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Dietary Intake of Persons with Type I Diabetes Who Use Continuous Subcutaneous Insulin Infusion Pumps

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DIETARY INTAKE OF PERSONS WITH TYPE I DIABETES
WHO USE CONTINUOUS SUBCUTANEOUS
INSULIN INFUSION PUMPS

by

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Who Use Continuous Subcutaneous
Insulin Infusion Pumps

by

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To date there have been no complete reports of the nutrient intakes of persons with Type I diabetes mellitus who use continuous subcutaneous insulin infusion (CSII) pumps. The purpose of this study was to describe the sample population and to determine the nutrient intake of adult Type I diabetics from the Salt Lake City, Utah area, who use CSII.

Seven male and 15 female CSII users, ages 25 to 53, completed a questionnaire and a three-day diet record as instructed. Diet records were coded and household measurements of foods were converted to gram weights for computerized nutrient analysis. Nutrient intake is reported as group mean and standard deviation for sex and age.

The average duration of diabetes was 17 years. The average length of CSII use was 1.6 years. Review of the medical charts revealed that weight gain since beginning CSII averaged 5.5 pounds irrespective of the duration of pump use.

The dietary intake of protein, calcium, phosphorus, vitamin A, thiamin, riboflavin, niacin, vitamin B_{12}, and ascorbic acid met or exceeded the Recommended Dietary Allowances (RDA) for both men and women. For males, mean nutrient intakes were below the RDA for zinc (82.7%), folate (82.2%), and vitamin B_6 (69.0%). For females, intakes were also below the RDA for zinc (64.0%), folate (58.3%), and vitamin B_6 (69.0%), as well as for iron (58.5%) and magnesium (88.0%).

The average percent of kilocalories from protein, carbohydrate and fat, (approximately 17%, 43%, and 40%) was similar for both the males and females. The day-to-day variation in carbohydrate intake for both sexes was not significantly different. Intake of added sugar in the diet was 6.6% and 5.8% of total kilocalories (14.8% and 13.9% of the carbohydrate kilocalories) for males and females, respectively.

In conclusion, dietary intake for this small group of CSII users was adequate in most nutrients. Of concern is the apparent inadequate intakes of zinc, folate, vitamin B_6 and iron for women, as compared to the current RDA standards. The distribution of kilocalories from protein, carbohydrate and fat approaches the 1979 recommendations by the American Diabetes Association. Weight gain may be a problem for some CSII pump users, and should be monitored.

(142 pages)

CHAPTER I

INTRODUCTION

Banting and Best (1922) discovered insulin over 60 years ago. The use of insulin in the treatment of diabetes mellitus has helped to prolong the life and good health of those who have diabetes. Today, the critical issue in diabetes is whether glycemic control prevents or minimizes degenerative complications associated with diabetes mellitus. Many researchers agree that continuous subcutaneous insulin infusion (CSII) helps individuals with Type I diabetes, hereby referred to simply as diabetes, to attain near normal glycemia (Pickup et al., 1980; Hamet et al., 1982; Home et al., 1982; Tamborlane et al., 1982). Some believe that insulin infusion pumps provide for conditions necessary for testing the hypothesis that normoglycemia prevents or minimizes degenerative complications of diabetes mellitus (Pickup et al., 1980, Schiffrin and Belmonte, 1981; Boulton et al., 1982). Marliss et al., (1981) state that, for the present, insulin infusion systems should be used only for research purposes. Others state that CSII treatment is a safe and effective means to attain euglycemia; they imply that subcutaneous insulin infusion may be appropriate for use at home by some persons with diabetes (Champion et al., 1980; Raskin, 1982). Many physicians trained in diabetes and insulin infusion pump treatment are guiding individuals in daily use of continuous subcutaneous insulin infusion as a replacement for daily multiple insulin injections. In 1982, over 4,000 continuous subcutaneous insulin infusion pumps were in use (Macek, 1982); the infusion pumps have now been commercially available for approximately four years in the United States.

The use of insulin infusion pumps does not preclude dietary management of diabetes. Knowledge of the actual dietary intake would provide a basis for determining nutritional needs and, therefore, recommendations for this special population of diabetics who use CSII. Presently, there are no published reports of complete dietary intakes of persons using CSII.

Background of the Problem

Continuous insulin infusion pumps, although still in the experimental stage, are preferred by some individuals with diabetes (Chantelau et al., 1982, Home et al., 1982). There is convincing evidence that treatment of diabetes utilizing insulin infusion pumps results in improved glycemic control as indicated by blood glucose monitoring and glycosylated hemoglobin values (Pickup et al., 1980, Hamet et al., 1982, Home et al., 1982, Tamborlane et al., 1982).

The literature describes many studies which report the favorable effects of CSII on diabetic complications. Hamet et al. (1982), Pietri, Ehle and Raskin (1980), and Raskin (1982) reported an improvement in nerve conductivity at six weeks and lasting up to one and one-half years in the longest experiment with CSII. Boulton et al. (1982) reported that symptoms of pain were relieved with improvement of neuropathy. Raskin et al. (1983) hypothesize that meticulous control of blood glucose with CSII could prevent microvascular complications. The authors reported that there was a significant decrease in width of skeletal muscle capillary basement membrane in patients who used CSII.

Studies indicate that subcutaneous insulin infusion can result in plasma lipids that favor a decreased risk for atherosclerosis (Falko, O'Dorisio, and Cataland, 1982; Pietri, Dunn and Raskin, 1980). This may be significant since there is an increased incidence of heart disease with diabetes.

The use of CSII in research has also indicated that there is normalization of amino acid metabolism (Tamborlane et al., 1979a) as well as growth hormone, catecholamine levels, (Tamborlane et al., 1979b) and glucagon levels (Raskin, Petri and Unger, 1979). CSII may also be beneficial in pregnancy (Rudolf et al., 1981) and possibly in individuals with brittle diabetes (Barbosa et al., 1981).

Despite the apparent favorable effects on metabolic dysfunctions normally associated with diabetes, authors agree that there is no conclusive evidence that CSII itself causes these improvements. Long term studies will help determine the true effectiveness of continuous subcutaneous insulin infusion systems.

Daily use of CSII by individuals with diabetes is growing and will probably continue to grow as third-party insurance coverage for these instruments is implemented. Therefore, it is apparent that health professionals need a more complete understanding of the nutritional needs as well as the food intake patterns of the patients who use CSII.

The goals of diet therapy for persons with diabetes as stated by the American Diabetes Association (1979) are to:

1. Attain and maintain optimal nutrition for good health.
2. Attain and maintain ideal body weight.
3. Provide for normal growth rate in children and pregnant women.
4. Maintain plasma glucose as near normal as possible.
5. Prevent or delay complications associated with diabetes.
6. Modify the diet as needed for complications.
7. Individualize the diet prescription.

The dietary management for individuals who use the insulin infusion pump includes these same basic components. The American Diabetes Association (1982) recently published a policy statement regarding continuous insulin infusion pumps which states that the "use of continuous insulin delivery in no way allows for discarding diet or daily scheduling of events necessary for total diabetes management."

To date there has been only one published report of dietary recommendations for CSII users; Grinvalsky and Nathan (1983) recommend that patients using CSII follow an "ADA-prudent low-fat diet," maintain ideal weight, eat three meals per day with snacks as needed, be consistent in meal size and meal timing, and continue to have no concentrated sweets. In addition, individuals who use CSII must be able to match insulin dose to meal size by estimating caloric content or carbohydrate content of meals (Hamet et al., 1982; Grinvalsky and Nathan, 1983).

This allows them to be sure that the insulin bolus, given before meals, is an appropriate amount to prevent postprandial glycemic excursions. Significant weight gain can occur (Hamet et al., 1982; Home et al., 1982; Grinvalsky and Nathan, 1983), possibly due to the flexibility of meal times and meal size that "the pump" affords.

Statement of the Problem

To date, there have been limited studies describing the actual dietary intake of persons with diabetes mellitus. Other than Chantelau et al., (1982), there are no reports on the dietary and nutrient intake of free-living persons with diabetes who use continuous subcutaneous insulin infusion.

Although dietary recommendations for individuals who use CSII pumps is similar to those who give daily injections, an analysis of actual dietary intake may provide valuable information. Dietitians, physicians and other health care providers may benefit from descriptive data obtained with dietary intake records.

Purpose of the Study

The purpose of this study was to determine and evaluate the typical dietary intake of people with diabetes mellitus who use continuous subcutaneous insulin infusion and to compare nutrient intake with the 1980 Recommmended Dietary Allowances (RDA) (Food and Nutrition Board, 1980) and with the principles of nutrition recommended by the American Diabetes Association (1979). This population will be described by demographic characteristics and other data obtained from questionnaire and medical records.

Objectives

1. To assess the nutritional intakes of men and women who use continuous subcutaneous insulin infusion pumps (CSII).
2. To compare nutrient intake with:
   a) 1980 Recommended Dietary Allowances (Food and Nutrition Board, 1980) for sex and age.
   b) American Diabetes Association recommendations (1979) for percentage of dietary protein, carbohydrate and fat.
   c) national food consumption trends.
3. To describe the consistency in daily carbohydrate intake.
4. To further characterize the population by describing:
   a) duration of diabetes and duration of the use of the continuous subcutaneous insulin infusion pump.
   b) glucose control utilizing existing glycosylated hemoglobin data which has been determined within three months of the individual's diet record.
   c) trends in weight change, if any, since beginning CSII.
   d) other information gathered from the questionnaire such as education level, occupation, sex and age, and dietary habits.

Significance of the Study

This study will help elucidate the actual dietary intake of people with Type I diabetes who use CSII. This study may provide insight into the need for a strict diet as opposed to a less restricted diet. By determining what a group of CSII users actually eat, it is hoped that health care providers can increase their understanding of the principles of diet modifications and therefore be more effective in providing individualized dietary instructions.

Methodology

Subjects

The sample population included 22 adult men and women, ages 25-53, with Type I diabetes mellitus, who used a continuous subcutaneous insulin infusion pump for one-half year or longer. Subjects were limited to those without severe diabetic complications such as renal failure or heart disease and were not pregnant or lactating. All participants were current patients of Dana Clarke, M.D., a diabetologist in Salt Lake City, Utah.

Procedure

Participants were initially contacted by letter and telephone to announce a meeting for pump users, a regular meeting provided by Dr. Clarke and his staff. At that time, all persons present were informed about the purpose of this study by this researcher. Others, contacted by telephone but who did not attend the meeting, received complete instruction over the telephone.

All prospective participants were instructed about keeping dietary records, which included how to estimate portion sizes and record intake accurately. Real food and plastic food models were used for demonstration. Participants were asked to record all food and drink consumed for three consecutive days including one weekend or non-working day. The importance of their accuracy and honesty was stressed. Participants were also asked to fill out a brief questionnaire which was designed to obtain descriptive information about the participant, his/her dietary habits, and other information related to diabetes and the use of their CSII pump. Participants were given a packet which included all materials and instructions needed to participate in the study (Appendices A-F).

The population was characterized utilizing questionnaire data, existing values of glycosylated hemoglobin (HbA_1) as an indication of glycemic control and trends in weight changes since beginning CSII therapy.

Foods were coded for computer analysis using the Nutrition Education Information System (NUTREDFO) nutrient database and software program. The program, developed by Utah State University in conjunction with a nutrition division of the United States Department of Agriculture, compares average three-day nutrient intake with the 1980 RDA (Food and Nutrition Board, 1980) for age and sex, and computes the percentage of total calories from carbohydrate, protein and fat. These percentages were then compared to the 1979 dietary recommendations for percent of kilocalories from the macronutrients, made by the American Diabetes Association. In addition, day-to-day variation in carbohydrate intake was determined statistically. All statistical analyses were done using computerized SPSS statistical programs.

Limitations

1. Data was collected on a small sample of 22 subjects in a single geographic area and under the care of a single diabetologist. Therefore, the sample population may not be totally representative of the true population of diabetics who use CSII.
2. Food records may differ from actual intake. Although it is recognized that a three-day diet record may differ on a weekly or monthly basis, it can be assumed that some consistency in food intake is present in a diabetic population which has been educated about their daily dietary needs for control of their diabetes. To reduce errors, the subjects were instructed on methods to accurately measure and record daily food intake.
3. Diet records were requested for the months of July or August. However, records of the participants were recorded anytime between July and December. Because of the limited number of subjects in this study, diet records of all months were accepted. It is unknown whether the seasonal variation of fresh foods may cause a misrepresentation of average intake of some nutrients.
4. Dietary analysis using any nutrient data base is only an approximation since food intake records are not absolute and are occasionally missing necessary details for accurate coding.

Additionally, nutrient content of a single type of food may vary. The NUTREDFO data base has the most up-to-date nutrient values available. However, the database is limited to 446 foods. Not all foods eaten by this population were on the database; therefore, some foods had to be assumed equivalent to other similar foods of the database.

5. The 1980 RDA are recommendations for healthy populations. Persons with diabetes mellitus may have different nutrient requirements although this has not yet been established. The RDA were used for individual and group comparisons in this population as an indication of dietary adequacy since no other standards are presently available.

6. Measurements of body weight may vary due to variations in the scale, recent food or fluid intake, or clothing.

CHAPTER II

REVIEW OF LITERATURE

The Prevalency of Diabetes Mellitus and Use of Insulin Infusion Pumps in Utah

A statewide survey for Utah, compiled in 1981, (Reiber and Kan, 1983) revealed the estimated prevalence of diabetes mellitus for Utah's civilian, non-institutionalized population to be 1.85 ± 0.11 percent ($\pm$ standard error), or approximately 27,200 individuals. Covering all age groups, there were an estimated 10,600 males (1.46 ± 0.14 percent of all males) and 16,550 females (2.23 ± 0.17 percent of all females in Utah). There were statistically more females than males ($p<0.001$).

In a report based on preliminary data received from the Center for Disease Control, (CDC) the Bureau of Chronic Disease Control in Utah (1982) compared statistics of CSII use from a ten-state study. The report stated that there were 144 patients using CSII in Utah at that time. This comprised 13.7% of the total number of patients using pumps in the ten-state study. The CDC report stated that no differences in age, sex, height or weight between Utah and the other nine states were apparent in those who used CSII. There was a higher incidence of complications from diabetes in Utah, however. Also, there was a greater reduction in hemoglobin A_{1c} (HbA_{1c}) levels in Utah with pump use; the mean HbA_{1c} level fell from 12.0% to 8.6% in Utah as compared to a mean decrease from 11.6% to 9.0% in the other states.

Diet and Nutrition in Type I Diabetes

"Synchronizing diet, insulin therapy, and exercise is the main emphasis of therapy" in Type I diabetes (Crapo, 1983). Therefore, dietary management is one of the keystones of treatment. In recent years, there has been considerable interest in and discussion of many nutritional issues involved in the care and treatment of diabetes mellitus. Yet, there is no conclusive evidence that one particular dietary regimen has long-term beneficial or deleterious effects. The current controversial dietary issues focus on the appropriate amounts and types of carbohydrates, the role of fiber, fats in the diet, and the use of caloric sweeteners. Both Nuttall (1983) and Crapo (1983) present a comprehensive review of literature concerning the controversial issues.

Conventional Diet for Diabetes

In 1979, the American Diabetes Association published recommendations and principles of nutrition and dietary management for persons with diabetes mellitus. These recommendations represent agreement, based on the available research, by experts in the field.

A basic nutritional principle for diabetes, which continues to be supported, is that essential nutrient requirements for persons with diabetes are the same as for healthy persons of the same sex and age (American Diabetes Association, 1979). Dietary intake of minerals and vitamins in amounts to meet the Recommended Dietary Allowances (Food and Nutrition Board, 1980) and adequate provision of macronutrients for growth will meet nutritional needs without special dietary or dietetic products. However, dietary modifications may be necessary in cases of metabolic abnormalities.

Special dietary considerations for Type I diabetes are outlined by the American Diabetes Association (1979). Regularity of meal times and number of meals per day is stressed for maintaining good metabolic control, as is day-to-day consistency of intakes of carbohydrates, fats and protein. It is recommended that intake should approach 12-20% protein and 50-60% carbohydrate with fats making up the difference (20-38%) of the total energy intake. Saturated fatty acids should comprise less than 10% of the total calories and polyunsaturated fatty acids should supply up to 10% of the total calories. Cholesterol restriction is advocated. It is recommended that consumption of simple sugars should be restricted and high fiber carbohydrate foods replace refined carbohydrates.

Although these goals are frequently stressed by health professionals, the dietary recommendations "should be as flexible as possible" for a more practical, acceptable meal plan (American Diabetic Association, 1979). Individualization of meal plans is also recommended.

Meal patterns are typically planned for the use of food exchange lists. The Exchange Lists for Meal Planning by the American Diabetes and Dietetic Associations (1976) is probably the most commonly utilized exchange list. The lists are designed to group foods with similar contents of major nutrients. There has been no consideration given to the physiologic response to foods within the food groups.

The Glycemic Index

Recent studies show a wide variation in the glucose response, or glycemic index, to ingestion of different foods with equal carbohydrate content for persons with or without diabetes. The glycemic index is defined as the area under the curve for a test food divided by the area under the curve for an equal amount of glucose, divided by 100 (Jenkins et al., 1981).

Crapo, Reaven and Olefsky (1977) found significant postprandial differences in glycemic and insulin responses to five foods in normal individuals. Potatoes and dextrose had similarly high glucose responses while rice and corn had the lowest glycemic responses with similar insulin responses. Bread was intermediate in glucose response. The authors concluded that the rate of digestion and absorption differed, as indicated by nearly identical total areas under the glycemic curves at two-hours postprandial for all foods tested. In a subsequent study with glucose intolerant subjects, Crapo et al. (1980) reported similar results with the same foods. However, the glucose and insulin responses were two times greater in these glucose intolerant subjects as compared to normal subjects in a previous study.

Jenkins et al. (1981) determined the glycemic index for 62 foods consumed by healthy subjects. Great differences in the glycemic responses were seen within food groups. Fructose and sucrose had glycemic indices of 20±5% and 59±10% respectively. The glycemic response to fructose was much lower than expected since absorption of simple sugars is believed to be rapid. Dried legumes had the lowest glycemic indices. The authors concluded that the simple carbohydrate exchange lists commonly used by people with diabetes mellitus may not be a good predictor of physiological response.

Test carbohydrates of glucose, fructose, potato starch, and wheat starch were also tested in meals as compared to single foods being tested. Meals of consistent amounts of total carbohydrate, protein, and fat were fed to healthy adults and to persons with Type I and II diabetes (Bantle et al., 1983). For all groups, fructose produced the lowest glucose response; the meal with sucrose was not significantly greater in glycemic response than the other test carbohydrates. However, the glucose responses were greater in persons with Type I diabetes than in normal persons. Those with Type II diabetes had an intermediate glucose response in comparison with the normal and Type I diabetes groups. Again, the physiological response to carbohydrates demonstrated the questionability of the use of the current exchange lists and the common recommendation to limit the intake of sugars in the diet.

The physiological response to various foodstuffs appears to be related to several factors. Jenkins et al. (1981) reported that both fat and protein intake with the test carbohydrates had a significant negative correlation to the glycemic index, possibly because fats may delay gastric emptying time and protein may stimulate insulin secretion. The effect of cooking starch also affects the glycemic response. Cooked starch, which may increase the availability of starch to amylase activity, had a glucose response similar to glucose while there was significantly less glucose response to raw starch

(Collings, Williams, and MacDonald, 1981 and Crapo, Reaven, and Olefsky, 1976).

Food form also plays a role in the physiological response to carbohydrate ingestion. For example, whole apples had a significantly lower glucose response than pureed apples (Haber et al., 1977). Similarly, ground rice, whether white or brown, produced a significantly greater glucose response than whole rice at 60 minutes postprandial (O'Dea, Nestel, and Antonoff, 1980). It was suspected that the ground forms were absorbed faster since the total areas under the glycemic curve are the same as the unground forms at four hours postprandial.

The rate of digestion of foods affects the blood glucose response to carbohydrate foods. This may be due to the presence of fiber (Jenkins et al.,1980a; Haber et al., 1977) and increased viscosity as in cooked starches (Collings et al., 1981).

Overall, the rate of digestion, food form, nutrient interactions, effect of cooking, and other factors affect glycemic response to carbohydrates. These studies have caused researchers to question the usefulness of the diabetic exchange lists. It is a current point of discussion whether the lists will become obsolete or be revised as more scientific data becomes available.

The Role of Fiber

The role of fiber in the diet of persons with diabetes has recently received national attention. Although there is no conclusive evidence to endorse specific dietary changes, the American Diabetes Association (1979) supports the view that increased intake of dietary fiber may be beneficial in the control of diabetes. Indeed, recent research supports the possible role fiber may play in the treatment of diabetes, particularly Type II diabetes.

Purified fiber supplements such as guar gum and pectin have been used to demonstrate the effect of fiber in flattening the glucose response curves in diabetes. Although useful for research, its practical use for therapeutic diets is questionable because it must be adequately mixed with foods and is unpalatable due to its viscosity (Jenkins, Taylor, and Wolever, 1982).

Guar gum, a galactomannan, and pectin, a product obtained from the cell walls of plants, are viscous fibers which are not hydrolyzed by intestinal enzymes and therefore are not available for absorption. Ingestion of guar in a meal resulted in a flattened postprandial glucose response curve in normal subjects, as well as in persons with Type I and Type II diabetes (Jenkins et al., 1976; Jenkins et al., 1977). Addition of pectin, and pectin plus guar had similar results (Jenkins et al., 1977). In a comparison of guar mixed with high and low carbohydrate diets (greater than and less than 40% carbohydrates, respectively), postprandial glycemic response was less in the high carbohydrate diet (Jenkins et al., 1980a). The authors concluded that the guar gum fiber is more consistently effective at the higher carbohydrate intakes with minimal mono and disaccharides. Guar gum taken with a glucose load at breakfast has improved glucose tolerance in the subsequent meal (Jenkins et al., 1980b). This indicates that fiber may affect both the meal with which it is taken and the subsequent meal.

Viscosity of guar and pectin fibers may play a role in decreasing the glycemic response. It may cause a slower gastric emptying time or a decrease in diffusion of available carbohydrate towards the absorptive mucosal surfaces. The viscous fibers produced a flatter glycemic response than particulate fibers such as wheat bran (Jenkins et al., 1978). However, in longer term studies, high fiber breads made with particulate fibers did improve glucose control in subjects with diabetes (Miranda and Horowitz, 1978; Bosello et al., 1980).

High carbohydrate diets with a high leguminous content, such as soybeans, lentils, dried red kidney beans, haricot beans or butter beans, had a significantly lower rise in postprandial blood glucose after a meal than a diet with equivalent carbohydrate content from bread (Jenkins et al.,1980c) or a diet low in carbohydrate (Simpson et al., 1981) in both normal and diabetic subjects. Simpson et al. (1981) reported that both insulin-dependent and non-insulin dependent persons with diabetes had an overall improvement in diabetes control on the high carbohydrate, high leguminous diet (67% fiber) in the six week crossover study. Glycosuria, HbA_{1c} and total cholesterol were significantly reduced.

Jenkins et al. (1980c) suggest that the improved glycemic response to a diet with a high legume content is due to the high fiber content of the legumes, and the slower rate of digestion as seen in their in vitro studies. Jenkins et al. (1980c) label this as "lente", or sustained-release, carbohydrate. In an overview of the role of fibers and carbohydrates in diets for diabetes, Jenkins (1982) states that these successful uses of dietary fiber may be due to the large portion of "lente carbohydrate sources under the caption of 'high-fiber'". He speculates that the knowledge of lente carbohydrate, together with other information on dietary fiber, effects on gastrointestinal events and nutrient interactions will determine the future practical applications of therapeutic diets for the person with diabetes mellitus.

Caloric Sweeteners

The conventionally tight restriction of refined foods containing simple sugars is presently under question (Bantle et al., 1983; Nuttall, 1983). Fructose consistently produced the smallest increments of plasma glucose levels compared to four other test-carbohydrate meals in normal persons and persons with Type I and II diabetes (Bantle et al., 1983). Meals with sucrose as the test carbohydrate did not produce a significantly different glucose response than test carbohydrates of potato, wheat, or glucose (Bantle et al., 1983). This research is supported by the data of Jenkins et al. (1981) who reported the relatively low glycemic indices of fructose and sucrose: 20±5% and 59±10%, respectively. Although it must be kept in mind that other factors such as nutrient interactions and dosage will affect the glycemic response to fructose and sucrose, research such as this indicates that these caloric sweeteners, when taken in moderate amounts with meals, may not adversely affect the metabolic control of diabetes. The research also supports the use of fructose as the more acceptable sweetener.

Nuttall (1983) argues against the empty-calorie concept as a reason for persons with diabetes to avoid simple sugars in their diet. He states that there is no scientific evidence to support this concept and cites the 1977-78 Nationwide Food Consumption Sruvey in which sweeteners (sucrose and corn syrup) averaged only 12% of the total daily food energy intake. Unless a person is on a reduced calorie diet or an atypical diet, Nuttall (1983) believes there is sufficient intake of the essential vitamins and minerals.

Dietary Fats

Atherosclerotic disease is the most common complication of diabetes mellitus and is responsible for three-fourths of the deaths of all persons with diabetes in North America (Steiner, 1981). The American Diabetes Association (1979) promotes a diet low in cholesterol and saturated fats with the total fat content not exceeding 38% of total calories, which makes up the difference of the lower limits of the recommended amounts of calories from protein and carbohydrate. The reasoning behind these recommendations is the potential deceleration or prevention of atherosclerosis. Despite the ambiguity of the relationship of atherosclerosis to diet, El-Beheri Burgess (1982) supports the rationale that a primary goal in the management of diabetes is to prevent atheroslerosis and that an isocaloric diet where carbohydrate (preferably complex carbohydrate) replaces fats, especially saturated fats and cholesterol, is a prudent attempt at prevention.

In a twelve-year cross-over study, a "serum cholesterol-lowering diet" resulted in decreased mortality from coronary heart disease in men (Miettinen et al., 1972). Saudek and Young (1981) also hypothesize that "diet plays a central role in the diabetics' cholesterol metabolism."

The concern that a high carbohydrate diet may induce hypertriglyceridemia, which may play a role in atherosclerosis, is not founded. Studies show that high carbohydrate diets reduced fasting blood glucose levels (Brunzell et al., 1971), reduced serum cholesterol (Stone and Connor, 1963), and, as well, did not produce hypertriglyceridemia (Stone and Connor, 1963; Farquhar et al., 1966).

Future studies may support or repudiate the necessity of fat restriction for the person with diabetes. For now, it appears prudent to support the recommendation of the American Diabetes Association (1979).

Diet and Nutrition for Persons with Type I Diabetes Who Use Continuous Subcutaneous Insulin Infusion

The role of the diet in the metabolic control of persons with Type I diabetes who use continuous subcutaneous insulin infusion (CSII) pumps is not yet clearly defined. Presently, it is thought that this group has the same nutritional needs as any other person with Type I diabetes as long as severe complications are absent. Requirements of essential micro- and macronutrients are based on the RDA (Food and Nutrition Board, 1980). The nutritional principles of the American Diabetes Association (1979) are also valid for this group. Indeed, for the present, the preceeding discussions must include those diabetics who use infusion pumps as well as those who use insulin injections, as there is little or no research on the role of carbohydrate, fiber and fat intakes or glycemic response with respect to the use of CSII.

Grinvalsky and Nathan (1983) are the first authors to address the dietary needs of persons with diabetes who use insulin infusion pumps. Based on their own experience with CSII users over a three year period, the authors describe guidelines that have been effective with their patients. They support the use of the American Diabetes Association (1979) guidelines of a prudent low fat diet, consistency in meal size and timing, and avoidance of concentrated sweets. The rationale that blood glucose will fluctuate more widely in the absence of these behaviors is the basis for their support of the guidelines.

Special educational differences for those who use CSII therapy are outlined (Grinvalsky and Nathan, 1983). These include that the individual be knowledgable in the carbohydrate content of foods in order to calculate and administer the appropriate preprandial insulin bolus. Weight maintainance must be carefully monitored to avoid weight gain. Snacks are not mandatory since regular insulin is used with the pumps, but it is suggested that the dietitian assist the individual in determining the number of snacks and timing. A thorough knowledge of how to prevent as well as treat hypoglycemia and the role of exercise in maintaining normoglycemia is essential.

The adequacy of traditional exchange lists for estimating carbohydrate contents of meals is questionable in light of the current literature of the glycemic responses to various carbohydrates.

Similarly, the restriction of sucrose and fructose can also be questioned for those who use CSII. Since it is obligatory for people who use CSII to monitor blood glucose daily (American Diabetes Association, 1982) these individuals have the opportunity to monitor their own physiological responses to various carbohydrates. This will allow them to adjust an insulin bolus accordingly by using algorithms as described by Skyler et al. (1981). Achieving desired control without adherence to exchange lists or strict avoidance of simple carbohydrates may then be possible.

Chantelau et al. (1982) found that when CSII users were allowed a more liberalized diet without utilizing a diet plan, but still avoiding simple sugars, the glycosylated hemoglobin, serum lipid levels, and weight were not affected over a four to six month period when compared to the use of a diet which followed the standards set by the American Diabetes Association (1979). Participants who had the liberalized diet consumed more fats, less carbohydrate, and ate fewer numbers of meals per day. This study supports the views of others who believe in the lifting of dietary restrictions to some degree, for some individuals. Others also hold similar opinions for the liberalization of diets for children (Guest, 1947; Forsythe and Payne, 1956; Dorchy, Mozin, and Leob, 1981; Rayner, 1982).

Ongoing research continues to provide insight into the role of diet in the life expectancy and metabolic management of those with insulin dependent diabetes mellitus. As yet, there is no conclusive evidence to direct the prescription of diets; however, it is likely that future data will help to put present dietary hypotheses into practical application. Therefore, flexibility in the planning and recommendations of dietary programs for persons with diabetes is advocated (American Diabetes Association, 1979; Chantelau et al., 1982; Jenkins et al., 1982; Crapo, 1983; Nuttall, 1983). Maintaining flexibility while attaining nutritional adequacy may be more practical and acceptable to those with diabetes than strict and unrealistic expectations.

Select Dietary Studies of Type I Diabetes Mellitus

In a comprehensive review of the literature it was observed that minimal data has been published about the dietary and nutrient intake of persons with diabetes. The majority of the data were from reports of the intake of children. There was only one cursory report of the macronutrient intake of free-living diabetics who use insulin infusion pumps. There were no reports of the micronutrient intake of persons who use CSII.

Sterky (1962) reported on the consumption of calories and ten key nutrients of school children based on a 24-hour dietary recall. He found that diabetic children consumed lower amounts of most nutrients than their paired non-diabetic counterparts. Protein intake was adequate based on the 1958 RDA. The fat consumption of diabetic boys was 40.9% and of girls was 46.0% of total calories. Average consumption for all age groups (7-20 years) was 41.6% carbohydrate and and 14.3% protein. An older age group (17-20 years of age) which was seen at a diabetes clinic of a children's hospital consumed 39.2% fat, 42.9% carbohydrate and 17.9% protein. Those of the same age group who were treated at other hospitals consumed 50.2% fat, 35.9% carbohydrate, and 13.9% protein.

Seppanen and Reunanen (1979) studied the diet habits of 185 adults with Type I and II diabetes in Finland. The diet of this group consisted of 41-46% carbohydrates, 16-18% protein and 38-40% fats. An outpatient group with diabetes consumed 12-14 grams sugar per day; those selected randomly ate 19-21 grams sugar per day. Over 66% of those individuals treated with insulin ate six or more meals per day.

In a small sample of subjects (n=7), Chantelau et al. (1982) reported on the dietary intake of the macronutrients of adults with diabetes who use CSII. The subjects consumed a diet which followed the American Diabetes Association recommendations (1979) then switched to a partial lifting of dietary restrictions. In the "less restricted diabetes diet" the subjects were free to choose the number of meals per day, timing of meals, and carbohydrate content of the meals. Consumption of simple sugars was still limited. On the "less restricted diet" which was maintained for three to four months, the subjects had 3-4 meals per day and meal times varied. Fat intake was 51 ± 5% of total calories, while carbohydrate was 34 ± 5% and protein 15 ± 2% of total calories. There were no significant differences in glycemia, as indicated by glycosylated hemoglobin and blood glucose monitoring, and no measurable change in serum lipids or body weight between the conventional and less restricted diets. There were no data reported on the vitamin or mineral content of the diets.

It is clear that descriptive studies of macro as well as micronutrient content of the diets of adults with diabetes with and without insulin infusion pumps would provide valuable information. Knowledge of the average dietary intakes, as compared to American Diabetes Association guidelines (1979) and the 1980 RDA would provide a valuable tool in devising recommendations and in counseling persons with diabetes who use continuous insulin infusion pumps.

Weight Changes with Continuous Subcutaneous Insulin Infusion Therapy

Several studies reported a gain in weight of subjects who use CSII (Hamet et al., 1982; Home et al., 1982). Home et al. (1982) found that body weight increased significantly from 67.0±2.9 kg with insulin injections three times daily, to 68.9±2.9 kg after 10 weeks of CSII ($p=0.023$). Seven of eight patients gained weight after 52 weeks of CSII pump treatment (average weight of 60 kg at 3 weeks CSII versus 62 kg at 52 weeks CSII). The authors believed that weight gain is a significant problem in patients using CSII.

Several factors may contribute to the observed weight gain. When euglycemia is attained there is no glycosuria and consequently, no loss of calories. The body utilizes or stores calories more efficiently therefore, there is a potential risk of weight gain. In addition, persons who use CSII tend to experiment with a more liberal diet. They may eat more simple carbohydrates or eat larger meals since insulin bolus can be adjusted accordingly, thus consuming extra calories.

Glycosylated Hemoglobin and Metabolic Control

A major goal for most people with diabetes mellitus is to attain euglycemia since it is hypothesized that blood glucose control to near normal levels may prevent or reduce the incidence of complications commonly associated with diabetes. Single blood glucose determinations indicate only the present state of control, therefore, physicians utilize measurements of glycosylated hemoglobin as an indication of the patient's long-term metabolic control.

Nathan et al. (1984) validated the clinical use of glycosylated hemoglobin as a useful tool of long-term diabetic control. The authors reported that long-term control is not otherwise obtainable by single blood glucose or urine measurements, or evaluation of signs and symptoms or frequency of hypo- or hyperglycemia by physicians. Goldstein (1984) supports the results of the study and suggests that routine measurement of glycosylated hemoglobin be done for monitoring glucose control.

Hemoglobin becomes glycosylated in a slow, nonenzymatic modification of the hemoglobin protein. After a series of chemical changes the glucose becomes irreversibly bound. The degree of glycosylation is dependent upon the ambient concentration of blood glucose over time. Erythrocytes have a half-life of 60 days. Therefore, measurements of glycosylated hemoglobin reflect the mean blood glucose concentration of the preceeding two to three months (Koenig et al., 1976; Gonen et al., 1977; Compagnucci et al., 1981).

Glycosylated hemoglobin A_1 (HbA_1) represents seven percent of the total hemoglobin normally found in a healthy adult. Glycosylated HbA_1

is composed of three smaller components: HbA_{1a}, HbA_{1b} and HbA_{1c}. Hemoglobin A_{1c} (HbA_{1c}), the largest of the three subfractions, represents four percent of the glycosylated hemoglobins. Increases of HbA_1 and HbA_{1c} above normal in persons with Type I diabetes mellitus have been confirmed (Bunn et al., 1976; Welch and Boucher, 1978; Gabbay et al., 1979). Both HbA_1 and HbA_{1c} have proven to be a valuable tool for the assessment of blood glucose control over the preceeding two to three months (Gabbay et al., 1977; Compagnucci et al., 1981; Bunn et al., 1976, Koenig et al., 1976; Gonen et al., 1977; Svendsen et al., 1980; Dunn et al., 1981; Goldstein et al., 1982).

Persons with diabetes who achieve blood glucose control are reported to have decreased glycosylated hemoglobin levels (Koenig et al., 1976). Therefore, it can be useful to monitor glycosylated hemoglobin values for determining efficacy of therapeutic regimens.

Method of Glycosolated Hemoglobin Determination

There are some methodologic problems with the determination of glycosylated hemoglobin, due to 1) the presence of modified hemoglobins which have similar mobility in column resins, 2) labile glycosylation of hemoglobin during transient postprandial glucose excursions, and 3) assay sensitivity to temperature or buffer pH (Goldstein et al., 1980; Compagnucci et al., 1981; Whitehouse and Gabbay, 1981). It has been recommended that treatment of erythrocytes with saline or the dialysis of hemolysates before the assay of HbA_1 or HbA_{1c} will remove the labile portion that would give a falsely high value (Goldstein et al., 1980, Compagnucci et al., 1981). Goldstein et al. (1982) states that there is yet no ideal method for quantitating glycosylated hemoglobins and that there is no consensus on standards, so that test results between laboratories cannot be directly compared. Therefore, each laboratory must establish its own standards and controls.

Glycosylated Hemoglobin and CSII

There is little disagreement that the use of insulin pump therapy is effective in significantly reducing blood glucose to near normal levels. Glycosylated hemoglobin A_1 levels were significantly reduced in many studies, up to 1½ years in the longest study (Tamborlane et al., 1981; Falko et al., 1982; Hamet et al., 1982; Home et al., 1982; Tamborlane et al., 1982). Table 1 represents the results of these studies.

Validity of Dietary Assessment Methods

Over the past three decades researchers have discussed the validity and reliability of dietary survey methods. Validity of the methodologies is difficult, especially for the diet history method since it requires that the "truth", or actual intake, be known. Studying and determining the validity of the methodologies is limited by time restraints and by practical difficulties such as direct unobtrustive observation of intake by trained persons or actual weighing of foods eaten. Gathering valid information of dietary intake is complicated further by the need to know if intake is "usual", which is difficult or impossible to determine.

Table 1. Values of HbA_1 before CSII and with CSII as reported by other authors.

HbA_1 pre-CSII*	HbA_1 post CSII*	Length of Study	Number of Subjects	Source
16.2 ± 1.2%	9.7 ± 0.3%	16 wk.	8	Tamborlane et al., 1981
11.2 ± 0.5%	9.8 ± 0.5%	9 mo.	12	Falko et al., 1982
13.5 ± 1.0%†	10.0 ± 0.7%	10 wk.	10	Home et al., 1982
14.6 ± 0.9%	9.9 ± 0.2%	20 mo.	17	Tamborlane et al., 1982
11.2‡	7.8‡	1½ yr.	8	Hamet et al., 1982

*Mean ± S.E.M.
†Represents a 10 week trial on optimized conventional therapy prior to CSII.
‡Approximations: exact values and deviation not available.

Reliability or reproducability of nutrient intake data is used by many researchers to support the validity of a method. However, reliability is also difficult to interpret. As Block (1982) points out, it is difficult to determine whether what is being measured is unchanged, whether differences in results are due to a reliable and valid methodology which show actual changes, or whether differences are due to an unreliable, invalid method that shows "false" differences.

Since validation and reliability of dietary methods is so difficult to determine, the "relative validity" of a method is commonly reported. Relative validity compares different methods with the assumption that one method is valid. Researchers can then make a statement on the usefulness of the methods.

It must be kept in mind that researchers have found that some methods provide good estimates of mean intake for a group, but not for individuals. For this discussion, the primary focus is on research results of studies for group mean intakes.

Diet Records

Diet records have been compared with other methods of determining food intakes among groups in order to determine the relative validity and reliability.

Gersovitz, Madden, and Smiciklas-Wright (1978) compared seven-day records and 24-hour dietary recalls in an elderly population. The 24-hour recalls were validated by unobtrusive, trained observers who recorded actual amounts eaten. The subjects recorded intake during that same week. Compared to the recall method, the records underestimated dietary intake, but there was no statistically significant difference between recorded and "actual" amounts consumed for eight of ten nutrients. These authors state that regression analysis indicates that "the dietary record is generally valid for group comparisons of nutrient intake during early days of record keeping but that validity declines in later days." They found that 85% of the population returned seven-day records with only two usable days of diet records, 78% returned records with five usable days, and only 60% returned seven usable records days. Usable records for all seven days were typically provided by a group which represented those who were more highly educated. Therefore, the authors caution "against using records of greater than several days duration" since the number of usable records may alter the nature of the sample population thus representing a biased sample group.

Chalmers et al., (1952) found that a one-day diet record characterized a group by its mean intake for all 10 nutrients studied. Children, college students, industrial workers, and pregnant women were studied.

Stuff et al. (1983) did comparison studies on dietary methods with lactating women. Three days including two week days and one weekend day were randomly selected from the original seven-day records to comprize a three-day diet record. They found that the three-day record gave good to strong agreement with the seven-day record (r=0.74 to 0.91) for calories, protein, fat, carbohydrate, calcium, phosphorus and iron. A one-day record showed fair agreement (r=0.42 to 0.63). Variations between individuals was found to be less than the day to day variation of an individual's intake. Stuff et al. (1983), therefore, concluded that a three-day diet record gave a good approximation of qualitative group nutrient intake, but is questionable for true estimates of individuals.

The results of Gertsovits et al. (1978) and Stuff et al. (1983) suggest that a diet record of three days duration is a good approximation of mean nutrient intake of a group.

Dietary Recall

Validity of the 24-hour recall method of dietary intake is more easily assessed than a diet record since direct observation and measurement is possible and the time required is not prohibatively long. Several authors conclude that this method can give fairly accurate and valid group means of nutrient intake.

Beaton et al. (1983) conducted a study using the 24-hour recall on 60 men and women. The recall was taken on six different occasions for each subject over an average of 60 days. They found that the 24-hour recall gave an accurate estimation of mean group intake, but not individual intake, due to high day-to-day intraindividual variability.

Gertsovits et al. (1978) found that weighed values of foods when compared to the recalled values of foods were not significantly different for nine of ten nutrients for elderly persons. These authors concluded that the 24-hour recall is a relatively valid estimate of group mean intake for elderly subjects. Mean recalled protein intake was the only nutrient that differed significantly from mean actual intake.

Gertsovits et al. (1978), Young et al. (1952b), and Adelson (1960) found that the seven-day record and the 24-hour dietary recall methods both gave similar and accurate mean intakes for groups. However, Young et al. (1952b) suggest that the 24-hour recall and seven-day record methods could be used interchangably in dietary studies only if the group population consisted of 50 or more subjects.

Madden, Goodmen and Guthrie (1976) tested the validity of the 24-hour recall by comparing it to weighed duplicate meals for 76 elderly persons. He found a significant relationship between "actual" and recalled intake for all nutrients studied concluding that the recall method is valid for groups. He did note a difference in calories for the two methods but it was not statistically different.

Although the 24-hour recall method of dietary analysis may give reliable group intake values, it has one disadvantage which must be considered in using for dietary studies. Madden et al. (1976) observed and reported that the 24-hour recall results in a "flat-slope syndrome" due to underreporting large food intakes and overreporting small food intakes. When plotted, a one-unit increase in actual intake corresponds to a less than one-unit increased in recalled intake. Therefore, the slope is flatter than the "actual" intake slope. Carter, Sharbaugh and Stapell (1981) and Stunkard and Waxman (1981) reported similar results with studies of children. The flat slope syndrome could lead to a failure to detect differences between groups due to an underestimation of extremes in intake.

Carter et al. (1981) concluded that the 24-hour recall method has limited usefulness. In a comparison of 24-hour recall versus observed intakes of a pediatric population, they found a significant difference between mean actual and recalled intakes of protein and calories. Gertsovits et al. (1978) also found a difference through not statistically significant, in protein intake in a similar study with an elderly population.

Whether the 24-hour recall represents "usual" intake is still debatable. From studies of Gertsovits et al. (1978) and Madden et al. (1976), however, one may conclude that the 24-hour recall method fairly accurately measures mean nutrient intake for groups, but its flat slope syndrome must be taken into consideration. It appears that further validation of this method would contribute to the confidence of its results.

Dietary History

The relative validity of the dietary history has been reported by many researchers. Young et al. (1952a) compared diet history to seven-day records of six groups (n=49 to 164). Although results varied somewhat within the groups, the diet history gave overall higher mean values of the ten nutrients studied, than did the seven-day records.

Diet histories also gave a higher mean value of eight and ten nutrients than the 24-hour recall method for grade school children and pregnant women, respectively, but lower mean values for four of ten nutrients in college students (Young et al., 1952b). Karvetti and Knuts (1981) also found that the diet history overestimated the nutrient intake as compared to 24-hour recalls in an adult Finnish population. Trulson (1954) and Karvetti and Knuts (1981) report that the seven-day record and the seven-day recall, respectively, gave more similar results to the diet history than did the 24-hour recall method or shorter records.

Overall, results from validity studies do not seem to clarify the usefulness of the dietary history method. The validity, in the sense of accurately reporting true intake, is not known.

In conclusion, most methods of determining dietary intake have some degree of validity when measured against one another. Yet, there is no conclusive evidence to use one method over another. A method should be utilized to meet the needs of the intended research questions and population. For this study, a three-day diet record was chosen as the method of choice since it may give a more accurate "true" intake than recall or history methods, and is applicable for group studies. A seven-day record was not considered since these CSII subjects are involved in other studies and the probability of non-compliance or increased numbers of unusable diet records was likely. Finally, the three-day-record was not time-intensive as diet history or diet recall methods would be.

CHAPTER III

METHODOLOGY

Objectives

This study was designed to determine the average dietary intake of a small population of adults with Type I diabetes who use continuous subcutaneous insulin infusion. Additional descriptive data gathered on the subjects further describe this population.

Description of the Subjects

The study population consisted of 22 adult subjects with Type I diabetes mellitus who had used continuous subcutaneous insulin infusion for three-quarters of a year or more. Ages ranged from 25 to 53 years. Participants had various mild diabetic complications such as neuropathy, retinopathy, and nephropathy (Table 2). Persons who were pregnant, lactating, or had severe heart disease or renal failure were not included in the study. All subjects were patients of Dana H. Clarke, M.D., an endocrinologist and diabetologist in Salt Lake City, Utah.

Research Approach

A descriptive research approach has been used in this study. Nutrient intake of the population is described and compared to the 1980 RDA (Food and Nutrition Board, 1980) and to the dietary recommendations for people with diabetes by the American Diabetes Association (1979). Other characterizing factors which further describe the population include duration of diabetes mellitus and CSII therapy, dietary habits, hemoglobin A_1 (HbA_1) values, and weight change since beginning CSII therapy.

Instrumentation

A questionnaire and three-day diet record returned by each participant, served as the major source of data for this study.

Participant Packet

Cover letter. A cover letter briefly describing the purpose of the study, requirements of the participant, and the voluntary nature of the study was included in each participant's packet (Appendix A).

Consent form. The packet included a consent form which was signed by those who chose to participate in the study (Appendix B). It stated that the participant understood the requirements of the study and gave permission for the investigator to review their medical charts in Dr. Clarke's office to obtain information on weights, HbA_1 values, and height. Participants understood that no invasive measures would be used and that all information obtained would remain confidential.

Research questionnaire. Subjects were asked to fill out a short questionnaire and return it in the preaddressed and stamped envelope. The questionnaire took five to ten minutes to complete and was designed to obtain descriptive information such as age, sex, occupation, duration of diabetes, number of years on continuous subcutaneous insulin pump therapy, history of dietary instructions for diabetes and pump use, as well as other dietary and diabetes related information (Appendix C).

Instructions for diet records. Specific written instructions for keeping diet records were included in the participant packet (Appendix D). It discussed different foods and how to best describe and record the foods and quantities eaten. Instructions were also verbally given to each participant.

Portion size guide. To aid in describing amounts of foods, particularly meats, a portion size guide was included in the packet (Appendix E). Sizes and thicknesses of meats and cheese were drawn to help participants more accurately estimate portion sizes.

Food intake record and example. Subjects received an examplary food intake record and an intake record for three days (Appendix F). Subjects were instructed to keep record of all foods and the quantity eaten for three consecutive days, including one weekend day, or non-working day for those who worked on weekends.

Participants were also asked to indicate, in the specified column on the diet record, whether food was eaten for treatment of an insulin reaction and to rate the reaction in terms of severity. Compliance to this request was poor and therefore not utilized for descriptive or statistical purposes in this study.

Procedures

Approval for study was obtained from Dana H. Clarke, M.D. for access to patients attending his Diabetes Health Care Clinic, and for access to medical records upon consent of the participants. No invasive procedures were necessary in this study. Subjects were asked to sign a consent form to allow the investigator to review their medical chart for a history of weights and existing HbA_1 values, a routine procedure.

Subjects were first informed of the study in a newsletter sent to all patients of Dr. Clarke's who used continuous subcutaneous insulin infusion pumps (Appendix G). The newsletter announced the time and date of a "pump meeting" which is typically held several times per year. The letter introduced this dietary study, its purpose, and the role of the participants recruited at the pump meeting.

The patients who resided in the Salt Lake City area were contacted by telephone two days prior to the date of the pump meeting to be reminded of the time and place of the meeting and to briefly reiterate the importance of the dietary study. Forty-three patients were contacted; three were not reached. Eight people had disconnected telephones and therefore were not contacted.

Recruiting Participants

Pump meeting. Approximately 35 individuals attended the meeting, of which about one-half were "significant others" to those who used CSII. From this group 13 people became participants in the study. Those people attending the pump meeting participated in an exercise conducted by this researcher in food quantitation and carbohydrate estimation (Appendix H). The objective of the exercise was twofold. First, it was a review in quantitation of food portions of 25 different foods presented as plastic food models or actual foods, for the purpose of becoming familiar with estimating portion sizes. This was intended to help in recording food intake for the study. Secondly, per Dr. Clarke's request, the exercise reviewed the estimation of the carbohydrate content of foods, which is thought to be critical for accurately giving a pre-meal insulin bolus required with the use of CSII. This exercise took a total of 30 minutes, half of which was a review and discussion of the portion sizes and carbohydrate content of all foods presented.

After the food demonstration, all patients present received a packet for participation in the study. The packet included: 1) a cover letter; 2) a consent form; 3) a questionnaire; 4) instructions for recording dietary intake; 5) a portion size guide; 6) an example diet record; 7) diet record sheets and 8) a pre-addressed stamped envelope to the researcher. The questionnaire and diet record sheets were printed on colored paper. All present were told that participation in the study was voluntary and that they were free to withdraw from the study at any time. They were informed about the purpose, significance, and their role in the study. An example of the computerized dietary analysis was available for their review. As stated in the newsletter and cover letter participants were told they would receive an individualized analysis of their diet as compared to the 1980 Recommended Dietary Allowances for their sex and age.

Instructions for recording food intake were given. Honesty in recording typical, actual and accurate intake was stressed. Patients were informed that diets would not be judged as "good" or "bad", so as to promote an accurate description of food intake. The verbal instructions for keeping diet records were identical to the printed material in the packet but was presented in a slightly condensed and rearranged format.

The group was asked to keep diet records for three consecutive days which was to include one weekend or non-working day. The questionnaire and diet records were discussed briefly. Consent form, questionnaires and diet records were to be returned in the preaddressed stamped envelope.

Telephone contacts. Nine people, contacted by telephone, stated they would not be able to attend the meeting, but were interested in participating in the study. Within one week of the initial contact, they were called again. At that time they were told of the purpose and significance of the study, and their role. They received identical information and instructions as the group who attended the "pump meeting." Telephone participants, however, did not have the food quantitation exercise that those at the group meeting had. It is unknown whether this had any affect on the accuracy of recording food intake. Contents of the packet were discussed over the phone. The packets were then mailed to those participants.

Recruit follow-up. One-third of the people who agreed to participate in the study returned the necessary information within three months. Follow-up telephone calls or letters, sent on five separate occasions, were made to encourage the remaining consenting participants to complete and return the required forms. Twenty-two participants responded by mid-December. Dates of the completed diet records ranged from July to December of 1983.

Final Letter and Individual Nutrient Intake Analysis

Each subject received a concluding letter about the study as well as an analysis of their diet reported as average intake for the three-day diet record (Appendix I). Fifteen major nutrients were listed, and these were compared to the 1980 Recommended Dietary Allowances based on the individuals sex and age. Those nutrients below 75% of the RDA standards were highlighted in yellow; it was suggested that the individual increase consumption of those foods which were a good source of the nutrients in question.

Hemoglobin A_1

Medical charts were reviewed for available hemoglobin A_1 values. A retrospective design, to further characterize the population by long-term glucose control, was used because HbA_1 values were recorded in the charts at irregular intervals dependent up the regularity of patient visits. Therefore, a single HbA_1 value dated three months prior to or following the date of the individual's diet record was arbitrarily used. When the dates of the recorded HbA_1 measurements did not meet this criteria, the subject was excluded from the description.

The assay technique used by this hematology laboratory was Bio-Rad Hemoglobin A_1 by Column Test (resin column) from Bio-Rad, Richmond, California 94804. Standards for HbA_1 used by this lab and subsequently by the physician were: adequate control (normal), 4.4-8.2%; fair control, 8.3-9.2%; less than optimal, 9.2% or greater.

Age and Duration of Diabetes and CSII Therapy

Birth date, year of diagnosis, and month and year of initiation of CSII therapy were recorded by the participants. Age was defined as age at last birthday. Duration of diabetes was defined as the number of years from the year of diagnosis through December of 1983. Similarly, duration of CSII use was defined as years plus fraction of a year from the date of initiating pump therapy through December of 1983.

Weight

The subject's weight was measured and recorded by the Diabetes Health Care clinic staff members using a platform beam balance scale. Subjects were normally weighed with indoor clothes and streetshoes on. Existing records of weight from the subjects' medical charts were used for this study. Pre-pump weight was defined as the recorded weight at the time of hospital admission for initiation of CSII therapy. If this data was unavailable,the most recent weight within two months prior to initiation of CSII was used. In one case, an individual had no pre-pump weight recorded; however, weight was very consistent during the preceding one and one-half years. Therefore, that weight was assumed to be the pre-pump weight for purposes of this study.

All subsequent recorded weights up to January of 1984 were used for this study. The frequency of patient visits after initiation of CSII therapy determined the availability of follow-up weight measurements. Participants who had no weight measurements recorded after initiation of CSII were excluded from this portion of the study.

Pre-Meal Insulin Bolus

When analyzing questionnaire data concerning the pre-meal insulin bolus, subjects often gave ranges of values for numerically answered questions such as the number of minutes before a meal or the ratio of grams of carbohydrate to units of insulin. When ranges were given, the midpoint of the range was used for further calculations and analysis.

Data Processing and Analysis

All data was coded and entered into the Utah State University VAX computer. Various computer programs were used to analyze the data.

Dietary Analysis

Foods from the three-day diet records were coded and household measures were converted to weight in grams for computer analysis. Foods were coded from a recently updated data base, called NUTREDFO. The Nutrition Education Information System (NUTREDFO) database contains nutrient data of 446 commonly consumed foods in their most basic edible form. This data base was developed by Utah State University (U.S.U.) in conjunction with the Nutrition Guidance and Education Research Division of the Human Nutrition Information Service, United States Department of Agriculture (USDA).

NUTREDFO has several features which make it unique. First, the nutrient composition data of the foods are the most up-to-date values available at this time, thus making the nutrient analysis more accurate than other databases. The primary source of the nutrient data was the revised USDA Agriculture Handbook No. 8. In some cases recently published values of nutrients were used, such as the zinc and folacin data which was recently reported in the Journal of the American Dietetic Association. In cases where data were not available, values were taken from USDA provisional tables, the National Food Consumption Survey (1976-1977) data tape or were imputed. Nutrient values were also imputed for yield and cooking losses based on retention factors determined by the USDA.

There are no zero values in NUTREDFO. This makes the database unique in providing more complete nutrient information and analysis. Finally NUTREDFO contains three data files. A permanent file holds the profiles of 26 nutrients for 446 basic foods. A temporary file allows the user to enter any food and its nutrient profile into the database to be used in dietary analyses. This provides a unique versatility to the database. The third file, a documentation file, describes the sources of all nutrient values in the permanent database. This can be valuable for updating the database over time with the user being able to access the dates and sources of the data for further analysis.

As with any other nutrient database, limitations are inherent. The limited number of foods of the database and the necessity of assuming that a food is equivalent to another food or combination of the basic foods result in some inaccuracies in the dietary analysis. Availability and accuracy of information for some nutrients is limited by the analytical methods available, which are not yet adequately developed.

Added sugar values represent the amount of carbohydrate in a food which has been added during processing. Most values were imputed except ready-to-eat cereals which have been analytically determined.

Pre-niacin values refer to preformed niacin in foods. Tryptophan, which is converted to niacin, and is considered in the establishment of the RDA for niacin, is not accounted for in this database.

Food codes and gram weights of foods were entered into an interactive nutrient analysis softwear program, designed to be used with the NUTREDFO database. The program analyzed the three-day intakes of each person for 26 nutrients:

Calories	Phosphorus
Protein	Zinc
Fat	Potassium
Total saturated fat	Sodium
Total monounsaturated fat	Vitamin A
Total polyunsaturated fat	Thiamin
Cholesterol	Riboflavin
Carbohydrate	Pre-niacin
Added sugar	Vitamin B_6
Alcohol	Vitamin B_{12}
Calcium	Vitamin C
Iron	Folacin
Magnesium	Pantothenic acid

For each individual the computerized analysis calculated 1) the mean intake for each nutrient over three days, 2) percentage of calories from carbohydrate, protein and fat based on mean intake, and 3) mean nutrient intake per 1000 kcals. It also determined, from mean intakes the percentage of 1980 RDA standards consumed based on sex and age (Appendix J). Actual nutrient intake was defined as the mean nutrient intake from the three-day food records.

Twenty of the twenty-two participants were in the age category of 23-50 years for the 1980 RDAs. However, two males, age 52 and 53, were also included within these standards in this study since the total population was small and males only comprised one-third of the population. For statistical purposes, this allowed a larger male population. The 1980 RDAs for men over 51 years of age are identical to those for men age 21-50 years except for three nutrients with lower standards: thiamin, niacin and riboflavin.

Statistical Analysis

Coded data from the questionnaire and from medical chart information were entered on-line into the U.S.U. VAX computer. Mean nutrient intake data of each subject was transferred to a separate data file for further statistical analysis.

The SPSS-9 (Statistical Package for the Social Sciences) was used for statistical analysis. Descriptive data from the questionnaire was analyzed. Mean nutrient intakes for mean and women were statistically computed.

A repeated measures analysis of variance test (MANOVA) was performed to test for differences in carbohydrate intake between the sexes and main effect of carbohydrate intake by day (day-to-day variation in carbohydrate intake).

CHAPTER IV

RESULTS

The purpose of this study was to describe a sample population of CSII users available for study and to compare the nutrient intake of this group to the 1980 Recommended Dietary Allowances (Food and Nutrition Board, 1980) and to the dietary recommendations for individuals with diabetes mellitus made by the American Diabetes Association (1979).

Subjects

The study population consisted of 22 subjects; 7 males and 15 females. All were residents of northern Utah except one, who resided in Wyoming. Subjects ranged in age from 25 to 53 years (Tables 2 and 3).

Demographic Data

From the questionnaire, martial status, education level and occupation were determined for this population. Fifteen were married, seven not married. Twelve subjects had college degrees and five subjects had high school degrees, while five had some other certification or degree.

Occupations of the subjects varied. Three were homemakers while three were students. The remaining subjects held skilled (n=9) or professional (n=7) jobs (Table 3).

Table 2. Characterizing factors of persons with diabetes who use CSII.

ID #	Years: Age	Dur.* D.M.	Dur.* CSII	HbA_1 (%)	Presence of Diabetic Complications**: Neuropathy	Retinopathy	Nephropathy
1	34	27	2½	6.0	X	X	X
2	38	18	2-1/3	8.8	X	X	
3	28	4	1	8.0			
4	25	15	1½	7.2	X	X	
5	29	21	1	8.7		X	
6	42	21	3/4	9.2	X	X	
7	32	8	2-1/3	-			
8	53	21	1½	-	X	X	X
9	29	16	2½	8.8	X	X	
10	31	4	1½	7.8			
11	37	27	2-3/4	7.2			
12	32	12	1½	9.1			
13	30	17	1	-			
14	27	13	2	7.1			
15	32	9	2¼	-			
16	30	14	2	12.3	X	X	X
17	36	17	1-1/3	-	X	X	X
18	39	17	3/4	-	X	X	
19	41	15	2	9.9	X		
20	47	15	1	10.2	X	X	
21	35	18	1-3/4	-	X	X	X
22	52	27	1-3/4	9.5	X	X	X
Mean	35.6	17.0	1.6				
S.D.	7.8	7.2	0.8				
Range	24.9-53.8	4.0-32.0	0.5-3.58				

*Duration of diabetes mellitus and CSII use through December 1983.

**Degree of complications not available.

Table 3. Demographic data of persons with diabetes who use CSII.

Category	n	Percentage
Sex		
Male	7	31.8
Female	15	68.2
Marital Status		
Married	15	68.2
Single	7	31.8
Ed. Level		
H.S. degree	5	22.7
College degree	12	54.5
Other degree or certification	5	22.7
Occupation		
College student	3	13.6
Skilled or professional*	16	72.7
Homemaker	3	13.6

*Skilled, n=9; Professional, n=7

Characterization of the Subjects as a Diabetic Population

This population of people with Type I diabetes mellitus who use continuous insulin infusion pumps can be characterized by several factors including duration of diabetes, duration of insulin therapy with CSII, hemoglobin A_1 (HbA_1) values and the participants' subjective ratings of their diabetic control. Results of the questionnaire concerning dietary habits and instructions further characterize this study group.

Duration of Diabetes and Insulin Therapy with CSII

The mean duration of Type I diabetes in this population was 17.0 ± 7.2 years. The continuous subcutaneous insulin infusion pump was used an average of 1.6 ± 0.8 years (Table 2).

Hemoglobin A_1

Existing hemoglobin A_1 values were obtained from medical charts. In order to be used for descriptive purposes in this study, the HbA_1 values had to be dated either three months prior to or three months from the date of the individual dietary records in order to be used. Fifteen of the 22 subjects met this crtieria. Table 2 and Figure 1 represent HbA_1 values for those individuals with available data.

Subject Self-Rating of Diabetes Control

All subjects rated their diabetic control on a scale of one to four (1=Excellent, 2=Good, 3=Fair, 4=Poor). One-half of the subjects

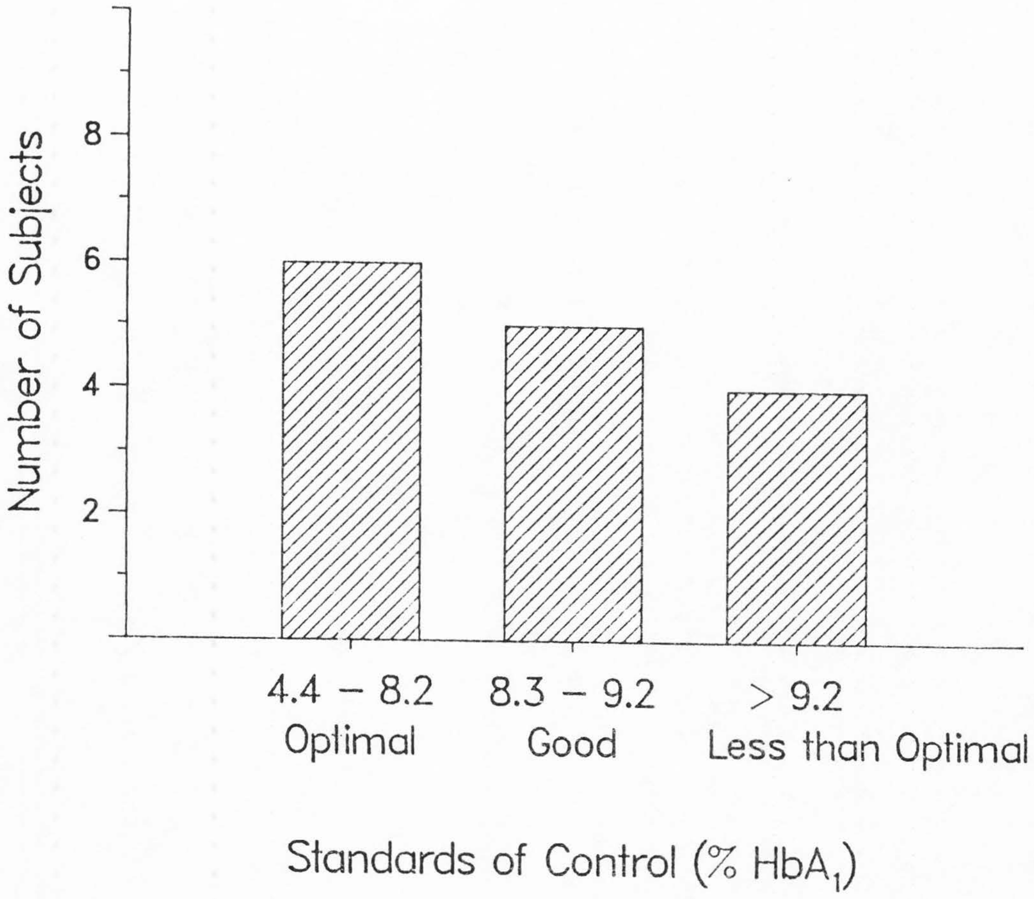


Figure 1. Distribution of HbA_1 values for men and women with CSII based on standards used by subjects' physician and hospital.

rated their control as "Good". Approximately one-quarter said they had fair control. Eighteen percent stated they had excellent control and nearly five percent rated their control as poor (Figure 2).

Dietary Instructions Received

Subjects responded to questions concerning who, if anyone, instructed them about their diet at the time of diagnosis for diabetes and at the time they began using a continuous subcutaneous insulin infusion pump (Table 4).

At the time of diagnosis, three subjects (13.6%) reported that they received no dietary instructions. Seven subjects (31.8%) received instructions from more than one person of which one was a registered dietitian. A total of 14 subjects (63.6%) received instructions from a dietitian, whether as the single person or one of two or more persons who gave the instructions. Four (18.1%) received instructions from nurse or physician.

Ten subjects (45.4%) reported receiving dietary instructions from more than one person at the time of initiation of CSII. Of these ten subjects, all had a physician as one of their instructors while nine had a registered dietitian as one of their instructors. For six subjects (27.2%), a physician, registered dietitian, and nurse all gave dietary instructions. Seven subjects (31.8%) received dietary instructions from a registered dietitian alone. Six subjects (27.2%) received no instructions from a dietitian. One subject (4.55) reported receiving no instructions concerning diet at the time CSII was initiated.

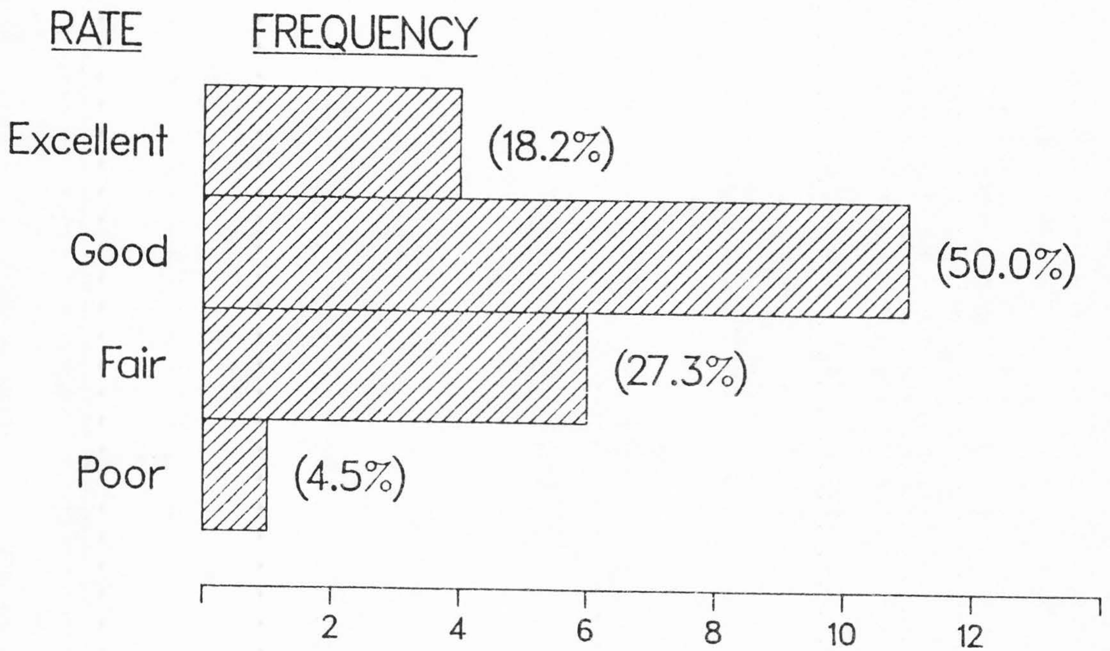


Figure 2. Self-rating of diabetes control by men and women who use CSII.

Table 4. Source of dietary instructions received by subjects at time of diagnosis for diabetes mellitus and at initiation of CSII.

	At time of diagnosis	At time of CSII initiation
No instructions received	3	1
Medical professional*	4	3
Registered dietitian (R.D.)	7	7
Other	1	1
More than one	7**	10***

*Physician or nurse

**Included R.D. in all cases

***Included R.D. in nine cases

Characterization of the Population by Eating Patterns

Subject response to questions pertaining to current dietary practices help to further characterize this population who use continuous subcutaneous insulin infusion pumps.

Use of a Diet Plan

Diet plans typically outline amounts of foods to be eaten at a meal from each food grouping. Fifty-five percent reported that they followed a diet plan, while using CSII. Forty-five percent reported they did not follow any type of diet plan (Table 5). The mean nutrient intakes of the subgroup which did not follow a diet plan were compared with the nutrient intake of the entire sample population.

Snack Incuded in Diet Plan

Table 5 represents some of the dietary habits of this group. Thirty-two percent of the sample population reported that snacks were incorporated into their daily diet plan. The remaining sixty-eight percent either did not have a snack in their diet plan or did not follow a diet plan. However, half of the ten subjects who did not follow a diet plan ate snacks regularly. Several subjects voluntarily stated that they ate snacks between meals when blood sugar levels were low.

Food Exchange Systems Used

Most people with diabetes follow some system of determining carbohydrate, fat, protein, and caloric content of their foods,

Table 5. Eating patterns of men and women who use CSII.

	Yes		No	
	n	Percentage	n	Percentage
Follows a diet plan	12	54.5	10	45.5
Snack(s) included in diet plan*	4	18.2	8	36.4
If not following a diet plan, snacks(s) regularly eaten*	5	22.7	5	22.7

*If subject wrote in "sometimes" it was categorized as "no".

especially if following a diet plan. In response to the questionnaire, seventy-three percent reported they followed the American Diabetic Association's system of Exchange Lists for Meal Planning (1976). Eighteen percent followed a simplified system called Food and You devised by Prater, Denton and Oakeson (1982). Nine percent did not follow a food system (Table 6).

Carbohydrate Exchange Systems Used

Sixty-four percent of the sample population utilized the Exchange Lists for Meal Planning (American Diabetes Association, 1976) for determining the carbohydrate content of their meals while using the insulin infusion pump. Fourteen percent used the Food and You food lists (Prater, Denton, and Oakeson, 1982). Twenty-three percent used some other method to determine carbohydrate content of foods such as the Barbara Krause Guide to Carbohydrates (Kraus, 1983) or Values of Portions Commonly Used (Pennington and Church, 1984). Some reported they used no system at all (Table 6).

Use of Dietetic Foods, Sugar Substitutes and Vitamin or Mineral Supplements

From the questionnaire, other dietary patterns were determined (Table 7). Sixty-eight percent of the population reported that they used dietetic foods. Foods listed by subjects included sugar-free soft-drinks, low-sugar jams, diet syrup, low calorie margarine, mayonnaise and salad dressing, and canned fruit in light syrup or packed in its own juices. Diet records reflected occasional use of these products as well. Diet soft-drinks were used most frequently.

Table 6. System used by persons who use CSII for following diabetic diet and for determining the carbohydrate content of meals.

	For Diabetic Diet		For Carbohydrate Content	
	n	Percentage	n	Percentage
American Diabetes Association Exchange Lists†	16	72.7	14	63.6
Food and You Choice Lists	4	18.2	3	13.6
Other*	0	0	5	22.7
None	2	9.1	0	0

*Pennington and Church (1984) and Barbara Kraus (1983).
†Used by subjects physician and hospital dietitian

Table 7. Use of dietetic foods, sugar substitutes, vitamin and mineral supplements and alcohol by persons who use CSII.

	Yes		No	
	n	Percentage	n	Percentage
Use dietetic foods	15	68.2	7	31.8
Use sugar substitutes	19	86.4	3	13.6
Use vitamin/mineral supplements*	13	59.1	9	40.9
Use alcohol	8	36.4	14	63.6

*Not included in nutrient analysis.

Eighty-six percent used sugar substitutes regularly, as determined from the questionnaire. Fifty-nine percent reported that they regularly took vitamin or mineral supplements. Write-in answers on the types taken commonly included multi-vitamins (n=9), vitamin C (n=4), vitamin E (n=3) and vitamin B complex (n=3). Some subjects took combinations of these supplements. Nutrient supplements were not accounted for in the nutrient analysis.

Use of Alcohol

Thirty-six percent reported they used alcohol (Table 7). This accounted for 0.63% and 1.93% of total caloric intake for men and women, respectively (Table 13).

Changes in Eating Patterns Since Initiation of CSII

Seventy-seven percent of this population reported that they ate differently after beginning continuous subcutaneous insulin infusion therapy (Figure 3). The three most frequently checked responses from a choice of six included: different amounts of foods ingested, different times of meals and a change in the amount of simple sugars in the diet. Several subjects voluntarily added their own comments, stating that they found that their meal times were more flexible, could be delayed, or skipped. Subjects often chose more than one answer.

Sixty-four percent reported that their diet pattern changed since beginning CSII. Specific changes were not identified.

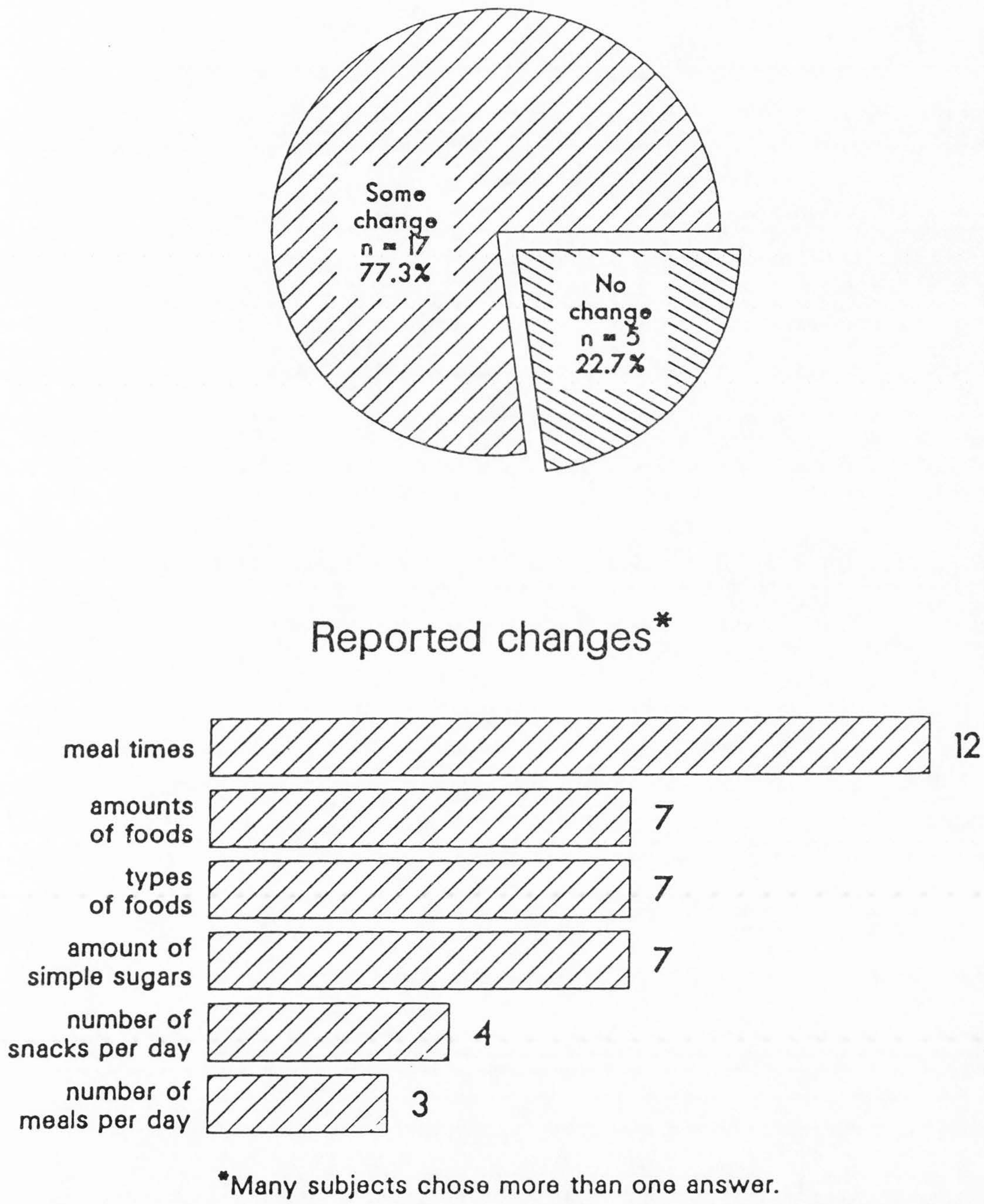


Figure 3. Changes in eating patterns since initiation of CSII.

Characterization of the Subjects by Changes in Insulin Reactions, Weight Changes and Insulin Bolus

Finally, this population can be described by the changes the subjects have observed in themselves since beginning on continuous subcutaneous insulin infusion and by pre-meal insulin requirements.

Insulin Reactions

In response to the questionnaire, participants answered questions pertaining to insulin reactions (Table 8). Seventy-three percent reported that they had an increase in the number of reactions with continuous subcutaneous insulin infusion therapy as compared to the insulin therapy they received prior to CSII. Only nine percent reported that there was no change in the number of reactions.

Fifty percent reported an increase in the "severity" of reactions with CSII as compared to insulin therapy prior to CSII. Approximately one-fourth of the population reported a decrease in severity of reactions; one-fourth reported no change in severity (Table 8).

Weight Changes

All weights available in the subjects' medical records from the time of initiation of CSII through January 1984 were collected (Table 9 and Figure 4). Because this was a retrospective study, it was not possible to get a consistent history or regularity of weight records on all subjects due to infrequent visits to their physician. However, it can be useful to look at trends in weight since initiation of CSII. The average weight gain was 5.5 pounds, irrespective of the length of time on the pump. The changes in weight ranged from a loss of 13

Table 8. Changes in frequency and severity of insulin reactions since changing to continuous subcutaneous insulin infusion: subjective answers to questionnaire.

	Number of Reactions		Severity of Reaction	
	n	Percentage	n	Percentage
Increase	16	72.7	11	50.0
Decrease	4	18.2	6	27.3
No change	2	9.1	5	22.7

Table 9. Weights and net weight changes using pre-pump* and post-pump weights, in pounds for subjects who CSII.

		Post-Pump Weight									
	Pre-	Number of Months Since Beginning CSII									Net Weight
ID #	Pump Wt.*	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	25-27	Change (lbs)
1	129.5	-	115	-	-	129	121	127.5	133.5	136.5**	+7.0
2	130	132	-	133	-	131.5	133	139.5	139.5	145**	+15.0
3	158	154.5	152	150	152**						-6.0
4	124	-	129	134	132	131.5**					+6.5
5	113	117	118	117	116						+3.0
6	152	151	154	156**							+4.0
7	136	138	-	-	-	145+	-	152+	154+		+18.0
8	194	-	187	189	183	185.5					-8.5
9	134.5	138	-	145	143.5	150	154	150	-	154**	+9.5
10	159	154	-	-	-	-	181**				+22.0
11	120	110*	120*	-	-	-	-	-	-	107**	-13.0
12	171	170.5	166	-	171	169					-2.0
13	110										-
14	-										-
15	174	-	179	179							+5.0
16	105	113	112	106	-	106	105	109			+4.0
17	120							121.5	123.5		+3.5
18	110	124									+14.0
19	140	141	140	-	143	142.5	142.5	-	144**		+4.0
20	174	180	187.5	-	188**						+14.0
21	141										-
22	173	172	-	173	178						+5.0

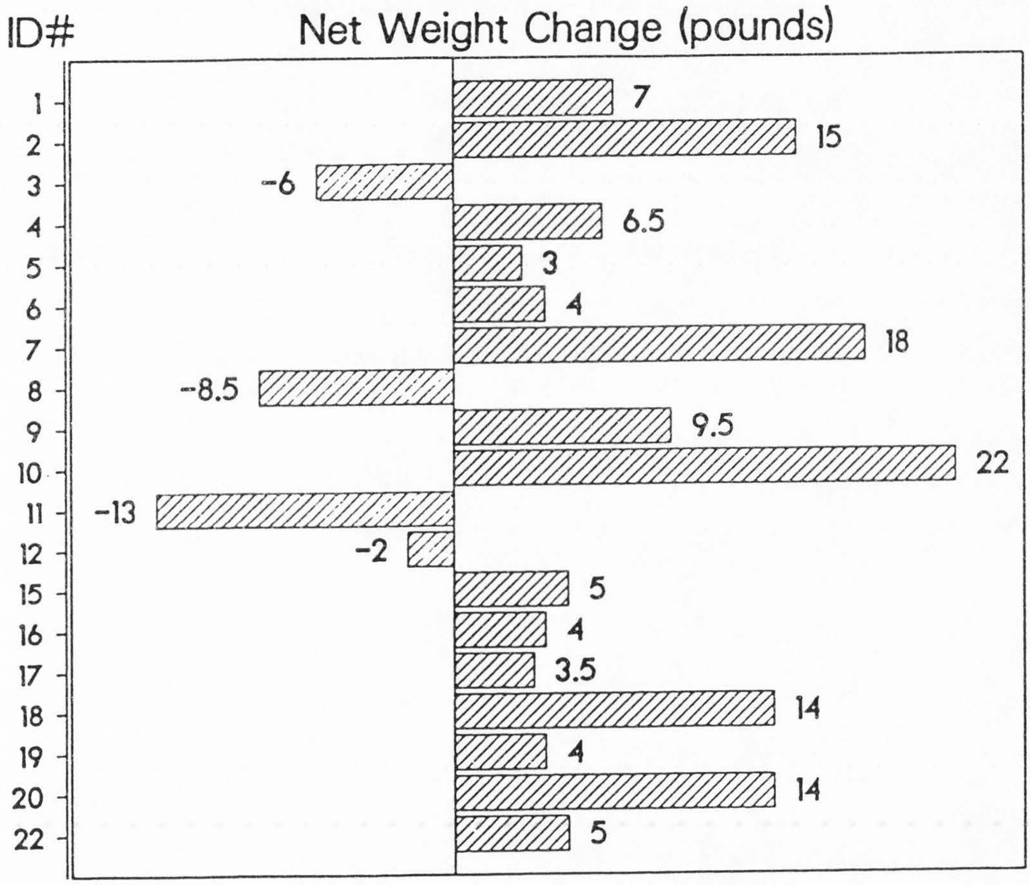
Mean net weight change ± standard deviation: 5.5±8.9 pounds

*Pre-pump weight: 0-2 months prior to initiation of CSII pump.

**Represents current weight, taken between November, 1983 and January 1984.

+Weights stated by subject but not recorded in medical chart; believed to be accurate.

Subjects #13, 14 and 21 had no available recorded weight history.



*Duration of CSII ranged from one-half to 3.5 years.

Figure 4. Retrospective study of individual's weight change, in pounds, irrespective of duration of CSII.

pounds to a gain of twenty-two pounds; more subjects gained weight than lost weight. Weight gain may be attributed to water retention in some subjects, possibly secondary to nephropathy.

Insulin Bolus

Twenty-one subjects responded to the question which asked them to write the length of time before a meal they gave themselves the pre-meal insulin bolus. On the average, this group had a pre-meal bolus time of 16.8 minutes. Times ranged from 3.0 to 32.0 minutes (Table 10). Some subjects gave a range of times, in which case the mid value was used to calculate the group average.

Seventeen subjects gave usable information on the ratio of grams of dietary carbohydrate per one unit of insulin used for the pre-meal insulin bolus. If several ratios were given for a single subjects, usually due to differences for morning, noon and evening meals, the mid-value was used to calculate the group average. The mean ratio was one unit of insulin per 11.4 grams of dietary carbohydrate (11.4:1) (Table 10).

Nutrient Intake Results

Nutrient intakes were reported as the group mean and standard deviation for each sex. The 1980 Recommended Dietary Allowances (RDA) and Estimated Safe and Adequate Daily Dietary Intake Standards (ESADDI) as determined by the Food and Nutrition Board (1980) were used as standards for nutrients and energy (Appendix J and K). Nutrient intakes were also expressed on a unit caloric basis. Standards for nutrient allowances per 1,000 kcals were taken from

Table 10. Timing and size of pre-meal insulin bolus for men and women who use CSII.

	n	Mean + S.D.+	Range
Timing of insulin bolus prior to meal (minutes)	21	16.8 ± 10.3	3.0 - 32.0
Size of pre-meal insulin bolus (gm CHO:1 unit insulin)	17	11.4 ± 2.6	8.0 - 17.0

+Standard deviation.

Hansen and Wyse (1980). The American Dietetic Association (1979) recommendations for percentage of kilocalories from protein, carbohydrate and total fat also served as standards for comparison (Table 14).

Nutrient intake results were calculated from the three-day diet records by a computerized nutrient analysis program. The diet records spanned six months, from July to December of 1983. The distribution of diet records over the months is represented here.

Month:	July	Aug.	Sept.	Oct.	Nov.	Dec.
No. of diet records	8	2	3	4	3	2

It was not known whether the effect of the seasons and avilability of fresh foods in the different months affected nutrient intake results. If anything, it may help represent a more realistic mean nutrient intake by including a half-year span of time.

Average intakes of nutrients, energy, cholesterol, added sugar and alcohol are shown in Tables 11 and 12 for men and women, respectively. Intakes of eleven nutrients, for males as a group, were greater than 100% of the RDAs. Intakes of B_6 and magnesium were greater than 90% of the RDAs. Average zinc and folate intakes for men were each near 82% of the RDAs.

Women consumed greater than 100% of the RDAs for eight nutrients: protein, calcium, phosphorus, vitamin A, thiamin, riboflavin, niacin, vitamin B_{12}, and ascorbic acid. Five nutrients were consumed in amounts less than the RDA: iron 59%, magnesium 88%, zinc 64%, vitamin B_6 69% and folate 58%.

Table 11. Dietary intake as mean and percent RDA for men who use CSII.*

Nutrient	Mean**	Range	% RDA
Kcals	2335.7 ± 631.1	1630.0 - 3281.0	86.5***
Protein (gm)	94.7 ± 24.9	63.0 - 134.3	169.1
Fat (gm)	103.9 ± 32.2	71.0 - 159.9	-
Sat (gm)†	35.6 ± 12.1	21.0 - 58.4	-
Poly(gm)†	21.7 ± 8.1	11.9 - 31.2	-
Mono(gm)†	39.4 ± 11.7	28.4 - 60.0	-
Cholesterol (mg)	423.1 ± 201.2	207.0 - 683.0	-
Carbohydrate (gm)	259.2 ± 74.6	155.8 - 349.5	-
Added Sugar (gm)	38.2 ± 45.5	5.1 - 134.3	-
Alcohol (gm)	2.1 ± 3.7	0.0 - 8.6	-
Calcium (mg)	1250.7 ± 546.8	803.0 - 2230.0	156.3
Iron (mg)	16.2 ± 6.6††	10.3 - 29.4	162.0
Magnesium (mg)	347.7 ± 121.1	219.0 - 529.0	99.3
Phosphorus (mg)	1660.6 ± 531.5	1207.0 - 2610.0	207.6
Zinc (mg)	12.4 ± 2.6	8.5 - 16.3	82.7
Potassium (mg)	3583.0 ±1013.5	2401.0 - 5445.0	130.3†††
Sodium (mg)	2867.7 ± 864.0	1711.0 - 4005.0	130.4†††
Vitamin A (I.U.)#	6516.4 ±2473.0	3457.0 - 9814.0	130.3
Thaimin (mg)	2.14± 0.77	1.29- 3.29	152.9
Riboflavin (mg)	2.73± 0.99	1.71- 4.05	273.0%
Pre-niacin (mg)##	25.9 ± 6.3	19.8 - 39.4	143.9
Vitamin B_6 (mg)	2.06± 0.80	1.36- 3.69	93.6
Vitamin B_{12} (mcg)	5.97± 2.50	2.42- 9.96	199.0
Ascorbic Acid (mg)	235.0 ± 132.5	44.0 - 481.0	391.7
Folate (mcg)	329.0 ± 124.7	180.0 - 487.0	82.2
Pantothenic Acid (mg)	6.49± 1.95	4.96- 10.54	118.0†††

*n=7; two men, ages 52 and 53 included in the RDA standards for age 23-50.

**Mean ± standard deviation.

***Midpoint of range for energy used to calculate % of RDA for kcals.

†Sat=saturated fats; Poly=polyunsaturated fats; Mono=monounsaturated fats.

†† =14.1 ± 3.5, 141% of RDA, when one value of 28.4 is omitted.

†††Represents percent of Estimated Safe and Adequate Daily Dietary Intakes midpoint; used

#Database and nutrient analysis program reports vitamin A in I.U.s.

##Represents preformed niacin; excludes niacin equivalents from tryptophan.

Table 12. Dietary intake as mean and percent RDA for women who use CSII.*

Nutrient	Mean**	Range	% RDA
Kcals	1438.6 ± 334.9	964.0 - 1900.0	71.9***
Protein (gm)	61.4 ± 9.5	48.1 - 81.3	127.7
Fat (gm)	64.7 ± 23.0	25.2 - 93.1	-
Sat (gm)†	24.6 ± 9.8	9.2 - 43.4	-
Poly (gm)†	12.1 ± 6.7	2.6 - 21.9	-
Mono (gm)†	22.6 ± 8.9	7.3 - 35.9	-
Cholesterol (mg)	255.2 ± 95.6	97.0 - 440.0	-
Carbohydrate (gm)	151.2 ± 41.3	61.7 - 228.4	-
Added Sugar (gm)	21.0 ± 15.7	3.0 - 57.3	-
Alcohol (gm)	4.0 ± 7.9	0.0 - 28.7	-
Calcium (mg)	848.3 ± 282.92	453.0 - 1276.0	106.0
Iron (mg)	10.5 ± 2.1	6.6 - 14.5	58.5
Magnesium (mg)	263.9 ± 68.0	175.0 - 408.0	88.0
Phosphorus (mg)	1137.9 ± 227.9	708.0 - 1472.0	142.2
Zinc (mg)	9.6 ± 2.9	6.1 - 16.7	64.0
Potassium (mg)	2514.7 ± 533.6	1536.0 - 3645.0	67.0††
Sodium (mg)	1878.9 ± 585.0	1225.0 - 3086.0	85.4
Vitamin A (I.U.)†††	6206.5 ± 4514.7#	1607.0 -19980.0	155.1
Thiamin (mg)	1.13± 0.29	0.58- 1.58	113.0
Riboflavin (mg)	1.82± 0.89	0.92- 4.48	151.6
Pre-niacin (mg)##	16.8 ± 3.6	10.5 - 22.9	129.2
Vitamin B_6 (mg)	1.38± 0.31	0.86- 2.01	69.0
Vitamin B_{12} (mcg)	4.81± 6.61	1.91- 28.33‡	160.0
Ascorbic Acid (mg)	116.0 ± 31.0	75.0 - 166.0	193.0
Folate (mcg)	233.3 ± 57.7	147.0 - 362.0	58.3
Pantothenic Acid (mg)	4.32± 0.81	3.28- 5.61	78.6††

*n=15, RDA standards for women, age 23-50.
**Mean ± standard deviation
***Midpoint of range for energy used to calculate % of RDA for kcals.
†Sat=saturated fats; Poly.=polyunsaturated fats; Mono=monounsaturated fats.
††Represents percent of Estimated Safe and Adequate Daily Dietary Intakes (1980 RDAs); midpoints used.
†††Database and nutrient analysis program reports vitamin A in I.U.s.
#4743.0 ± 1831.0, 118.6% of RDA, when values of 1998.0 and 1145.7 are omitted.
##Represents pre-formed niacin; excludes niacin equivalents from tryptophan.
‡3.13 ± 1.21, 104.3% RDA, when one value of 28.33 is omitted.

It has been suggested that a ratio of 0.02 mg of vitamin B_6 per gram of protein ingested be a basis for calculating the vitamin B_6 allowance (Food and Nutrition Board, 1980). When using this ratio for calculating vitamin B_6 needs in this study population the vitamin B_6 intake is adequate for both men and women (Figure 5).

The nutrients for which the Food and Nutrition Board (1980) has determined the Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) were within the allowed range of intakes for both men and women, but greater than the midpoint values for men.

When nutrient intakes are expressed on a unit caloric basis (nutrient per 1,000 kcal) and compared to standards (Hansen and Wyse, 1980), results are similar to when intake is compared to the RDAs. The diets of men and women did not meet the allowances for iron, zinc, and folate. However, intakes of magnesium and vitamin B_6 for women were adequate by this method of evaluation. Table 13 represents nutrient intake per 1,000 kcals for men and women.

Results of nationwide dietary studies showed similar trends in nutrient intake for the nation (Windham et al., 1981). This study population had consistently greater amounts of the nutrients in their diets, except for vitamin B_{12} for men, when compared to national consumption results (Figures 6-10).

The distribution of kilocalories from protein, carbohydrate, and fats was similar for men and women (Table 14). The contribution of kilocalories from added sugar, defined as sugar added to foods by the subject or sugar added to foods by the food industry (ready-to-eat cereals, pop and canned fruit, for example), was also similar for both

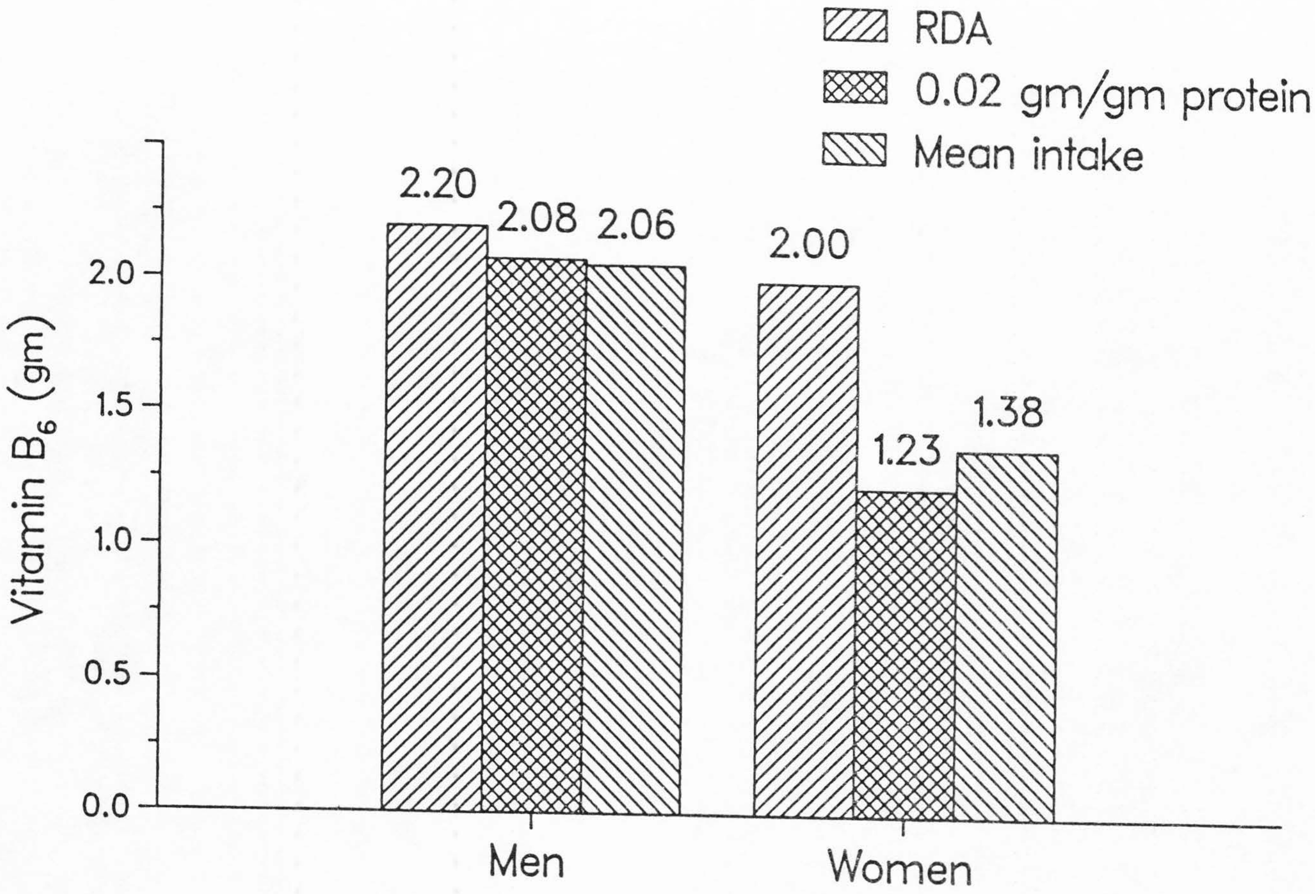


Figure 5. Mean intake of vitamin B_6 as compared to the RDA and to the recommended ratio of vitamin B_6 to protein for the CSII study population.

Table 13. Nutrient intake expressed as nutrient per 1,000 kcals for men and women who use CSII.

Nutrient	Men	Women	Allowance per 1,000 kcal*
Protein (gm)	41.2	44.2	25
Calcium (mg)	522	619	450
Iron (mg)	7.0	7.5	8.0
Magnesium (mg)	147	190	150
Phosphorus (mg)	710	823	450
Zinc (mg)	5.4	6.8	8.0
Potassium (mg)	1553	1820	2500†
Sodium (mg)	1247	1298	1500†
Vitamin A (I.U.)	2973	4763	400 mcg R.E.††
Thiamin (mg)	0.95	0.79	0.5
Riboflavin (mg)	1.19	1.18	0.6
Pre-niacin (mg)	11.4	12.3	7.0 N.E.+
Vitamin B_6 (mg)	0.89	1.02	1.0
Vitamin B_{12} (mcg)	2.59	3.63	1.5
Ascorbic Acid (mg)	106	85	30
Folate (mcg)	141	117	200
Pantothenic Acid(mg)	2.8	3.16	2.0

* From Hansen and Wyse (1980)

† RDA not established

†† Based on international units, the allowance per 1,000 kcal would be 2,000 I.U.

\+ Niacin equivalents include tryptophan; the nutrient analysis for this study only evaluated the pre-formed niacin content of foods.

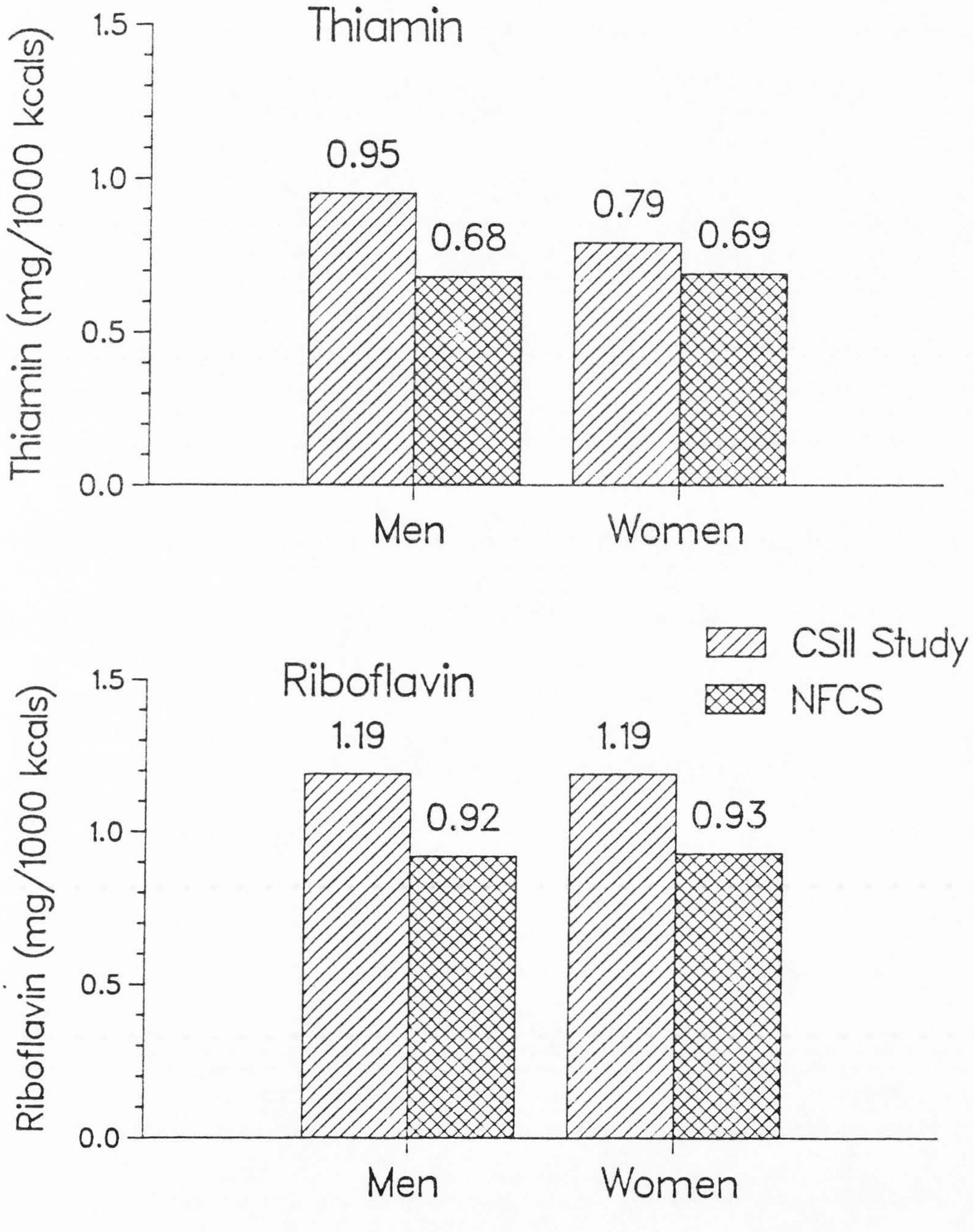


Figure 6. Mean intake of thiamin and riboflavin per 1,000 kilocalories: CSII study and NFCS (1977-78).

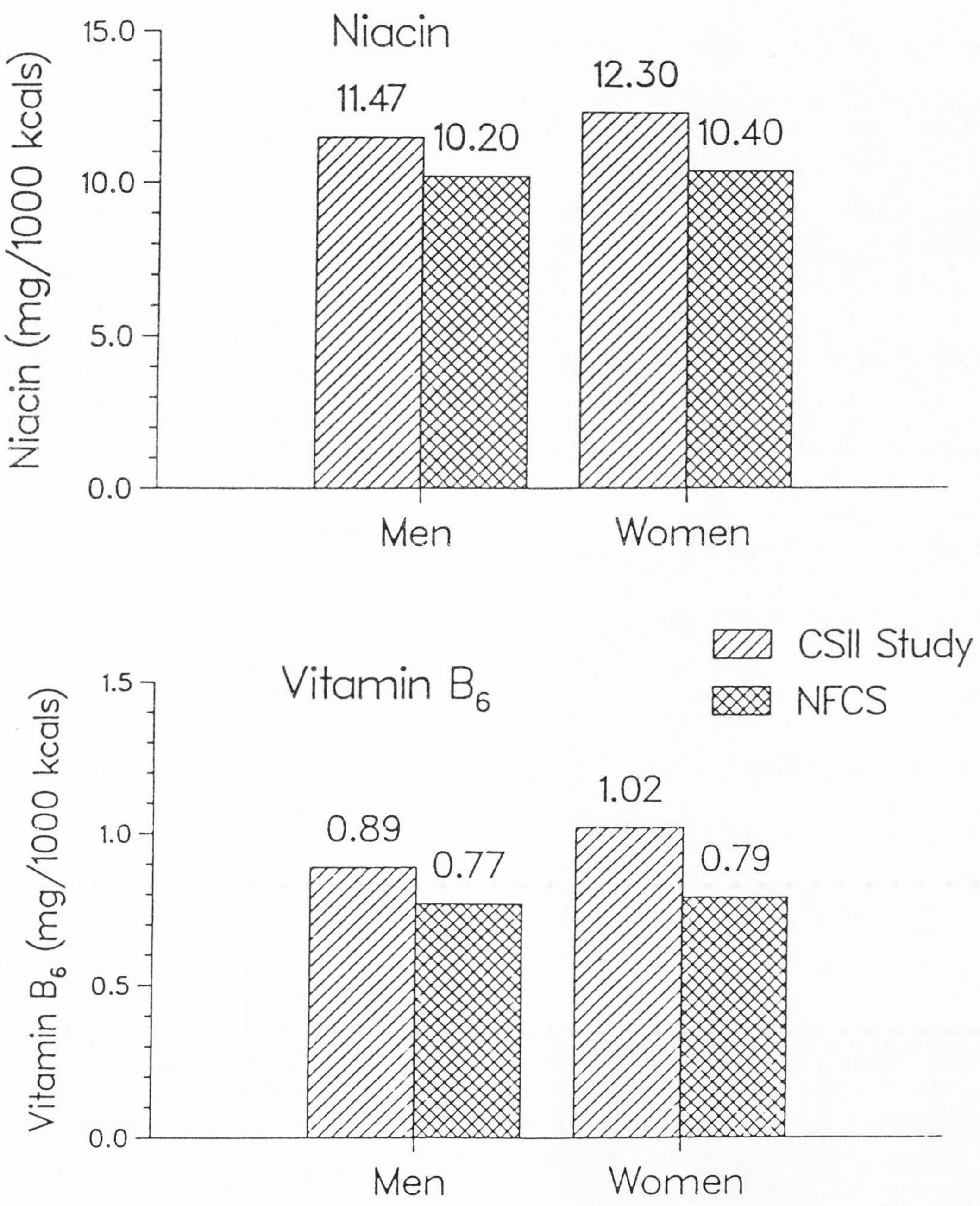
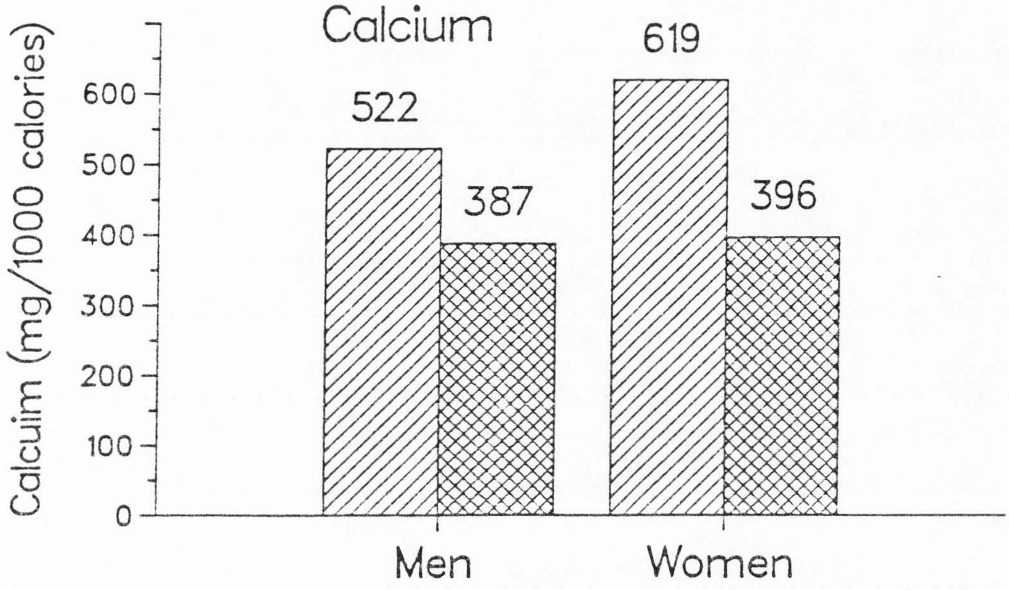


Figure 7. Mean intake of niacin and vitamin B_6 per 1,000 kilocalories: CSII study and NFCS (1977-78).



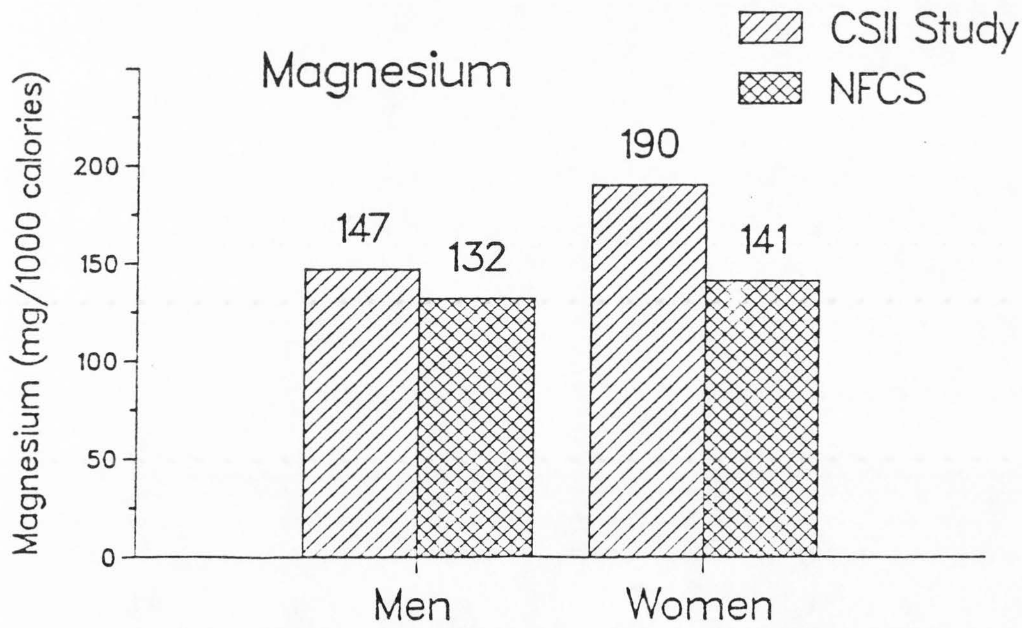


Figure 8. Mean intake of calcium and magnesium per 1,000 kilocalories: CSII study and NFCS (1977-78).

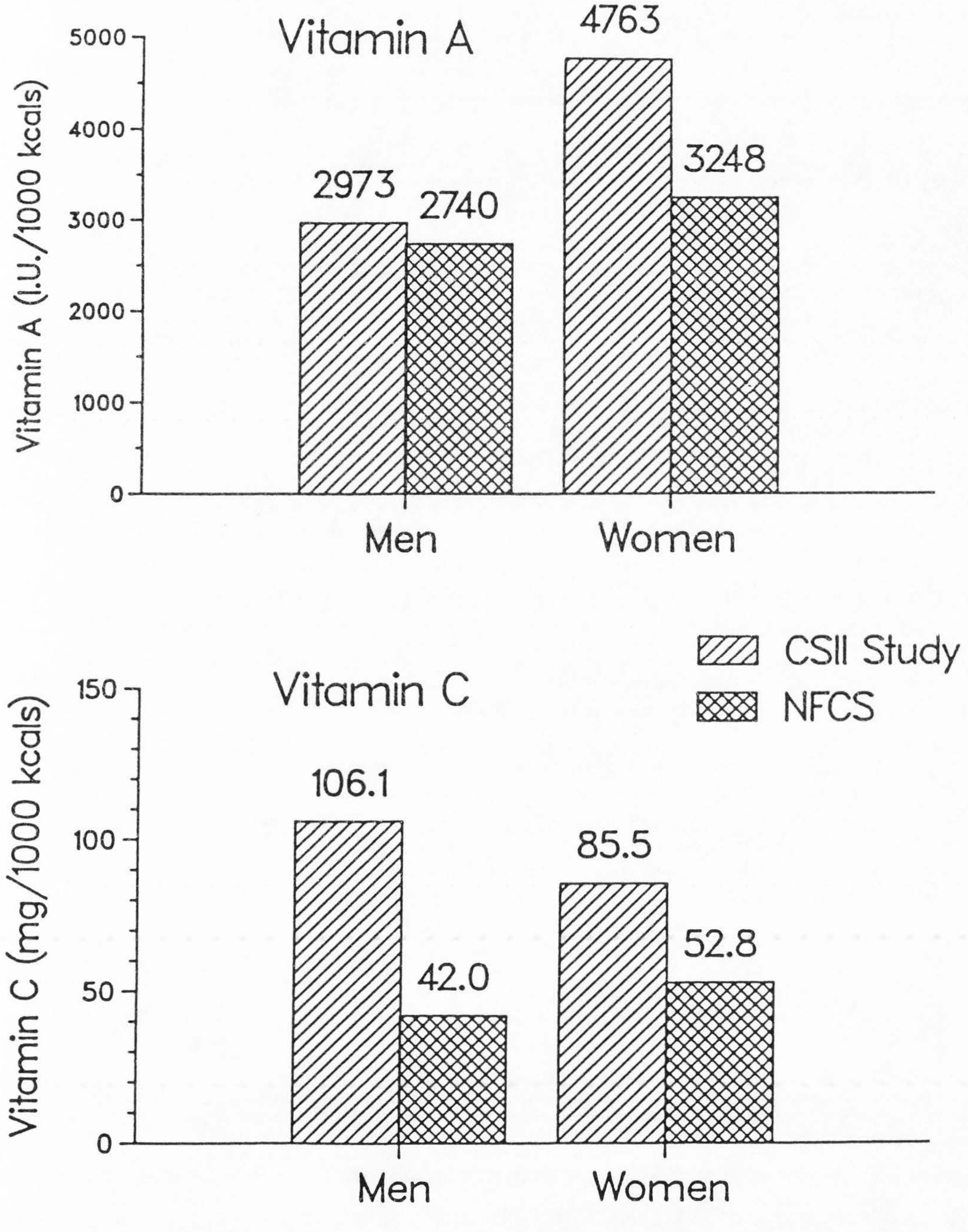
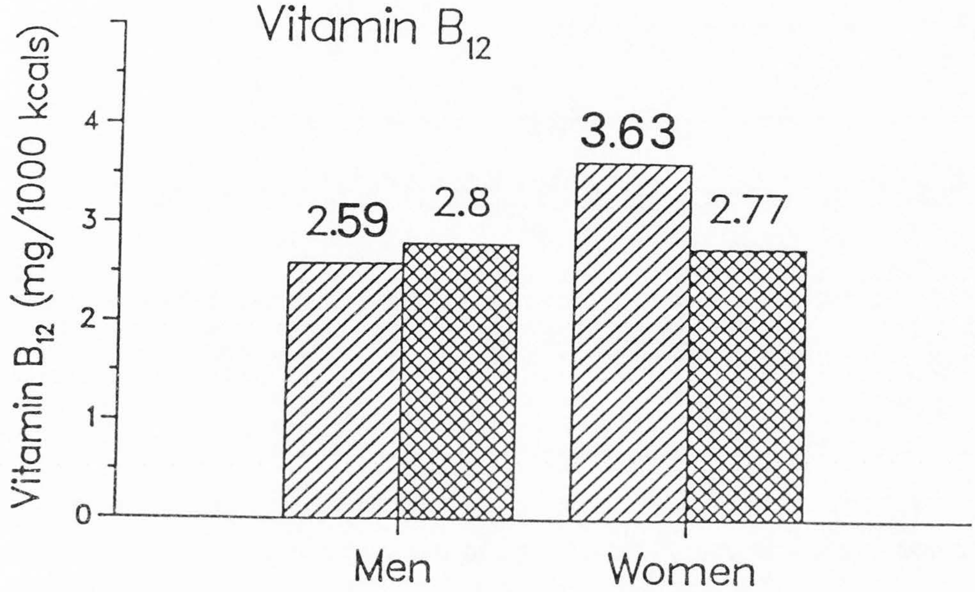


Figure 9. Mean intake of vitamin A and vitamin C per 1,000 kilocalories: CSII study and NFCS (1977-78).



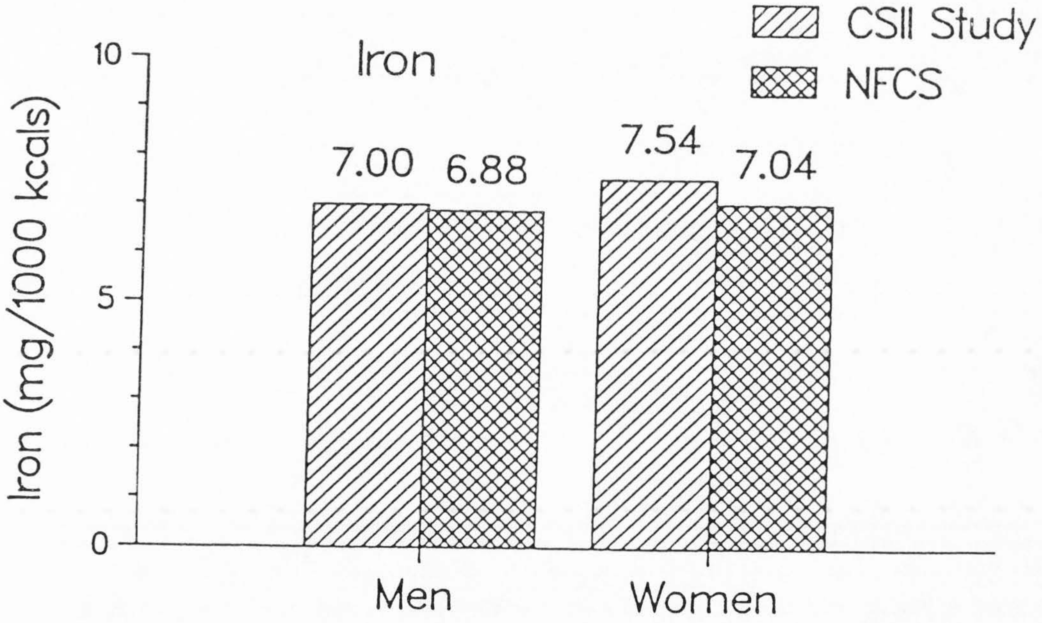


Figure 10. Mean intake of vitamin B_{12} and iron per 1,000 kilocalories: CSII study and NFCS (1977-78).

Table 14. Percentage of total calories supplied by protein, carbohydrate, added sugar, fat and alcohol: men and women who use CSII.

Average percent of total kcals from:	Men*	Women*	ADA** Recommendations
Protein	16.2%	17.0%	12-20%
Carbohydrate(CHO)	44.4%	42.0%	50-60%
Percent of CHO as added sugar	14.8%	13.9%	
Added Sugar	6.55%	5.83%	
Fat	40.0%	40.5%	20-38%
Saturated Fat	13.7%	15.4%	<10%
Polyunsaturated Fat	8.4%	7.6%	≤10%
Alcohol	0.63%	1.93%	

*n = 7 men, n = 15 women
**American Diabetes Association
Totals may not add up to 100% due to averaging; added sugar is included in carbohydrate totals.

sexes. Added sugar represented nearly 15% of the carbohydrate kilocalories for the groups.

Table 15 represents the group mean of carbohydrate intakes for each day of the three-day diet record. Statistical analysis by repeated measures analysis of variance (MANOVA) demonstrates that there was no significant difference between carbohydrate intake on the three days for men or women, implying consistency of day-to-day carbohydrate intake (Table 16). However, there was a significant difference of mean carbohydrate intake for men versus women. The MANOVA test indicates that there was no significant difference of the two-way interaction within days for men and women thus implying that the interval difference of carbohydrate intake between the sexes was not significantly different from day-to-day. This also appears evident by casual observation of the data in Table 14.

Nutrient Intake of Persons Who Follow No Diet Plan

Ten of the 22 subjects reported that they did not follow a diet pattern. This subpopulation could be considered to be following a "liberalized" or "less restricted diabetes diet," which Chantelau et al. (1982) define as a diet which contains very limited quantities of simple sugars with a free choice in the number, timing, and carbohydrate content of meals. When these ten people, two males and eight females, were compared to the entire sample population there were no significant differences between the groups or mean nutrient intakes (Table 17).

Table 15. Group mean carbohydrate intake based on three-day diet record: men and women who use CSII.

Sex	n	Mean* Carbohydrate Intake (gm)		
		Day 1	Day 2	Day 3
Male	7	275.4 ± 89.3	255.2 ± 76.4	247.0 ± 81.6
Female	15	152.5 ± 49.6	154.8 ± 69.3	151.6 ± 50.4

*Mean ± standard deviation.

Table 16. Repeated measures analysis of variance (MANOVA) to test for differences in carbohydrate intake between sexes, day-to-day variation within sex, and effect of day.

Source of Variation	df	MS	F	F (0.05)
Sex	1	161,743.67	18.53*	4.35
Subject				
Subject/sex (error 1)	20	8,727.89		
Day Effect	2	516.04	0.241	3.23
day by sex	2	1024.74	0.479	3.23
day by subject/sex (error 2)	40	2141.12		
Total df	65			

*Significant at $p < 0.05$

Table 17. Nutrient intake of subgroup of men and women using CSII who follow no diet plan as compared to intake of total sample population.

	No diet plan Men and Women (n=10)	CSII Population Men and Women (n=22)
Kcals	1688 ±541.98	1724 ±609.48
Pro	67.64± 20.0	71.81± 22.20
Fat	77.8 ± 27.5	77.13± 31.57
T Sat	26.92± 9.6	28.09± 11.57
Poly	16.5 ± 7.7	15.1 ± 8.3
Mono	28.1 ± 11.6	27.9 ± 8.9
Chol	325.7 ±156.10	308.6 ±155.1
CHO	182.8 ±702	187.3 ± 72.6
+Sug	32.8 ± 37.9	26.4 ± 28.6
ETOH	2.6 ± 3.5	3.3 ± 6.8
Ca	876 ±305	976 ±419
Fe	11.8 ± 3.9	12.35± 4.79
Mg	274 ± 78	290 ± 94

Table 17. (continued)

	No diet plan Men and Women (n=10)	CSII Population Men and Women (n=22)
Phos	1179 ± 305	1304 ± 421
Zn	10.12 ± 2.53	10.46 ± 3.04
K	2718 ± 787	2854 ± 861
Na	2184 ± 801	2193 ± 814
Vit A	6650 ±5490	6305 ±3918
Thia	1.31 ± 0.51	1.44 ± 0.67
Ribo	1.71 ± 0.58	1.97 ± 0.85
Niac	18.4 ± 4.6	19.72 ± 6.23
B_6	1.35 ± 0.38	1.59 ± 0.59
B_{12}	5.49 ± 8.17	5.18 ± 5.58
Vit C	147 ± 66	154 ± 94
Folate	237 ± 68	263 ± 93
P.A.	4.76 ± 1.20	5.00 ± 1.60

No significant differences by T-Test, $p<0.05$

CHAPTER V

DISCUSSION

Purpose of the Study

This study described factors which characterized a small population of persons with insulin-dependent diabetes mellitus who use subcutaneous insulin infusion pumps. Descriptive data included demographic data, nutrient intakes, dietary habits, hemoglobin A_1 values and a retrospective history of weight measurements since beginning CSII therapy. Based on a three-day diet record, this study determined the mean intake of 26 nutrients for men and women. Intake data were compared to the 1980 Recommended Dietary Allowances and the 1979 American Diabetes Association dietary recommendations for diabetics. There has been limited published data on the nutrient intake of persons who use CSII.

Methods and Procedures

Data were collected from 22 participants of the Salt Lake City, Utah area who were patients of an endocrinologist. A questionnaire was used to collect demographic and dietary habit information. Subjects kept a three-day diet record, which included one weekend day. Upon consent, medical records were reviewed for existing data which included HbA_1 values, weight, and diabetic complications of diabetes.

Questionnaire and medical chart data were used to describe the population. Foods were coded and household measurements converted to gram weights. Dietary analyses were completed using NUTREDFO, a computerized nutrient data base and analysis program. Further statistical analyses were done to determine the mean nutrient intake for each sex, and the day-to-day variation in carbohydrate intake.

Major Findings

There was an average weight gain of 5.5 ± 8.9 pounds for 19 subjects with medical records containing a history of weights since beginning continuous subcutaneous insulin infusion. This may represent a significant trend in weight change that occurs with persons with diabetes who choose to use CSII therapy.

Nearly 50% of the subjects (n=10) reported that they did not follow a diet plan. Therefore, this subgroup may be following what has been described as a "liberalized diet." Nutrient intake for this group was not significantly different from the group means.

Nutrient intake for both men and women met or exceeded the Recommended Dietary Allowances (1980) for most nutrients. For men, intake may be inadequate for zinc, vitamin B_6 and folate. These same nutrients were also consumed in amounts below the RDA for women. In addition, the intakes of magnesium and iron was inadequate for women. Nutrient consumption followed the national trends.

The percentage of calories from protein, carbohydrates and fats approached the recommended percentages given by the American Diabetes Association (1979).

There was no significant difference in the day-to-day intake of carbohydrate intake for men or women, indicating consistency in daily consumption of carbohydrate. As might be expected, men consumed significantly more carbohydrates, in grams, than women.

Discussion

Nutrient Intake Compared to Published Standards

Vitamin and mineral intake met the 1980 Recommended Dietary Allowances of most nutrients for men and women. For men, intakes of zinc, vitamin B_6, and folate fell below the 1980 RDAs. Although these nutrients were greater than 80% of the RDA, it may represent inadequate intake, especially for zinc and folate (82.7% and 82.2% RDA, respectively). The RDA (1980) are designed to be guidelines for population groups. Since this group of men consumed these vitamins in amounts below the RDA, it may be concluded that, as a group, intake of these nutrients was inadequate. However, it must be kept in mind that individual needs may vary and that the RDA values are designed to exceed the requirements for most healthy individuals. It is not known whether persons with diabetes have different requirements.

For women, there were inadequate intakes of zinc, vitamin B_6, and folate as well as iron, and magnesium. Of particular concern are the very low intakes of iron (58.5% RDA), zinc (64.0% RDA), vitamin B_6 (69.0% RDA), and folate (58.3% RDA).

A suggested intake of 0.02 mg vitamin B_6 per gram of protein eaten can be a basis for calculating the vitamin B_6 allowance (Food and Nutrition Board, 1980). When following this guideline the men and women of this study consumed vitamin B_6 in adequate amounts (Figure 5). Intake was also adequate on a per 1,000 kcals basis

(Table 13). Windham et al. also (1981) reported that the NFCS data showed that there was adequate intake of adequate vitamin B_6 when requirements were calculated as 0.02 mg per gram of protein consumed.

The Food and Nutrition Board (1980) recognizes that the zinc content of the American adult diet may not meet the recommended amounts and that careful dietary planning is needed to meet the RDA for zinc. Meats are a primary source of dietary zinc. Assuming that meats provided the main source of protein for subjects in this study, it would follow that since the group consumed over 100% of the RDA for protein, then the requirement for zinc should also meet or nearly meet the RDA for zinc. Since this was not the case, zinc, too, may be limited in availability.

Nutrient Intake per 1,000 Kilocalories

When nutrient intakes are compared to nutrient allowances per 1,000 kcals, a similar trend of nutrient intake is seen. When evaluated in this manner, the intakes of men versus women who use CSII in this study are easier to compare. Per 1,000 kcals the women's diets are more nutrient dense than the mens in all major nutrients except thiamin, riboflavin and ascorbic acid (Table 13). This data shows that if women consumed approximately 2000 kcals per day, nutrient needs would be met. Since the average caloric intake was 1438 kcals, the needs were not met. Despite the relatively low caloric intake for women, and men as well, the foods consumed were nutrient dense, thus providing adequate amounts of most nutrients.

Nutrient Intake Compared to National Food Consumption Survey

Studies which review the USDA Nationwide Food Consumption Survey (NFCS) of 1977-1978 show similar inadequate intakes of the nutrients listed as inadequate in this study. From the survey data, Peterkin et al. (1981) found that intakes for men, age 20-50, were 93% of the RDA for vitamin B_6, 88% of the RDA for folate, 179% of the RDA for iron, 97% of the RDA for zinc, and 133% of the RDA for calcium while the average caloric intake was 2700 kcals. These values are very close to the values for this population of people who use CSII and whose average caloric intake was 2335 kcals.

Peterkin et al. (1981) reported that women in the NFCS, age 20-50, consumed the following nutrients, reported as percentage of the RDA: 78% vitamin B_6, 71% folacin, 77% iron, 100% magnesium, 69% zinc, and 103% calcium. With the exception of zinc, these values are all considerably greater than values from this study for women with diabetes who use insulin infusion pumps. Part of this discrepancy may be due to the greater caloric intake of women in the NFCS survey (2000 versus 1438 kcals), thus contributing more essential nutrients with the higher caloric intake.

Windham et al. (1981) compared intake on a nutrient per 1,000 calorie basis. They reported that intakes of iron, magnesium, and vitamin B_6, as well as calcium were inadequate for both men and women in the 1977-78 USDA Nationwide Food Consumption Survey (NFCS). Folacin and zinc were not evaluated. They reported intake in terms of Index of Nutritional Quality (INQ) which is defined as the amount of nutrient per 1,000 kcals divided by the nutrient allowance per 1,000 kcals. By dividing the INQ by the nutrient allowance per 1,000 kcals, the nutrient amount per 1,000 kcals can be derived. Ten of the twelve nutrients reported by Windham et al. (1981) are compared to results of this study, on a per 1,000 calorie basis. For all nutrients considered, the persons with diabetes in this study consumed a greater amount, on the average, than the national consumption survey with the exception of vitamin B_{12} for men (Figures 6-10).

Calcium intake in the CSII study was more than adequate while it did not meet the RDA in the results of the NFCS published by Windham et al. (1981). Consumption of calcium was approximately 88% of the allowance per 1,000 kilocalories in the NFCS (Windham et al., 1981). In this study calcium intake was 116% and 137% of the allowance per 1,000 kilocalories, and 156% and 106% of the RDA for men and women, respectively. Peterkin et al. (1981) reported that calcium intakes for men and women, ages 20-50 in the NFCS were 133% and 103% of the RDA. Windham's data represents all persons over four years of age which may be the reason for the disparity between the published results. It appears that this study population consumed milk products regularly and therefore calcium intake was adequate and comparable to NFCS results of Peterkin et al. (1981).

Windham et al. (1981) question the availability of iron as well as calcium, magnesium and vitamin B_6 in the diet to meet the RDA. Their analysis of the National Food Consumption Survey shows that iron densities (mg per 1000 kcals) were similar for men and women and did not meet the RDAs. This implies that availability of the nutrient is limited in the food supply. Therefore, persons with a lower caloric intake, as seen in this population of diabetic women using insulin infusion pumps, may be at even greater nutritional risk for deficiencies of nutrients which have limited dietary availability.

The dietary intake of carbohydrate, protein, and fat for this population approaches the recommendations by the American Diabetes Association (1979) for both men and women. The intake is also very similar to the intake of adults with diabetes reported by Seppanen and Reunanen (1979). An increase of complex carbohydrates and a decrease of fat intake would improve the diets to meet the guidelines.

The breakdown of total carbohydrate into added sugars, representing sugar added to foods by the food industry or the subject, indicates that such sugars represent approximately six percent of the total calories for the sample population. This is considerably lower than the national average of 14% of total calories for caloric sweeteners determined from the 1977-1978 USDA National Food Consumption Survey by Peterkin et al. (1981) for men and women of the same age group. It can be concluded, therefore, that this study population limits their intake of simple sugars, as recommended, and that nutrition education appears to be effective. However, the variability is quite high, which may be due to the ability of these CSII pump users to experiment with ingestion of simple sugars while adjusting the insulin bolus.

It can be hypothesized that consumption of simple sugars is greater with the insulin pump than it would be without it for this group. There may be greater consumption of sugars due to the added flexibility of the pump by using algorhythms to compensate for extra snacks or sweets in the diet. Furthermore, maintainance of blood glucose levels at normal levels can cause more insulin reactions. Sixteen subjects (72.7%) reported an increase in the number of reactions and 11 (50.0%) reported an increase in the severity of reactions with the pump (Table 8). Therefore, there would tend to be a greater need for sugar in the diet to counter the insulin reactions. These two factors, increased flexibility and increased number and severity of insulin reactions, may be the source of a large portion of the sugar consumption.

The mean consumption of total and saturated fats exceeds the recommended intake advocated by the American Diabetes Association (1979). Both sexes consumed approximately 43% of total calories as fat as compared to the recommended 20-38%. Men consumed 13.7% of the total calories as saturated fat while women consumed 15.4% of the total calories as saturated fat. An intake of less than 10% is recommended. Intakes of polyunsaturated fats should supply up to 10% of total calories. This study population consumed polyunsaturated fats within the recommended limit: men, 8.4% and women, 7.6%. However, the reliability of these values cannot be assumed to be absolute. The dietary records kept by the subjects failed to state whether lean or regular meats, or trimmed or total edible portions were consumed. Most records were, therefore, coded for regular, total edible portions of meats. This could, result in a misrepresentation of total and saturated fat and cholesterol consumption, as well as a slight overrepresentation of total caloric intake. Since most persons with diabetes are aware of the increased risk for developing atherosclerosis, they probably reduce fat intake by trimming meats and by consuming lean meats. If this assumption is true, and may well be considering the overall adequacy of the diets, then the total fat intake may be within the recommended range of 20%-38% of total calories, as well.

The American Diabetes Association (1979) recommends consistency in daily carbohydrate intake and consistency in mealtimes for persons with diabetes. Grinvalsky and Nathan (1983) extend these recommendations to include diabetics who use insulin infusion pumps. In this study, both the men and women ate consistent amounts of carbohydrate during the three day diet record period. There was no significant difference in the repeated measures ANOVA test (Table 16). Individuals ate consistently with respect to meal times during the three days. However, responses to the questionnaire indicated that the most common change of dietary habits since beginning insulin infusion therapy was the mealtimes. Several subjects voluntarily stated that the flexibility of mealtimes was one of the greatest attributes of the pump and implied that it also gave them a "better lifestyle" by providing more freedom of choices in everyday living situations.

Nutrient Intake of Persons Who Follow No Diet Plan

Some authors question the necessity of imposing dietary restrictions on persons with diabetes (Guest, 1947; Forsyth and Payne, 1956; Rayner, 1982; Chantelau et al., 1982: Crapo and Olefsky, 1983; Nuttall, 1983). Whether the restrictions actually improve diabetes control or complications is not known. In this study, there were no significant differences in mean nutrient intake between a subgroup of ten people who reported that they did not follow a diet plan, and the entire sample population (Table 17). These findings demonstrate that it is not necessary to require all persons using CSII to follow a strict diet plan. A partial lifting of dietary restrictions, such as the liberalized diet described and supported in the research of Chantelau et al. (1982) may be appropriate for some users of CSII, as well as other persons with Type I diabetes.

Changes in Weight with CSII

Trends of weight changes since beginning insulin infusion pump treatment indicated that a gain of weight may be a significant problem. This population gained an average of 5.5 pounds, without regard to length of time with CSII. Other authors also found a significant weight gain for persons who used CSII as compared to insulin injection therapy (Hamet et al., 1982; Home et al., 1982). Similar to this study, the authors reported a weight increase of approximately two kilograms (4.4 pounds). It appears that weight gain can be a significant problem for most people who use CSII. The long-term weight changes are not yet known, but if the trend of weight gain continued over many years, it could contribute to the complications of diabetes. Potential weight changes with CSII pose additional responsibilities for health care providers. Persons who use CSII should be told of the possible "side-effect" of weight gain, with an explanation of the cause. Some individuals will require education for weight loss or maintainance. Weight should be monitored throughout CSII use or until it is evident that the individual's weight is maintained at the desired weight.

Dietary Habits

It is not possible to determine if the dietary habits of this sample population of persons who use insulin infusion pumps is or is not representative of the true population of CSII users. However, this data can be used as a baseline for comparison of dietary habits with other similar studies.

Conclusions

The nutrient intake of this population of persons with Type I diabetes using CSII was adequate in most nutrients as compared to the 1980 RDAs (Food and Nutrition Board, 1980). Nutrients of concern are zinc, folate, and vitamin B_6 for both sexes, plus iron and magnesium for women. These possible nutrient inadequacies are very similar to those nutrients found to be inadequate in the 1977-1978 USDA Nationwide Food Consumption Survey. Therefore, it can be concluded that nutrient intake for this group paralleled the national trends of nutrient intake.

For some of the well educated people who use CSII, a lifting of dietary restrictions seems reasonable. The nutrient intake of a subgroup which did not follow a diet plan was similar to the total group intake thus supporting the philosophy of flexibility when counseling patients using CSII.

The percentage of total calories from the macronutrients approximated the recommendations by the American Diabetes Association

(1979). In addition, the group generally followed the recommended restriction of sugars in the diet. Actual intakes of fats was difficult to determine since food records were not specific with regard to cuts of meats and degree of leanness of meats eaten. Carbohydrate intake was consistent from day-to-day, as recommended. Overall, it was concluded that these subjects have had good educational training on food intake for managing diabetes as well as general nutritional needs. Dietitians had been involved in the educational training in most cases.

A potential problem for this group was weight gain. Based on previously published reports, weight gain may be a significant concern for most diabetics who use CSII. Therefore, it is advised that health care providers monitor weight and provide consultation for individuals who use continuous subcutaneous insulin infusion in order to prevent additional weight gain after initiating the use of CSII. Weight gain may be desirable for some individuals, but this was not the case in this study population.

As a result of this study and the findings that have been reported, it is apparent that nutritional counseling is an extremely important component of the continual care, education, and monitoring of the CSII patient. Insulin pump therapy does not negate the importance of the cornerstone of glucose control. The well informed person who uses CSII enjoys flexibility and additional options in their food intake and lifestyle. This study has described those facts. This study has also made a comparison of actual food intake of a selected sample of the CSII population to the standards for nutrients stated by the Food and Nutrition Board, to the recommended percentage of daily calories from the energy producing nutrients by the American Diabetes Association, and to national food consumption trends.

The reported data should prove useful to practitioners dietitians, physicians, and others involved in nutritional care. The data should also provide impetus for monitoring, on a systematic basis, all persons with diabetes who use CSII.

Recommendations

Recommendations for further study follows:

1. Replication of the study using a larger sample size, and a different geographical area. This would allow for comparisons in nutrient intake.
2. In depth instruction to participants on an accurate description of meats intake including cuts of meats, leaness of meats, cooking methods and whether total edible or separate lean portions are eaten. This would provide a more accurate representation of total fats and proportion of types of fats consumed.
3. A prospective longitudinal study of persons with diabetes using CSII would be very significant. This would allow for measurements of weight and HbA_1 at regular intervals. Dietary analysis repeated during different seasons would provide a more complete representation of actual nutrient intake for the given population.

4. A comparative study of nutrient intake with other selected populations of persons with type I diabetes mellitus, who do not use CSII therapy, but are on daily multiple insulin injections.
5. Adding to the design of this study, a method for assessing the energy needs for basal requirements and additional expenditure for physical activity. This individualized information would then be programmed into the individual prescription.

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APPENDICES

Appendix A

Participant Packet Cover Letter

Dear Participant:

Thank you for your interest and participation in this nutrition study which is being done cooperatively with your physician, Dr. Dana Clarke, 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. All that is required of you is to keep an accurate 3-day diet record and to answer the questionnaire. All information you provide will remain strictly confidential. You are under no obligation and are free to withdraw from this study at any time.

Enclosed you will find a questionnaire, food intake record sheets, and instructions for recording your food intake. It is important to keep accurate records of food intake, including fluids, condiments (ketchup, sauces, margarine etc.) and vitamin/mineral pills or other supplements. Your honesty and accuracy in recording your food intake will help health care professionals, as well as Dr. Clarke and his assistants, understand your dietary needs and further assist you in your food selections.

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 available to you upon request. Information on your nutritional intake should be of personal benefit to you; therefore, please keep complete records of the sizes and amounts of all foods and drinks. Thank you for your participation.

Sincerely,

Laurie Schaetzel-Hill
Graduate Student

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

Dana Clarke, M.D.

Appendix B

Consent Form

INFORMED CONSENT FORM

Dietary Intake of Type I Diabetics 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 and to complete a questionnaire.

I give my consent to allow the investigator to review my medical chart for the following data: hemoglobin A_1, 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 C

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 diet plan? ____ Yes ____ No

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 ________
Names 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 carbohydate

Diabetes Control

How often do you have reactions?

31. Daily: None ____ Number of times _____

32. Weekly: None ____ Number of times _____

33. Monthly: None ____ Number of times _____

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

35. Severity of reactions has: ___ increased ____ decreased
___ no change

36. How do you rate your diabetes control?
____ Excellent ____ Good ____ Fair ____ Poor

Other Questions

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

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

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.

Would you like to receive a copy of the computerized dietary analysis?

____ Yes ____ No

Appendix D

Instructions for Diet Record

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 amount 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 add 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 is 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 cookies: 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

Please measure in ounces the glass or cup usually used. Use this glass for beverages during the diet record period.

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 amount (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 (Yellow 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.

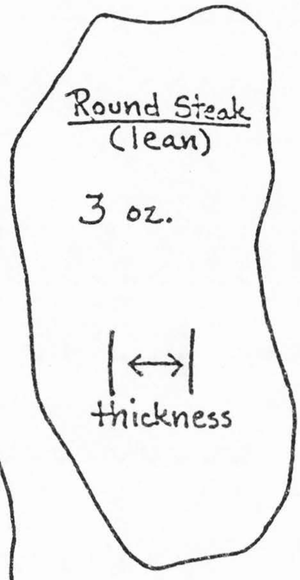
3. Include amounts used in cooking.

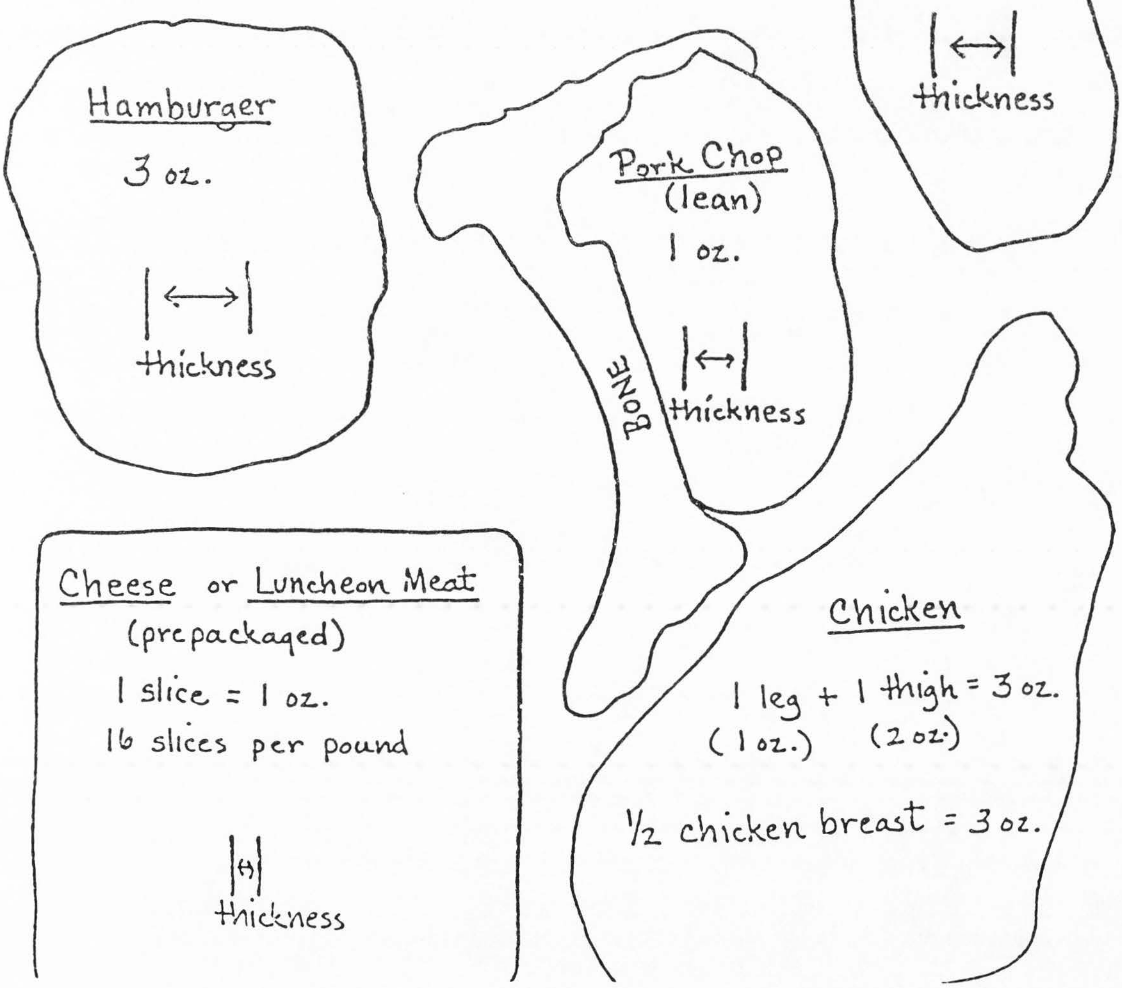
Appendix E

Portion Size Guide

PORTION SIZE GUIDE*

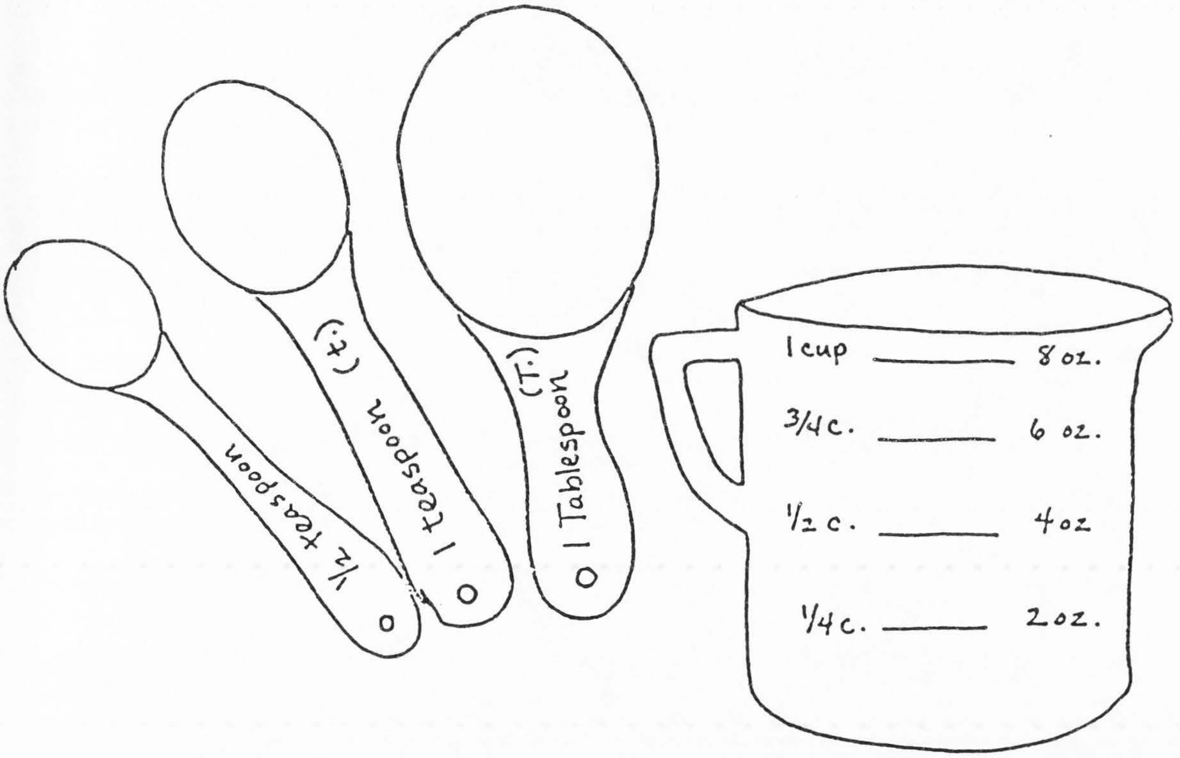
Use these portion sizes to estimate weight of meats and cheese.





*Reduced 25% for thesis publication.

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



Appendix F

Food Intake Record and Example

FOOD INTAKE RECORD

NAME____ HEIGHT________________ WEIGHT________________

DATES RECORDS WERE KEPT________________________ DAYS OF WEEK: M T W Th F Sat Sun

THESE DAY'S INTAKES WERE: Typical________ More than usual________ Less than usual________

REACTIONS DURING THESE DAYS WERE: Mild________ Moderate________ Severe________

VITAMIN/MINERAL SUPPLEMENTS USED? Yes________ No________ Brand____________________

HOW OFTEN? Daily________ Every Other Day________ Weekly________ Other________________

TIME	FOR REACTION? (rate)	WHERE EATEN	FOOD	DESCRIPTION	AMOUNT

FOOD INTAKE RECORD

NAME EXAMPLE HEIGHT______ WEIGHT______

DATES RECORDS WERE KEPT______ DAYS OF WEEK: M T W Th F Sat Sun

THESE DAY'S INTAKES WERE: Typical______ More than usual______ Less than usual______

REACTIONS DURING THESE DAYS WERE: Mild______ Moderate______ Severe______

VITAMIN/MINERAL SUPPLEMENTS USED? Yes______ No______ Brand______

HOW OFTEN? Daily______ Every Other Day______ Weekly______ Other______

TIME	FOR REACTION? (rate)	WHERE EATEN	FOOD	DESCRIPTION	AMOUNT
7:00	no	home	pancakes	4" diameter, mix, with egg and mile	2
			margarine	Parkay soft	1 Tbsp.
			syrup	Mrs. Butterworth's	2 Tbsp.
			orange juice	frozen reconstituted, Minute Maid	4 oz. (1/2
			milk	2%	8 oz. (1 c.
10:00	mild	work	ginger snaps	Nabisco	3 small
12:30	no	McDonalds	hamburger	regular, with lettuce and catsup	1
			french fries	small bag	1/2 bag
			milk	whole	10 oz.
			apple	medium	1
4:00	no	home	cottage cheese	lowfat-1%	1/2 c.
			pinapple	canned, cruched, juice pack	2 Tbsp.
6:00	no	home	fried steak	beef round, 4"by 3" by 1/2"	1 piece
			mashed potato	instant, with milk and margarine	3/4 c.

Appendix G

Letter for CSII Pump Meeting

June 30, 1983

Hello!

Summer is here and we have scheduled another pump get together. It will be held on Wednesday, July 13, 1983 at 7:00 p.m. at Holy Cross Hospital in the Far West Conference Room (stop at the information desk for directions).

We are planning to review common problems of diets and to review quantitation of foods so that you can better estimate the size of your insulin bolus in relation to food. As you know, proper food and insulin matchup is critical for fine tuning pump therapy. At our last meeting we had "unknown" food quantities and had people guess the amounts. Most of us were surprised at our results. We plan to duplicate that experiment to increase our knowledge of food quantities. Bring your "eye" for food.

In addition, we will have a guest dietitian from Utah State University, Laurie Schaetzel-Hill. Laurie will help with part of the meeting and will be recruiting participants for a research project she is conducting. The research will look at the dietary intake of people who use insulin pumps. She would like to recruit pump users from this office. If you agree to participate, she will be asking you to answer a brief (5-10 minute) questionnaire and keep a three day diet record. In exchange she will provide a computerized dietary analysis for each study participant. Her analysis will include vitamins, minerals, protein, carbohydrate, fat and cholesterol An example of the dietary analysis will be available at the meeting for your review.

We are sure you all are interested in your own diet and we feel that your participation in this study will benefit you. Donna has already had Laurie analyze a three day diet record and found it both interesting and useful. We encourage your participation in the study and assure you that all information provided will be kept confidential.

We look forward to seeing you on July 13th. We feel it will be a productive, informative meeting for you.

Sincerely,

Dana H. Clarke, M.D.

Appendix H

Exercise on Food Quantitation and Carbohydrate Content

Food	Measurement	Grams Carbohydrate
Peanut Butter with bread	1 slice bread	15
Popcorn	3 c.	15
Apple	Small	10
Grapes	23	20
Roast beef	3 oz. (6 x 3½ x ¼")	--
Lettuce	1 c.	free
Tuna sandwich	1 slice bread, 3 Tbs. tuna with mayo	15
Broccoli	1/3 c.	3
French fries	small order	25, with 10 gm fat
Potato chips	15	15 (1 gm/chip)
Vegetable soup	1 c.	15
Cheese	1 oz. slice	--
Cherry pie	1/6 pie	60 (WOW!!)
Milk, 2%	½ c.	6
Hamburger, fried	2 oz. (3 x 2 x ½")	--
Chicken, baked (leg and thigh)	3 oz. (5 x 2 x ½)	--
Orange, fresh	Medium	13
Beer, Budweiser	12 oz.	14
(Lite Beer)	(12 oz.)	(6)
Snicker bar	1 bar	22
Marshmallow	1 average	6 (no fat)
M & Ms	1 small package	24
Gum drops	1 oz. (28 pieces)	24 (no fat)
	8-9 pieces	10

Appendix I

Final Letter and Individual Nutrient Analysis for Participant

UTAH STATE UNIVERSITY · LOGAN, UTAH 84322

COLLEGE OF AGRICULTURE

COLLEGE OF FAMILY LIFE

DEPARTMENT OF
NUTRITION AND
FOOD SCIENCES
UMC 87

February 10, 1984

Dear

Thank you for participating in this study on the dietary intake of people with diabetes who use insulin pumps. The study has been very successful and will give us insight into the dietary intake of persons who use a continuous insulin infusion pump.

As promised, we are returning a summary of your three-day dietary intake based on the diet record you provided. A copy is also being sent to Dr. Clarke to be put in your medical chart. We apologize for the delay in returning this information to those of you who were so prompt in sending the completed diet records and questionnaire.

Nutrients consumed during your three day diet record have been averaged. Your average intake has been compared to the Recommended Dietary Allowances (RDA) for your age and sex. The RDAs are the levels of intake of essential nutrients which are considered to be adequate to meet the needs of practically all healthy persons, as determined by the Food and Nutrition Board, National Research Council.

The RDAs are based on a reference person of average size and moderate activity. Your individual needs may be somewhat different, particularly for calories, because of your height, weight and level of physical activity. Therefore, please use this information as a guideline to your nutritional needs.

For nutrients which are less than 75% of the RDA, we suggest you increase your intake of foods which are good sources of those particularly nutrients. The other nutrients can be assumed to be adequate.

February 10, 1984
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Further questions regarding your diet plan and its appropriateness for you should be discussed with Dr. Clarke's office.

Sincerely,

Laurie Schaetzel-Hill, R.D.   Barbara Prater, Ph.D., R.D.

P.S. Please note that the stated sodium intake does not represent salt added by you during cooking or at the table. Therefore, sodium intake is likely to be higher, depending on the quantity of salt you add.

Also, the fat intake may be slightly different, dependent upon whether you use lean meats and/or trim fat from meats you eat. It was assumed that you ate regular non-lean or non-trimmed meats unless stated otherwise in your diet records.

Date ____________________
Name ____________________
Address ____________________
Date of
diet record ____________________

Research conducted by
Utah State University
Dept. of Nutrition and Food Science
Nutritional intake of persons with Diabetes who use insulin infusion pumps
Laurie Schaetzel-Hill, R.D. (Grad. Student)
Barbara Prater, Ph.D., R.D. (Assoc. Prof.)

Nutrient	Your Average Intake	Recommended Dietary Allowance	Percent of RDA
Calories (kcals)		2000 (1600-2400)	
Protein (gm)		44	
Minerals			
Calcium (mg)		800	
Iron (mg)		18	
Zinc (mg)		15	
Potassium (mg)		3750 (1875-5625)	Not yet established
Sodium (mg)		2200 (1100-3300)	Not yet established
Vitamins			
Vitamin A (IU)		4000	
Thiamin (mg)		1.0	
Riboflavin (mg)		1.2	
Niacin (mg)		13	
B_6 (mg)		2.0	
B_{12} (mcg)		3.0	
Vitamin C (mg)		60	
Folacin (mcg)		400	

Percent of total calories from:
- Protein
- Carbohydrate
- Fat

Date ______________________
Name ______________________
Address ____________________
Date of
diet record ________________

Research conducted by
Utah State University
Dept. of Nutrition and Food Science
Nutritional intake of persons with Diabetes who use insulin infusion pumps
Laurie Schaetzel-Hill, R.D. (Grad. Student)
Barbara Prater, Ph.D., R.D. (Assoc. Prof.)

Nutrient	Your Average Intake	Recommended Dietary Allowance	Percent of RDA
Calories (kcals)		2700 (2300-3100)	
Protein (gm)		56	
Minerals			
Calcium (mg)		800	
Iron (mg)		10	
Zinc (mg)		15	
Potassium (mg)		3750 (1875-5625)	Not yet established
Sodium (mg)		2200 (1100-3300)	Not yet established
Vitamins			
Vitamin A (IU)		5000	
Thiamin (mg)		1.4	
Riboflavin (mg)		1.6	
Niacin (mg)		18	
B_6 (mg)		2.2	
B_{12} (mcg)		3.0	
Vitamin C (mg)		60	
Folacin (mcg)		400	

Percent of total calories from:
- Protein
- Carbohydrate
- Fat

Appendix J

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	0.5[g]	360	240	50	10	3	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 K

1980 Estimated Safe and Adequate Daily Dietary Intakes

	Age (years)	Vitamins: Vitamin K (μg)	Biotin (μg)	Panto-thenic 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

	Age (years)	Trace Elements[b]: Copper (mg)	Man-ganese (mg)	Fluoride (mg)	Chromium (mg)	Selenium (mg)	Molyb-denum (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

	Age (years)	Electrolytes: Sodium (mg)	Potassium (mg)	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.