

Table 19. Variability of caloric intake between days 1[+], 2 and 3

Source	Degrees of Freedom	Mean Square	Variance Ratio (F)	Table Value of F (α=0.05)
Subjects	9	1.5367×10^6		
Days	2	6.5×10^4	0.465*	3.55
Error	18	1.3967×10^5		
Total	29			

[+]Days 1,2 and 3 are Sunday, Monday and Tuesday, respectively
*Insufficient to conclude that significant variance exists between days

Table 20. Variability of caloric intake between days[+] 5, 6 and 7

Source	Degrees of Freedom	Mean Square	Variance Ratio	Table Value of F (α=0.05)
Subjects	11	2.9647×10^5		
Days	2	3.77×10^4	0.203*	3.44
Error	22	1.8617×10^5		
Total	35			

[+]Days 5, 6 and 7 are Thursday, Friday and Saturday, respectively.
*Insufficient to conclude that significant variance exists between days

variation. Over half of the subjects responded affirmatively to following a specific meal plan but only one subject's dietary intake record showed the same number of meals and snacks over all three days of the intake period. Five subjects had the number of meals and snacks on one day at least double the number consumed on a separate day. This variation in the number of meals and snacks on CSII is consistent with the findings of Capper et al. (1985). When looked at on an individual basis, variability in carbohydrate intake varies by over 200 gm between days for one subject and by over 100 gms for four others. Seven additional individuals had daily variability in carbohydrate intake exceeding 50 grams (Table 21). Capper et al. (1985) noted greater variability and experimentation with the size of meal intake when subjects switched from CIT to CSII. Health professionals may find it beneficial to consider the large degree of individual variability in food intake among many pump wearers when planning patient education and care.

Physical Activity

During the three-day intake period subjects were also asked to keep a record of their physical activity. Each 24-hour period was entered into the PUBLIC ENERGY program at Utah State University along with the subjects height, weight, and age. BEEs were calculated separately and then added to each day's physical activity to obtain estimates of total caloric output. Mean BEE for males was 1680 $\pm$ 111 kcals and for females 1448 $\pm$ 76 kcals. Mean caloric output for the three-day period was 3027 $\pm$ 422 kcals for men (Table 22) and 2443.21 $\pm$

Table 21. Individual variability of daily carbohydrate intake and number of meals and snacks

Subject #	Day 1		Day 2		Day 3	
	Number of Separate Meals and Snacks	Total Carbohydrate Intake (gm)	Number of Separate Meals and Snacks	Total Carbohydrate Intake (gm)	Number of Separate Meals and Snacks	Total Carbohydrate Intake (gm)
01	3	125.1	2	114.6	3	152.2
02	3	123.7	4	166.0	3	162.0
03	3	134.0	7	199.8	7	365.6
04	3	118.9	4	229.2	3	259.5
05	3	133.9	2	147.3	3	211.7
06	7	210.7	6	227.1	4	244.9
07	4	253.9	5	339.8	4	269.7
08	4	94.3	2	79.9	3	108.7
09	3	231.5	4	168.9	4	158.9
10	5	374.0	4	263.7	5	282.3
11	5	309.9	7	340.3	9	365.7
12	4	193.7	6	288.4	2	88.4
13	8	240.2	5	273.0	3	255.4
14	3	225.3	5	217.7	5	247.9
15	3	202.4	3	207.0	3	161.1
16	4	174.1	3	136.9	3	127.6
17	4	280.3	4	388.3	5	373.6
18	3	96.6	3	95.6	8	182.1
19	3	138.1	4	200.9	4	127.7
20	3	123.3	4	134.5	3	161.6
21	3	213.3	4	187.9	4	158.8
22	4	159.0	4	147.3	2	106.6
Mean ± SD[+]	3.9±1.4	188.9±73.4	4.2±1.4	207.0±82.1	4.1±1.8	207.8±86.4

[+]SD, standard deviation

Table 22. Physical activity and basal energy expenditure of male subjects

Subject	BEE	Physical activity[x] + BEE[xx]			
		Day 1	Day 2	Day 3	3 Day Mean
	kcals*	kcals	kcals	kcals	kcals
01	1734	3028	2768	2611	2836
04	1613	2392	3358	3030	2927
05	1668	2624	2919	3100	2881
07	1740	2458	4808	4699	3988
10	1856	3578	3026	3023	3209
11	1654	3210	3090	2161	2820
14	1473	2024	2810	3005	2613
17	1701	2728	3070	3017	2938
Mean ± SD	1680±111	2756±497	3231±663	3081±727	3027±422

n = 8

[x]Physical activity = Based on Durnin and Passmore (1967)

[xx]BEE = Basal energy expenditure calculated by Harrison Benedict Equation (Mahalko and Johnson, 1980)

*kcals, kilocalories

+SD, standard deviation

230.04 kcals for women (Table 23). Energy expenditures for men were significantly higher than those for women ($p = .05$).

A comparison of mean caloric intake with mean energy expenditure revealed a negative caloric difference, i.e. calorie intake less than caloric output in 21 subjects. The mean caloric difference between calories consumed vs calories burned for men was -678 ± 473 kcals (Table 24) and for women -903 ± 428 kcals (Table 25).

Average daily rates of energy expenditures for men and women living in the United States have been estimated by the Food and Nutrition Board (1974). Men age 23-50 years had an average daily expenditure of approximately 2700 ± 400 kcals. This is based on a 70 inch, 154 lb reference individual. The men in this sampling exceeded this estimation by over 300 kcals, but fell within the upper limit of the range given. Two men studied were in the over 51 year age group. They had mean energy expenditures for the three-day period of 2927 kcals and 2938 kcals respectively. Estimated energy expenditure for this age group was 2400 ± 400 kcals/day based on the same reference individual.

Using a 64 inch, 120 lb reference woman as a basis, the average daily caloric expenditure for women was estimated at approximately $2,000 \pm 400$ kcals or about 450 kcals less than the mean caloric output of the sample group studied. The estimated expenditure for women 19-22 years was 2100 ± 400 kcals. One woman in this study fell into this age group and her individual mean caloric expenditure over the three-day study period was 2441 kcals.

Table 23. Physical activity and basal energy expenditure of females (CSII)

Subject	BEE	Physical activity[x] + BEE[xx]			
		Day 1	Day 2	Day 3	3 Day Mean
	kcals[*]	kcals	kcals	kcals	kcals
02	1452	2291	2231	3082	2534
03	1473	2628	3867	2273	2923
06	1302	2140	2250	2203	2198
08	1482	2941	1902	2757	2533
09	1523	2011	2248	2144	2134
12	1445	2124	2207	2991	2441
13	1436	2696	2245	2522	2488
15	1402	2519	2238	2763	2507
16	1565	2676	3067	2837	2860
18	1471	2267	2255	2087	2203
19	1516	2374	2243	2392	2336
20	1335	2273	2402	2360	2345
21	1473	2555	2094	2619	2423
22	1370	2059	2534	2246	2280
Mean + SD[+]	1488±76	2397±278	2413±493	2520±325	2443±230

n = 14

[x]Physical activity, Based on Durnin and Passmore (1967)

[xx]BEE, Basal energy expenditure calculated by Harrison Benedict equation (Mahalko and Johnson, 1980)

[*]kcals, kilocalories

[+]SD, standard deviation

Table 24. Caloric intake and output for males (CSII)

Subject #	3 Day Mean Total Caloric Intake	3 Day Mean Total Caloric Output	Difference
	kcals*	kcals	kcals
01	1617	2836	-1219
04	1812	2927	-1115
05	2291	2881	-590
07	2835	3988	-1153
10	2920	3209	-289
11	2061	2820	-759
14	2203	2613	-410
17	3046	2938	+108
Mean±SD+	2348±532	3027±422	-678±473

Physical Activity based on Durnin and Passmore (1967) and Basal Energy Expenditure calculated by Harrison Benedict Equation (Mahalko and Johnson, 1980)
*kcals=kilocalories
+SD=standard deviation

Table 25. Caloric intake and output for females (CSII)

Subject #	3 Day Mean Total Caloric Intake	3 Day Mean Total Caloric Output	Difference
	kcals*	kcals	kcals
02	1629	2534	-905
03	1634	2923	-1289
06	1742	2198	-456
08	986	2533	-1547
09	1244	2134	-890
12	1786	2441	-655
13	2206	2488	-282
15	1667	2507	-840
16	1140	2860	-1720
18	1946	2203	-257
19	1384	2336	-952
20	1259	2345	-1086
21	1693	2423	-730
22	1253	2280	-1027
Mean±SD	1541±340	2443±230	-903±428

Physical Activity based on Durnin and Passmore (1967) and Basal Energy Expenditure calculated by Harrison Benedict Equation (Mahalko and Johnson, 1980)
*kcals=kilocalories
+SD=standard deviation

The three-day diet record is inappropriate for energy balance studies or as a prediction of fat gain or loss since it does not assess very small increments of activity. It is, however, a useful approximation of energy expenditure (Bouchard et al., 1983; Reiff et al., 1967; Acheson et al., 1980). This researcher noted a tendency to lump activities into one large category. For example, nurses would go on duty and fill in four hours of time under energy level "e," or nursing chores, and did not separate increments into setting while charting versus pushing a wheel chair patient. Similiarly, a subject would go shopping for two hours at various places, but not separate the time into walking, driving, loading and unloading goods, etc. The majority of subjects grouped time into smaller 15 to 60 minute intervals.

The discrepancy between caloric expenditure for this sample and for the reference individuals may be secondary to a combination of 1) the tendency to overestimate energy output (Acheson et al., 1980), 2) the grouping of large units of time under one activity, and 3) the desire to appear "appropriately" active over the three-day study period.

CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

Nutrient Intake Compared with Standards and Recommendations

Subject's mean nutrient intakes met or exceeded the RDA's (1980) for the majority of nutrients. Both sexes had low intakes of vitamin B_6, magnesium, zinc, folate, and total calories. In addition, women had suboptimal iron ingestion. Although intakes of zinc and folate were marginal, males consumed a diet fairly dense in all nutrients as evidenced by intake of nutrients per 1,000 kcal that nearly met or were above the levels established by Hansen and Wyse (1980). On a nutrient per 1,000 kcal basis women still had insufficient intakes of iron, magnesium, vitamin B_6, folate, and zinc. Women in this study would benefit from information regarding foods rich in these nutrients.

Due to the small sample size statistically reliable conclusions could not be drawn from a comparison of an age and sex matched group from this sample and NHANES II (1983). A simple visual comparison suggests very similar mean intakes of total calories and most vitamins and minerals with the exception of higher levels of vitamin A, calcium, and polyunsaturated fat for the study group.

Mean protein intake for the sample was within the range specified by the ADA (1979), but exceeded new levels suggested in the 1987 ADA dietary recommendations. Total fat, saturated fat, and monounsaturated fat consumption as a percentage of total calories were above levels suggested by the ADA (1979, 1987). The percentage of

carbohydrate intake was below the lower limit of the range suggested. Educationally, emphasis must be placed on increasing carbohydrate intake while lowering fat and protein consumption if ADA recommendations (1979, 1987) are to be met by this group.

Daily Variability in Carbohydrate, Calorie and Number of Meals

Statistical analysis yielded insufficient evidence of significant variation in either caloric or carbohydrate intake between similar days. The number of meals and snacks varied substantially between days for several subjects and only one person studied ate the same number of meals and snacks for all three days of the intake period. It appears that the number of meals and snacks eaten throughout the day are quite flexible within this sample of CSII users.

Glycemic Control

Daily mean glucose levels obtained by SBGM were near normal levels. Despite these figures, seven out of 18 glycosylated hemoglobin values obtained within two months of the intake period were above normal limits. This may indicate that glycemic control of some subjects may not be as good over the long term, as suggested by the blood glucose values obtained during the three-day study period.

Weight Changes

Although a high degree of individual variability was evident men showed a small net decrease in weight after initiation of CSII. Generally a slight gain in weight is seen after initiation of CSII. Over time these men may have compensated for the decreased caloric

requirement that follows improvement in glycemic control via decreased caloric intake, increased physical activity, or both. The slight mean weight gain observed in female subjects is similar to that noted by other researchers. Education of the pump wearer regarding the possibility of weight gain and ways to appropriately offset the probable decrease in caloric requirements should help to reduce this potential problem.

Physical Activity

Both men and women studied had mean daily energy expenditures near the upper range or exceeding estimated average daily expenditures and far in excess of mean caloric intake. This may be due to the large blocks of time specified as one activity when multiple activities were probably being performed, i.e. shopping should have been separated into walking, driving, carrying groceries, etc. and generally was not. Greater accuracy regarding activities during small time increments is necessary to get a more precise estimate of energy expenditure within this group. However, this information is useful in the clinical setting for evaluating general activity trends of individual patients.

Recommendations

Recommendations for further study include:

1. Following individual subject's weight at specified intervals after initiation of CSII to evaluate trends in weight changes.
2. Following individual subject's glycosylated hemoglobins at specified intervals after initiation of CSII to evaluate changes.

3. Repetition of this study using a large sample size and utilizing subjects from different regions of the United States.
4. Obtaining lipid profiles of study participants to be evaluated in conjunction with dietary intake.
5. A comparison of nutrient intakes of CSII wearers with age and sex matched individuals with IDDM who do not use the pump.

Recommendations for clinical use of this data include:

1. Dietary education of CSII users regarding:
   a. Dietary modifications to increase complex carbohydrate intake.
   b. Dietary modifications to decrease total fat, saturated fat, and protein intake.
   c. Guidelines for dietary intake patterns with emphasis on appropriate spacing of meals and snacks.
   d. Good food sources of zinc, folate, vitamin B_6, and magnesium. Females should also be instructed on good food sources of iron and ways to enhance iron absorption.
2. Periodic update and review of general guidelines for diet on CSII and counting of carbohydrates and proteins.
3. Education on the role of physical activity, and on the appropriate use of exercise, in IDDM.
4. Individual counseling to provide the best match between the CSII users diet, physical activity, and lifestyle.

Summary

Females had a mean increase in weight of 3.13 lbs but males had a net decrease in weight of 1.79 pounds after initiation of CSII. Since

a small weight gain is generally reported after pump use begins, this may reflect a reduction in weight after an initial weight gain.

The majority of subjects reported a decrease in the number and severity of reactions after initiation of CSII. Mean blood glucose for the three-day study approached normal limits. However, this may reflect an increase in compliance over the study period since seven out of 18 glycosylated hemoglobin levels were above normal.

Energy expenditures were higher than those reported for the general population. Activities were often grouped into blocks of time and minute to minute changes in activity levels were not obtained, which may partially account for the discrepancy.

No significant differences were found in carbohydrate or calorie intake between days, although a large variation in the number of meals and snacks from day to day was noted.

Average nutrient intake of males met or exceeded the RDA (1980) for all nutrients except folate, zinc, vitamin B_6, and magnesium. Women had mean intakes of zinc, iron, and folate at levels less than two-thirds the RDA (1980). Nutrient consumption of vitamin B_6 and magnesium were also low for females. Both sexes had calorie intakes well below the mid-point for the range given by the RDA (1980) but only females mean caloric intake actual fell below the range given.

On a nutrient per 1,000 kcal basis men met or exceeded allowances for all nutrients except zinc and folate. Intake of these two nutrients were only slightly below recommendations. Dietary intake of females was below suggested levels for iron, zinc, folate, and, to a lesser extent, vitamin B_6 and magnesium.

Men and women had mean protein intake within the range specified by the ADA (1979) but levels exceeded the 0.8 gm/kg of body weight suggested in the 1987 ADA update. Overall fat intake was somewhat higher and carbohydrate intake lower than ADA (1979, 1987) recommendations.

A comparison of the mean nutrient intake of seven females from the study was made with an age and sex matched population from NHANES II (1983). Although statistical analysis was unreliable secondary to the small sample size, intake of most nutrients, including total caloric intake, appeared similar for both groups.

This information may be used to make recommendations for the diabetic using CSII and as a basis of information in the counseling of those patients. Persons studied appeared to differ substantially in the amount of SBGM they performed and in their dietary intake and physical activity patterns. Although education of the diabetic should follow general guidelines, individual counseling is important to improve the subject's use of diet, physical activity, and SBGM to obtain the best possible glycemic control. Since weight increase may occur on CSII, weights should be monitored and individual counseling undertaken if inappropriate weight gain is noted. Periodic glycosylated hemoglobin maybe useful to both the clinician and the subject in the evaluation of long-term control.

The decision to use CSII necessarily involves the subject, to an even greater degree than most other persons with DM, in his or her own diabetic management. The clinician must guide, advise, and support the individual's self-management of diabetes. Nutrition education and

individual counseling, addressing specific concerns in diet, physical, activity, and glycemic control may help to optimize this self-management.

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APPENDICES

Appendix A. Cover Letter and Informed Consent Form

UTAH STATE UNIVERSITY · LOGAN, UTAH 84322-8700

Department of Nutrition and Food Sciences
College of Agriculture
College of Family Life
Telephone (801) 750-2126

Dear _____

Your participation is requested in a nutrition study which is being done cooperatively with your physician, Dr. Dana Clarke, Dr. Kathleen Ford and Utah State University, Department of Nutrition and Food Sciences.

The purpose of this study is to determine the typical dietary intake of people with diabetes who use an insulin infusion pump. You would be requested to:

1. answer a brief questionnaire
2. keep an accurate 3-day diet record
3. record the blood glucose levels that you normally take
4. keep a record of your physical activity during the 3 day food intake period

During the 3-day food intake period all information you provide will remain strictly confidential. You are under no obligation and are free to withdraw from the study at any time.

A computer printout of the average of the three day food records with a comparison to the Recommended Dietary Allowances related to you as an individual will be sent to you upon completion of the study.

Your participation would be greatly appreciated and aide in further understanding of nutrition and diabetes.

If you would be interested in participating more information will be presented at the next pump group meeting. If you are unable to attend the meeting, but still wish to participate please fill in the lines provided with your name, address and phone number and return this letter in the enclosed envelope.

Name _____

Address _____

Phone _____

Sincerely,

Teresa J. Matheny, R.D.
Graduate Student

Barbara M. Prater, Ph.D., R.D.
Associate Professor

Dana Clarke, M.D.

Kathleen Ford, M.D.

Donna Tomky, R.N., A.N.P.

INFORMED CONSENT FORM

Dietary Intake and Physical Activity of Subjects with Type I Diabetes Mellitus Who Use Insulin Infusion Pumps

I have been informed of the nature of this study and I understand that I am asked to keep a three-day diet record, a three-day physical activity record, and to complete a questionnaire.

I give my consent to allow the investigator to review my medical chart for the following data: hemoglobin A_1C, height, weight changes since starting on the pump, and blood pressure. I understand that all information will remain confidential and that the study will be reported without reference to my name, but may be reported as group data.

_____ _____

Signature of Participant Date

_____ _____

Signature of Investigator Date

_____ _____

Signature of Physician Date

Appendix B. Questionnaire

__ __ __

QUESTIONNAIRE FOR USERS OF INSULIN INFUSION PUMPS

Please answer all questions completely by checking the appropriate answer or writing in the space provided. Questions refer to the present unless specified otherwise.

1. Name:_____

2. Address:_____
City State Zip

__ __ __ 3. Birthdate:_____ 4. Telephone Number:_____

__ __ 5. Sex:_____ Male _____ Female 6. Married:_____ Yes _____ No

__ __ 6. Student:_____ Yes _____ No 7. Year of diagnosis of diabetes:_____

__ __ 8. Date you started using pump:_____ Month _____ Year

__ 9. What is your education level? _____ high school degree
_____ college degree
_____ other degree or certification (specify)

10. Occupation_____

Nutrition

__ __ 11. Are you presently following a modified diet: _____ Yes _____ No
If yes, which of the following: _____ low salt _____ low fat _____ other
Specify _____

__ 12. What is the calorie level? _____ Calories/day _____ Don't know

__ 13. Does your diet plan include snacks between meals? _____ Yes _____ No

__ 14. If you don't follow a diet plan, do you usually eat snacks between meals?
_____ Yes _____ No

__ 15. Who, if anyone, gave diet instructions to you at the time of your diagnosis?
___ No instruction ___ Doctor ___ Nurse ___ Dietitian ___ Other

__ 16. Who, if anyone, gave diet instructions to you when you started using the insulin pump?
___ No instruction ___ Doctor ___ Nurse ___ Dietitian ___ Other

__ 17. Who, if anyone, instructed you on how to count carbohydrates in your meals?
___ No instruction ___ Doctor ___ Nurse ___ Dietitian ___ Other

__ 18. What kind of food grouping system, if any, do you use?
___ No grouping system ___ ADA Exchange ___ Food and You ___ Other

19. What system do you use to determine how much carbohydrate is in your meals?
__ _____ ADA Exchanges _____ Food and You
_____ Other: Please explain _____

___ 20. Has your diet plan changed since you started using the "pump"?
___ Yes ___ No

___ 21. Do you eat differently since switching to the pump? ___ Yes ___ No

___ 22. If yes, what differences? (please describe, briefly)
a. amounts of food?
b. types of foods?
c. time of meals?
d. numbers of meals per day?
e. numbers of snacks per day?
f. amount of simple sugars?
g. other _____

___ 23. Do you feel you need further dietary instructions? ___ Yes ___ No
If yes, please describe _____

24. What special dietetic foods, if any, do you use?
None _____ Name of foods _____

25. Do you take vitamin or mineral pills? ___ Yes ___ No
Name Brand _____

26. What sugar substitutes, if any, do you use? None _____
Name of substitutes _____

___ 27. Do you include alcoholic beverages in your diet? ___ Yes ___ No

___ 28. If yes, how do you "count" them? ___ Carbohydrate ___ Calories ___ Fat

___ 29. How long before a meal do you give your pre-meal insulin bolus?
_____Minutes

___ ___ 30. What ratio of insulin to carbohydrate do you use for the pre-meal bolus?
_____ Units insulin per _____ grams carbohydrate

___ 31. Has your weight changed since using the pump? ___ Yes ___ No

___ If yes, have you gained or lost weight? ___ Gained ___ Lost

___ How many pounds have you gained or lost? _____ lbs.

Diabetes Control
How often do you have reactions?

___ 32. Daily: None ___ Number of times ___

___ 33. Weekly: None ___ Number of times ___

___ 34. Monthly: None ___ Number of times ___ Other (please describe)

___ 35. Since changing to the insulin pump, the number of reactions has:
___ increased ___ decreased ___ no change

___ 36. Severity of reactions has: ___ increased ___ decreased ___ no change

___ 37. How do you rate your diabetes control?
_____ Excellent ___ Good ___ Fair ___ Poor

___ 38. What do you use to monitor your blood sugar?
Chemstrips ___ Glucometer ___ Other _____

39. How often do you monitor your blood sugar? _____

___ 40. Are there specific foods that cause a rapid rise in your blood glucose?

___ Yes ___ No

If yes, please list these in descending order with the food that caused the highest rise in blood glucose as number 1.

1.
2.
3.
4.
5.

Other Questions

41. What are your greatest concerns regarding the insulin pump?

42. How do you feel about using the insulin pump?

43. Would you be interested in a personal interview concerning your diet and physical activity record?

_____ Yes _____ No

Thank you very much for answering these questions. The information will be very helpful to health providers, educators, and your physician in understanding your needs and daily challenges.

Appendix C. Instructions for Diet Records and Portion Size Guide

INSTRUCTIONS FOR DIET RECORDS

List everything taken in "Food" column: examples below will assist you in describing the food. Record "amount" eaten in household measures (table-or teaspoons, cups) or by size or weight. Also note time and location in appropriate columns.

The following points should be remembered to make the diet record worth all of your efforts:

CEREALS

1. List brand name and type of cereal and amount eaten in cups (or fractions).

2. For cooked cereals, note if amount refers to dry cereal or cooked form; also specify amont of liquid used to prepare if different from package directions.

3. If milk, sugar, fruit, etc. added, note kind and amount that is actually eaten; i.e. if 1/4 cup but leave 3 Tbsp., specify 1 Tbsp. as amount.

CHEESE AND YOGURT

1. Note kind of cheese. For cheese sold with different fat contents, specify type used (example: cottage cheese - reg. 4% or lowfat; mozzarella - whole or part skim).

2. For unsliced cheese, note dimensions (all 3), weight, or measure (cup, tbsp., etc.) of slice or portion eaten. For presliced, note weight/slice.

3. Yogurts: note brand, if made with lowfat or whole milk and if plain or fruit flavored.

FRUITS AND VEGETABLES

1. Specify fresh, frozen, canned (sweetened or unsweetened; juice pack or water pack) dried, etc. and how prepared.

2. If margarine, milk, cheese, or crumbs added, note kind and amounts.

3. SALADS: Specify amounts of ingredients eaten (example: lettuce, 1 cup, tomato, 1/4 med., carrot 1 tbsp. shredded) or proportions (example: 1 cup fruit salad - half apple, half grapes). IT IS NOT ENOUGH TO JUST LIST INGREDIENTS! SOME QUANTIFICATION IS NEEDED.

SOUPS

1. Canned soups: note if amount refers to diluted soup, and whether diluted with milk or water and whether in accordance with instructions on can.

2. Homemade soups: specify all ingredients and amounts used in soup, and how much soup eaten. If soup is topped with extra ingredients be sure to include (i.e. croutons, cheese, etc.)

DESSERTS

1. List brand, or "homemade", or "bakery".

2. Candies or cooked: note kind and size.

3. Pies: note pan size and fraction eaten (1/5 of 9" pie) or size of wedge.

4. Cakes: Give dimensions of piece and specify icing, fillings, toppings, etc.

BEVERAGES

1. Milk: state if whole, 2%, skim, evaporated. List name and amounts of any flavoring or supplements, etc. added to milk.

2. Fruit Juices: list if fresh, frozen, canned or powdered; specify if sweetened or unsweetened. Give brand name, if possible.

3. Tea or Coffee: list amount of sugar, cream, lemon or artificial sweeteners/creamers added. If using an instant tea mix, please note if presweetened.

BREADS

1. Record kind - white, rye, whole wheat, etc. State if homemade or commercial (brand name, if possible), and if toasted. If piece was irregular shape, give dimensions (length, width and thickness) - this is especially important when loaf is bought unsliced, such as French bread.

2. If butter, margarine, jelly, mayonnaise, etc. added, note amount and kind.

3. Sandwiches: list all ingredients and amounts (example: bread, whole wheat, 2 slices; lettuce, 1 leaf, tomato, 1 slice, mayo. 1 tbsp.).

MEATS - POULTRY - FISH

1. Give weight in ounces after cooking, or specify if weight is for uncooked portion. If weight in ounces is unknown, give dimensions (all 3) for the portion. See Portion Size Guide (blue sheet).

2. Specify the cut of meat (example: chicken drumstick, chuck, rib or sirloin steak, etc.)

3. Specify how prepared - fried, baked, broiled, etc.

EGGS

1. Note size of egg used if other than large: note how prepared.

2. If milk, margarine, drippings, etc. used, note how prepared.

FATS

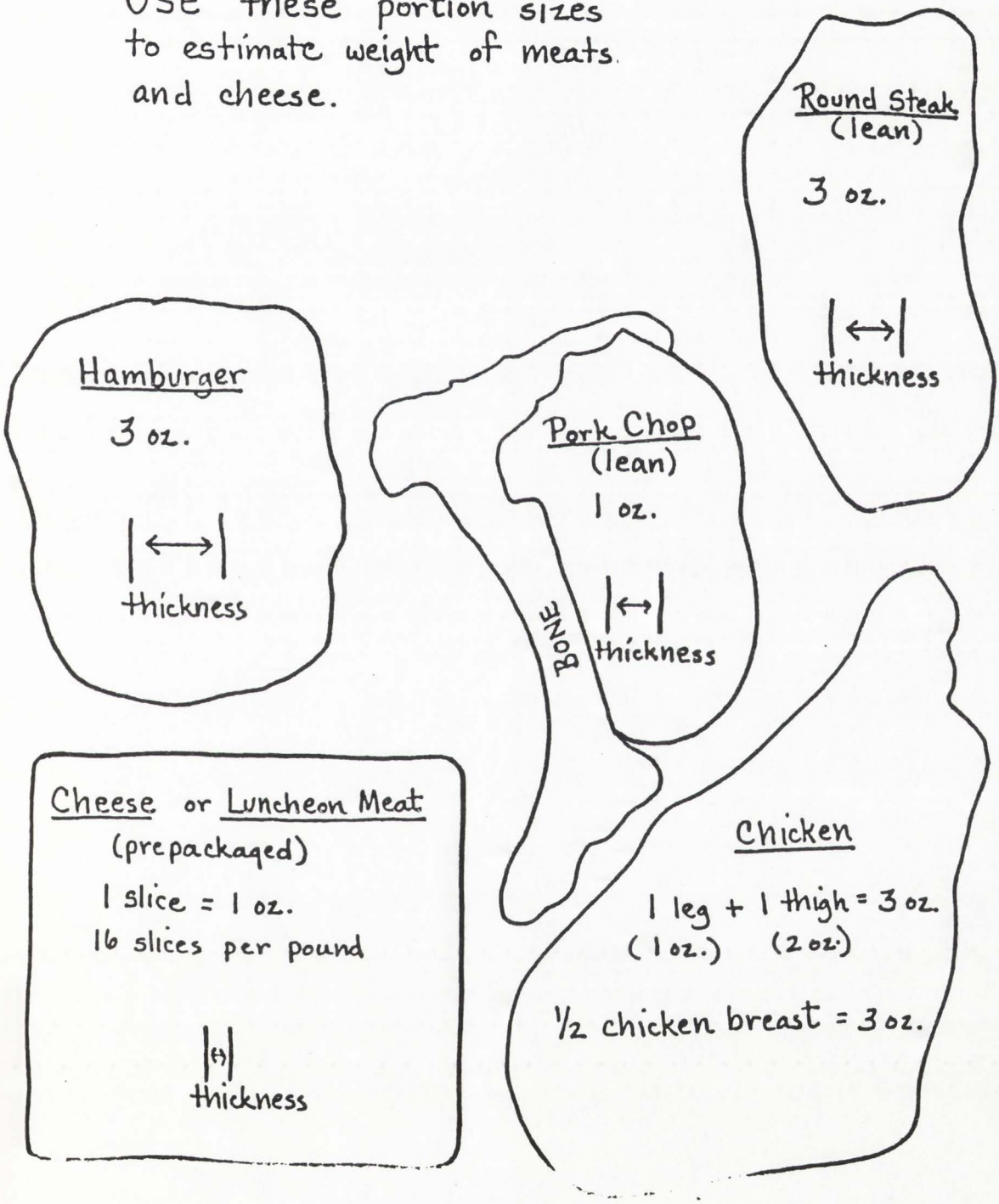
1. Note if butter or margarine used. Give brand name and specify if tub (soft) or stick margarine, or if whipped, diet spread, etc.

2. Record amount eaten in teaspoons or tablespoons.

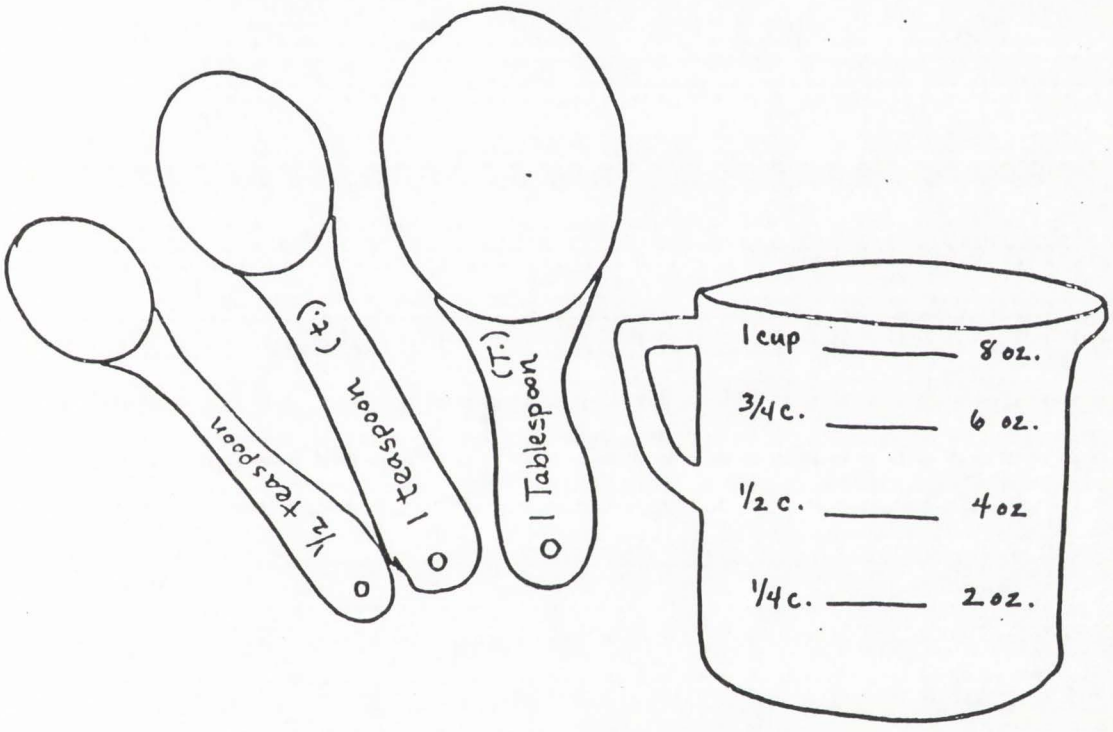
3. Include amounts used in cooking.

PORTION SIZE GUIDE

Use these portion sizes to estimate weight of meats and cheese.



Use household measuring spoons & measuring cups to estimate portion sizes.



Appendix D. Blood Glucose Value Record

It would be helpful in analyzing your food intake to have blood glucose values recorded on the days you keep your food intake record. If possible, blood glucose levels should be taken approximately one half hour before eating. Please record these on the following form.

Example instrument used	Day 1 Time	Day 1 Reading (mg/dl)	Day 2 Time	Day 2 Reading (mg/dl)	Day 3 Time	Day 3 Reading (mg/dl)
glucometer	7:30 AM	138	8:00	151	7:15	85
	11:30 AM	140	12:00	101	11:30	110
	6:00	108	6:00	95	7:15	125

instrument used	Day 1 Time	Day 1 Reading (mg/dl)	Day 2 Time	Day 2 Reading (mg/dl)	Day 3 Time	Day 3 Reading (mg/dl)

Appendix E. Food Intake Record and Sample Sheet

EXAMPLE

SAMPLE

FOOD INTAKE RECORD

Name John Doe Height 6' 0" Weight 190 lbs.

Date Record Was Kept Aug. 20, 1984 Day of Week: M T W Th F Sat Sun

These Day's Intakes Were: Typical X More Than Usual ____ Less Than Usual ____

Did you use a vitamin supplement today? Yes X No ____ Dose 1 Brand Theragram M

What is your basal insulin dose? 30 units What insulin concentration are you on? U40

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT
No	7:00AM	7 units	6:45AM	pancakes	4" diam. mix & milk & egg	2
				margarine	Parkay, soft	1 Tbsp
				syrup	Aunt Jemimah, maple	2 Tbsp
				orange juice	frozen, reconstituted Minute Maid,unsweetened	4 oz
				milk	2%	8 oz
No	10:00AM	1.5 units	9:35AM	apple	medium	1
No	12:30PM	8 units	12:10PM	hamburger	regular, McDonalds	1
				french fries	small bag, McDonalds	1/2 bag
				milk	whole	8 oz
No	4:00PM	10 units	3:45PM	cottage cheese	lowfat 1%	1/2 cup
				pineapple	canned, crushed, juice pack	2 T
				fried steak	beef, round, 4"x3"x1/2"	6 oz.
				mashed potato	instant w/milk, margarine	1/2 C
				salad: lettuce	iceberg, chunks	3/4 C
				tomato	medium	1/2
				dressing	7 Seas 1000 Island	2 T

FOOD INTAKE RECORD DAY 1

Name _____ Height _____ Weight _____

Date Record Was Kept _____ Day of Week: M T W Th F Sat Sun

This Day's Intake Was: Typical ____ More Than Usual ____ Less Than Usual ____

Did you use a vitamin supplement today? Yes ____ No ____ Brand _____

What is your basal insulin dose? _____ What insulin concentration are you on? _____

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

FOOD INTAKE RECORD DAY 2

Name _____ Height _____ Weight _____

Date Record Was Kept _____ Day of Week: M T W Th F Sat Sun

This Day's Intake Was: Typical ____ More Than Usual ____ Less Than Usual ____

Did you use a vitamin supplement today? Yes ____ No ____ Brand _____

What is your basal insulin dose? _____ What insulin concentration are you on? _____

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

FOOD INTAKE RECORD DAY 3

Name _____ Height _____ Weight _____

Date Record Was Kept _____ Day of Week: M T W Th F Sat Sun

This Day's Intake Was: Typical ____ More Than Usual ____ Less Than Usual ____

Did you use a vitamin supplement today? Yes ____ No ____ Brand _____

What is your basal insulin dose? _____ What insulin concentration are you on? _____

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

FOR REACTION	TIME MEAL EATEN	AMOUNT OF BOLUS GIVEN	TIME BOLUS GIVEN	FOOD	DESCRIPTION	AMOUNT

Appendix F. Physical Activity Record and Instruction Sheet

INSTRUCTION SHEET
PHYSICAL ACTIVITY ASSESSMENT

To help accurately assess your energy level and caloric requirement we would like you to categorize your physical activity for the same three days that you record your dietary intake.

Instructions:

1) Record the time of activity.
2) Record the length of activity, specifying the time spent at various energy levels.
3) Account for every minute of the day from midnight to midnight. (1,440 minutes in all.)
4) If you are unable to categorize the activity record the specific activity, the time of day, and minutes spent doing the activity at the top of that days form.

EXAMPLE

*Energy Expenditure Chart

Clock Time	Total Minutes	Activity	Energy Level a	b	c	d	e	f	g	h
12PM-7AM	420	sleep	420							
7-7:30	30	dressing			30					
7:30-8:20	50	eating/cooking		25	25					
8:20-9:30	70	walked to school			50	20				
9:30-12:30	180	sitting in class		180						
12:30-1:00	30	eating		30						
1:00-4:00	180	driving car			180					
4:00-6:00	120	dancing					120			
6:30-7:00	35	eating		35						
6:00-6:30	25	shower		25						
7:00-7:45	45	vacuum				45				
7:45-10:00	135	watch TV		135						
10:00-11:00	60	study		60						
11:00-12:00	60	sleep	60							
Energy level totals			480	490	285	65	120	0	0	
Total minutes		1,440								

Energy Level	Type of Activity
a	Sleep or lying still: relaxed.
b	Sitting or standing still: studying, sewing, eating, listening, writing.
c	Very light activity: driving a car, walking slowing on level ground, washing, shaving, cooking, dressing.
d	Light exercise: walking at moderate speed, sweeping, driving a truck.
e	Moderate exercise: fast walking, dancing, bicycling at moderate speed Light manual work: window washing, nursing chores, waiting on tables, moving furniture, cleaning vigorously
f	Heavy exercise: fast dancing, fast uphill walking, recreational sports, basketball, volleyball, canoeing or rowing, archery, bowling, table tennis. Moderate manual work: carpentry, loading and unloading goods.
g	Severe exercise: tennis, jogging, skiing, gymnastics. (Noncompetitive.)
h	High intensity sports activities or sports competition: wrestling, boxing, racing, rowing, swimming, carrying very heavy loads. Intense manual work.

Physical Activity Assessment

Name _____ Date _____ Day _____

*Energy Expenditure Chart (See Example on INSTRUCTION SHEET)

Clock Time	Total Minutes	Activity	Energy Levels a	b	c	d	e	f	g	h
Total minutes for each energy level										
Total minutes for day										

Appendix G. Participant Summary Sheet and Final Letter

UTAH STATE UNIVERSITY · LOGAN, UTAH 84322-8700

Department of Nutrition and Food Sciences
College of Agriculture
College of Family Life
Telephone (801) 750-2126

Dear

Thank you for participating in this study on the dietary intake and physical activity of individuals with Diabetes Mellitus who use continuous insulin infusion pumps.

Enclosed is a summry of your three day dietary intake and physical activity records.

Specific nutrients from your three day dietary intake have been averaged and compared to the Recommended Dietary Allowances (RDA) for your age and sex. The RDAs are the levels of specific nutrients which are considered adequate to meet the needs of practically all healthy people as established by the Food and Nutrition Board, National Research Council of the National Academy of Science. Your individual requirements for a given nutrient may vary slightly from the RDA for that nutrient depending on your body size and level of physical activity. If your intake of a specific nutrient is less than 75% of the RDA, it is advisable to increase your intake of food rich in that nutrient.

RDAs have not been established for sodium or potassium. Your sodium intake only reflects the sodium content of the foods consumed and does not represent salt added to food. Thus, your actual intake of sodium may be higher depending on the amount of salt that you add.

Thank you,

Teresa Matheny, R.D.

Barbara M. Prater, Ph.D., R.D.

Date _____
Name _____
Address _____
_____
Dates of
Diet and
Activity
Records _____

Research conducted by Utah State University Department of Nutrition and Food Science on nutritional intake and physical activity of persons with Diabetes Mellitus who use insulin infusion pumps

Teresa Jean Matheny, R.D. (Graduate Student)
Barbara Prater, Ph.D., R.D. (Associate Professor)

NUTRIENT	YOUR AVERAGE INTAKE	RECOMMENDED DIETARY ALLOWANCE	PERCENT OF RDA
Calories (kcals)			
Protein (gm)		44 gm	
Minerals			
Calcium (mg)		800 mg	
Iron (mg)		18 mg	
Zinc (mg)		15 mg	
Vitamins			
Vitamin A (IU)		4,000 IU	
Thiamin (mg)		1.0 mg	
Riboflavin (mg)		1.2 mg	
Niacin (mg)		13 mg	
B_6 (mg)		2.0 mg	
B_{12} (mcg)		3.0 mcg	
Vitamin C (mg)		60 mg	
Folacin (mcg)		400 mcg	

Your daily intake of Potassium and Sodium averaged from the three day diet record.

*Potassium (mg)

*Sodium (mg)

*No Recommended Dietary Allowances have been established for these minerals

Your percent of daily calories averaged from the three day diet record from

Protein

Carbohydrate

Fat

Caloric expenditure for your body to maintain it's basic metabolic function is calculated using your age, sex, height, and current weight as you reported in the questionniare. That basic caloric expenditure for you is

_____

According to your submitted record of daily activities an additional caloric expenditure has been calculated. Based upon an average of your three day physical activity record that additional caloric expenditure for you is

_____

Your daily basal caloric expenditure plus your average daily physical activity caloric expenditure equals a total of

_____

If you have questions or need clarification concerning this information you may contact Teresa Jean Matheny, R.D., at 583-9414.

Thank you for participating in this study. A copy of this summary has been sent to Dr. Dana Clarke's office.

Date _____
Name _____
Address _____
_____
Dates of
Diet and
Activity
Records_____

Research conducted by Utah State University Department of Nutrition and Food Science on nutritional intake and physical activity of persons with Diabetes Mellitus who use insulin infusion pumps

Teresa Jean Matheny, R.D. (Graduate Student)
Barbara Prater, Ph.D., R.D. (Associate Professor)

NUTRIENT	YOUR AVERAGE INTAKE	RECOMMENDED DIETARY ALLOWANCE	PERCENT OF RDA
Calories (kcals)			
Protein (gm)		56 gm	
Minerals			
Calcium (mg)		800 mg	
Iron (mg)		10 mg	
Zinc (mg)		15 mg	
Vitamins			
Vitamin A (IU)		5,000 IU	
Thiamin (mg)		1.4 mg	
Riboflavin (mg)		1.6 mg	
Niacin (mg)		18 mg	
B_6 (mg)		2.2 mg	
B_{12} (mcg)		3.0 mcg	
Vitamin C (mg)		60 mg	
Folacin (mcg)		400 mcg	

Your daily intake of Potassium and Sodium averaged from the three day diet record.

*Potassium (mg)

*Sodium (mg)

*No Recommended Dietary Allowances have been established for these minerals

Your percent of daily calories averaged from the three day diet record from

Protein

Carbohydrate

Fat

Caloric expenditure for your body to maintain it's basic metabolic function is calculated using your age, sex, height, and current weight as you reported in the questionniare. That basic caloric expenditure for you is

_____

According to your submitted record of daily activities an additional caloric expenditure has been calculated. Based upon an average of your three day physical activity record that additional caloric expenditure for you is

_____

Your daily basal caloric expenditure plus your average daily physical activity caloric expenditure equals a total of

_____

If you have questions or need clarification concerning this information you may contact Teresa Jean Matheny, R.D., at 583-9414.

Thank you for participating in this study. A copy of this summary has been sent to Dr. Dana Clarke's office.

Appendix H. Recommended Dietary Allowances (1980)

1980 Recommended Dietary Allowances

FOOD AND NUTRITION BOARD, NATIONAL ACADEMY OF SCIENCES–NATIONAL RESEARCH COUNCIL
RECOMMENDED DAILY DIETARY ALLOWANCES,[a] Revised 1980
Designed for the maintenance of good nutrition of practically all healthy people in the U.S.A.

	Age (years)	Weight (kg)	Weight (lb)	Height (cm)	Height (in)	Protein (g)	Fat-Soluble Vitamins: Vitamin A (μg RE[b])	Vitamin D (μg[c])	Vitamin E (mg α-TE[d])	Water-Soluble Vitamins: Vitamin C (mg)	Thiamin (mg)	Riboflavin (mg)	Niacin (mg NE[e])	Vitamin B-6 (mg)	Folacin[f] (μg)	Vitamin B-12 (μg)	Minerals: Calcium (mg)	Phosphorus (mg)	Magnesium (mg)	Iron (mg)	Zinc (mg)	Iodine (μg)
Infants	0.0–0.5	6	13	60	24	kg × 2.2	420	10	3	35	0.3	0.4	6	0.3	30	0.3[g]	360	240	50	10	5	40
	0.5–1.0	9	20	71	28	kg × 2.0	400	10	4	35	0.5	0.6	8	0.6	45	1.5	540	360	70	15	5	50
Children	1–3	13	29	90	35	23	400	10	5	45	0.7	0.8	9	0.9	100	2.0	800	800	150	15	10	70
	4–6	20	44	112	44	30	500	10	6	45	0.9	1.0	11	1.3	200	2.5	800	800	200	10	10	90
	7–10	28	62	132	52	34	700	10	7	45	1.2	1.4	16	1.6	300	3.0	800	800	250	10	10	120
Males	11–14	45	99	157	62	45	1000	10	8	50	1.4	1.6	18	1.8	400	3.0	1200	1200	350	18	15	150
	15–18	66	145	176	69	56	1000	10	10	60	1.4	1.7	18	2.0	400	3.0	1200	1200	400	18	15	150
	19–22	70	154	177	70	56	1000	7.5	10	60	1.5	1.7	19	2.2	400	3.0	800	800	350	10	15	150
	23–50	70	154	178	70	56	1000	5	10	60	1.4	1.6	18	2.2	400	3.0	800	800	350	10	15	150
	51+	70	154	178	70	56	1000	5	10	60	1.2	1.4	16	2.2	400	3.0	800	800	350	10	15	150
Females	11–14	46	101	157	62	46	800	10	8	50	1.1	1.3	15	1.8	400	3.0	1200	1200	300	18	15	150
	15–18	55	120	163	64	46	800	10	8	60	1.1	1.3	14	2.0	400	3.0	1200	1200	300	18	15	150
	19–22	55	120	163	64	44	800	7.5	8	60	1.1	1.3	14	2.0	400	3.0	800	800	300	18	15	150
	23–50	55	120	163	64	44	800	5	8	60	1.0	1.2	13	2.0	400	3.0	800	800	300	18	15	150
	51+	55	120	163	64	44	800	5	8	60	1.0	1.2	13	2.0	400	3.0	800	800	300	10	15	150
Pregnant						+30	+200	+5	+2	+20	+0.4	+0.3	+2	+0.6	+400	+1.0	+400	+400	+150	[h]	+5	+25
Lactating						+20	+400	+5	+3	+40	+0.5	+0.5	+5	+0.5	+100	+1.0	+400	+400	+150	[h]	+10	+50

[a] The allowances are intended to provide for individual variations among most normal persons as they live in the United States under usual environmental stresses. Diets should be based on a variety of common foods in order to provide other nutrients for which human requirements have been less well defined. See text for detailed discussion of allowances and of nutrients not tabulated. See Table 1 (p. 20) for weights and heights by individual year of age. See Table 3 (p. 23) for suggested average energy intakes.

[b] Retinol equivalents. 1 retinol equivalent = 1 μg retinol or 6 μg β carotene. See text for calculation of vitamin A activity of diets as retinol equivalents.

[c] As cholecalciferol. 10 μg cholecalciferol = 400 IU of vitamin D.

[d] α-tocopherol equivalents. 1 mg *d*-α tocopherol = 1 α-TE. See text for variation in allowances and calculation of vitamin E activity of the diet as α-tocopherol equivalents.

[e] 1 NE (niacin equivalent) is equal to 1 mg of niacin or 60 mg of dietary tryptophan.

[f] The folacin allowances refer to dietary sources as determined by *Lactobacillus casei* assay after treatment with enzymes (conjugases) to make polyglutamyl forms of the vitamin available to the test organism.

[g] The recommended dietary allowance for vitamin B-12 in infants is based on average concentration of the vitamin in human milk. The allowances after weaning are based on energy intake (as recommended by the American Academy of Pediatrics) and consideration of other factors, such as intestinal absorption; see text.

[h] The increased requirement during pregnancy cannot be met by the iron content of habitual American diets nor by the existing iron stores of many women; therefore the use of 30–60 mg of supplemental iron is recommended. Iron needs during lactation are not substantially different from those of nonpregnant women, but continued supplementation of the mother for 2–3 months after parturition is advisable in order to replenish stores depleted by pregnancy.

Appendix I. Nutrients per 1,000 Calories: Recommended Levels and Safe and Adequate Daily Dietary Intakes

Nutrient allowances per 1,000 kcal derived from the 1980 Recommended Dietary Allowances (6)

age and sex group	energy	protein	fat-soluble vitamins			water-soluble vitamins							minerals					
			vitamin A	vitamin D	vitamin E	ascorbic acid	thiamin	ribo-flavin	niacin	vitamin B_6	folacin	vitamin B_{12}	calcium	phosphorus	magnesium	iron	zinc	iodine
	kcal	gm.	μgR.E.	μg.	mg.αT.E.	← mg. →			mg.N.E.	mg.	← μg. →		← mg. →					μg.
children																		
1-3 yr.	1,300	18	303	8	4	35	0.5	0.6	7	0.7	77	1.5	615	615	115	11.5	7	54
4-6 yr.	1,700	18	294	6	4	27	0.5	0.6	7	0.8	118	1.5	471	471	118	5.9	6	53
7-10 yr.	2,400	14	292	4	3	19	0.5	0.6	7	0.7	125	1.3	333	333	104	4.2	4	50
males																		
11-14 yr.	2,700	17	370	4	3	19	0.5	0.6	7	0.7	148	1.1	444	444	130	6.7	6	56
15-18 yr.	2,800	20	357	4	4	21	0.5	0.6	6	0.7	143	1.1	429	429	143	6.4	5	54
19-22 yr.	2,900	19	345	3	3	21	0.5	0.6	7	0.8	138	1.0	276	276	121	3.5	5	52
23-50 yr.	2,700	21	370	2	4	22	0.5	0.6	7	0.8	148	1.1	296	296	130	3.7	6	56
51 + yr.	2,400	23	417	2	4	25	0.5	0.6	7	0.9	167	1.3	333	333	146	4.2	6	63
females																		
11-14 yr.	2,200	21	364	5	4	23	0.5	0.6	7	0.8	182	1.4	546	546	136	8.2	7	68
15-18 yr.	2,100	22	381	5	4	29	0.5	0.6	7	1.0	191	1.4	571	571	143	8.6	7	71
19-22 yr.	2,100	21	381	4	4	29	0.5	0.6	7	1.0	191	1.4	381	381	143	8.6	7	71
23-50 yr.	2,000	22	400	3	4	30	0.5	0.6	7	1.0	200	1.5	400	400	150	9.0	8	75
51 + yr.	1,800	24	444	3	4	33	0.5	0.7	7	1.1	222	1.7	444	444	167	5.5	8	83

Estimated safe and adequate daily dietary intakes.

Nutrient	Range for Adults	Per 1,000 kcal
vitamin K	70 - 140 μg	30 μg
biotin	100 - 200 μg	50 μg
pantothenic acid	4 - 7 mg	2 mg
copper	2.0 - 3.0 mg	1 mg
manganese	2.5 - 5.0 mg	1.5 mg
fluoride	1.5 - 4.0 mg	1 mg/l H_2O
chromium	0.05 - 0.2 mg	0.03 mg
selenium	0.05 - 0.2 mg	0.035 mg
molybdenum	0.15 - 0.5 mg	0.08 mg
sodium	1,100 - 3,300 mg	1,500 mg
potassium	1,875 - 5,625 mg	2,500 mg
chloride	1,700 - 5,100 mg	1,500 mg

From Hansen and Wyse, 1980.

Appendix J. Estimated Safe and Adequate Daily Dietary Intakes (1980)

		Vitamins		
	Age (years)	Vitamin K (μg)	Biotin (μg)	Pantothenic Acid (mg)
Infants	0–0.5	12	35	2
	0.5–1	10–20	50	3
Children	1–3	15–30	65	3
and	4–6	20–40	85	3–4
Adolescents	7–10	30–60	120	4–5
	11+	50–100	100–200	4–7
Adults		70–140	100–200	4–7

		Trace Elements[a]					
	Age (years)	Copper (mg)	Manganese (mg)	Fluoride (mg)	Chromium (mg)	Selenium (mg)	Molybdenum (mg)
Infants	0–0.5	0.5–0.7	0.5–0.7	0.1–0.5	0.01–0.04	0.01–0.04	0.03–0.06
	0.5–1	0.7–1.0	0.7–1.0	0.2–1.0	0.02–0.06	0.02–0.06	0.04–0.08
Children	1–3	1.0–1.5	1.0–1.5	0.5–1.5	0.02–0.08	0.02–0.08	0.05–0.1
and	4–6	1.5–2.0	1.5–2.0	1.0–2.5	0.03–0.12	0.03–0.12	0.06–0.15
Adolescents	7–10	2.0–2.5	2.0–3.0	1.5–2.5	0.05–0.2	0.05–0.2	0.10–0.3
	11+	2.0–3.0	2.5–5.0	1.5–2.5	0.05–0.2	0.05–0.2	0.15–0.5
Adults		2.0–3.0	2.5–5.0	1.5–4.0	0.05–0.2	0.05–0.2	0.15–0.5

		Electrolytes		
	Age (years)	Sodium (mg)	Potassium (mg)[b]	Chloride (mg)
Infants	0–0.5	115–350	350–925	275–700
	0.5–1	250–750	425–1275	400–1200
Children	1–3	325–975	550–1650	500–1500
and	4–6	450–1350	775–2325	700–2100
Adolescents	7–10	600–1800	1000–3000	925–2775
	11+	900–2700	1525–4575	1400–4200
Adults		1100–3300	1875–5625	1700–5100

[a] Because there is less information on which to base allowances, these figures are not given in the main table of RDA and are provided here in the form of ranges of recommended intakes.

[b] Since the toxic levels for many trace elements may be only several times usual intakes, the upper levels for the trace elements given in this table should not be habitually exceeded.

APPENDIX K. Metropolitan Height and Weight Tables

1983 METROPOLITAN HEIGHT AND WEIGHT TABLES FOR ADULTS

These tables correct the 1983 Metropolitan tables to height without shoe heels

Men (indoor clothing*)

			Small Frame		Medium Frame		Large Frame	
Feet	Inches	Cms.	Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms
5	1	154.9	128–134	58.2–60.9	131–141	59.5–64.1	138–150	62.7–68.2
5	2	157.5	130–136	59.1–61.8	133–143	60.4–65.0	140–153	63.6–69.5
5	3	160.0	132–138	60.0–62.7	135–145	61.4–65.9	142–156	64.5–70.9
5	4	162.6	134–140	60.9–63.6	137–148	62.3–67.2	144–160	65.5–72.7
5	5	165.1	136–142	61.8–64.5	139–151	63.2–68.6	146–164	66.4–74.5
5	6	167.6	138–145	62.7–65.9	142–154	64.5–70.0	149–168	67.7–76.4
5	7	170.2	140–148	63.6–67.2	145–157	65.9–71.4	152–172	69.1–78.2
5	8	172.7	142–151	64.5–68.6	148–160	67.2–72.7	155–176	70.5–80.0
5	9	175.3	144–154	65.5–70.0	151–153	68.6–74.1	158–180	71.8–81.8
5	10	177.8	146–157	66.4–71.4	154–166	70.0–75.5	161–184	73.2–83.6
5	11	180.3	149–160	67.7–72.7	157–170	71.4–77.3	164–188	74.5–85.5
6	0	182.9	152–164	69.1–74.5	160–174	72.7–79.1	168–192	76.4–87.3
6	1	185.4	155–168	70.5–76.4	164–178	74.5–80.9	172–197	78.2–89.5
6	2	188.0	158–172	71.8–78.2	167–182	75.9–82.7	176–202	80.0–91.8
6	3	190.5	162–176	73.6–80.0	171–187	77.7–85.0	181–207	82.3–94.1

Women (indoor clothing*)

			Small Frame		Medium Frame		Large Frame	
Feet	Inches	Cms.	Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms
4	9	144.8	102–111	46.4–50.0	109–121	49.5–55.0	118–131	53.6–59.5
4	10	147.3	103–113	46.8–51.4	111–123	50.0–55.9	120–134	54.5–60.9
4	11	149.9	104–115	47.3–52.3	113–126	51.4–57.2	122–137	55.5–62.3
5	0	152.4	106–118	48.2–53.6	115–129	52.3–58.6	125–140	56.8–63.6
5	1	154.9	108–121	49.1–55.0	118–132	53.6–60.0	128–143	58.2–65.0
5	2	157.5	111–124	50.5–56.4	121–135	55.0–61.4	131–147	59.5–66.8
5	3	160.0	114–127	51.8–57.7	124–138	56.4–62.7	134–151	60.9–68.6
5	4	162.6	117–130	53.2–59.0	127–141	57.7–64.1	137–155	62.3–70.5
5	5	165.1	120–133	54.5–60.5	130–144	59.0–65.5	140–159	63.6–72.3
5	6	167.6	123–136	55.9–61.8	133–147	60.5–66.8	143–163	65.0–74.1
5	7	170.2	126–139	57.3–63.2	136–150	61.8–68.2	146–167	66.4–75.9
5	8	172.7	129–142	58.6–64.5	139–153	63.2–69.5	149–170	67.7–77.3
5	9	175.3	132–145	60.0–65.9	142–156	64.6–70.9	152–173	69.1–78.6
5	10	177.8	135–148	61.4–67.3	145–159	65.9–72.3	155–176	70.5–80.0
5	11	180.3	138–151	62.7–73.6	148–162	67.3–73.6	158–179	71.8–81.4