I. Research Proposal

1. Background

Diabetes has been described as the "the perfect epidemic" afflicting an estimated 104 million people worldwide (1). By 2010, this figure is expected to double (2). Diabetes is not only a common chronic disease but it meets all 3 criteria for a public health disorder (3). The goal of the clinical management of all forms of diabetes is to control metabolic abnormalities in order to prevent acute (hyperglycemia and hypoglycemia) and long-term complications (retinopathy, nephropathy, neuropathy and cardiovascular disease) without negatively impacting on quality of life (3). Two landmark studies (4,5) have confirmed that attainment of glycemic control as close to normal as possible is necessary for prevention of long term complications in both type 1 (4) and type 2 (5) diabetes and this requires an intensive approach to management. Nutrition is of utmost importance in intensive management (6) and has often been described as the cornerstone of diabetes care (3). The main focus in the nutritional management of diabetes is to improve glycemic control by balancing food intake with endogenous and /or exogenous insulin levels (7). Historically, there have been several attempts to control the glycemic response to food, particularly carbohydrate-containing foods, including use of very low carbohydrate and starvation diets, artificial sweeteners and pharmacological preparations such as fast acting insulin and inhibitors of carbohydrate absorption (8). One way to classify the glycemic response of various carbohydrate-containing foods is Glycemic Index (GI). This term was first coined by Jenkins to describe the extent that blood glucose rises after a test food in comparison to a reference food, usually white bread (9). Although the concept of the GI has made it easy to predict the glycemic response of predominantly carbohydrate-containing foods, the clinical utility of this concept has been seriously questioned, especially as it pertains to mixed meals (10). As well, there has been concern that patients may misapply the GI concept (10). This concern is similar to the one raised when the Canadian Diabetes Association released the "sucrose guidelines" in 1992 (11). Dietitians were at first reluctant to teach clients with diabetes how to incorporate the "added sugar choices" into their meal plan out of concern that they would misapply the information and would lead to a deterioration in metabolic control. A long-term study of free-living adults with type 2 diabetes revealed that this concern was unfounded as metabolic control did not deteriorate (12).

Although currently not endorsed by the American Diabetes Association (13), the GI is being advocated by most diabetes and health organizations world wide including the World Health Organization, the Diabetes Nutrition Study Group of the European Association for the Study of Diabetes and the Canadian Diabetes Association (7). The use of the GI in clinical practice, and in particular the use of low GI diets, is being advocated by a joint Food and Agriculture Organization (FAO) and World Health Organization (WHO) Expert Consultation (14). The report of this consultation suggests using the GI as a way to guide food choices and to develop exchange lists. The report also suggests how the GI can be applied to mixed meals or whole diets.

Currently, in the management of diabetes, glycemic control is assessed by fasting, pre-meal and long-term blood glucose levels (3). However, post-prandial glycemia should also be considered as it may be an independent risk factor in the development of complications related to diabetes (15-17). As post-prandial glycemia is influenced by both the amount and the source of carbohydrate (7), the Glycemic Index is a very important concept to consider. Furthermore, there is a growing body of scientific evidence, including data from epidemiological (18,19) and clinical studies (20-22) linking low Glycemic Index diets with improved outcomes including decreased risk of development of type 2 diabetes (18,19) and improved metabolic control (20-22) and quality of life (20) in individuals with established diabetes.

2. Objective and Hypothesis

Given the growing body of evidence regarding the potential benefits of the Glycemic Index in the prevention and clinical management of diabetes and in view that the GI concept is being advocated by the World Health Organization and the Canadian Diabetes Association, it is important to determine the current practices and perceptions of Canadian dietitians with respect to the use of the Glycemic Index in the nutritional management of individuals with diabetes mellitus.

Objective

The objective of this study is to determine factors associated with use and non-use of the Glycemic Index concept. The factors to be studied are: perceptions (benefits, barriers, confidence in teaching Glycemic Index); knowledge and sociodemographic and professional characteristics (age, gender, province of work, number of years since graduation, number of clients with diabetes counseled per week).

Hypothesis

Dietitians who "use" the Glycemic Index will be more likely to have greater perceived benefits, fewer perceived barriers and greater perceived confidence in teaching the Glycemic Index and higher knowledge scores than "non-users" of the Glycemic Index.

3. Research Design

Study Design

A Canada-wide survey using a case-control study design will be employed. Our sampling frame will be all dietitians who are active members of Dietitians of Canada and the Ordre Professionnel des Diététistes du Québec.

Methods

Our sampling strategy will consist of two parts. Part 1: all dietitians who are active members of Dietitians of Canada (n=4955 members) and the Ordre Professionnel des Diététistes du Québec or OPDQ (n=2000 members) will be contacted. Permission has been requested from the respective associations to contact members (Appendix 1). Student and retired members will be excluded. Members who belong to the respective associations will be sent a post-card (Appendix 2). Via this post-card, dietitians will be asked whether they counsel patients with diabetes and if yes, do they use the Glycemic Index in their teaching. Dietitians who counsel individuals with diabetes and who currently use the Glycemic Index in their practice will comprise the "case-group" and a

random sample of those who counsel individuals with diabetes but who do not currently use the GI concept in their practice will comprise the "control-group."
Part 2: Individuals in the "case-group" and the "control-group" will be sent the complete questionnaire along with a consent form (Appendix 3). Incentives will be used in both parts of the sampling strategy to increase the response rate. This will consist of a monetary prize totaling $1,000.00. There will be 10 prizes of $50 each offered to winners who return the post-card and 1 prize of $500 to one winner who returns the completed questionnaire. Winners will be notified by mail. Names of winners will be held confidential.

Sample Size

We estimate that approximately 7000 dietitians will be sent the post-card and that approximately 70% will return it (70% response rate). Among respondents (n=5000), we estimate that 50% will counsel patients with diabetes (n=2500) and that 15% will "use" the Glycemic Index (n=375). Therefore, a total of about 375 dietitians will comprise the "case-group." For each dietitian in the "case-group", we require at least 3 dietitians in the "control-group" (23) for a total of about 1125 dietitians in the "control-group." With 375 cases, the minimal detectable odds ratio (relative risk) is 1.85 with 80% power and an alpha level of 0.05 (23). The control group will be selected using *stratified random sampling* technique according to the percentage of members by province as indicated by the membership profile of Dietitians of Canada. An estimated total sample size of 1500 dietitians will be sent the consent form and complete questionnaire and (Appendix 3). Of these, we estimate that approximately 80% will respond. We will ensure this response rate by contacting non or late responders via a "second mailing" of the questionnaire.

Post-Card

Please refer to Appendix 2. The post-card will be used in part 1 of the sampling strategy whereby all dietitians who are active members of Dietitians of Canada and the Ordre Professionnel des Diététistes du Québec will be contacted. The post-card will be translated into french (with back-translation) prior to distribution to dietitians who are membres of OPDQ. The post-card is designed to determine the number of dietitians who counsel individuals with diabetes and whether or not they use the Glycemic Index in their practice. The information provided from these post-cards will be used to form the case and control groups who will then receive the Glycemic Index Survey described on the next page.

Glycemic Index Survey

Please refer to Appendix 3. The survey is designed to address the predictor variables of interest (described in the next page) and to obtain sociodemographic and professional characteristics data related to the practice of dietitians involved in diabetes nutrition education. These may aid in better understanding and characterizing users from non-users of the Glycemic Index concept. Sociodemographic and professional characteristics variables of importance, which may be potential confounders, include: age, gender, year of graduation, region or province, type of practice, number of individuals with diabetes counseled per week and membership in diabetes associations. These will be important variables to consider in our analyses. The survey consists of 21 questions in total, 4 pages in length and takes approximately 10 minutes to complete. The questionnaire will be translated into french (with back-translation) and pilot tested and validated (face and

content validity) with a sample of practicing dietitians (n=10; 5 francophone and 5 anglophone) prior to distribution of the final version to the target population.

Outcome and Predictor Variables

A "user" of the Glycemic Index concept will be defined as a dietitian who counsels individuals with diabetes and who teaches the Glycemic Index to clients with diabetes mellitus. A "non-user" will be defined as a dietitian who counsels individuals with diabetes but who does not teach the Glycemic Index to clients with diabetes.

Our predictor variables are: *percieved barriers* to using the GI concept in practice; *perceived benefits or utility* of using the GI concept in practice, *perceived confidence* of using the GI concept in practice and *knowledge* related to the GI concept. Perceived benefits and perceived barriers will be determined via questions # 9 (6 items, 4-point ordinal scale) and # 10 (9 items, 4-point ordinal scale). The formulation of these questions are based on the Health Belief Model (24). Perceived confidence in teaching the GI concept, will be determined via question # 11 (1 item, 4-point ordinal scale) and is based on Social Cognitive Theory (25). Knowledge pertaining to the GI concept will be determined via question # 8 (6 items, true or false).

Statistical Analyses

The main analyses will be via logistic regression. Questions on benefits, barriers, confidence and knowledge will be included in a model to identify factors associated with being a "user" or "non-user" of the GI concept. Alternatively, the variables for benefits, barriers and knowledge can be converted to quasi-continuous measures by calculating, for each person, the proportion of benefits, barriers and correct responses so identified. For this type of data, an adjusted t-test (where "user" or "non-user" is the group) will be carried out using multiple linear regression analyses. Adjustments will be made for sociodemographic and professional characteristics as previously described.

Time Line for Study

Period	Major Activities
0-3 months	Pilot testing of survey and distribution of post-cards.
3-4 months	Return of post-cards and formation of case and control groups.
4-5 months	Preparation and distribution of survey.
5-7 months	Return of surveys.
7-9 months	Distribution and return of reminder surveys.
9-12 months	Data entry and analyses. Preparation and submission of manuscript.

4. Relevance of the Proposal to Dietetic Practice

Optimal glycemic control is essential for the prevention and progression of complications in diabetes. Dietitians should be aware of emerging concepts that can impact on the health status of individuals with diabetes mellitus. This study is therefore congruent with the research priorities of Dietitians of Canada in that Glycemic Index is an emerging concept that will lead to *new roles for dietitians* in improving the health status of all Canadians, particularly those afflicted with diabetes. Since only about half of Canadian dietitians currently have an email address (26), a postal survey will allow us to reach all dietitians and thus enhance the generalizability of our findings. The main limitation of this and all survey studies is the possibility of "response bias." By conducting a postal survey and by employing a case-control design, we can better target our population of interest, therefore minimizing response bias and enhancing our ability to generalize our findings to all Canadian dietitians. In addition to obtaining valuable information on what facilitates use of the GI concept, we will also obtain an accurate estimate of prevalence of use which could serve as a benchmark for development of strategies to enhance use of the Glycemic Index concept in practice which, in turn, could be of benefit to individuals with diabetes mellitus.