RELIABILITY AND VALIDITY OF A QUESTIONNAIRE TO ASSESS CARBOHYDRATE COUNTING SKILLS, KNOWLEDGE OF HEART-HEALTHY FOODS, AND NUTRITION LABEL-READING SKILLS IN ADULTS WITH DIABETES

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Abstract

Diabetes mellitus affects the metabolism of carbohydrates, thus patients should monitor carbohydrate intake and eat a heart-healthy diet using nutrition labels. To assess carbohydrate counting skills, knowledge of heart-healthy diet, and nutrition label-reading skills the Heart-Healthy Carb Quiz (HHCQ) was developed and assessed for its validity and reliability in adults with diabetes. Data were analyzed for 55 subjects; average age was 41.7 ± 17.6 years and 29 participants were women. Thirty-six participants had type 1 diabetes and 19 had type 2; average duration of diabetes was 14.3 ± 12.3 years. Average HbA_{1c} was 8.0% ± 2.0%. HHCQ total scores correlated significantly with CarbQuiz total scores ($r=0.39$, $p = 0.003$) and the HHCQ demonstrated good stability in the test-retest measure ($r=0.74$, $p = 0.001$) (both assessed using a Pearson product-moment correlation). Cronbach α was 0.70; inter-item total correlation was 0.45. This study supports the validity and reliability of the HHCQ.

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Chapter 1: Introduction

Diabetes mellitus is a chronic disease that affects nearly 26 million people in the United States. It is a disease that affects the metabolism and uptake of carbohydrates, so diet is an inherently important factor when controlling blood glucose (1-9). Maintaining tight glycemic control is important in decreasing risk for macrovascular and microvascular complications (10). Because carbohydrates are the major macronutrient that affects blood glucose, monitoring carbohydrates in the diet is very important (2, 7). Carbohydrate counting is a method of monitoring carbohydrates that improves glycemic control in individuals with diabetes (1). In addition to monitoring carbohydrates, people with diabetes should eat a diet that is considered "heart-healthy" because of the increased risk for heart disease (1). Label-reading skills are important in both carbohydrate counting and recognition of foods that are heart healthy (8, 11).

To assess patient skills in these areas and meet educational benchmarks, clinicians need a valid, reliable questionnaire of appropriate length to administer in the clinical setting. The only tool currently available to assess carbohydrate counting skill in an adult population is an assessment named CarbQuiz by Kern et al. (12). However, this tool has significant limitations. Its use appears to be aimed at a population who monitors carbohydrate intake by counting 15-gram carbohydrate choices rather than counting grams of carbohydrate. It also contains questions that assume all people with diabetes have similar blood glucose level reactions to consuming carbohydrates or doing exercise. In addition, the CarbQuiz does not assess patient understanding of heart-

healthy foods, which is important for patients with a disease that increases the risk of heart disease. No other tool to assess carbohydrate counting skill in adults with diabetes has been published.

Specific Aims

The aim of this study was to assess validity and reliability of a short questionnaire named the Heart Healthy Carb Quiz (HHCQ) that measures carbohydrate counting skills and understanding, knowledge of heart-healthy foods and nutrition label-reading skills in adults with diabetes for use in the clinical setting.

Specific Aim 1: Assessing Validity. To evaluate the HHCQ as a valid measure of carbohydrate counting skills, knowledge of heart-healthy foods, and nutrition label-reading skills in adults with diabetes.

Specific Aim 2: Assessing Reliability. To evaluate the HHCQ as a reliable measure of carbohydrate counting skills, knowledge of heart-healthy foods, and nutrition label-reading skills in adults with diabetes.

Chapter 2: Review of Literature

Introduction

Diabetes affects 25.8 million people in the United States, and that number continues to rise (13). The Diabetes Control and Complications Trial highlighted the importance of tightly controlling glycemia in order to prevent long-term complications (10). With intensive control of glycemia, using a goal of 70-120 mg per deciliter for pre-prandial glucose levels, patients significantly decreased risk of retinopathy by 50%, neuropathy by 69%, nephropathy by 34%, and hypercholesterolemia by 34% (10). However, intensive treatment should be implemented with caution due to the increased risk of hypoglycemia (10). In addition to these complications, diabetes also increases the risk of cardiovascular disease (10, 14-17).

Carbohydrate counting has been used for decades as a way to control blood glucose levels (2, 18), and the American Diabetes Association (ADA) recommends carbohydrate counting as a method of control for all people with diabetes (1). In the clinical setting, practitioners need appropriate assessment tools to determine the level of carbohydrate counting skills their patients have; however, the majority of assessment tools are used to measure general diabetes knowledge including insulin adjustments, the effect of diabetes on quality of life, general nutrition knowledge, attitudes toward food, patterns of nutrition and exercise and numeracy skills related to diabetes (3, 19-23). Questionnaires to assess knowledge of carbohydrate counting are largely lacking in the field and should include assessment of nutrition label-reading skills because of their

importance in selecting appropriate foods, as well as assessment of knowledge of heart-healthy diet due to the increased risk with diabetes. In order to develop an appropriate questionnaire to fill this gap, a valid procedure should be identified and followed. The purpose of this literature review was to determine the need for validation of an original brief questionnaire assessing carbohydrate counting skills and understanding, knowledge of heart-healthy foods, and nutrition label-reading skills for use in the clinical setting.

Diet and Diabetes

Diabetes relates directly to the metabolism and uptake of carbohydrates, thus diet plays an essential role in the control of blood glucose levels in persons with diabetes (2-9). In the early 1900s, before the advent of insulin, the main focus of dietary intervention was the restriction of carbohydrates, particularly sucrose (5). The ADA now promotes carbohydrates as part of a healthy diet and recommends carbohydrates come from a variety of foods, especially those containing fiber (1). Many people, including the public and some healthcare providers, still believe sugar should be avoided in the diet for diabetes (5). Sugar is allowed in the diet but should be included in the total number of carbohydrates when monitoring carbohydrates (1).

Carbohydrate Counting and Glycemia

Because carbohydrates are the major macronutrient affecting blood sugar, the primary emphasis of dietary care in diabetes focuses on carbohydrates (2, 7). Carbohydrate counting emerged in the first half of the 20th century as a method of monitoring carbohydrate intake but did not become widely accepted until its use in the Diabetes Control and Complications Trial in the early 1990s (2, 10, 18). Now the ADA recognizes that counting carbohydrates is essential to maintain good glycemic control in all persons with diabetes and lists carbohydrate counting as one of the key strategies for assessing intake of the nutrient (1). The ADA recommends that people with type 1 diabetes use a method of carbohydrate monitoring to either match insulin doses to carbohydrate intake or match carbohydrate intake with insulin doses (1).

Carbohydrate counting does not have to be precise to yield beneficial results. Smart et al. (24) demonstrated that two-hour post-prandial blood glucose levels were similar whether subjects dosed for the exact amount of carbohydrates consumed or either 10 grams more or less. Various methods of carbohydrate counting, such as using carbohydrate point equivalents or counting grams, do not affect the accuracy of estimation by children with type 1 diabetes or their caregivers (25). Consistency in counting carbohydrates may be more important than accuracy for long-term maintenance of glycemia (25). Blood glucose control also improves when patients eat similar amounts and types of carbohydrate from day to day (4). However, for patients

who wish to vary the type and amount of carbohydrates they consume, carbohydrate counting is a good alternative to a specific diet for diabetes (4, 7).

Research indicates that carbohydrate counting has a positive effect on many areas of diabetes treatment. A number of studies have shown that carbohydrate counting improves glycosylated hemoglobin (HbA_{1c}), a measure of average blood glucose levels over the past 90 days, in patients with type 1 or type 2 diabetes (18, 26-28). Intensive management of glycemia using insulin is associated with weight gain in people with insulin-dependent diabetes (10). In a study of people with insulin-dependent type 2 diabetes that took place over six months, researchers found that all subjects gained weight. However, subjects in the control group gained 3.6 kilograms while subjects in the carbohydrate counting group gained only 2.4 kilograms (28). Although the difference was not significant in this study, carbohydrate counting may help to control weight. Persons receiving carbohydrate counting education may also cope better with problem solving, seeking social support, and avoidance (26). In addition to these coping skills, patients believe that carbohydrate counting can increase the food choices and freedom of timing of meals of persons with type 1 diabetes (29).

Diabetes and Heart Disease

One of the major co-morbidities and the leading cause of death in persons with diabetes is cardiovascular disease (13, 15). Diabetes is linked to increased risk of heart failure, heart attack, stroke, and congestive heart failure (14-17). Diet affects

macrovascular markers related to heart disease and the ADA recommends that people with type 2 diabetes eat foods low in saturated and *Trans* fats, cholesterol, and sodium and make lifestyle changes including participating in regular exercise. Additionally, the ADA recommends that all people with diabetes consume a similar healthy dietary pattern (1). Patients with type 2 diabetes who more closely adhere to dietary recommendations by the ADA can improve metabolic control of total cholesterol, HDL and LDL cholesterol, serum triglycerides, BMI, and the trend for insulin requirements (30). A diet that reduces cardiovascular risk may also reduce the risk of retinopathy, nephropathy and other microvascular complications (1).

Importance of Label-Reading

To enable consumers to make healthy decisions based on the information presented on nutrition labels, they must be able to read and understand labels (8, 11). Food label use and nutrition knowledge are positively related (31), but consumers' actual ability to read labels differs from what they claim to understand (11). In a study by Miller et al. (9), women with type 2 diabetes who were 65 years of age scored an average of 49% on a food label knowledge test. Persons with diabetes report usually reading food labels (8), and overall, people with chronic diseases are more likely to read food labels than people without chronic disease (32). However, people with diabetes are more likely to look at the amount of sugar in products rather than total carbohydrates (8, 31), even though total carbohydrates affect blood glucose levels (2,

7). Mackison and colleagues (11) recognized the need to assess label-reading skills and developed a questionnaire to assess the use and understanding of nutrition labels. This may be a helpful tool to determine the validity of questions regarding label-reading skills in the new questionnaire. However, the Mackison questionnaire was created in Europe, where the label design differs from the nutrition label used in the United States.

Current Assessment Tools

A thorough review of the literature reveals only one questionnaire developed specifically to assess carbohydrate counting skills in adults with diabetes. In 2008, Kern et al. (32) created a questionnaire with six domains and 43 questions to assess the knowledge of carbohydrate counting in adult patients with diabetes. Validation was confirmed by administering the questionnaire to 100 male patients and 15 nutritionists uninvolved in the formation of the questionnaire (12).

There are significant limitations to this questionnaire's usefulness. Its use appears to be aimed at a population who monitors carbohydrate intake by counting 15-gram carbohydrate choices rather than counting grams of carbohydrate. It also contains questions that assume all people with diabetes have similar blood glucose level reactions to consuming carbohydrates or doing exercise. The questionnaire does not assess knowledge of heart healthy foods, which are important in a diet for diabetes because of the increased risk of heart disease. The majority of subjects included in the study had type 2 diabetes, although many people with type 1 diabetes use carbohydrate

counting. Finally, the questionnaire was only tested with men, and ideally an assessment tool would be tested in both men and women. No other tool to assess carbohydrate counting skills in adults with diabetes has been published.

Need for Clinically Appropriate Assessment Tools

To effectively evaluate patient understanding and decrease the risk of hypoglycemia, health professionals need a validated tool to assess carbohydrate counting skills in the clinical setting. Smart et al. (25) recognized that practitioners know little about the competence level of children and their caregivers in regards to carbohydrate counting and appropriate insulin dosing. Patient self-reports of carbohydrate knowledge may not reflect actual understanding and consistent use of carbohydrate counting. The same may be true for adults; the amount of education regarding diabetes care and nutrition knowledge varies widely in the adult population. Some patients with type 1 or type 2 diabetes receive extensive training in carbohydrate counting while others may receive little or none by a health professional.

To assess knowledge level, Smart et al. (25) conducted a study in children, adolescents, and their caregivers and found most participants to estimate carbohydrates within 10-15 grams at each meal. However, this study only assessed knowledge levels for children with type 1 diabetes and their caregivers. Because of the variance between patients, clinicians need a validated tool to assess individual patient

knowledge. The researchers of this study recognize a limitation of their study assessment is the lack of this tool (25).

It is important for clinicians to know at what level patients are able to count carbohydrates, as subjects who use carbohydrate counting may experience more hypoglycemia as compared to subjects using a simple algorithm to adjust insulin (28). Bergenstal et al. (28) notes that "insulin-to-carbohydrate ratios allow flexibility in food choices and enable relatively precise matching of mealtime insulin needs but can seem complex and may be difficult for some patients to implement". Thus, persons using carbohydrate counting to maintain glycemic control must understand the concept well enough to use it safely. In addition, when patients with type 1 diabetes do not count the carbohydrates, it may be related to lack of knowledge (33). In order to assess the skill level and knowledge of patients, clinicians need a validated assessment tool. Murata and colleagues (30) suggest that measuring food intake in patients with diabetes could make nutrition counseling more specific and effective. Similarly, with tools that specifically measure knowledge of carbohydrate counting, health practitioners could more effectively target education according to the patient's needs.

Need for Adequate Measures for use in Research

In the research setting, studies measuring the effectiveness of carbohydrate counting programs often fail to assess baseline knowledge of this skill (2, 7, 18, 26, 28, 34). In the previously mentioned study by Bergenstal et al. (28), researchers found that

controlling glycemia using a simple algorithm called a sliding scale to adjust insulin is as effective as using carbohydrate counting. However, the researchers noted that the simple algorithm group may have learned to keep carbohydrates consistent with each meal or may have had previous knowledge of carbohydrate counting. Absence of an appropriate, validated assessment of baseline knowledge of carbohydrate counting may bias results (28).

In studies that use a quiz or questionnaire to assess carbohydrate counting knowledge, none have been previously validated (27, 33, 35). Other research measures used to assess carbohydrate counting knowledge include using patient logs of blood glucose levels and carbohydrates consumed at meals (7), assessing patient ability to teach carbohydrate counting concepts (7), conducting qualitative interviews (34) and reviewing diet history with a dietitian (18).

Questionnaire Development

A valid, reliable questionnaire that assesses the knowledge of carbohydrate counting, recognition of heart-healthy foods, and label-reading skills in adult patients should be developed. Rattray et al. (36) describes the process of creating questionnaires as a "logical, systematic and structured approach".

Domains included in similar questionnaires are carbohydrate recognition and counting skills; nutrition label reading skills; effect of carbohydrates and insulin on blood glucose levels; and appropriate insulin dosing based on blood glucose level and

carbohydrates consumed (12, 37). Questions should include both positively and negatively worded statements. After development, questions should be submitted for further review to an expert panel (19, 36). Item analysis using a small sample size would help to determine which questions to retain (36). Food logs of the target patient population should be reviewed to create a list of appropriate food items included in the questionnaire (37). To avoid boredom for the test-takers, demographic questions should be placed at the end of the questionnaire (11, 36). Readability of the questionnaire should be at a sixth grade reading level, as assessed by Flesh-Kincaid (37).

Questionnaire Validation

There are several different ways to measure the validity of the questionnaire, including internal and external validity. External validity refers to the extent to which results from a study are generalizable to other populations. Internal validity measures whether or not a tool assesses what it is meant to assess and may include measures of face validity, content validity and criterion-related validity. To validate a new questionnaire, the focus is on measures of internal validity.

The first step in creating a valid questionnaire is to ensure its face validity, which is a basic test to ensure that the questionnaire appears to test what it is meant to test. Face validity can be determined by experts in the field (38, 39). However, face validity is a very basic test of validity and should be followed with an assessment of content validity. Content validity actually measures the extent to which the questionnaire tests

the skill that it is meant to assess (38, 39). A thorough review of literature and meeting with experts on the subject will create good content validity (11, 23, 36, 40). In a tool related to diabetes, experts may include dietitians, diabetologists, certified diabetes educators, endocrinologists, nurses, and psychologists with experience working with patients with diabetes, as well as patients with diabetes (6, 12, 19, 23, 37, 40, 41). The expert panel can conduct the content analysis and create relevant domains that the questionnaire should include (19, 37). For a tool that assesses knowledge of a diet, it is appropriate to administer the questionnaire to nutritionists and diabetes professionals, who should score highly if the questionnaire has good content validity (12).

Criterion-related validity assesses how accurately a questionnaire measures a skill as compared to a standard measure (38). Subjects can complete a second, previously validated questionnaire measuring similar concepts such as CarbQuiz, by Kern et al. (12) and results can be compared using Pearson correlations to assess this type of validity (6, 21, 40). Another way to measure criterion-related validity is to compare scores to predicted behavior. A subject with a high score on a carbohydrate counting knowledge questionnaire is more likely to have a lower HbA_{1c} level (12, 37). Wilcoxon rank-sum tests may be used to evaluate comparisons between scores and other standard measures, such as patient education level, expert assessment of knowledge, type of diabetes and history of diabetes education to further assess criterion-related validity (12, 19, 37, 41). Wilcoxon rank-sum tests are best used for data that are non-parametric; however, Pearson product-moment correlations should be

used for data that are parametric and continuous. Wilcoxon rank-sum tests are less powerful and are more likely to miss a difference between the groups than Pearson product-moment correlations (42). All cases presented are examples of concurrent validity, in which the questionnaire score and standard measure are assessed in the same clinic visit (39).

Questionnaire Reliability

Reliability assesses the repeatability and internal consistency of the questionnaire, making sure that all items within the questionnaire measure a similar concept. Measures of reliability include coefficients of stability, coefficients of equivalence, internal consistency, and split-half tests.

A coefficient of stability measures the ability of a questionnaire to produce similar results over time and is evaluated by test-retest (23, 36, 38, 39, 41, 43, 44). A coefficient of equivalence is found by administering a similar tool to the one being tested, then assessing the correlation between the two (39). The same Pearson's correlation used to establish criterion-related validity between a new questionnaire and the CarbQuiz by Kern et al. (12) can also assess the coefficient of equivalence. Internal consistency measures how well items of the test relate with one another and how well different items on the test measure the same skill. If items are not similar enough, they will not be consistent in measuring the objective; however, if they are too similar questions may be redundant (38, 39, 43). To measure internal consistency in

questionnaires rated on a continuous scale, Cronbach α can identify which questions are not grouped correctly (6, 11, 19, 36, 37, 40, 41). To further assess internal consistency, item-total correlation compares individual item scores to scores of the total exam (36, 43). Questionnaires with few questions should use a corrected item-total correlation and questions within a specific domain should have a similar score to the total exam (36, 40, 41). Finally, a split-half test measures correlation between two theoretically identical halves of the test (39, 43). The authors of PedCarbQuiz (37) measured this by calculating Spearman's correlations between two similar halves of the questionnaire.

Conclusion

Diabetes is a chronic disease that affects many people in the United States. Carbohydrate counting improves glycemic control in individuals with diabetes and is an important factor in management of the disease. People with diabetes should eat a diet that is considered "heart-healthy" because of the increased risk for heart disease. Nutrition label-reading skills are important in both carbohydrate counting and recognition of foods that are heart healthy. Currently there is not an assessment tool that has been validated for use in a clinical setting to assess these skills. To fulfill this need, a valid, reliable questionnaire of appropriate length should be created to use in clinical practice.

Chapter 3: Materials and Methods

Purpose of the Research

The aim of this study was to assess validity and reliability of a short questionnaire named the Heart Healthy Carb Quiz (HHCQ) to measure carbohydrate counting skills, knowledge of heart-healthy foods and nutrition label-reading skills in adults with diabetes. The questionnaire is easy to score and short, so it took little time for patients to complete. The aim of the study was to close the current gap in literature and provide clinicians an effective measure to evaluate patient understanding of diet.

Experimental Design and Analysis of Data

Questionnaire Development. The creation of a new questionnaire, the Heart Healthy Carb Quiz (HHCQ) to assess carbohydrate counting skills and understanding, knowledge of heart-healthy foods, and nutrition label-reading skills was an iterative process with many steps and revisions. First a large pool of questions was developed based on knowledge and application objectives. The knowledge objectives included identification of foods with carbohydrates, knowledge of heart-healthy foods, and nutrition label-reading skills. Application objectives included ability to build a meal with the appropriate amount of carbohydrates and ability to select a heart-healthy food by reading a nutrition label (12, 37). Questions included both positively and negatively worded statements.

After questions in the pool were identified, questions and objectives were taken to an expert panel for review (19, 36). The expert panel consisted of two endocrinologists, two certified diabetes educators, two dietitians who work with patients with diabetes, and one clinical psychologist (6, 12, 19, 23, 37, 40, 41). After meeting with the panel, the questionnaire was refined by eliminating poorly written or irrelevant questions or creating new questions. The dietitians who participated have had experience with the target population and helped identify foods commonly eaten to be included in the questionnaire. The revised questionnaire was submitted a second time to the expert panel for review.

After approximately half of the subjects completed the HHCQ, slight revisions were made to the wording of the questions based on comments and suggestions of the subjects who had completed the original questionnaire. Readability of the final version of the HHCQ is less than a fourth grade reading level, as assessed by Flesh-Kincaid (37).

Aim One: Assessing Validity. To evaluate the HHCQ as a valid measure of carbohydrate counting skills, knowledge of heart-healthy foods, and nutrition label-reading skills in adults with diabetes.

To validate the HHCQ, measures included internal validity, including measures of face validity, content validity and criterion-related validity. To first ensure face validity, the pool of questions was created with the help of a dietitian who works with patients with diabetes and a certified diabetes educator. To ensure content validity, a thorough review of literature was completed and the questionnaire was reviewed at two points in

time by a panel of experts on the subject of diabetes. The expert panel conducted a content analysis and refined the relevant domains that the HHCQ should include (19, 37). All hypotheses were based on concurrent validity, in which the HHCQ score and standard measure were assessed in the same clinic visit (39).

Hypothesis 1. Consistent with a determination of good criterion-validity, the correlation between the HHCQ and CarbQuiz would be greater than 0.3. A positive correlation would indicate that patients who score highly on the CarbQuiz will also score highly on the HHCQ. It does not indicate that one variable causes the other, but rather indicates the association between the two (45).

Hypothesis 2. HHCQ total scores would positively correlate with patient education level, amount of experience with carbohydrate counting as assessed by duration of diabetes, and history of diabetes education. This would again indicate criterion-validity.

Hypothesis 3. Adults with type 1 diabetes would score higher on the HHCQ than adults with type 2 diabetes.

Hypothesis 4. Women will score higher on the HHCQ than men.

Hypothesis 5. HbA_{1c} levels will negatively correlate with HHCQ total scores.

Aim 2: Assessing Reliability. To evaluate the HHCQ as a reliable measure of carbohydrate counting skills, knowledge of heart-healthy foods, and nutrition label-reading skills in adults with diabetes.

Reliability assesses the repeatability and internal consistency of the HHCQ, making sure that all items within the questionnaire measure a similar concept. Measures of reliability include coefficients of stability, coefficients of equivalence, internal consistency, and split-half tests.

Hypothesis 6. Consistent with a determination of good stability, within subject correlations between HHCQ administered at time 1 and time 2 (test-retest) would be at least 0.80.

Hypothesis 7. Cronbach α would score between 0.70-0.90, indicating good internal consistency without repetitive questions (36).

Hypothesis 8. Item-total correlation would be >0.3, indicating that questions measure the same underlying concept (36).

Instrumentation

See Appendices for versions 1 and 2 of the HHCQ, answer key for the HHCQ, baseline demographic form, and 6-week demographic form.

Inclusion and Exclusion Criteria

Subjects were included in the study if they were older than 18 years, had a diagnosis of either type 1 or type 2 diabetes for at least six months, reported use of carbohydrate counting for any reason, and were able to read and write in English at a sixth grade

reading level. Subjects were excluded if they did not self-select foods or required assistance in daily diabetes self-care.

Procedure

Subjects were recruited from the Cray Diabetes Center, the outpatient diabetes center at the University of Kansas Medical Center. In addition, adult patients receiving care from the University of Kansas Medical Center's outpatient pediatric clinic were also recruited. A broadcast e-mail was sent to the hospital and school at KU Medical Center. A member of the research team obtained written, informed consent and administered questionnaires to subjects who met screening criteria. The order of the questionnaires varied between subjects to eliminate potential bias. Total time with each subject was usually between 20 to 30 minutes.

All subjects who completed the HHCQ initially gave permission to be re-contacted to complete the questionnaire a second time. Subjects were randomized and 50% were mailed the HHCQ and a second demographic form about six weeks after filling out the initial questionnaires. The length of six weeks was chosen because knowledge of carbohydrate counting skills, heart-healthy diet, and nutrition label-reading skills were not likely to change during this time. Randomization was batched; after ten people completed the initial HHCQ a random number generator (www.random.org) was used to select subjects who were mailed a second HHCQ and brief demographic data form. Sixteen subjects (29% of all subjects) completed the HHCQ a second time. There were

no significant differences in characteristics between patients who completed the HHCQ a second time compared to subjects who did not.

De-identified demographic data and individual item answers for both the HHCQ and the CarbQuiz were entered into a Microsoft Excel® spreadsheet. A formula was used to calculate total scores for each question, each subscale, and for the entire questionnaire. Subscales relate to the objectives identified that the HHCQ assesses. Question 1 is a subscale representing ability to identify foods with carbohydrates. Question 2 is a subscale identifying participants' ability to build a meal with the appropriate amount of carbohydrates. Question 3 is a subscale that assessed knowledge of heart-healthy foods. Questions 4 through 6 and question 8 are grouped as a subset that identifies nutrition label-reading skills. Question 7 (all three parts) represent a subscale that assesses ability to select a heart-healthy food by reading a nutrition label.

HHCQ items were scored based on an objective answer key developed before the start of the study. See the Appendices for a copy of the answer key used. Briefly, for question 1, subjects were awarded one-quarter point for each correctly circled food and for each food that was correctly left blank. For question 2, carbohydrate grams were added for each food the participant wrote down; the grams for each food were based on the standard carbohydrate grams in each food as listed in the USDA Nutrient Database (46). Question 2 was then scored on a sliding scale based on the total number of grams of carbohydrate in the meal written by the subject; if the meal consisted of 50 to 70 grams, eight points were awarded. If the meal consisted of 40 to 49 grams or 71 to

80 grams, six points were awarded. If the meal consisted of 35 to 39 grams or 81 to 85 grams, four points were awarded. If the meal consisted of 30 to 34 grams or 86 to 90 grams, two points were awarded. For meals consisting of less than 30 grams or more than 90 grams of carbohydrates, no points were awarded for question two. For questions 3 through 6, one point was awarded for each correct answer. Question 7a was worth one point. For both 7b and 7c, participants were awarded one point for each correct answer, which could be any of the following: total fat, saturated fat, *Trans* fat, cholesterol, sodium, or fiber; a total of six points was possible for questions 7b and 7c combined. Similarly, participants could earn one point for each correctly circled answer in question 8 for a total of two points. There are 31 total possible points for the HHCQ.

The CarbQuiz was scored using the same method the original authors used, with each individual question having a dichotomous answer and worth one point. There are 43 possible points on the CarbQuiz.

Statistical analysis

Statistical analysis was completed using SPSS (Somers, NY). Correlations between variables measured on a continuous scale were calculated using a Pearson product-moment correlation; these variables included HHCQ scores versus CarbQuiz scores, HHCQ scores versus A1c values, and HHCQ scores at time 1 versus time 2 (test-retest). A point-biserial correlation was used to test correlations with amount of experience with carbohydrate counting (assessed by determining length of diabetes diagnosis) as this

value was recorded on a continuous scale. A point-biserial correlation is used much like a Pearson product-moment correlation, but is used for analyses involving one dichotomous variable and one continuous variable. In the analyses using point-biserial correlations, a value of at least 0.25 was accepted (47).An analysis of variance (ANOVA) was used to test the difference in HHCQ scores by education level (re-coded into three levels: high school education, some college education, and college or graduate degree) and history of diabetes education (re-coded into four levels: never had education; 1-5 times; 6-10 times; more than 10 times). Differences in HHCQ scores comparing women versus men and people with type 1 diabetes versus type 2 diabetes were tested using an independent sample t-test. Other statistical analyses used to confirm HHCQ reliability included Cronbach α and item-total correlation.

Ethics

This research project was approved by the Human Subjects Committee of the University of Kansas Medical Center. A member of the research team explained the research study to the participants who signed a written consent form before completing any forms.

Electronic records of subject information and data were de-identified before storage on a secure network drive, to which only members of the research team had access. Each subject was given a study-specific identification number so that data

collected could not be identified with a patient name. All paper records were stored in a locked file to which only research team members had access.

Chapter 4: Results

Sample Characteristics

Fifty-eight participants signed a written consent form to participate in the study and data were analyzed for 55 subjects. One subject was unable to complete all questionnaires and was dropped from the study. Another subject completed only half of the HHCQ; her data were also dropped from analysis. A third subject completed the questionnaire with the help of his wife and so was excluded on the basis of the inclusion/exclusion criteria. Twenty-five subjects completed the first version of the HHCQ and 30 subjects completed the second version.

For the final sample, the average age was 41.7 years ± 17.6; 29 participants were women and 26 were men. Most of the sample described themselves as non-Hispanic white (n = 51), with two listing themselves as African-American and two listing themselves as Hispanic white. Most of the subjects indicated that they held at least supplemental private insurance (n = 41); five subjects had Medicare, two subjects had Medicaid, and two indicated that they did not have insurance. The majority of participants had at least some college education (n = 45).

Thirty-six participants had type 1 diabetes and 19 had type 2; average length of duration of diabetes was 14.3 ± 12.3 years. The average HbA_{1c} was higher than the 7.0% recommended by the American Diabetes Association (8.0% ± 2.0%). Most subjects reported monitoring carbohydrate intake by counting either grams (n=33) or 15 gram carbohydrate choices (n=18). Two subjects indicated that they use the plate method to

monitor carbohydrate intake and two subjects selected “other,” listing “none” and “weigh food” as the method used. Most (n = 44) of the participants indicated that at least one of the reasons that they use carbohydrate counting is to adjust insulin doses. Other reasons for using carbohydrate counting included weight loss, consistent carbohydrate diet, doctor prescribed, or an “other” category in which patients wrote that they used it because “it is easy” or “to manage their diabetes.” Twenty-four of the participants included in the sample used an insulin pump, and 42 used short-acting insulin. Average time to complete the HHCQ was almost eight minutes (7:59 ± 3:36); average time to complete the CarbQuiz was about six and a half minutes (6:37 ± 2:55). Many patients had secondary diagnoses related to diabetes. These included heart disease (n = 9), hypertension (n = 19), atherosclerosis (n = 4), high cholesterol (n = 14), retinopathy (n = 3), kidney disease (n = 1), neuropathy (n = 10), or gastroparesis (n = 2). See Table 1 for study population characteristics.

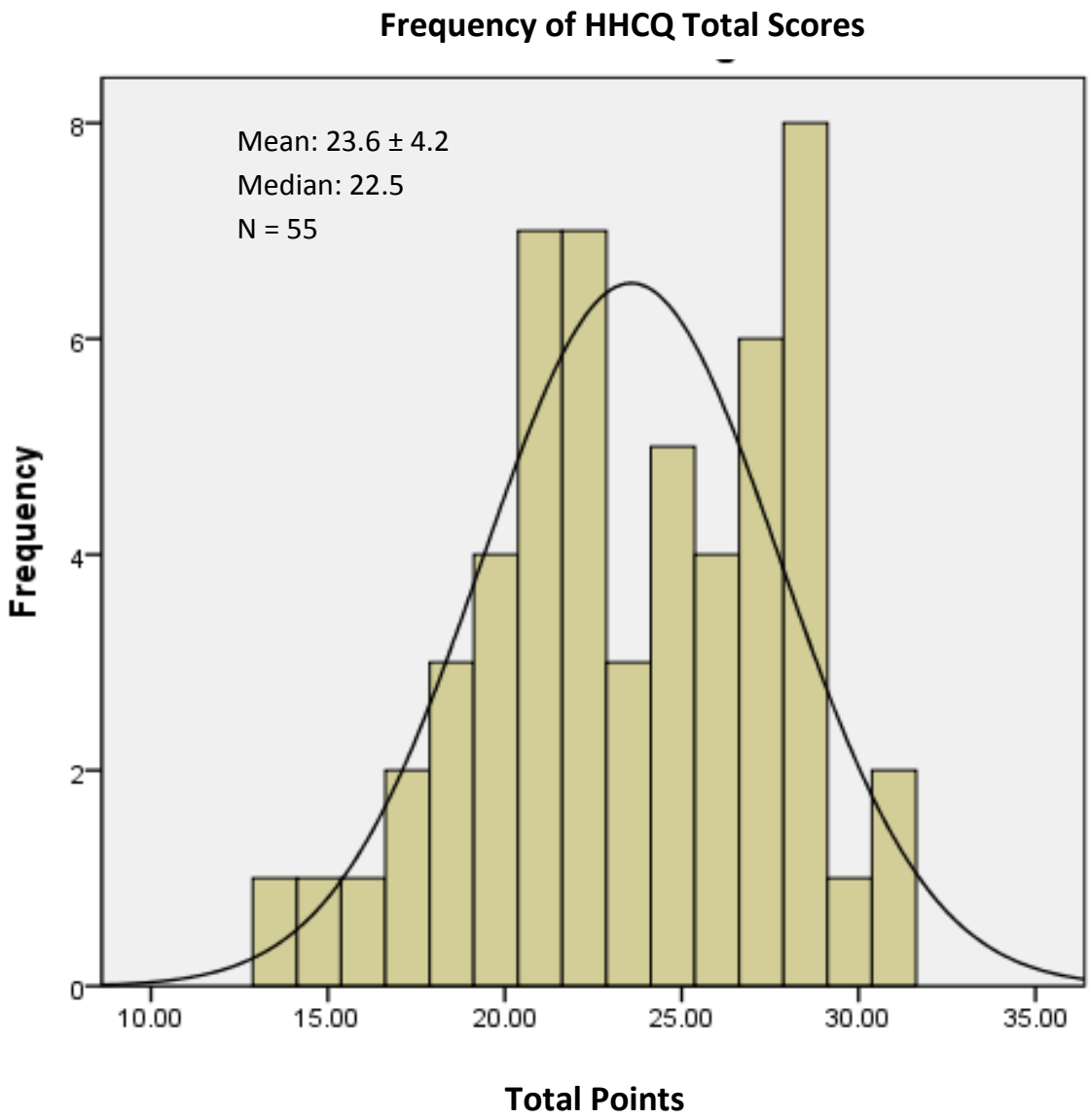
Table 1: Study Population Characteristics

Characteristic	N	Percent	Characteristic	N	Percent
Male	26	47%	**Secondary Diagnosis:**		
Female	29	53%	**Heart Disease**	9	16%
			Hypertension	19	35%
			Atherosclerosis	4	7%
			High Cholesterol	14	26%
			Retinopathy	3	6%
			Kidney Disease	1	2%
			Neuropathy	10	18%
			Other	9	16%
Type 1 Diabetes	36	66%	**Not using insulin pump**	31	56%
Type 2 Diabetes	19	35%	**Using insulin pump**	24	44%
Race:			**Not using short-acting Insulin**	13	24%
White, non-Hispanic	51	93%	**Using short-acting insulin**	42	76%
African-American	2	4%			
Hispanic White	2	4%			
Insurance:			**Education:**		
Private	40	73%	**Some High School**	3	6%
Medicare	4	7%	**High School Graduate**	7	13%
Medicaid	2	4%	**Some College**	21	29%
Private and Medicare	1	2%	**Associate's Degree**	2	4%
None	2	4%	**College Degree**	16	29%
Missing Data	6	11%	**Graduate Degree**	6	11%

HHCQ Scores

There are 31 total points possible for the HHCQ; the mean score in this sample was 23.6 ± 4.2 and the median was 23.6. Scores fell along a normal distribution, but the curve was bimodal. Figure 1 depicts a histogram of HHCQ total scores.

Figure 1: Frequency of HHCQ Total Scores



There was no significant difference between patients who scored on either side of the median in terms of age, type of diabetes, or sex. Of note in question 1, there were more participants who incorrectly failed to circle dry beans and green peas than subjects who circled these foods and scored correctly. Thirty-six participants scored at least six points on question 2 (eight points possible for this question) and 13 subjects scored zero points. Most participants earned all three points on question 3 (three points possible) (n = 50) and no participants scored less than two points on this question. This may indicate that question 3 is too easy and thus not a valid measure of heart-healthy diet knowledge. Questions 7b and 7c were very similar in their wording and how subjects scored on the items (Table 4). Out of 55 participants, 36 earned the same amount of points on both questions, and a paired samples test showed no significant difference in mean scores for these questions (2.2 ± 1.0 versus 2.3 ± 1.1, t(59) = -1.27, p = 0.21). See Table 2 for question 7b versus 7c and a comparison of the two versions of the HHCQ.

Table 2: Non-significant Comparisons of the HHCQ

Comparison	Mean ± SD	Result	p value
HHCQ Version 1 Total Score	23.8 ± 4.7	t(53)=0.36	0.72
HHCQ Version 2 Total Score	23.4 ± 3.8		
HHCQ 7b Score	2.2 ± 1.0	t(59)=-1.27	0.21
HHCQ 7c Score	2.3 ± 1.1		

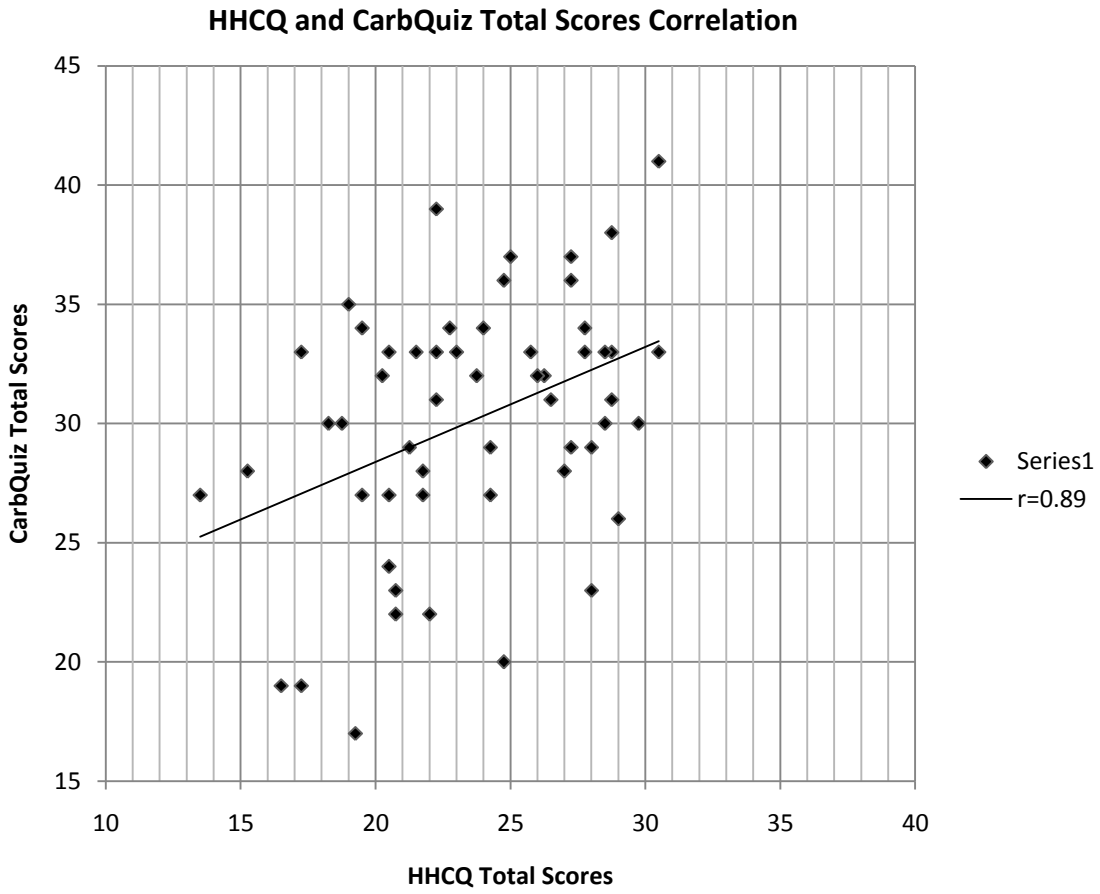
Forty-five participants scored either 4 or 5 points (total possible is 5 points) for the nutrition label-reading subscale (questions 4-6 and question 8. This again may indicate that these questions are too easy.

There was no difference in HHCQ total scores for the first version and the second version of the HHCQ as assessed by an independent sample t-test [23.8 ± 4.7 versus 23.4 ± 3.8, t (53) = 0.36, p = 0.72] (Table 2). Because there was no difference between the two versions of the HHCQ, all HHCQ scores were included in tests for reliability and validity.

Aim One: Assessing Validity

Consistent with hypothesis #1, HHCQ total scores correlated with the CarbQuiz total scores (r= 0.39, p= 0.003). There is a moderate positive association between the two questionnaires.(45). Figure 2 shows a visual representation of this association.

Figure 2: HHCQ and CarbQuiz Total Scores Correlation



Contrary to hypothesis #2, other measures of criterion validity were not significant for the HHCQ, as shown in Table 3.

Table 3: HHCQ Validity Scores

Predictor Variable	N	HHCQ total score mean ± SD	Statistics for HHCQ	CarbQuiz total score mean ± SD	Statistics for CarbQuiz
High School Education	10	23.4 ± 4.6	F(2,52)=1.44	30.0 ± 4.1	F(2,52)=0.41
Some College Education	23	22.6 ± 3.8	p=0.25	29.4 ± 5.2	p=0.67
College or Graduate Degree	22	24.7 ± 4.3		30.9 ± 5.9	
Total	55	23.6 ± 4.2		30.1 ± 5.2	
Not using short-acting insulin	13	23.5 ±4.0	t(53)=-0.05	28.1 ± 6.0	t(53)=-1.62
			p=0.96		p=0.11
Using short-acting insulin	42	23.6 ± 4.3		30.7 ± 4.9	
Reason for Carbohydrate Counting:			F(6,48)=1.23		
			p=0.31		
Weight Loss	2	24.8 ± 6.0			
Consistent Carbohydrate Diet	2	20.9 ± 1.9			
Adjust Insulin Dose	39	24.1 ± 4.0			
Doctor Prescribed	3	19.6 ± 6.3			
Other	1	.			
Weight Loss + Insulin Adjustment	5	23.0 ± 4.5			
Weight Loss + Other	3	23.6 ± 4.2			
Lifetime Diabetes Education:			F(3,51)=0.59		
			P=0.62		
None	1	21.8			
1-5 times	15	24.8 ± 3.8			
6-10 times	14	23.1 ± 4.3			
10 or more	25	23.2 ± 4.5			

Diabetes Education within Last Two Years:			F(3,51)=1.41 p=0.25		
None	21	24.0 ± 4.3			
1-5 times	18	24.6 ± 3.9			
6-10 times	12	21.6 ±4.2			
10 or more	4	22.7 ± 5.1			
Type 1 Diabetes	36	24.1 ±4.3	t(53)=1.18	31.3 ± 5.2	t(53)=2.50
Type 2 Diabetes	19	22.6 ± 4.1	p=0.25	27.8 ± 4.5	p=0.02
Male	26	23.9 ± 4.2	t(53)=0.53	30.5 ± 4.6	t(53)=0.52
Female	29	23.3 ± 4.2	p=0.60	29.8 ± 5.8	p=0.61
Length of Diabetes Duration	53		r=0.11 p=0.42		r=-0.14 p=0.33
HbA_{1c}	54		r=-0.15 p=0.27		r=-0.23 p=0.09
Method of Carbohydrate Counting:			F(3,51)=1.88 p=0.15		
Grams	33	24.2 ± 4.1			
Plate Method	2	19.6 ± 3.4			
15-gram Carbohydrate Choices	18	23.5 ± 4.2			
Other	2	18.5 ± 2.8			
Method of Carbohydrate Counting:			F(1,49)=0.36 p=0.55		F(1,49)=4.89 p=0.03
Grams	33	24.2 ± 4.1		31.5 ± 4.8	
15-gram Carbohydrate Choices	18	23.5 ± 4.2		28.3 ± 4.9	

There were no significant differences in total scores for the HHCQ nor the CarbQuiz based on level of schooling [F (2, 52) = 1.44, p = 0.25 and F (2, 52) = 0.41, p = 0.67, respectively]. Neither the HHCQ nor the CarbQuiz total scores were significantly associated with length of diabetes, as measured by a Pearson Product-Moment Correlation (r = 0.11, p = 0.42; r = -0.14, p = 0.33, HHCQ and CarbQuiz, respectively). An Analysis of Variance showed no significant associations between participants' HHCQ total score and history of diabetes education, either for total education in the person's lifetime or education within the last two years [F (3, 51) = 0.59, p = 0.62 and F (3, 51) = 1.41, p = 0.25, respectively].

Contrary to hypotheses #3, there was no difference between the mean scores for the HHCQ for subjects with type 1 diabetes (24.1 ± 4.3) versus subjects with type 2 diabetes (22.7 ± 4.1) (t (53) = 1.18, p = 0.25). However, subjects with type 1 diabetes scored significantly higher (31.3 ± 5.2) than subjects with type 2 diabetes (27.3 ± 4.5) on the CarbQuiz [t (53) = 2.50, p = 0.02]. Although hypothesis #4 stated that women would do better than men on the HHCQ, there was no significant difference in total scores for the HHCQ (men = 23.9 ± 4.2; women = 23.3 ± 4.2) nor the CarbQuiz (men = 30.5 ± 4.6; women = 29.8 ± 5.8) [t (53) = 0.53, p = 0.60; t (53) = 0.52, p = 0.60, respectively].

Contrary to hypothesis #5, there was no association between HbA_{1c} values and either the HHCQ total scores (r= -0.15, p = 0.27) nor CarbQuiz total scores (r = -0.23, p = 0.09). There were also no differences in total scores based on subjects' use of short-acting insulin for either the HHCQ [t (53) = -0.05, p = 0.96] nor the CarbQuiz [t (53) = -

1.62 p = 0.11] (Table 2). An Analysis of Variance showed no association between total HHCQ scores and reasons listed for counting carbohydrates [F(6,48)=1.23, p = 0.31].

There were no significant differences between HHCQ scores based on the method of monitoring carbohydrate intake when comparing counting grams (24.2 ± 4.1) to carbohydrate choices (23.5 ± 4.2) [F (1, 49) =0.36, p = 0.55]. However, participants reporting that they count grams scored significantly higher on the CarbQuiz (31.4 ± 4.8) than participants counting carbohydrate choices (28.3 ± 5.0) [F (1, 49) =4.89, p = 0.03], indicating that the CarbQuiz may be a better measure to use if the patient reports counting carbohydrate grams.

The only test to validate the heart-healthy portion of the HHCQ did not produce a significant result, as shown in Table 4.

Table 4: Heart-Healthy Subscale Validity Scores

Predictor Variable	N	Mean ± Standard Deviation	Result	P value
No heart-healthy or weight loss diet education	35	8.9 ± 1.6	t(54)=1.30	0.20
Some Heart-healthy or weight loss diet education	21	8.1 ± 2.5		
No heart-healthy or weight loss diet education within 2 years	43	8.8 ± 1.7	t(54)=1.5	0.13
Some heart-healthy or weight loss diet education within 2 years	13	7.8 ± 2.8		

There were no differences in mean scores on the heart-healthy subscale of the HHCQ (questions 3 and 7) based on subjects' history of heart-healthy or diet education. This was tested using a series of independent sample t-tests comparing groups for education within the last 2 years (yes or no) and education reported in patients' lifetime (yes or no). Analyses revealed no significant differences in either group [Lifetime education: t (54) = 1.3, p = 0.20); education in last 2 years: t (54) = 1.5, p = 0.13].

Aim Two: Assessing Reliability

Reliability of the HHCQ was assessed by testing its stability over time and its internal consistency. Results are shown in Table 5.

Table 5: HHCQ Reliability Statistics

Reliability Test	Mean ± Standard Deviation	Result	P Value
Cronbach alpha		0.695	
Test-retest		0.74	0.001
Inter-item Total Correlation		0.45	

Consistent with hypothesis #6 the HHCQ demonstrated good stability in the test-retest measure, with the Pearson product-moment correlation of 0.74 (p = 0.001) (initial hypothesis >0.8). Cronbach α was 0.70, indicating good internal consistency without repetitive questions; hypothesis #7 stated that this score would be between 0.70-0.90.

All subscale inter-item correlations were greater than hypothesis #8 value of 0.3 (p's< 0.05) as shown in Table 6. Inter-item total correlation was 0.45 (Table 4).

Table 6: Inter-item Total Correlations

	HHCQ #2 Score	HHCQ #3 Score	HHCQ #4-6, 8 Score	HHCQ #7 Score	HHCQ Total Score
HHCQ #1 Score	r=0.13 p=0.31	r=0.41 p=0.001	r=0.49 p=0.000	r=0.43 p=0.001	r=0.60 p=0.000
HHCQ #2 Score		r=0.38 p=0.003	r=0.312 p=0.02	r=0.33 p=0.01	r=0.73 p=0.000
HHCQ #3 Score			r=0.73 p=0.000	r=0.72 p=0.000	r=0.79 p=0.000
HHCQ #4-6, 8 Score				r=0.56 p=0.000	r=0.75 p=0.000
HHCQ #7 Score					r=0.79 p=0.000

Chapter 5: Discussion

Interpretation of Study Results

Study Variables. Initial hypothesized variables included the CarbQuiz total score, education level, amount of experience with carbohydrate counting, history of diabetes education, diabetes diagnosis, sex, and HbA_{1c} values as potential correlates of HHCQ total scores. All of these were included in the analyses as well as some additional variables based on observations while administering the questionnaires. The additional variables included method of monitoring carbohydrate intake (counting grams versus counting 15-gram carbohydrate choices), use of short-acting insulin, reason for counting carbohydrates, and heart-healthy or weight-loss diet education.

Aim One: Assessing Validity. Total scores for the HHCQ were moderately positively associated with total scores for the CarbQuiz, suggesting the HHCQ is a valid tool to measure carbohydrate counting ability in adults with diabetes. However, none of the other tests for criterion validity were found to be significant.

Traditionally, women have been responsible for grocery shopping and preparing meals; because of this it was anticipated that women would have a heightened awareness of carbohydrate content in foods. The data did not support this hypothesis. In addition, another hypothesis was that people with type 1 diabetes would score higher than people with type 2 diabetes, but there was no difference in HHCQ scores based on diagnosis. This may be related to the fact that most of the sample indicated that they monitor carbohydrate intake to adjust insulin dose. Also there were almost twice as

many subjects with type 1 diabetes as subjects with type 2 diabetes. When recruiting subjects, most patients with type 2 diabetes who were seen at the clinic did not use carbohydrate counting; those that did use carbohydrate counting were more likely to be taking short-acting insulin than the general patient population with type 2 diabetes. In contrast, subjects with type 1 diabetes scored significantly higher than subjects with type 2 diabetes on the CarbQuiz. This may indicate that the CarbQuiz would be a better tool to use if the patient has type 1 diabetes, but the HHCQ measures both subsets equally. Interestingly, the initial validation of the CarbQuiz included mostly patients with type 2 diabetes (121 out of 132 subjects), whereas the current study included more patients with type 1 diabetes (36 out of 55).

There were no significant differences between HHCQ scores based on the method of monitoring carbohydrate intake when comparing counting grams to counting carbohydrate choices, but participants counting grams scored significantly higher on the CarbQuiz than participants counting carbohydrate choices. This may indicate that the CarbQuiz is a better measure to use if the patient reports counting carbohydrate grams. However, in practice the CarbQuiz is designed for patients who count carbohydrate choices. One subset of questions only lists possible answers in carbohydrate choices, while another question specifically asks about the number of grams in a carbohydrate choice. Thus, it is not entirely clear how experience counting in grams conferred an advantage to patients who participated in this study. For patients who have never used

or heard of carbohydrate choices, these questions are irrelevant at best; at worst they will not correctly represent the patient's knowledge of carbohydrate counting.

The lack of correlation between diabetes education and HHCQ total scores was also surprising, but may be explained by the methods used to collect data regarding diabetes education. Diabetes education was self-reported and no follow-up with patient comments was completed. Part of the reason for this was feasibility; there were not have life-long or two-year education records for many of the patients. The wording on the questionnaire may also have been confusing to patients; just because patients had diabetes education does not necessarily mean that they had carbohydrate counting training. In addition, patients gain knowledge in a variety of ways; simply because they did not have formal training may not indicate their carbohydrate counting abilities. Similarly, no significant differences were found in scores for the heart-healthy subset of questions (questions 3 and 7) on the HHCQ. This may have been because the methods of data collection regarding heart-healthy diet education were poor. The question assessing heart-healthy knowledge included both "heart-healthy and weight loss education" in the sentence. Because weight loss diets are not always comparable with heart-healthy diets, this is a limitation of the question.

Aim Two: Assessing Reliability. The internal consistency of the HHCQ was nearly within range of the hypothesized Cronbach α, indicating the HHCQ has good internal consistency without repetitive questions (36). The HHCQ is a relatively short questionnaire that analyzes several objectives. Overall the HHCQ has questions that are

similar enough to be relevant to each other but does not ask the same question twice. Test-retest reliability was slightly lower than the hypothesized value ($r = 0.74$, $p = 0.001$ versus hypothesized value of >0.8), but overall still indicates that the HHCQ has good stability over time.

Limitations of the Study

Sample Characteristics. A convenience sample was used to select participants for the study. Because the sample was not random this presents a potential for bias in the sample. Other limitations include the inability of this questionnaire to be used in populations who do not speak English or whose diet is different than that of the study population. Patients with other types of diabetes, such as Cystic Fibrosis-Related Diabetes or gestational diabetes were excluded from the study; this somewhat limits the generalizability of the results, although the HHCQ is still valid for a wide range of patients.

One strength of the study was the inclusion of both men and women who had either type 1 or type 2 diabetes and the inclusion of participants from a wide age range (41.7 ± 17.6 years), increasing the generalizability of the results. A specific strength of the second version of the HHCQ is its reading level of 3.2, as assessed by Flesch-Kincaid, which may make it appropriate for use in a wide population of adult patients with diabetes. The CarbQuiz had a reading level of 4.9, assessed by Flesh-Kincaid.

Measurement Characteristics. Potential limitations in the procedure include weakness in the test-retest reliability measure; because the questionnaire was mailed to subjects for the second test, some subjects were lost to follow-up and there is a possibility that subjects used outside resources to answer questions. However, it is unlikely that subjects took extra time to look up answers to complete the questionnaire. In addition, if subjects had received additional education between first and second test times, this may bias the results. To account for this, participants filled out a second demographic form to measure further education, but this only assessed formal education.

There were limits in the way that data were collected for the amount of diabetes education. A better indicator of carbohydrate counting ability would have been to have a professional assess the knowledge of each participant; due to time and personnel constraints this was not possible for the present study. The only direct measure to assess whether the HHCQ was valid for measuring knowledge of a heart-healthy diet did not produce significant results. Knowledge and ability to apply heart-healthy knowledge would be better assessed by a professional interviewing the participant.

Applications

The HHCQ is a valid, reliable tool that can be used in either the clinical or research setting. It is particularly attractive because of the short time that it takes to complete the questionnaire. Patients would be able to complete the HHCQ while

waiting to be checked in to see the provider, then the provider could use the information to direct the conversation with the patient. In addition, more information can be gleaned from the HHCQ than the total score alone. Educators could walk through the questionnaire with patients, having them explain why they selected the answers they did.

Researchers could use the HHCQ to assess carbohydrate counting skills and heart-healthy knowledge at the start of the study to account for variations in patient knowledge that could potentially affect blood sugar control. The HHCQ may also be a useful tool for assessing the effectiveness of new education programs. However, the HHCQ has not been formally tested for this use.

Future Directions

The HHCQ may be better validated by comparing total scores to a professional's analysis of the patients' carbohydrate counting and heart-healthy diet knowledge. Scores of the HHCQ could also be compared to 24-hour recalls to compare how knowledge translates into action. To assess its sensitivity, the HHCQ could be administered pre- and post-education to determine if the HHCQ is sensitive to changes in patients' carbohydrate counting knowledge. The HHCQ could be computerized so that the measure could be easily scored and assimilated into the electronic medical record.

In addition to new ways to assess validity, future directions include changes to the HHCQ. It may be helpful to reduce the reading level further by including pictures of

foods in place of words. A focus group including a subset of patients from the original study could help conduct a cognitive review of the HHCQ to understand qualitatively how the measure reads. By understanding this some questions may be re-worded to make it a more accurate assessment. Question 7c will be dropped from the second version of the HHCQ, as it scored very similarly to question 7b. This will serve to shorten the length of time it takes to complete the questionnaire and eliminate a repetitive question.

Conclusion

The aim of this study was to assess validation and reliability of the HHCQ to measure carbohydrate counting knowledge and skills, knowledge of heart-healthy foods, and nutrition-label reading skills. The creation of a valid, reliable questionnaire that takes little time to complete will be very useful in a clinical setting. Patients often misestimate their understanding of carbohydrate counting, foods included in a healthy diet, and nutrition labels. The ability to quickly and easily assess these skills will allow physicians, diabetes educators, and dietitians to tailor the conversation to what the patient needs. This will maximize the efficiency of the education session, so that both the patient and provider are satisfied by the interaction. The results support the validity and reliability of the HHCQ, which will have immediate and direct effects in day-to-day practice in the clinical setting.

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APPENDIX A

Initial Question Pool

An appropriate diet for diabetes:

A. Contains no sugar
B. Is low in carbohydrates
C. Is a healthy diet for most people
D. Is high in carbohydrates

What would be most appropriate to eat first if your blood sugar is 45?

A. 2% Milk
B. Orange juice
c. Diet Soda
D. Handful of raisins and peanuts

Circle the foods that contain carbohydrates (> 5 g/serving):

Ground beef	Black beans	Guacamole	Birthday Cake
Regular Soda	Unsweetened Fruit Juice	Corn	Cheddar Cheese
Bacon	Diet Soda	Milk	Olive Oil
Almonds	Unsweetened Corn Flakes	Celery	Doritos

Choose foods for breakfast that are heart-healthy, so that the meal contains 60 grams of carbohydrates (4 carbohydrate choices)

1 Pancake	1 Slice Toast	1 Fried Egg	½ cup oatmeal
2 Tbsp Regular Syrup	1 c. Frosted Mini Wheats	1 oz. almonds	1 c. skim milk
12 oz. black coffee	2 Tbsp. cream	2 Eggs, scrambled	2 slices bacon
2 sausage links	2 Tbsp. sugar-free syrup	1 slice French Toast	1 c. 2% milk
½ cup fresh strawberries	2 Tbsp. peanut butter	½ cup hashbrowns	½ bagel
2 Tbsp cream cheese	Glazed Krispy Kreme Donut	1 c. Frosted Flakes	1 c. juice
Medium apple	½ c. orange juice	Waffle	Grits
Biscuit	Gravy	Ham slice	Cinnamon roll

Choose foods for a meal that is heart-healthy and contains 60 grams of carbohydrates (4 carbohydrate choices)

1 cup whole-grain pasta	½ cup broccoli	½ cup marinara	1 c. black bean
2/3 cup brown rice	1 cup skim milk	1 cup 2% milk	4 oz grilled salmon
½ cup green peas	½ cup zucchini	1 6-inch tortilla	Can of regular soda
3 oz grilled chicken breast	1 slice cheese pizza	1 cup grapes	½ cup baked beans
1 slice 100% whole wheat bread	8 oz. T-bone steak	Soft beef taco	½ cup potatoes
1 cup spinach salad	½ cup blueberries	½ cup French Fries	1/3 lb. hamburger on bun
2 Tbsp Italian vinaigrette	2 Tbsp croutons	1 oz. Feta cheese	2 Tbsp Ranch dressing

Circle the foods that contain 15 grams of carbohydrate or represent 1 carbohydrate choice:

Medium orange	1 c. pasta	3 oz. chicken	1/3 c. Mac & Cheese
1 hamburger bun	1/3 c. rice	Medium banana	1/3 lb. hamburger patty
Large baked potato	2 c. raw spinach1	6-inch flour tortilla	2 Tbsp. peanut butter
8 oz. orange juice	½ cup green beans	½ cup pasta	½ medium banana

Circle the foods that contain less than 5 grams of carbohydrate:

Large raw carrot	½ cup green peas	1 can diet soda	½ cup unsweetened fruit juice
1 oz turkey meat	1 cup skim milk	6 oz. pork chop	1 slice 100% whole wheat bread
1 oz Mozzarella cheese	½ cup strawberries	½ cup black beans	½ cup corn

Do you adjust your insulin according to your blood sugar and amount of carbohydrates that you plan to eat?

If yes, please answer the following:

What is your insulin sensitivity factor? _____

What is your insulin-to-carbohydrate ratio? _____

If your blood sugar is 250 before lunch and you plan to eat 75 g of carbohydrate, how much insulin should you take? _____

Circle the food that is the most heart-healthy of each group

A.	Refried beans	Black beans	Baked Beans
B.	Olive Oil	Margarine	Butter
C.	Multigrain bread	Enriched white bread	100% Whole grain wheat bread
D.	90% lean ground beef	80% lean ground turkey	85/15 ground beef

Which types of fats raise your "bad" cholesterol?

Trans Fats
Saturated fats
Monounsaturated fats
Poly-unsaturated fats
Omega-3 Fatty Acids
Omega-6 Fatty Acids

Which types of fats raise your "good" cholesterol?

Trans Fats
Saturated fats
Monounsaturated fats
Poly-unsaturated fats
Omega-3 Fatty Acids
Omega-6 Fatty Acids

Circle the "starchy" vegetables:

Green Beans	Corn	Tomatoes	Carrots	Green Peas
Potatoes	Radishes	Cucumbers	Zucchini	Bell Peppers

For the following questions, refer to the Nutrition Facts label on the left:

Nutrition Facts	
Serving Size ¼ cup dry (46g)	
Servings Per Container 7.5	
Amount Per Serving	
Calories 172	Calories from Fat 25
	% Daily Value
Total Fat 2.8 g	**4%**
Saturated Fat 0 g	**0%**
Trans Fat 0 g	**0%**
Cholesterol 0 mg	**0%**
Sodium 1 mg	**0%**
Carbohydrate 31 g	**10%**
Dietary Fiber 3 g	**13%**
Sugars 3 g	
Protein 6 g	
Vitamin A 0%	Vitamin C 0%
Calcium 0%	Phosphorus 23%
Iron 12%	Riboflavin 50%

Nutrition Facts	
Serving Size 1 cup (56g)	
Servings Per Container about 4	
Amount Per Serving	
Calories 210	Calories from Fat 10
	% Daily Value
Total Fat 1 g	**2%**
Saturated Fat 0 g	**0%**
Trans Fat 0 g	**0%**
Cholesterol 0 mg	**0%**
Sodium 350 mg	**15%**
Carbohydrate 45 g	**15%**
Dietary Fiber 7 g	**26%**
Sugars 18 g	
Protein 4 g	
Vitamin A 15%	Vitamin C 10%
Calcium 4%	Phosphorus 20%
Iron 25%	Riboflavin 25%

1. How many calories would you eat if you consumed this entire package? _____

2. How many grams of carbohydrates are in one cup (dry) of this product? _____

3. Would you consider this to be a heart-healthy food item?

a. Yes
b. No
c. I don't know

4. When looking at a food label, what is the first thing you should look for?

a. Sugar
b. Protein
c. Calcium
d. Serving Size

5. True or False: If a food claims that it is "low-fat," it is okay to eat the entire package.

6. What is the serving size for this food?

_____

APPENDIX B

Baseline Demographic Form

Last Name:_____ **First Name:** _____ **MI:** ____

Address:_____ **City:** _____ **State:** ____ **Zip Code:** _____

Date of Birth: _____ **Sex:** _____ **Today's Date:** _____

Diabetes Diagnosis (circle one): Type 1 Type 2 **Date of diagnosis:** _____

Race/Ethnicity: Caucasian/white Black/African-American

Hispanic/white Hispanic/black Other:_____

Health Insurance: Private Medicaid None

Highest education completed (circle one):

Some High School Some College Associate's Degree

High School Graduate or GED Bachelor's Degree Graduate Degree

Most recent HbA1c: _____ **Date of HbA1c:** _____

Do you use carbohydrate counting on a regular basis? Yes No

What is your reason for using carbohydrate counting? (circle all reasons)

Weight Loss/Maintenance Consistent Carb Diet

Use to Adjust Insulin Dose Doctor prescribed Other: _____

What method do you use to count carbohydrates? (circle one)

Count Grams Exchange System Plate Method

Count 15g Carb Choices Count 10g Carb Choices Other: _____

Have you ever received one-on-one diabetes education? Yes No

If yes, please answer the following questions:

How many times have you seen a dietitian in relation to your diabetes in your life?

1-2 times 3-5 times

6-10 times More than 10 times

How many times have you seen a CDE (Certified Diabetes Educator) in your life?

1-2 times 3-5 times

6-10 times More than 10 times

How many times have you seen a dietitian in relation to your diabetes in the past two years?

1-2 times 3-5 times

6-10 times More than 10 times

I have not seen a dietitian within the last two years

How many times have you seen a CDE (Certified Diabetes Educator) in the past two years?

1-2 times 3-5 times

6-10 times More than 10 times

I have not seen a CDE within the last two years

Have you ever attended a diabetes education class? Yes No

If yes, please answer the following questions:

How many times have you attended a diabetes education class in your life?

1-2 times 3-5 times

6-10 times More than 10 times

How many times have you attended a diabetes education class in the past two years?

1-2 times 3-5 times

6-10 times More than 10 times

I have not attended a diabetes education class within the last two years

Have you ever received carbohydrate counting education? Yes No

If yes, please answer the following questions:

How many times have you received carbohydrate counting education in your life?

1-2 times
3-5 times
6-10 times
More than 10 times

How many times have you received carbohydrate counting education in the past two years?

1-2 times
3-5 times
6-10 times
More than 10 times
I have not received carbohydrate counting education within the last two years

Have you ever received heart-healthy or weight loss diet education? Yes No

If yes, please answer the following questions:

How many times have you received heart-healthy or weight loss diet education in your life?

1-2 times
3-5 times
6-10 times
More than 10 times

How many times have you received heart-healthy or weight loss diet education in the past two years?

1-2 times
3-5 times
6-10 times
More than 10 times
I have not received carbohydrate counting education within the last two years

Which other health conditions have you been diagnosed with?

Heart Disease (any kind) High Blood Pressure Atherosclerosis

High Cholesterol High LDL “Bad” Cholesterol Low HDL “Good” Cholesterol

Retinopathy Kidney Disease Neuropathy

Other: _____

Please list the medications you are currently taking related to your diabetes:

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

APPENDIX C

6-Week Demographic Form

Last Name:_____ **First Name:** _____ **Today's Date:**_____

Most recent HbA1c: _____ **Date of HbA1c:** _____

Have you ever received one-on-one diabetes education in the past six weeks? Yes No
If yes, please answer the following questions:

How many times have you seen a dietitian in relation to your diabetes in the past six weeks?

_____ times

How many times have you seen a CDE (Certified Diabetes Educator) in the past six weeks?

_____ times

Have you attended a diabetes education class in the past six weeks? Yes No

If yes, how many times have you attended a diabetes education class in the past six weeks?

_____ times

Have you received carbohydrate counting education in the past six weeks? Yes No

If yes, how many times have you received carbohydrate counting education in the past six weeks?

_____ times

Have you received heart-healthy or weight loss diet education in the past six weeks? Yes No

If yes, how many times have you received heart-healthy or weight loss diet education in the past six weeks?

_____ times

APPENDIX D

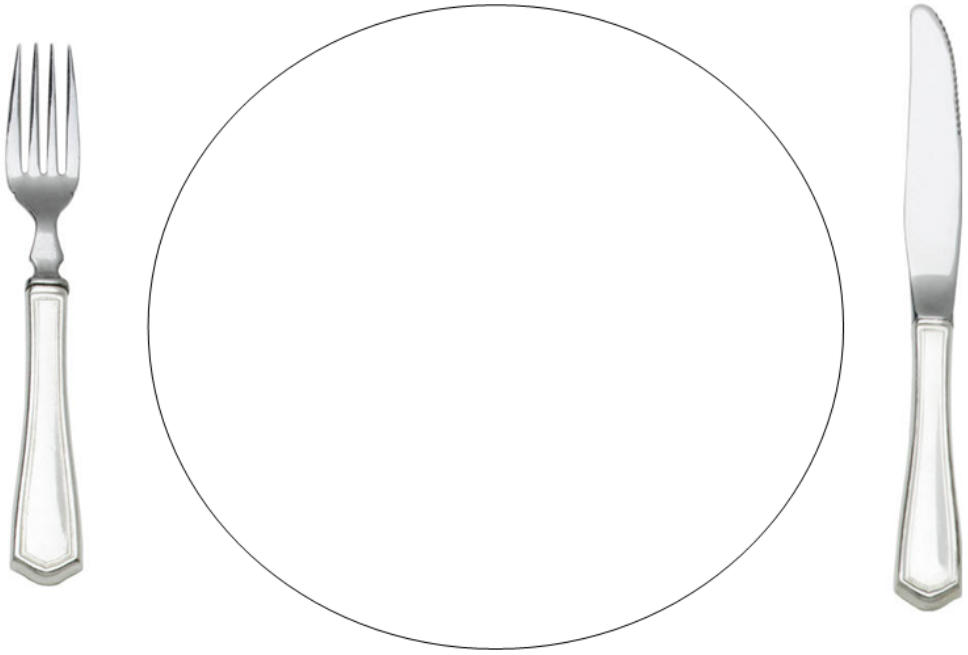
Heart-Healthy Carb Quiz Version 1

Heart Healthy Carb Quiz Subject #:_____

1 cup cooked dry beans	1 cup noodles	½ cup carrots	1/3 cup white rice
½ cup spaghetti sauce	1 cup 2% milk	4 oz grilled salmon	1 cup fruit juice
2-inch chocolate chip cookie	½ cup green peas	Can of regular soda	Can of diet soda
3 oz grilled chicken breast	1 slice cheese pizza	1 cup canned fruit	2 Tbsp. Peanut butter
1 slice 100% whole wheat bread	8 oz. T-bone steak	Taco Bell soft taco	½ cup corn
Medium French Fries	1 cup tossed salad	Medium apple	McDonald's Big Mac
1 packet salad dressing	String Cheese	1 oz. bag Doritos	Deli turkey sandwich
6-inch beef tostado	½ cup ice cream	Hot dog on bun	Baked potato

1. Circle the foods in the box that contain at least 1 carbohydrate serving (15 grams carbs).

2. Choose foods from the box to make a meal that has 60 grams of carbohydrates (4 carb choices). Write the foods in the plate below:



3. Circle the food that is the most heart-healthy of each group:

Group 1:	Group 2:	Group 3:
A. Olive Oil	A. White hamburger bun	A. Pulled pork
B. Margarine	B. Enriched white bread	B. T-bone steak
C. Butter	C. 100% Whole wheat bread	C. Grilled Salmon

For the rest of the questions, use the Nutrition Facts labels on the left:

Label A:

Nutrition Facts	
Serving Size 1 cup (56g)	
Servings Per Container about 4	
Amount Per Serving	
Calories 210	Calories from Fat 10
	% Daily Value
Total Fat 1 g	**2%**
Saturated Fat 0 g	**0%**
Trans Fat 0 g	
Cholesterol 0 mg	**0%**
Sodium 115 mg	**5%**
Total Carbohydrate 45 g	**15%**
Dietary Fiber 7 g	**26%**
Sugars 18 g	
Protein 4 g	
Vitamin A 15%	Vitamin C 10%
Calcium 4%	Iron 25%

Label B:

Nutrition Facts	
Serving Size ½ sandwich(108g)	
Servings Per Container 2	
Amount Per Serving	
Calories 270	Calories from Fat 130
	% Daily Value
Total Fat 15 g	**23%**
Saturated Fat 5 g	**25%**
Trans Fat 0.8 g	
Cholesterol 38 mg	**13%**
Sodium 520 mg	**22%**
Total Carbohydrate 22 g	**8%**
Dietary Fiber 1.5 g	**7%**
Sugars 5 g	
Protein 13 g	
Vitamin A 3%	Vitamin C 1%
Calcium 13%	Iron 13%

4. What is the serving size for Label A? _____

5. How many grams of carbohydrates are in one cup of Label A? _____

6. How many calories would you eat if you ate the entire package of Label A?

_____

7a. Which food is more heart-healthy?

a. Label A
b. Label B
c. I don't know

7b. List 3 things that make this food heart-healthy:

_____

_____

_____

7c. List 3 things that are not heart-healthy about the other food:

_____

_____

_____

8. On a food label, circle the 2 most important things to look for and use in carb counting:

Sugar	Protein	Calcium	Serving Size
Total Carbohydrates	Fat	Fiber	Calories

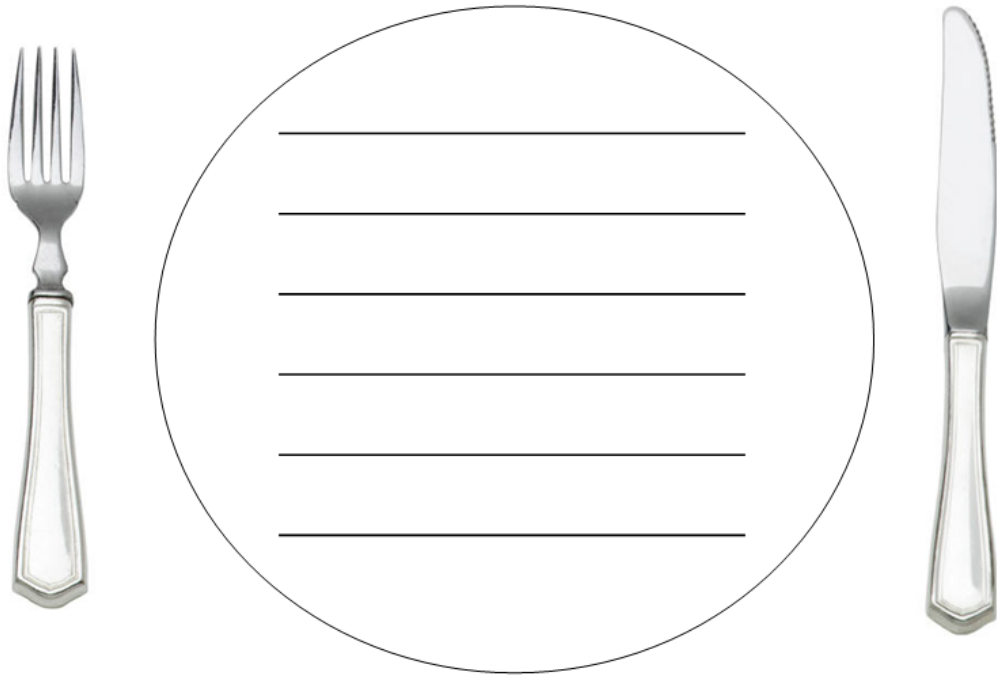
APPENDIX E

Heart-Healthy Carb Quiz Version 2

1. **Circle the foods in the box that contain <u>15 grams</u> of carbohydrate OR MORE per serving (1 carb choice or more).**

1 cup cooked dry beans	1 cup noodles	½ cup carrots	1/3 cup white rice
½ cup spaghetti sauce	1 cup 2% milk	4 oz grilled salmon	1 cup fruit juice
2-inch chocolate chip cookie	½ cup green peas	Can of regular soda	Can of diet soda
3 oz grilled chicken breast	1 slice cheese pizza	1 cup canned fruit	2 Tbsp. Peanut butter
1 slice 100% whole wheat bread	8 oz. T-bone steak	Taco Bell soft taco	½ cup corn
Medium French Fries	1 cup tossed salad	Medium apple	McDonald's Big Mac
1 packet salad dressing	String Cheese	1 oz. bag Doritos	Deli turkey sandwich
6-inch beef tostado	½ cup ice cream	Hot dog on bun	Small baked potato

2. Choose foods from the box to MAKE A MEAL that has <u>60 grams</u> of carbohydrates (<u>4 carb choices</u>). Write the foods in the plate below. Use as many lines as you need.



3. Circle the food that is the most heart-healthy of each group:

Group 1:	Group 2:	Group 3:
A. Olive Oil	A. White hamburger bun	A. Pulled pork
B. Margarine	B. Enriched white bread	B. T-bone steak
C. Butter	C. 100% Whole wheat bread	C. Grilled Salmon

For the rest of the questions, use the Nutrition Facts labels on the left:

Food A:

Nutrition Facts	
Serving Size 1 cup (56g)	
Servings Per Container about 4	
Amount Per Serving	
Calories 210	Calories from Fat 10
	% Daily Value
Total Fat 1 g	**2%**
Saturated Fat 0 g	**0%**
Trans Fat 0 g	
Cholesterol 0 mg	**0%**
Sodium 115 mg	**5%**
Total Carbohydrate 45 g	**15%**
Dietary Fiber 7 g	**26%**
Sugars 18 g	
Protein 4 g	
Vitamin A 15%	Vitamin C 10%
Calcium 4%	Iron 25%

Food B:

Nutrition Facts	
Serving Size ½ sandwich(108g)	
Servings Per Container 2	
Amount Per Serving	
Calories 270	Calories from Fat 130
	% Daily Value
Total Fat 15 g	**23%**
Saturated Fat 5 g	**25%**
Trans Fat 0.8 g	
Cholesterol 38 mg	**13%**
Sodium 520 mg	**22%**
Total Carbohydrate 22 g	**8%**
Dietary Fiber 1.5 g	**7%**
Sugars 5 g	
Protein 13 g	
Vitamin A 3%	Vitamin C 1%
Calcium 13%	Iron 13%

4. What is the serving size for Food A? _____

5. How many grams of carbohydrates are in one cup of Food A? _____

6. How many calories would you eat if you ate the entire package of Food A?

_____

7a. Is Food A or Food B more heart-healthy?

a. Food A
b. Food B
c. I don't know

7b. List 3 things that make the food you chose heart-healthy:

_____

_____

_____

7c. List 3 things that are not heart-healthy about the other food:

_____

_____

_____

8. On a food label, circle the 2 most important things to look for and use in carb counting:

Sugar	Protein	Calcium	Serving Size
Total Carbohydrates	Fat	Fiber	Calories

APPENDIX F

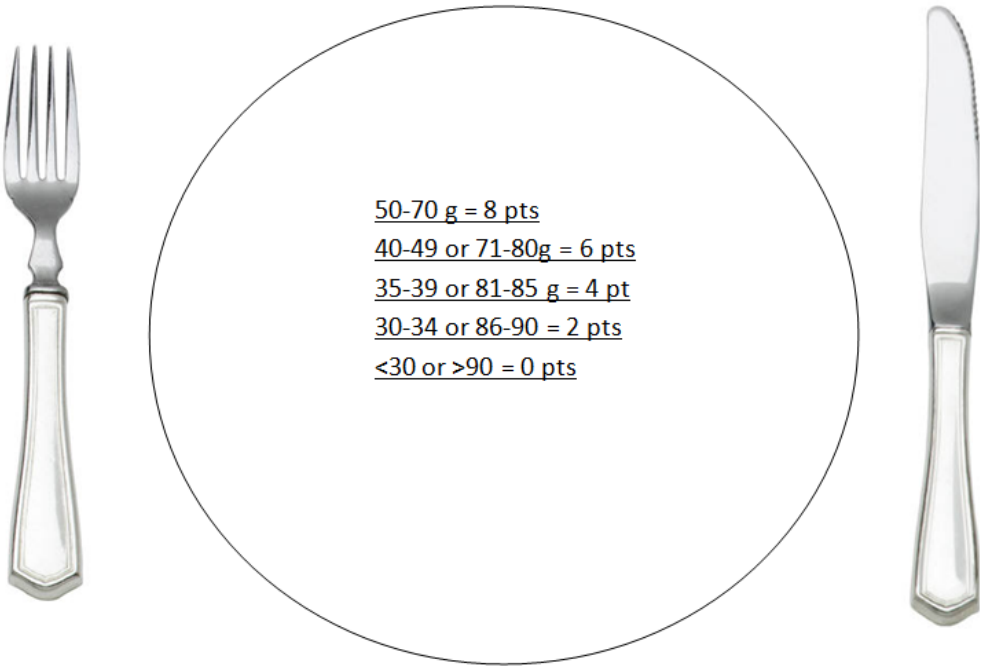
Heart-Healthy Carb Quiz Answer Key

Heart Healthy Carb Quiz – Total pts possible: 31 Subject #:_____

1. Circle the foods in the box that contain 15 grams of carbohydrate OR MORE per serving (1 carb choice or more). (1/4 pt each correct answer; 8 points possible)

1 cup cooked dry beans (40)	**1 cup noodles (43)**	½ cup carrots (6)	**1/3 cup white rice (14)**
½ cup spaghetti sauce (10)	**1 cup 2% milk (12)**	4 oz grilled salmon (0)	**1 cup fruit juice (28)**
2-inch chocolate chip cookie (9)	**½ cup green peas (11)**	**Can of soda (35)**	Can of diet soda (1)
3 oz grilled chicken breast (0)	**1 slice ch pizza (38)**	**1 cup fruit (41)**	2 T Peanut butter (6)
1 slice whole wheat bread (14)	8 oz. T-bone steak (0)	**soft taco (21)**	**½ cup corn (15)**
Medium French Fries (45)	1 cup tossed salad	**Medium apple (25)**	**Big Mac (44)**
1 packet salad dressing (2)	String Cheese (1)	**1 oz. bag Doritos (18)**	**turkey sandwich (29)**
6-inch beef tostado (23)	**½ cup ice cream (16)**	**Hot dog on bun (23)**	**Sm Baked potato (30)**

2. Choose foods from the box to make a meal that has 60 grams of carbohydrates (4 carb choices). Write the foods in the plate below:



3. Circle the food that is the most heart-healthy of each group: (right = 1; wrong = 0 for each)

Group 1:	Group 2:	Group 3:
A. Olive Oil	A. White hamburger bun	A. Pulled pork
B. Margarine	B. Enriched white bread	B. T-bone steak
C. Butter	**C. 100% Whole wheat bread**	**C. Grilled Salmon**

For the rest of the questions, use the Nutrition Facts labels on the left:

Label A:

Nutrition Facts	
Serving Size 1 cup (56g)	
Servings Per Container about 4	
Amount Per Serving	
Calories 210	Calories from Fat 10
	% Daily Value
Total Fat 1 g	**2%**
Saturated Fat 0 g	**0%**
Trans Fat 0 g	
Cholesterol 0 mg	**0%**
Sodium 115 mg	**5%**
Total Carbohydrate 45 g	**15%**
Dietary Fiber 7 g	**26%**
Sugars 18 g	
Protein 4 g	
Vitamin A 15%	Vitamin C 10%
Calcium 4%	Iron 25%

Label B:

Nutrition Facts	
Serving Size ½ sandwich(108g)	
Servings Per Container 2	
Amount Per Serving	
Calories 270	Calories from Fat 130
	% Daily Value
Total Fat 15 g	**23%**
Saturated Fat 5 g	**25%**
Trans Fat 0.8 g	
Cholesterol 38 mg	**13%**
Sodium 520 mg	**22%**
Total Carbohydrate 22 g	**8%**
Dietary Fiber 1.5 g	**7%**
Sugars 5 g	
Protein 13 g	
Vitamin A 3%	Vitamin C 1%
Calcium 13%	Iron 13%

4. What is the serving size for Label A? (1 pt) 1 cup

5. How many grams of carbohydrates are in one cup of Label A? (1 pt) 45g

6. How many calories would you eat if you ate the entire package of Label A? (1 pt)
840

7a. Which food is more heart-healthy? (1 pt)

a. Label A
b. Label B
c. I don't know

7b. List 3 things that make this food heart-healthy: (3 pts)

Low fat, no sat fat, no trans fat, no cholesterol, low sodium, high fiber

7c. List 3 things that are not heart-healthy about the other food: (3 pts)

High fat, high saturated fat, contains trans fat, has cholesterol, high sodium, low fiber

8. On a food label, what are the 2 most important things to look for and use in carb counting? (2 pts)

Sugar	Protein	Calcium	**Serving Size**
Total Carbohydrates	Fat	Fiber	Calories