9-29-2010

Relationship between concern for vision loss and self-care management in type 1 and type 2 diabetics

Esi Nkyekyer

RELATIONSHIP BETWEEN CONCERN FOR VISION LOSS AND SELF-CARE MANAGEMENT IN TYPE 1 AND TYPE 2 DIABETICS.

A Thesis Submitted to the

Yale University School of Medicine

in Partial Fulfillment of the requirements for the

Degree of Doctor of Medicine

By

Esi Wusiwa Nkyekyer

2010

RELATIONSHIP BETWEEN CONCERN FOR VISION LOSS AND SELF-CARE MANAGEMENT IN TYPE 1 AND TYPE 2 DIABETICS

Esi W. Nkyekyer, Ron A. Adelman. Department of Ophthalmology,Yale University, School of Medicine, New Haven, CT.

The purpose of this study is to assess the following hypotheses: concern for vision loss is associated with self-care behavior and glucose control; concern for overall diabetes complications is associated with self-care behavior and glucose control; concern for vision loss accounts for a significant proportion of the association between concern for overall diabetes complications and self-care behavior and glucose control in Type 1 and Type 2 diabetic subjects.

The study sample consists of 100 participants (24 Type 1 diabetics, 69 Type 2 diabetics, 7 unknown) over the age of 18 presenting to the Yale Diabetes Center from June 2009 to August 2009. In addition to demographic and health-related surveys, the following questionnaires were administered: Visual Functioning Questionnaire (VFQ), Fear of Complications Questionnaire (FCQ), and Summary of Diabetes Self-Care Activities (SDSCA) questionnaire. The $VFQ_{Item\ 3}$ score is used to measure concern for overall eyesight (*lower* scores correlate with *greater* concern); the FCQ_{Vision} score to measure concern for potential vision loss (l*ower* scores correlate with *decreased* concern); the $FCQ_{Composite}$ score to measure concern for overall diabetes complications (*lower* scores correlated with *decreased* concern); and the $SDSCA_{Composite}$ score to measure self-care behavior (*lower* scores correlate with *poorer* self-care behavior). Spearman Correlation analysis, Linear Regression analysis, ANCOVA and ANOVA are used to assess relationships between VFQ, FCQ, SDSCA composite and subscale scores and HgA1c. The main outcome measures are self-care behavior and HgA1c.

Results show that in the Type 1 Diabetes group, lower $SDSCA_{Composite}$ scores correlate with lower $VFQ_{Item\ 3}$ scores ($r_{Spearman}$=0.521, p=0.009). The correlation is further confirmed by linear regression analysis. For the Type 2 Diabetics group, there is a statistically significant positive linear relationship between HgA1c levels and FCQ_{Vision} (F_{Linear} (1,53) = 7.56, p = 0.008, ω=0.468) and $FCQ_{Composite}$ scores (F_{Linear} (1,53) = 7.80, p = 0.007, ω=0.504).

In conclusion, Type 1 diabetics with poor self-care practices are more concerned about overall eyesight and vice versa. Type 2 diabetics with poor glycemic control have greater concern for potential vision loss and overall diabetes complications and vice versa. This knowledge may be used to target patient education efforts to effectively improve self-care behavior in both Type 1 and Type 2 diabetic populations. Future research is needed to investigate factors contributing to these associations.

ACKNOWLEDGEMENTS

I gratefully acknowledge Dr. Ron Adelman, my research advisor, for striking the necessary balance between allowing me to work independently while providing ample guidance and mentorship during this discovery process. My heart-felt thanks go to Dr. Silvio Inzucchi and Geralyn Spolett for graciously accommodating me while I recruited and worked with patients at the Yale Diabetes Center. I am also indebted to Sunkyung Yu, without whom I would have remained stranded in the world of statistical analysis. Finally, but not at all in the least, I acknowledge the undying love and support of Kwaku Sefa-Dedeh, whose honesty, humor, and realism made this journey all the more enjoyable.

TABLE OF CONTENTS

1. Introduction

Diabetes is rapidly on the rise. According to national estimates for 2007, 10.7% of individuals 20 years and older and 23.1% of all people 60 years and older suffer from diabetes; at least 57 million Americans are pre-diabetic and therefore at risk of developing diabetes and its associated complications (1). It is well established that poor glycemic control in diabetic patients is associated with increased risk for microvascular complications (2, 3). As such, careful management of diabetes as a chronic disease is necessary to prevent early onset of these complications (4). This management lies in the hands of the patient, health care professionals (primary care physicians, internists, endocrinologists, ophthalmologists, nurses), health care institutions and policy-making bodies. The patient is ultimately responsible for eating healthier, maintaining a normal body weight, taking medications and monitoring glucose levels. Health care professionals play a pivotal role in educating patients about diabetes while addressing their health care needs. Health care institutions and policy making bodies take charge of designing cost-effective systems of management that provide the necessary infrastructure to optimize patient care. Each level of care faces unique challenges when addressing the continued needs of patients with chronic diseases such as diabetes. To make productive advances in diabetes management, every facet of the collaborative effort must work to develop creative and effective solutions to these challenges. This is particularly important as only 7.3% of diabetic patients meet therapeutic goals for the 3 most important measures of risk for diabetes complications: HbA_{1c} level, blood pressure, and low-density lipoprotein cholesterol (5).

Diabetic retinopathy is a major microvascular complication of poor glycemic control in diabetic patients and the leading cause of new cases of blindness in the United States in persons aged 20

to 70 years (1, 3, 6). On average, diabetic patients are more likely to suffer from correctable as well as uncorrectable vision loss than their non-diabetic counterparts (7). Among the 10.2 million Americans aged 40 and older with diabetes, approximately 1 in 3 have diabetic retinopathy and 1 in 12 are affected by vision threatening retinopathy (8); in all persons over the age of 18, 1 in 300 persons has diabetic retinopathy, and in 1 of 600, this retinopathy is vision-threatening (9). An analysis by Roy et al demonstrated that 75 to 82% of persons with Type 1 diabetes have some degree of retinopathy, and in 30 to 32% of patients, these retinal changes threaten vision (9). With diabetes on the rise, future projections suggest that diabetic retinopathy will substantially increase as a public health problem, particularly in the aging population (10). The number of Americans 40 years or older with diabetic retinopathy and vision-threatening diabetic retinopathy is expected to triple by 2050, from 5.5 million to 16.0 million and from 1.2 million to 3.4 million respectively, with increases among those 65 years or older expected to be more pronounced (2.5 million to 9.9 million for diabetic retinopathy and 0.5 million to 1.9 million for vision-threatening diabetic retinopathy) (10).

Ophthalmologists play a significant role in screening diabetic patients for diabetic retinopathy and providing temporizing treatments to slow progression from non-proliferative to proliferative disease. The purpose of this study is to determine if there is any relationship between patients' attitudes towards diabetes-associated vision loss and their self-care behaviors. By understanding patient attitudes and concerns about vision loss, ophthalmologists, in conjunction with primary care physicians, nurses and other health professionals may be better positioned to substantially influence self-care behavior in the diabetic patient population.

a. Impact of Diabetes-Associated Vision Impairment on Diabetic Patients

Visual impairment in diabetic patients is associated with a spectrum of psychosocial sequelae often related to the onset, progression and extent of visual loss. Bernbaum et al (11) observed that patients with fluctuating visual impairment from diabetic retinopathy (commonly seen in the initial stages of diabetic retinopathy) experienced greater emotional distress and depression than patients with stable visual impairment from diabetic retinopathy. Compared with both fully-sighted and partially-sighted diabetic patients, Cox et al found that individuals with total visual loss experienced greater psychological distress, anxiety, and somatization (12).

Furthermore, visual impairment from diabetic retinopathy has been shown to reduce health-related quality of life (HRQoL) measures. Lloyd et al used multiple methods (including EuroQoL (EQ-5D), Health State Utilities Index (HUI)-3, and the National Eye Institute Visual Functioning Questionnaire (VFQ) to estimate utility loss among patients with varying degrees of vision loss from diabetic retinopathy. They showed that a decline in visual acuity from 20/20 to counting fingers was significantly associated with a decrease in the majority of utility measures (13). Sharma et al in a review of current literature examining the impact of diabetic retinopathy and diabetic macular edema on HRQoL, amassed both qualitative and quantitative evidence for a decrease in HRQoL in persons with diabetic retinopathy (14). Furthermore, they found evidence that laser photocoagulation can improve health-related quality of life (14). Klein et al examined the association between the VFQ composite and subscale scores and visual acuity, diabetic retinopathy, and other characteristics in Type 1 diabetics. Their findings demonstrated that lower total VFQ scores were independently associated with poorer visual acuity and more severe retinopathy (15). Quality of life areas that are particularly affected by diabetic retinopathy and

declining vision include independence, mobility, leisure and social interactions, and self-care activities (16, 17).

Although the afore-mentioned studies demonstrate the impact of diabetes-associated vision loss on HRQoL measures, a review of the literature utilizing an extensive search of PubMed yielded no investigations into how concern for vision loss among diabetics is related to their self-management behaviors or glycemic control.

b. Patient Attitudes Towards Diabetes-Associated Vision Loss

Type 1 and Type 2 diabetic patients have been shown to be primarily concerned about long term complications of diabetes such as amputation, cardiovascular disease, nephropathy, neuropathy, retinopathy and stroke (18). Loss of vision is of particular concern to a substantial proportion of the diabetic population. In patients who have not experienced other complications of diabetes, vision loss from diabetic retinopathy is often perceived as the most devastating complication (17). Luckie et al assessed the presence and intensity of fear of vision loss among diabetic patients and found 37% to be preoccupied with this concern and 47.4% to have an intense fear of vision loss (19). Furthermore, although visual acuity and the experience of previous laser treatment were predictive of the presence of fear in Type 2 diabetics and the diabetic population as a whole, these factors only minimally explained reported patient concern, thereby suggesting that predictors of fear of loss of vision in the diabetic population are much more complex (19). Although a search of the literature yielded no quantitative comparisons between fear of other diabetes complications and fear of vision loss, Hendricks et al showed in an exploratory study that diabetic retinopathy is the most feared long-term complication among Type 2 diabetic patients (18).

Despite the high level of concern for vision loss, many diabetic patients do not have regular eye examinations. Both circumstantial factors and patient attitudes to ocular screening prevent diabetic patients from attending eye clinics for routine dilated fundoscopic examinations. Circumstantial barriers reported in the literature include lack of health insurance, patient finances, lack of time and inadequate access to care (20-24). Patient attitudes are often associated with a poor understanding of diabetic retinopathy as a microvascular complication of diabetes, and can as such affect the regularity with which patients have routine dilated fundoscopic examinations. Lewis et al in a qualitative study of diabetic patients demonstrated that lack of awareness of the potential for severe yet asymptomatic retinopathy was the greatest barrier to receiving eye care among diabetic patients (23). Furthermore, fear of laser treatment and guilt about poor glycemic control deterred patients from having regular eye examinations (23). Moss et al found that among diabetic patients who had not had an ocular examination within the past year, the most common reasons for not having done so were the absence of eye problems and never being told about the need for an eye examination (22). Minority patients in particular have poor knowledge of the ocular complications of diabetes. Among African American diabetic patients, a small proportion have heard of (36%) or can correctly describe (8%) diabetic retinopathy, while many (79%) believe there are no effective treatments for the disease (25). Finally, the frequency of eye examinations among Hispanic individuals is less than the national average; only 36% of newly diagnosed diabetic patients and 52% of patients with diabetes for more than a year report knowledge of eye disease as a consequence of diabetes, while 31% and 48% respectively know the importance of dilated eye examinations (26). Lack of knowledge appears therefore to play a significant role in patient attitudes towards routine ocular examinations for the detection of diabetic eye disease.

c. The Relationship between Concern for Vision Loss and Self-Care behavior among Diabetic Patients

Despite the considerable concern that patients have for vision loss, a search of the literature does not reveal many investigations into the relationship between concern for vision loss and overall self-care behavior or glycemic control among diabetic patients. Oehler et al, in a descriptive study of diabetic patients in group therapy, observed that with deterioration of vision, diabetic patients developed an increased awareness of the need for good glycemic control and of the risks of other severe diabetic complications (27). Moreover, a quantitative study by Klein et al to examine the association of the VFQ composite and specific scale scores with visual acuity, diabetic retinopathy, and other characteristics in a cohort of persons with Type 1 diabetes, showed that better glycemic control significantly correlated with lower vision-related concern, frustration, irritation and loss of independence in patients with Type 1 diabetes (15). Studies investigating similar associations have not been performed in patients with Type 2 diabetes. Additionally, the relationship between concern for vision loss and measures of diabetes self-care activities has not been investigated. Finally, no work has yet been done to determine how diabetic patients' concern for vision loss quantitatively compares to their concern for other long-term complications of diabetes, or the proportion of the association between concern for overall diabetes complications and diabetes health care activities/glycemic control that is accounted for by concern for vision loss alone. The primary aim of this study is therefore to determine if there is any relationship between diabetic patients' concern for vision loss, their self-care behavior and level of glycemic control. The results of such investigations could pave the way for more effective patient-centered approaches to improving self-care behavior and disease outcomes in diabetic patients. Understanding how patients' concern for vision loss compares to their concern for other diabetes complications as well as its impact on diabetes self-care activities and glycemic control could further motivate health-care

providers focus adequate attention on this concern, thereby potentially improving self-care behavior and health outcomes for diabetic patients.

2. Specific Hypotheses and Aims

a. Primary Aims:

i. To test the hypothesis that, concern for vision loss is associated with diabetes self-care activities and glucose control (HgbA1c levels) in diabetic subjects.

ii. To test the hypothesis that, concern for overall diabetes complications is associated with diabetes self-care activities and glucose control (HgbA1c levels) in diabetic subjects.

b. Secondary Aim:

i. To test the hypothesis that, a significant proportion of the correlation between concern for overall diabetes complications and diabetes self-care activities/glucose control is accounted for by concern for vision loss in diabetic subjects.

In this study, concern for vision loss was divided into two components: concern for overall eyesight which was measured using the $VFQ_{Item\ 3}$ score, and concern for potential vision loss which was measured using the FCQ_{Vision} score.

3. Methods

a. **<u>Design:</u>** This is a cross-sectional observational study of the relationship between concern for vision loss/concern for overall diabetes complications and diabetes self-care activities/ glycemic control in Type 1 and Type 2 diabetic subjects. The study was

approved as a request for exemption by the Yale University School of Medicine Institutional Review Board.

b. Subjects: One hundred male and female diabetic subjects, over the age of 18 were enrolled into the study. No further exclusion and inclusion criteria were defined for this study.

c. Intake: All patients presenting to the Yale Diabetes Center for scheduled clinic visits were approached for recruitment into the study. This process of recruitment included an explanation of the goals of the study, the role the subject would play and an invitation to take part in the study. Interested subjects who agreed to participate were then screened for eligibility by being asked their age. Eligible subjects (age over 18) then completed the interviewer-administered study assessments either before or after their scheduled clinic visit.

d. Assessments: Study assessments include a demographic data sheet, a health information sheet, the Visual Functioning Questionnaire (VFQ) (28), the Fear of Complications questionnaire (FCQ) (29) and the Summary of Diabetes Self-care Activities (SDSCA) questionnaire (30). The VFQ, FCQ and SDSCA are all questionnaires that have been validated in the literature. All assessment tools can be found in the Appendix of this manuscript.

Demographic Data Sheet:

This questionnaire was used to collect the following demographic data from participants: age, gender, language most spoken at home, race, employment status, income, marital status and health insurance status.

Health information Sheet:

This questionnaire was adapted from a similar questionnaire used by Gwira et al in a study of factors associated with failure to follow up after glaucoma screening in African American patients (31). This questionnaire includes items on glucose control, diabetes complications, and family history of diabetes and diabetes complications. Of note, patients were asked in this questionnaire to categorize their most recent HgA1c within the past 3 months. It is this categorization that was used as the measure of glucose control in this study.

National Eye Institute Visual Functioning Questionnaire (VFQ):

The VFQ is a questionnaire that was created to measure the components of self-reported vision-related health status of greatest significance to individuals with chronic eye disease. The survey assesses the impact of visual symptoms and disability on health-related quality of life domains such as emotional well-being and social functioning. The VFQ comprises the following subscale measures: general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision. Absolute composite and subscale scores on the VFQ were converted to percentage scores as described in the VFQ manual (28). I

In this study, $VFQ_{Item\ 3}$ was used as a measure of concern for *overall* eyesight, that is concern related to current subjective vision loss as well as concern about future potential vision loss. Scoring of $VFQ_{Item\ 3}$ is such that *lower* scores indicate *greater* overall concern for eyesight. The mental health subscale score ($VFQ_{Mental\ Health}$) was used as a measure of vision-associated emotional distress, with *lower* scores indicating *greater* emotional distress. This subscale score comprises 5 core questions on concern for overall eyesight ($VFQ_{Item\ 3}$), as well as eyesight-associated frustration ($VFQ_{Item\ 21}$), dependence ($VFQ_{Item\ 22}$), embarrassment ($VFQ_{Item\ 25}$), and one optional question about eyesight-associated irritability ($VFQ_{Item\ A12}$). All 5 components of the $VFQ_{Mental\ Health}$ score were used such that the final VFQ survey instrument had 26 items.

Fear of Complications Questionnaire (FCQ):

The FCQ is a 15-item scale that was designed by Taylor et al to measure fear of diabetes complications in patients with Type 1 diabetes (29). The questionnaire comprises items related to general fears of diabetes complications, specific fears (e.g. of blindness, kidney problems, heart disease), lifestyle fears, and fear of complications associated with poor glucose control. Validation of the questionnaire demonstrated that it identified fear that was a uniquely diabetes-related emotion, though moderately related to the presence of complications and general negative affectivity. Although the original questionnaire was scored to only obtain a composite score, in this study the questionnaire was also broken down into the following subscale score measures: fear of long term ($FCQ_{Long\ term}$), vision-related (FCQ_{Vision}), heart-related (FCQ_{Heart}), kidney related (FCQ_{Kidney}), stroke-related (FCQ_{Stroke}), peripheral vascular disease-related complications ($FCQ_{Circulation)}$ and fear of complications from poorly controlled blood glucose levels ($FCQ_{Blood\ Glucose}$). The absolute

subscale and absolute composite scores were converted to percentage scores prior to statistical analysis. The FCQ vision subscale score (FCQ_{Vision}) was used as a measure of concern for *potential* vision loss.

Summary of Diabetes Self-Care Activities (SDSCA) Questionnaire:

The Summary of Diabetes Self-Care Activities (SDSCA) is a brief, self-report questionnaire of diabetes self-management that includes items assessing the following aspects of the diabetes regimen over the previous 7 days: general diet, specific diet, exercise, blood-glucose testing, foot care, medication compliance and smoking. A revised version of the questionnaire created by Toobert et al was used in this study (30). The measure is a reliable and valid and found to be useful for both research and practice. The absolute SDSCA subscale and composite scores were converted to percentage scores prior to statistical analysis. In this study the $SDSCA_{Composite}$ score was the primary score of interest and was used as a measure of overall self-care activities in diabetic patients.

e. <u>Statistical Analysis:</u>

All statistical analyses were performed using PASW Statistics 17 (SPSS). Data from the questionnaires was manually entered into the SPSS program.

Pre-Study Power analysis:

Effect size estimates were computed from four papers that describe either fear of vision loss alone or fear of overall diabetes complications, predictors of these fears and how they impact a number of outcome variables (15, 19, 29, 32). Effect sizes were estimated per group i.e. Type 1 and Type 2 diabetic subjects. For an effect size (correlation coefficient *r*)

of 0.25 or greater, alpha of 0.05, and power of greater than 0.80, a total per group sample size of 98 is needed. This sample will also make it possible to determine a difference between two correlation coefficients of 0.30 or greater. Furthermore, a sample size of 98 per group will allow for an effect size (i.e. difference in questionnaire scores between Type 1 and Type 2 diabetic subjects) of 20 or greater. Given an anticipated drop-out rate of 10%, the final total number of subjects needed for enrollment is 215.

Population Comparisons:

Chi-square analysis was used to compare nominal and ordinal characteristics between Type 1 and Type 2 diabetic subjects. Subjects with unknown diabetes status were not included in the Chi-square analysis because the majority of expected counts for variables studied in this group were less than 5. Independent sample Student T-test was used to compare means of continuous variables (i.e. age, questionnaire scores) between Type 1 diabetic and Type 2 diabetic subjects. Student T-test analysis was also used to compare VFQ, FCQ, SDSCA questionnaire scores between participants with and without diabetic retinopathy.

Correlations:

In order to decide which type of correlation analysis, the distribution of all questionnaire scores was analyzed using values of skewness and kurtosis. As most of the scores were not normally distributed, Spearman correlation analysis was used instead of Pearson correlation analysis. The majority of SDSCA subscale and composite scores had a negatively skewed distribution. All the VFQ subscale and composite scores had negatively skewed distributions. The FCQ composite and subscale scores were either normally

distributed or positively skewed. Spearman correlation analysis was used to assess relationships between VFQ, FCQ, and SDSCA subscale and composite scores. This analysis was performed for Type 1 diabetics alone, Type 2 diabetics alone, unknown diabetics alone and all groups combined. Given the study aims and hypotheses, the statistical significance of the following correlations was of particular interest:

1. Correlation between $VFQ_{Item\ 3}$ score and $SDSCA_{Composite}$ score
2. Correlation between $VFQ_{Mental\ Health}$ score and $SDSCA_{Composite}$ score
3. Correlation between $VFQ_{Composite}$ score and $SDSCA_{Composite}$ score
4. Correlation between FCQ_{Vision} score and $SDSCA_{Composite}$ score
5. Correlation between $FCQ_{Composite}$ score and $SDSCA_{Composite}$ score

Linear and Multiple Regression Analysis:

Linear regression analysis was used to determine the relationship between the $SDSCA_{Composite}$ score as the dependent variable and $VFQ_{Item\ 3}$, $VFQ_{Mental\ Health}$, $VFQ_{Composite}$, FCQ_{Vision}, and $FCQ_{Composite}$, and scores as the independent variables. This was performed for Type 1 diabetics alone, Type 2 diabetics alone, unknown diabetics alone and all groups combined. The only statistically significant relationship found was that between $VFQ_{Item\ 3}$ and $SDSCA_{Composite}$ scores. Multiple regression analysis was then performed with the other individual components of the VFQ mental health score (items 21, 22, 25, and A12) held constant to assess their impact on the linear relationship between $VFQ_{Item\ 3}$ and the $SDSCA_{Composite}$ score.

Analysis of Confounding Factors using ANCOVA:

ANCOVA was used to determine how controlling for potential confounding factors influenced the association between $VFQ_{Item\ 3}$ and $SDSCA_{Composite}$ scores in the Type 1 diabetes group. The confounding factors of particular interest that were adjusted for individually and combined together in this analysis were: age, gender, employment, marital status, insurance, length of time with diabetes, medication type, history of diabetic retinopathy, history of laser treatment for diabetic retinopathy and presbyopia. The following eye-related parameters were also controlled for individually and simultaneously: diabetic retinopathy, myopia, presbyopia, macular degeneration, cataract, glaucoma, cataract surgery, laser therapy for diabetic retinopathy. Levene's test for equality of variances was used to test the null hypothesis that the error variance of $SDSCA_{Composite}$ score was equal across all groups. In these analyses $VFQ_{Item\ 3}$ was run as the covariate, the $SDSCA_{Composite}$ score as the dependent variable and the confounding variables as fixed factors. Effect sizes (η^2 and r) for the association between $VFQ_{Item\ 3}$ scores and $SDSCA_{Composite}$ scores were also generated.

Assessing Relationship between Questionnaire Scores and HgA1c using ANOVA:

ANOVA was used to determine the relationship between HgA1c levels and VFQ_{Item3}, $VFQ_{Mental\ Health}$, $VFQ_{Composite}$, FCQVision, and $FCQ_{Composite}$ scores. Planned contrasts were used to compare mean questionnaire scores of participants in different HgA1c categories. This analysis was performed for Type 1 diabetics alone, Type 2 diabetics alone, unknown diabetics alone and all groups combined.

4. Results

Population Comparisons:

A total of 100 patients (24 Type 1, 69 Type 2, 7 Unknown) were examined. Type 1 diabetic participants were younger (mean age 44.0yrs compared to 59.2yrs; $p< 0.001$) and more likely to be female (75.0%, 49.3%; $\chi^2=4.78$, $p=0.029$) than Type 2 diabetic participants. Type 1 diabetics were also more likely to be employed (50.0%, 34.8%; $\chi^2=11.6$, $p=0.009$), less likely to be disabled (8.30%, 18.3%; $\chi^2=11.6$, $p=0.009$) and less likely to be retired (8.30%, 34.8%; $\chi^2=11.6$, $p=0.009$) than their Type 2 diabetic counterparts. Type 1 diabetic subjects were more likely to be single (45.5%, 20.3%; $\chi^2=11.7$, $p=0.008$) and have private (54.2%, 34.8%; $\chi^2=14.2$, $p=0.047$) and state (12.4%, 4.30%; $\chi^2=14.2$, $p=0.047$) insurance. Not surprisingly, Type 1 diabetic participants had had diabetes for longer (greater than 20 years: 37.5%, 18.8%; $\chi^2=27.0$, $p<0.001$) and were also more likely to use insulin injections (58.2%, 29.0%; $\chi^2=45$, $p<0.001$) and have insulin pumps (37.5%, 0.00%; $\chi^2=45.0$, $p<0.001$) than their Type 2 counterparts. Of particular note was the fact that Type 1 diabetic participants were significantly more likely to report diabetic retinopathy (62.5%, 17.4%; $\chi^2=17.6$, $p<0.001$) and report past laser treatment for diabetic retinopathy (41.7%, 14.5%; $\chi^2=7.79$, $p=0.005$) than Type 2 participants. Type 1 participants were less likely to have presbyopia (54.2%, 76.8%; $\chi^2=4.43$, $p=0.035$) (Table 1a).

There were no significant differences between Type 1 and Type 2 diabetic subjects in language most spoken at home, race, yearly income level or highest level of education. There was no significant difference in the distribution of HgA1c levels between the two groups. There was also no significant difference in smoking status, the incidence of myopia, cataract, cataract surgery, macular degeneration, glaucoma, and time of last eye examination or eye examination with dilatation between the two groups. Furthermore, there was no significant difference in the incidence

of diabetes-related kidney disease, stroke, heart disease, myocardial infarction, hypertension, peripheral vascular disease, or amputation between the two groups. Finally, there was no significant difference between the two groups with regards to family history of diabetes-associated kidney disease, diabetic retinopathy, stroke, blindness or amputation.

With regards to questionnaire scores, there were significant differences between Type 1 and Type 2 diabetic subjects in $SDSCA_{Blood\ Glucose\ Testing}$, $SDSCA_{Foot\ Care}$, and $SDSCA_{Composite}$ scores. On average, Type 1 diabetics tested their blood glucose more regularly, took better care of their feet and had better overall self-care practices than their Type 2 diabetic counterparts (Table 1b). Tables 1c – e show scores that are significantly different between patients with and without diabetic retinopathy for all groups combined, Type 1 diabetics alone and Type 2 diabetics alone.

Correlations:

Correlation between $SDSCA_{Composite}$ Score and $VFQ_{Item\ 3}$ /$VFQ_{Mental\ Health}$ Scores:

For participants with Type 1 Diabetes, there was a statistically significant positive correlation between the $SDSCA_{Composite\ score}$ and the $VFQ_{Item\ 3}$ score ($r_{Spearman}$=0.521, N=24, p=0.009) (Table 2a). Therefore, decreased self-care behavior (↓$SDSCA_{Composite\ score}$) was associated with greater concern for overall eyesight (↓ $VFQ_{Item\ 3}$) and vice versa. There was also a statistically significant positive correlation between the $SDSCA_{Composite}$ score and the $VFQ_{Mental\ Health}$ score (r=0.413, N=24, p=0.045) (Table 2a). Therefore a decrease in level of self-care (↓$SDSCA_{Composite}$) was associated with greater vision-related emotional distress (↓ $VFQ_{Mental\ Health}$) and vice versa. Correlation analyses between $SDSCA_{Composite}$ score and the other four components of the $VFQ_{Mental\ Health}$ score (i.e. vision-related frustration ($VFQ_{Item\ 21}$), dependence ($VFQ_{Item\ 22}$), embarrassment ($VFQ_{Item\ 25}$) and irritability ($VFQ_{Item\ A12}$)) were individually performed. There were no significant correlations

between the afore-mentioned score components and the $SDSCA_{Composite}$ score (Table 2b). As such, $VFQ_{Item\ 3}$ alone accounts for the statistical significance of the association between vision-associated emotional distress ($VFQ_{Mental\ Health}$) and self-care behavior ($SDSCA_{Composite}$) (Table 2b).

For patients with Type 2 diabetes, patients with unknown diabetes type, and all patients combined there were no statistically significant correlations between the $SDSCA_{Composite}$ score and $VFQ_{Item\ 3}$ nor between the $SDSCA_{Composite}$ score and the $VFQ_{Mental\ Health}$ score (Table 2c – e). Despite the non-significance of these correlations it is interesting to note that they were all negative for these subject groups (Table 2c – e), meaning that a decrease in self-care behavior (↓ $SDSCA_{Composite}$) was associated with less concern for overall eyesight (↑ $VFQ_{Item\ 3}$) and less vision-related emotional distress (↑ $VFQ_{Mental\ Health}$) .

Correlation between $SDSCA_{Composite}$ Score and FCQ_{Vision} / $FCQ_{Composite}$ Scores:

For Type 1, Type 2, Unknown and all groups combined there were no statistically significant correlations between the $SDSCA_{Composite}$ score and FCQ_{Vision} score nor between the $SDSCA_{Composite}$ score and the $FCQ_{Composite}$ score (Table 2a – e). As such, there was no significant association between self-care behavior and concern for potential vision loss or between self-care behavior and concern for overall potential diabetes complications. Despite the lack of statistical significance of the association between $SDSCA_{Composite}$ and $FCQ_{Vision,}$ it is interesting to note that the correlation was negative in the Type 1 diabetes group ($r = - 0.178, N=24, p =0.404$), but positive in the Type 2 ($r=0.131, N= 69, p=0.285$), and Unknown ($r =0.182, N = 7, p = 0.696$) diabetes groups and all groups combined ($r=0.08, N = 100, p = 0.381$) . The correlation between $SDSCA_{Composite}$ and $FCQ_{Composite}$, though lacking statistical significance, was negative in the Type 1 group ($r = -0.359$, $N=24, p =0.085$) and all groups combined ($r = -0.035, N=100, p= 0.727$) but positive in the Type 2

(r = 0.012, N=69, p=0.924) and unknown diabetic groups (r=0.144, N=7, p=0.75). In this instance a negative correlation means that a decrease in self-care behavior (↓ $SDSCA_{Composite}$) is associated with an increase in concern for potential vision loss/concern for overall diabetes complications (↑ FCQ_{Vision} /$FCQ_{Composite}$) and vice versa , while a positive correlation means that a decrease in self-care behavior (↓ $SDSCA_{Composite}$) is associated with a decrease in concern for potential vision loss/concern for overall diabetes complications (↓ FCQ_{Vision}/$FCQ_{Composite}$) and vice versa .

Correlation between $SDSCA_{Composite}$ Score and $VFQ_{Composite}$ Score:

For Type 1, Type 2, Unknown and all groups combined there were no significant correlations between $SDSCA_{Composite}$ score and $VFQ_{Composite}$ score (Table 2 a – e). Despite the non-significance of these correlations, it is interesting to note that for the Type 1 diabetes group, Type 2 diabetes group, and all groups combined the correlations had a trend towards being positive (Type 1: r=0.357, N=24, p=0.057; Type 2: r=0.022, N=69, p= 0.861; All patients: r = 0.082, N= 100, p = 0.419), while for the Unknown diabetes group the correlation was negative (Unknown: r = -0.036, N=7, p= 0.939). In this instance a negative correlation means that a decrease in self-care behavior (↓ $SDSCA_{Composite}$) is associated with an increase in vision-related quality of life (↑ $VFQ_{Composite}$) and vice versa , while a positive correlation means that a decrease in self-care behavior (↓$SDSCA_{Composite}$) is associated with a decrease in vision-related quality of life (↓ $VFQ_{Composite}$) and vice versa .

<u>Linear and Multiple Regression Analysis</u>

Linear regression analysis demonstrated that in Type 1 diabetic subjects the concern for overall eyesight component ($VFQ_{Item\ 3}$) of the $VFQ_{Mental\ Health}$ score significantly predicted self-care behavior (β=0.118,β_s=0.481, p=0.017) (Table 3a). Furthermore, 23.1% of the variance in the $SDSCA_{Composite}$

score was predicted by the $VFQ_{Item\ 3}$ score (Table 3a, Figure 1, 2). When the other individual components of the $VFQ_{Mental\ Health}$ score (items 21, 22, 25, and A12) were included in the analysis (i.e. held constant), the strength of the relationship between $VFQ_{Item\ 3}$ and $SDSCA_{Composite}$ scores increased (β=0.155, β_s=0.630, p=0.018) with this model accounting for 35.7% of the variance in $SDSCA_{Composite}$ score (Table 3b).

Fear of other complications of diabetes (as measured by the FCQ subscale scores) was adjusted for using multiple regression analysis. The association between $VFQ_{Item\ 3}$ and $SDSCA_{Composite}$ score in the Type 1 diabetic group became statistically insignificant when fear of long-term complications ($FCQ_{Long\text{-}term}$), peripheral vascular disease ($FCQ_{Circulation}$) and fear of overall diabetes complications ($FCQ_{Composite}$) were individually adjusted for (Table 3b). Linear regression analysis showed no significant relationship between the $VFQ_{Mental\ Health,}$ $VFQ_{Composite}$, FCQ_{Vision} and $FCQ_{Composite}$ scores as the predictor variables and the $SDSCA_{Composite}$ score as the dependent variable in the Type 1 diabetes group.

ANCOVA:

In the individual analysis of cofounding variables for the Type 1 diabetes group, the relationship between the $VFQ_{Item\ 3}$ scores and the $SDSCA_{Composite}$ scores remained statistic ally significant when all factors except for employment status (F= 2.973 (1,19), p=0.101, $r_{VFQ\ Item\ 3}$ = 0.368) and diabetic retinopathy (F = 4.274 (1,21), p = 0.051, $r_{VFQ\ Item\ 3}$ = 0.411) were controlled for (Table 4). However, the effect of employment is questionable given that the error variance of SDSCA scores across the employment groups is not equal. Furthermore, although having diabetic retinopathy was associated with lower $SDSCA_{Composite}$ scores than not having diabetic retinopathy, this association was not statistically significant (Table1c –d). The relationship between $VFQ_{Item\ 3}$ scores and

$SDSCA_{Composite}$ scores also become insignificant when all of the variables that differed significantly between Type 1 and Type 2 diabetic groups (i.e. age, gender, employment status, marital status, health insurance, years with diabetes, medication type, diabetic retinopathy, laser treatment, presbyopia) were included in the analysis. The relationship remained statistically significant when the other eye-related factors (macular degeneration, myopia, cataract, glaucoma, cataract surgery) were individually controlled for. Furthermore, with $VFQ_{Item\ 3}$ run as a covariate and diabetic retinopathy, myopia, presbyopia, macular degeneration, cataract, glaucoma, cataract surgery and laser treatment for diabetic retinopathy as fixed factors, the association between $VFQ_{Item\ 3}$ and $SDSCA_{Composite}$ score remained significant ($F(1, 14) = 8.14$, $p = 0.013$, $r_{VFQ\ Item\ 3}=0.500$, $B= 0.128$) (Table 4a).

ANOVA

ANOVA was used to determine the effect of $VFQ_{Item\ 3}$, $VFQ_{Mental\ Health}$ score, $VFQ_{Composite}$ score, FCQ_{Vision}, $FCQ_{Composite}$ and $SDSCA_{Composite}$ scores on HgA1c values. In the Type 2 Diabetes Group, There was a significant effect of HgA1c on all FCQ subscale scores except $FCQ_{Circulation}$ (Table 5b). This effect had a significantly linear trend between HgA1c and all FCQ subscale scores (except FCQ_{Kidney} and $FCQ_{Circulation}$) such that as HgA1c levels increased, the respective FCQ subscale scores increased proportionately (Table 5b). Planned contrasts showed that for any HgA1c level > 5.9, there was an associated increase in FCQ_{Vision}, $FCQ_{Blood\ Glucose}$, $FCQ_{Composite}$ scores. Furthermore, compared to HgA1c levels ranging from 8.0 – 8.9, HgA1c levels greater than 9.0 were associated with higher $FCQ_{Composite}$, FCQ_{Vision}, $FCQ_{Blood\ Glucose}$, $FCQ_{Long\ Term}$, FCQ_{Stroke} and FCQ_{Heart} scores. Calculation of individual model effect sizes (ω) and contrast effect sizes (r) showed that the association between FCQ_{Vision} and HgA1c had the third largest effect size,

preceded only by the association between HgA1c and FCQComposite and FCQBlood Glucose scores respectively (Table 5b, 5c).

For all groups combined, there was a significant effect of HgA1c on $FCQ_{Composite}$, $FCQ_{Blood\ Glucose}$ and FCQ_{Stroke} scores (Table 5b). However, this effect was only significantly linear between HgA1c and all $FCQ_{Blood\ Glucose}$ scores, such that as HgA1c levels increased, the $FCQ_{Blood\ Glucose}$ score increased proportionately (Table 5b). Planned contrasts showed that compared to HgA1c levels ranging from 8.0 – 8.9, HgA1c levels >9.0 were associated with higher $FCQ_{Composite}$, $FCQ_{Blood\ Glucose}$ and FCQ_{Stroke} scores. Calculation of individual model effect sizes (ω) and contrast effect sizes (r) demonstrated that the association between $FCQ_{Blood\ Glucose}$ and HgA1c had the largest effect size, followed by the association between HgA1c and FCQ_{Stroke} and $FCQ_{Composite}$ scores respectively (Table 5b, 5c).

No significant effect between HgA1c and FCQ Composite and subscale score was found for the Type 1 diabetes group. Furthermore, for the Type 1 diabetes group, Type 2 diabetes group and all groups combined no statistically significant effects of HgA1c values on $VFQ_{Item\ 3}$, $VFQ_{Mental\ Health}$, and $VFQ_{Composite}$ scores respectively were determined.

5. Discussion

Type 1 Diabetes Group

This study has demonstrated that in Type 1 diabetics, self-care behavior ($SDSCA_{Composite}$) is negatively correlated with concern for overall eyesight ($VFQ_{Item\ 3}$) but not significantly associated with concern for potential vision loss (FCQ_{Vision}). The correlation between self-care behavior and concern for overall eyesight becomes statistically insignificant when diabetic retinopathy and

employment status are individually adjusted for, and when demographic variables that differ significantly between the Type 1 and Type 2 diabetic groups are controlled for simultaneously. Furthermore, individually adjusting for fear of overall complications ($FCQ_{Composite}$), long-term complications ($FCQ_{Long\text{-}term}$) and peripheral vascular disease ($FCQ_{Circulation}$) causes the linear relationship between concern for overall eyesight and self-care behavior to become statistically insignificant. Linear regression analysis confirms the correlation between concern for overall eyesight as a predictor variable and self-management behavior as the dependent variable, however causality cannot be proved from these results. It is therefore possible that concern for overall eyesight, either because of current subjective vision loss or future potential vision loss, generates a mentality in Type 1 diabetic patients that results in poorer self-care behavior. However, it is more plausible that Type 1 diabetics with poor self-care behavior are simply more concerned about overall eyesight because of their awareness of the consequences of inadequate self-management practices, or because they already have diabetes-related eye disease that they know can be worsened by their poor self-care behavior.

In the Type 1 diabetes group, there were no statistically significant relationships between concern for overall diabetes complications ($FCQ_{Composite}$) and self-care behavior ($SDSCA_{Composite}$), or between HgA1c values and self-care behavior ($SDSCA_{Composite}$), concern for overall eyesight ($VFQ_{Item\ 3}$), vision-associated emotional distress ($VFQ_{Mental\ Health}$) and concern for overall diabetes complications ($FCQ_{Composite}$) respectively. Although there was a negative correlation between self-care behavior and vision-associated emotional distress ($VFQ_{Mental\ Health}$) in the Type 1 diabetes group, concern for overall eyesight ($VFQ_{Item\ 3}$) was the only one of the five components of the $VFQ_{Mental\ Health}$ score that significantly contributed to this correlation; the other four components of the $VFQ_{Mental\ Health}$ score did not individually contribute in a statistically significant manner to this

correlation (Table 2a). As such, the $VFQ_{Mental\ Health}$ score can essentially be equated to the $VFQ_{Item\ 3}$ score when describing the relationship between $SDSCA_{Composite}$ and $VFQ_{Mental\ Health}$.

Given the absence of a statistically significant relationship between concern for potential vision loss (FCQ_{Vision}) and self-care behavior ($SDSCA_{Composite}$), it is possible that there are elements of concern for overall eyesight ($VFQ_{Item\ 3}$) that are not measured by the FCQ_{Vision} score but are associated with self-care behavior. This is supported by the observation that although FCQ_{Vision} and $VFQ_{Item\ 3}$ are positively correlated (Table 2b), the correlation coefficient is less than 1. Since FCQ_{Vision} measures concern for potential vision loss, one can speculate that concern for current subjective vision loss accounts for a significant proportion of the relationship between concern for overall eyesight ($VFQ_{Item\ 3}$) and self-care behavior in the Type 1 diabetes group. It would not be surprising if this were indeed the case, since 62.5% of subjects in the Type 1 diabetes group reported having the diagnosis of diabetic retinopathy(Table 1a), and are as such more likely to be concerned about current subjective vision loss than they are about potential future vision loss.

The validity of the effect of employment on the relationship between self-care behavior and concern for overall eyesight is questionable, particularly since the error variance of $SDSCA_{Composite}$ scores across the employment categories is not equal. Nonetheless, further analysis of the data shows that both employed and unemployed members of the Type 1 diabetes group have significantly better self-care behavior than their disabled counterparts. 'Disabled' in this context refers to participants on social security disability insurance who are unable to work because of medical conditions spanning all organ systems. Selby et al (33) have demonstrated that lower income and lower general health status are associated with poor self-care behavior and poorly controlled diabetes (i.e. HgA1c >8%, systolic blood pressure > 140 mmHg and LDL-cholesterol >

130 mg/dL). It is therefore conceivable that subjects who are employed have greater financial resources and fewer physical impediments than their disabled counterparts, thereby enabling them to better adhere to self-management practices. The same can be said for unemployed subjects who may not be as well equipped financially as their employed counterparts, but are more likely to be physically able to comply with self-care activities than their disabled counterparts. Employment status presumably accounts for a substantial proportion of the self-care behavior of Type 1 subjects in this study such that adjusting for it minimizes the observed interaction between concern for overall eyesight and self-management behavior and makes the association statistically insignificant.

To further understand the impact of diabetic retinopathy on the relationship between self-care behavior and concern for overall eyesight, it is interesting to note that the presence of diabetic retinopathy is associated with lower $SDSCA_{Composite}$ scores (i.e. poorer self-care behavior) in the Type 1 diabetic group though not in a statistically significant manner (Table 1d). Furthermore, diabetic retinopathy is associated with lower $VFQ_{Mental\ Health}$ scores (i.e. greater concern for overall eyesight) in a statistically significant manner among Type 1 diabetic participants (Table 1d). Klein et al (15) have shown a statistically significant correlation between severity of diabetic retinopathy and concern for overall eyesight (as measured using the $VFQ_{Mental\ Health}$ score): less severe diabetic retinopathy was associated with less concern for overall eyesight while more severe diabetic retinopathy was associated with greater concern for overall eyesight. Given the relationship between diabetic retinopathy and concern for overall eyesight in the Klein study as well as the potential association between diabetic retinopathy and self-care behavior in this study, it is very probable that the relationship between concern for overall eyesight and self-care behavior is substantially attributable to the presence of diabetic retinopathy in Type 1 diabetics. This is further

supported by the fact that adjusting for other eye-related factors (i.e. macular degeneration, myopia, presbyopia, cataract, glaucoma, cataract surgery, laser therapy) had no effect on the statistical significance of the relationship between concern for overall eyesight and self-care activities. A larger sample size may however be required to prove the statistical significance of the association between diabetic retinopathy and self-care behavior to further support this explanation.

In this study no significant correlation between concern for overall diabetes complications ($FCQ_{Composite}$) and self-care behavior ($SDSCA_{Composite}$) nor between concern for potential vision loss (FCQ_{Vision}) and self-care behavior were demonstrated in the Type 1 diabetes group. As such it is not possible to determine what proportion of the correlation between concern for overall diabetes complications and diabetes self-care behavior is accounted for by concern for overall eyesight or concern for potential vision loss in Type 1 diabetic participants. Nonetheless the individual effects of concern for overall, long-term and peripheral vascular complications ($FCQ_{Composite}$, $FCQ_{Long\text{-}term}$, and $FCQ_{Circulation}$ scores respectively) on the significance of the linear relationship between concern for overall eyesight ($VFQ_{Item\ 3}$) and self-care behavior ($SDSCA_{Composite}$) ,suggest that these concerns contribute in such a way as to make the negative relationship between self-care behavior and concern for overall eyesight statistically insignificant. For instance, it is possible that better self-care behavior is associated with greater concern for the afore-mentioned categories of complications therefore canceling out the effect of self-care behavior on concern for overall eyesight. The associations between self-care behavior and concern for overall diabetes complications and between self-care behavior and concern for potential vision loss respectively may be better evaluated in a larger sample population of Type 1 diabetic participants.

There is evidence in the literature to suggest that diabetic patients with deteriorated vision develop an increased awareness of the need for good glycemic control and the risks of other diabetic complications (27). As has been demonstrated in the literature, one would expect increased awareness or education about diabetes complications and management to result in an improvement in self-care behavior and glycemic control (34-37). However, in this study, there is no statistically significant difference in $SDSCA_{Composite}$ score between Type1 diabetic patients with and without diabetic retinopathy (Table 1d). This discrepancy therefore suggests that there are elements associated with having diabetic retinopathy that prevent our study population of Type 1 diabetics from taking better care of themselves. In this study, Type 1 diabetic subjects with diabetic retinopathy had a longer duration of diabetes than their counterparts without diabetic retinopathy (73.3% reported 20 or greater years of diabetes compared to 44.4% of subjects without diabetic retinopathy). Both Eiser et al and Shah et al have demonstrated that diabetic patients with longer disease duration are more reluctant to change their self-management practices ((38, 39). As such, it is possible that despite the likely increase in awareness of diabetes complications among subjects with diabetes-associated vision loss, resistance to change yields poor self-care behavior I this population.

Although the primary hypotheses of this study did not specify the expected direction of the relationship between concern for overall eyesight and self-care behavior, the negative correlation between these two variables highlights a significant discrepancy between patients' health-related beliefs and behaviors regardless of the direction of the relationship. If poorer self-care behavior predicts greater concern for overall eyesight, then patients' concern for overall eyesight most likely arises from awareness of the consequences of their poor self-care practices. If on the other hand,

greater concern for overall eyesight predicts poorer self-care behavior, disempowering attitudes towards self management, such as decreased sense of self-efficacy (i.e. perceived capability to change behavior) and anxiety may be at play. In this age of rising prevalence of chronic disease, there has been a concomitant response in the redesign of primary care systems to improve management and outcomes of long-term illness(40-45). Motivational interviewing has come to the forefront as an effective way of helping health systems (at the clinician-patient level) deliver integrated chronic disease care while empowering patients to effectively self-manage their long-term diseases (45).

Motivational interviewing is a 'client centered directive method of enhancing intrinsic motivation to change by exploring and resolving ambivalence' (46). The principles of the motivational interviewing approach are captured by the alliterations: Express Empathy; Develop Discrepancy; Roll with Resistance; Support Self Efficacy, and the acronym R.U.L.E: Resist the righting reflex; Understanding your patient's dilemma and motivations; Listen to and Empower your patients (46, 47). Motivational interviewing is currently utilized by clinicians to successfully improve patient outcomes in a wide range of settings including diabetes management. For instance, in teenagers with Type 1 diabetes, motivational interviewing was shown in a multicenter randomized controlled trial by Channon et al to result in lower HgA1c levels as well as better psychosocial measures (e.g. more positive well-being and improved quality of life) than their counterparts who received support visits (48). In patients with newly diagnosed Type 2 diabetes, Brug et al found a significant reduction in saturated fat intake and increase in fruit intake among patients of dieticians trained in motivational interviewing (49).

Motivational interviewing could be used to effectively address the ambivalence identified in this study between participants' concern for overall eyesight and self-care behavior. The presence of such ambivalence suggests that there are factors in the lives of these Type 1 diabetic patients that have (from the perspective of the participants) a more compelling risk-benefit ratio than the self-management practices that could improve their disease profile. For instance, one might imagine a Type 1 diabetic subject voicing ambivalence in the following way: 'I want to control my diabetes to prevent (further) damage to my eyes. However if I exercise I am more likely to become hypoglycemic.' or 'I want to control my diabetes to prevent (further) damage to my eyes. However, cooking healthy meals takes up time that I could use watching television.' Motivational interviewing could be used by all level clinicians (physicians, nurses, ophthalmologists etc) to help Type 1 diabetics unearth such ambivalence and create avenues for patients' active participation in finding practical ways of resolving this ambivalence and improving self-care behavior.

Type 2 Diabetes Group

ANOVA analysis demonstrated positive linear associations between HgA1c levels and concern for overall diabetes complications ($FCQ_{Composite}$), concern for potential vision loss (FCQ_{Vision}), concern for complications from poorly controlled blood glucose ($FCQ_{Blood\ Glucose}$), concern for long-term diabetes complications ($FCQ_{Long\ Term}$), concern for heart disease (FCQ_{Heart}), and concern for stroke (FCQ_{Stroke}) respectively in the Type 2 diabetes group. Based on effect size calculations, concern for potential vision loss (FCQVision) was the second most likely specific concern to be associated with HgA1c levels; concern for complications from poorly controlled blood glucose levels ($FCQ_{Blood\ Glucose}$) was the most likely specific to be associated with HgA1c levels. There was no statistically significant association between concern for overall eyesight ($VFQ_{Item\ 3}$) and HgA1c levels. Furthermore, in the Type 2 diabetes group, there were no statistically significant associations

between self-care behavior ($SDSCA_{Composite}$) and concern for overall eyesight ($VFQ_{Item\ 3}$), self-care behavior and concern for potential vision loss (FCQ_{Vision}), or self-care behavior and concern for overall diabetes complications ($FCQ_{Composite}$). In this instance also, it is not possible to prove causality. As such participants with high HgA1c scores could be more concerned about potential vision loss, overall diabetes complications or other specific complications because of their awareness of the consequences of poorly controlled glucose levels. Though less plausible, it is also possible that participants with high levels of concern about potential vision loss, overall diabetes complications or other specific complications have poorly controlled glucose levels because of high stress or anxiety or poor self-care behavior resulting from high stress or anxiety.

Despite the association between concern for potential vision loss and HgA1c and between concern for overall diabetes complications and HgA1c, there was no statistically significant relationship between self-care behavior and HgA1c. As in other studies in the literature (34-37) , one would have expected self-care behavior to positively correlate with glycemic control. It is likely that in this study where HgA1c was categorized and not measured as a continuous variable, statistical analysis performed to determine the relationship between self-care behavior and glycemic control was less reliable. It is also conceivable that better glycemic control is associated more with interventions that occur in the clinic setting (e.g. medication changes to improve hyperglycemia) than with the participants' own self-management practices. Furthermore, this is a study in which self-care behavior was assessed by participants' self-reported perception of their health behavior. As such varying levels of awareness of best self-care practices may have caused participants to both over- and under-estimate the degree to which they were in fact managing their own health. The balancing out effect of educational awareness on self-care trends may explain the absence of a statistically significant relationship between self-care behavior and HgA1c. Finally, although

current research suggests that the strength and direction of the relationship between stress and blood glucose control varies considerably between individuals (50, 51), there is evidence to suggest that recent severe stressors are associated with poorer glycemic control (52) and that stress management training can improve glycemic control (53). It is therefore possible that increased fear of overall diabetes complications induces a stress response that perpetuates poorly controlled blood glucose levels and worse HgA1c values therefore decreasing the impact of adherence to self-care practices.

Looking at the results obtained in this study, it is possible to say that Type 1 diabetics are concerned about overall eyesight because of poor self-care behavior and high incidence of diabetic retinopathy, while Type 2 diabetics are concerned about potential vision loss and overall diabetes complications because of their awareness of poor glycemic control. If better self-care behavior does indeed predict good glycemic control, it can be inferred for the Type 2 diabetes group that poorer self-management behavior is associated with increased concern for vision loss and overall diabetes complications. Given this potential incongruence between health care beliefs and behavior, motivational interviewing could also be effectively used to increase Type 2 diabetic patient involvement in self-management practices.

<u>All Groups Combined</u>

In this study, there were no statistically significant relationships between concern for overall eyesight, concern for potential vision loss and self-care behavior or glycemic control (HgA1c) for all groups combined. The statistically significant associations demonstrated between HgA1c and $FCQ_{Composite}$, $FCQ_{Blood\ Glucose}$ and FCQ_{Stroke} scores respectively are most likely the result of combining the associations seen in the Type 1 and Type 2 diabetic groups alone.

Study Limitations:

This study has a number of limitations. The predicted sample size for this study was 215. However, only 100 subjects were enrolled. This discrepancy is primarily due to the fact that after one month of recruiting participants for this study at the Yale Diabetes Center, the proportion of patients presenting to the clinic who had already completed the study increased substantially. With a less than optimum sample size, it is not possible to conclude with confidence that the study yielded all the statistically significant results that it had the potential for. Furthermore, given the numerous statistically significant demographic and health-related differences between the Type 1 and Type 2 diabetes groups, there were many potential sources of confounding. However, the small sample size made it difficult to control for different combinations of all the potential confounding variables without decreasing the power of the study. As such only individual adjustments for confounding variables on the relationship between concern for vision loss and self-management behavior were considered as truly reliable. A larger sample size would make it possible to control for different combinations of the confounding variables to further unveil any synergistic effects they may have on the outcomes of interest in this study.

All the participants surveyed were patients at the Yale Diabetes Center. Patients who are cared for in a diabetes clinic are not necessarily representative of the broad spectrum of diabetes patients. This sampling framework may therefore reduce the generalizability of the results obtained. According to 2004 to 2006 national survey data for people ages 20 years or older, 6.6 percent of non-Hispanic whites, 7.5 percent of Asian Americans, 10.4 percent of Hispanics, and 11.8 percent of non-Hispanic blacks had diagnosed diabetes (54). In New Haven County 69.9% of the population is non-Hispanic White, 13.0% is black, 13.3% is Hispanic and 3.5% is Asian (55). Inferring from this data, one would expect the racial distribution among diabetic patients attending

the Yale Diabetes Clinic to be as follows: 60% non-Hispanic white, 19% black, 18% Hispanic, and 4% Asian. The population sample in this study therefore has a greater representation of whites (63%) and blacks (21%) and a smaller representation of Hispanics (10%) and Asians (2%) than expected. Furthermore, since care of diabetic patients occurs in diverse contexts, participants could have also been recruited from general practices, community centers etc to allow for better representation as well as comparison of various diabetes care contexts. Finally, a control group of non-diabetic subjects was not utilized in this study. The presence of a non-diabetic control group would have allowed for comparison of health beliefs and behaviors between members of the general population and diabetic subjects.

All questionnaires in this study were interviewer-administered. To allow for more accurate answering of questionnaires, it may have been better to a give participants the opportunity to complete the questionnaires on their own. This is particularly pertinent to the SDSCA questionnaire - a measure of self-care behavior over the previous 7 days. The predominantly negative skew of the SDSCA composite and sub-scale score distributions could be due to participants' desire to please the interviewer. The fact that a 100% medication compliance rate was measured among all 100 subjects further highlights the way in which this 'desire to please the interviewer' could have influenced the responses to interviewer-administered questionnaires. Furthermore, although the format for administering the questionnaires was standardized, the likelihood of interviewer bias is high particularly since the interviewer was also responsible for analyzing the data collected.

Baseline mental health conditions were neither measured nor adjusted for in this study. 'Concern' for overall eyesight and 'fear' of overall and specific diabetes complications are multi-faceted psychosocial constructs. Mental health states such as depression and anxiety could therefore have

influenced the way in which participants answered the afore-mentioned questionnaires. For instance, participants with greater baseline anxiety may have exhibited greater concern for overall eyesight and fear of diabetes complications. Furthermore, there is evidence in the literature demonstrating that greater severity of depression symptoms is associated with poorer diet and medication regimen adherence and functional impairment in diabetic patients (56). As such mental health states such as depression could also have affected the way in which participants answered the SDSCA questionnaire. Anxiety and depression could have been measured using questionnaires such as the Hospital Anxiety and Depression (HAD) scale (57), and adjusted for accordingly in the study analyses.

In this study, all health information including HgA1c values within the previous 3 months was determined from participants' reports and was therefore subject to substantial recall error. To standardize and increase the accuracy of the process of acquiring HgA1c data, participants' HgA1c could have been tested at the time of completion of the questionnaires using an instant, point-of-care HgA1c measuring instrument. This method would have yielded continuous HgA1c values that could have then been easily used in correlation and regression analysis to obtain more reliable results. Along the same lines, information such as diabetes type, as well as the presence and severity of eye ailments (e.g. diabetic retinopathy, glaucoma, cataract etc) could have been confirmed either by examination of the participants or chart review. By depending on participants for provision of health information, one assumes that they are actively involved in and knowledgeable about their health when this may not necessarily be the case.

Visual acuity of participants was not determined in this study. Nonetheless, the $VFQ_{Composite}$ score has been shown to be significantly correlated with visual acuity such that higher scores are

associated with better visual acuity (15). In this study, independent sample T-test analysis showed no significant differences in $VFQ_{Composite}$ scores between Type 1 and Type 2 diabetes groups thereby suggesting that there were no significant differences in visual acuity. However, given the multi-faceted nature of the $VFQ_{Composite}$ score, it was not in fact used in this study as a measure of visual acuity. To better isolate the effect of visual acuity on the relationship between concern for vision loss and self-care behavior, a direct and objective measure of visual acuity would have been more effective.

Although the educational level of participants was accounted for in this study, knowledge of diabetes was not specifically measured. According to a study by Osborn et al, having more knowledge about diabetes independently and directly predicted better self-care behavior; better self-care behavior predicted improved glycemic control (58). Given the afore-mentioned findings, it is conceivable that participants' level of diabetes knowledge is a factor that needs to be controlled for in order to better evaluate the relationship between concern for vision loss and self-care behavior. This is especially important since prior studies have shown that only a small proportion of diabetic patients are actually aware of diabetic retinopathy as a complication of diabetes (25, 26) – a fact that further begs the question of whether patients can be concerned about vision loss when they are not aware of the problem of diabetic eye disease. Validated measures of diabetes knowledge include the Diabetes Knowledge (DKN) Scale (59) and the 24-item Diabetes Knowledge questionnaire (60), either of which could have been included in the questionnaire packet utilized in this study.

One of the goals of this study was to test the hypothesis that a significant proportion of the correlation between concern for overall complications and diabetes self-care activities/ glycemic

control is accounted for by concern for overall eyesight/potential vision loss in diabetic subjects. However, the measures for concern for overall eyesight ($VFQ_{Item\ 3}$) and concern for overall diabetes complications ($FCQ_{Composite}$) were derived from two distinct and separately validated questionnaires. As such, had there been statistically significant correlations between self-care behavior and concern for vision loss and self-care behavior and concern for overall diabetes complications respectively, it would not have been possible to accurately determine what proportion of the latter correlation was accounted for by the former. To make the comparison plausible, the measure of concern for vision loss would have ideally been a subscale score of a questionnaire measuring overall concern for diabetes complications. For the Type 2 diabetic group in which statistically significant relationships were demonstrated between FCQ_{Vision} and HgA1c and $FCQ_{Composite}$ and HgA1c in the Type 2 diabetes group, the effect sizes are a useful way of comparing the strength of the associations between FCQ subscale scores and HgA1c but not for determining the proportion of the relationship between FCQComposite and HgA1c that they account for. Although FCQ subscale scores were calculated in this study, the FCQ was not designed to have these subscale scores and as such is not be the most appropriate questionnaire for determining the proportion of the correlation between concern for overall complications and diabetes self-care activities that is accounted for by concern for vision loss. A more suitable study instrument would therefore have to be designed and validated for this purpose.

6. Conclusions

Poorer self-care behavior is associated with greater concern for overall eyesight and vice versa in Type 1 diabetics. Adjusting for diabetic retinopathy and employment status individually affect the statistical significance of this relationship. The incongruence between health care attitudes (concern for overall eyesight) and behaviors (diabetes self-care activities) can be targeted by health care providers using interventions such as Motivational Interviewing to promote active participation of this diabetic population in finding practical ways of resolving this ambivalence and improving self-care behavior. In Type 2 diabetic subjects, higher HgA1c levels are associated with increased concern for potential vision loss and increased concern for overall diabetes complications and vice versa. However, there is no statistically significant relationship between self-care behavior and glycemic control. Future studies to better understand the factors driving the afore-mentioned associations could result in the creation of new models of care or support the implementation of already existing models of care for better health outcomes in the diabetic population.

7. Tables

Table 1a. Population Comparisons - Chi-Square Analysis of Demographic Characteristics of Type 1 and Type 2 Diabetes Groups.

	Type 1 DM	**Type 2 DM**	**Chi Square (χ^2)**	**Significance (2-tailed)#**
Gender			4.78	0.029
Female	18 (75.0%)	34 (49.3%)		
Male	6 (25.0%)	35 (50.7%)		
Employment Status			11.7	0.009
Employed	12 (50.0%)	24 (34.8%)		
Unemployed	8 (33.3%)	8 (11.6%)		
Disabled	2 (8.30%)	13 (18.8%)		
Retired	2 (8.30%)	24 (34.8%)		
Marital Status			11.7	0.008
Single	11 (45.8%)	14 (20.3%)		
Married	13 (54.2%)	34 (49.3%)		
Divorced	0 (0.00%)	14 (20.3%)		
Other	0 (0.00%)	7 (10.1%)		
Health Insurance			14.2	0.047
Medicare Only	1 (4.2%)	11 (15.9%)		
Medicaid Only	2 (8.30%)	13 (18.8%)		
Private Only	13 (54.2%)	24 (34.8%)		
Medicare and Medicaid	1 (4.20%)	3 (4.30%)		
Medicare and Private	2 (8.30%)	14 (20.30%)		
Medicaid and Private	2 (8.30)	0 (0.00%)		
Federal/State	3 (12.5%)	3 (4.30%)		
None	0 (0.00%)	1 (1.40%)		
Years with DM			16.1	<0.001
Less than 20 years	9 (37.5%)	56 (81.2%)		

Great than 20 years	15 (62.5%)	13 (18.8%)		
Medication Type			45.0	<0.001
Pills/Tablets	0 (0.00%)	22 (31.9%)		
Insulin (Injection)	14 (58.3%)	20 (29.0%)		
Insulin (Pump)	9 (37.5%)	0 (0.00%)		
Pills/Tablets and Insulin	1 (4.20%)	24 (34.8%)		
None	0 (0.00%)	3 (4.30%)		
Diabetic Retinopathy			17.6	<0.001
Yes	15 (62.5%)	12 (17.4%)		
No	9 (37.5%)	57 (82.6%)		
Laser Treatment			7.79	0.005
Yes	10 (41.7%)	10 (14.5%)		
No	14 (58.3%)	59 (85.5%)		
Presbyopia			4.43	0.035
Yes	13 (54.2%)	53 (76.8%)		
No	11 (45.8%)	16 (23.2%)		

#Only statistically significant distribution differences are here reported

Table 1b. Population Comparisons - Differences in Questionnaire Scores Between Participants with Type 1 and Type 2 Diabetes

Variable	**Type 1 DM**	**Type 2 DM**	**T-test value**	**Significance (2- tailed)#**
Age (yrs)	44.0 (±14.2)	59.2 (± 13.2)	-4.76	<0.001
SDSCA $_{\text{blood sugar testing}}$ (%)	97.0 (± 8.66)	80.1 (±30.5)	4.10	<0.001
SDSCA $_{\text{foot care}}$ (%)	85.7 (±18.0)	71.1 (± 31.6)	2.76	0.007
SDSCA $_{\text{Composite}}$ (%)	78.1 (±9.50)	70.2 (±17.4)	2.84	0.006

#Only statistically significant differences in scores are here reported.

Table 1c. Differences in Questionnaire Scores Between Participants with and without Diabetic Retinopathy (All Groups Combined)

Variable (± SD)	Diabetic Retinopathy (Yes)	Diabetic Retinopathy (No)	T-test value	Significance (2-tailed)
$FCQ_{Long\ term}$	66.3 ± 28.0	51.8 ± 29.3	2.22	0.028*
FCQ_{Vision}	54.3 ± 34.5	36.5 ± 31.6	2.44	0.017*
FCQ_{Kidney}	44.0 ± 33.7	27.2 ± 32.1	2.29	0.024*
$FCQ_{Composite}$	52.6 ± 25.2	41.9 ± 26.0	1.84	0.068
$SDSCA_{Blood\ Glucose}$	95.0 ± 13.4	81.4 ± 29.9	3.12	0.002*
$SDSCA_{Foot\ Care}$	85.7 ± 19.3	71.9 ± 31.2	2.64	0.010*
$SDSCA_{Composite}$	74.2 ± 10.6	71.4 ± 17.5	0.785	0.434
$VFQ_{General\ Vision}$	66.7 ± 24.8	80.0 ± 14.9	-2.62	0.013*
$VFQ_{NearActivities}$	76.9 ± 28.6	90.9 ± 16.3	-2.40	0.022*
$VFQ_{Distant\ Activities}$	77.2 ± 28.1	92.4 ± 11.5	-2.74	0.010*
$VFQ_{Mental\ Health}$	76.3 ± 28.5	90.3 ± 9.87	-2.51	0.018*
$VFQ_{Role\ Difficulties}$	78.2 ± 33.4	92.3 ± 18.1	-2.08	0.046*
$VFQ_{Dependency}$	82.7 ± 29.4	98.3 ± 7.47	-2.72	0.011*
$VFQ_{Color\ Vision}$	85.2 ± 24.3	97.6 ± 12.6	-2.53	0.016*
$VFQ_{Composite}$	79.8 ± 23.3	91.8 ± 8.51	-2.63	0.014*
$VFQ_{Item\ 3}$	47.2 ± 38.8	62.3 ± 30.1	-2.06	0.042*
$VFQ_{Item\ 21}$	76.9 ± 38.6	96.2 ± 15.4	-2.54	0.012*
$VFQ_{Item\ 22}$	77.8 ± 37.6	95.5 ± 14.6	-2.39	0.023*
$VFQ_{Item\ 25}$	87.0 ± 28.1	99.7 ± 2.93	-2.33	0.028*

*Statistically significant difference in scores between diabetic subjects with and without diabetic retinopathy (all groups combined)

Table 1d. Differences in Questionnaire Scores Between Participants with and without Diabetic Retinopathy (Type 1 Diabetes Group only)

Variable (± SD)	Diabetic Retinopathy (Yes)	Diabetic Retinopathy (No)	T-test value	Significance (2-tailed)
FCQ_{Vision}	54.4±31.2	25.9±22.2	2.40	0.026*
$SDSCA_{Exercise}$	99.0±3.70	93.7±13.1	-3.26	0.004*
$SDSCA_{Composite}$	75.7 ±8.72	82.3 ±8.78	-1.79	0.087
$VFQ_{Distant\ Activities}$	76.1±30.5	95.4±11.1	-2.21	0.039*
$VFQ_{Role\ Difficulties}$	77.5±33.1	100.0±0.0	-2.63	0.02*
$VFQ_{Mental\ Health}$	74.0±28.1	93.3±6.1	-2.57	0.021*
$VFQ_{Dependency}$	81.1±30.6	100.0±0.0	-2.39	0.031
$VFQ_{Driving}$	72.2±33.8	98.3±3.7	-2.64	0.022*
$VFQ_{Color\ Vision}$	86.7±20.8	100.0±0.0	-2.48	0.027*
$VFQ_{Peripheral\ Vision}$	80.0±33.0	100.0±0.0	-2.35	0.034*
$VFQ_{Composite}$	79.6±23.7	96.6±3.0	-2.74	0.015*
$VFQ_{Item\ 3}$	41.7±38.6	66.7±30.6	-1.65	0.113
$VFQ_{Item\ 21}$	75.0±40.1	100.0±0.0	-2.42	0.030*
$VFQ_{Item\ 22}$	75.0±40.1	100.0±0.0	-2.42	0.030*

* Statistically significant differences in scores between diabetic subjects with and without diabetic retinopathy (Type 1 diabetes group).

Table 1e. Differences in Questionnaire Scores Between Participants with and without Diabetic Retinopathy (Type 2 Diabetes Group only)

Variable	Diabetic Retinopathy (Yes)	Diabetic Retinopathy (No)	T-test value	Significance (2-tailed)#
FCQ_{Kidney}	48.1±38.9	26.3±32.2	2.06	0.044
$SDSCA_{Foot\ Care}$	85.7±19.0	68.0±33.0	2.52	0.018

#Only statistically significant differences in scores are here reported.

Table 2a. Significant and non-significant Spearman Correlations of Interest for the Type 1 Diabetic Group (N= 24)

Spearman's rho		SDSCA Composite score	VFQ Item 3	VFQ Mental Health Score	VFQ Composite Score	FCQ Vision Score	FCQ Composite Score
SDSCA Composite score	Correlation Coefficient	1.000	**.521****	**.413***	**0.393**	**-0.178**	**-0.359**
	Sig. (2-tailed)	.	0.009	0.045	0.057	0.404	0.085
VFQ Item 3	Correlation Coefficient	**.521****	1.000	**.967****	**.610****	**-.483***	**-.556****
	Sig. (2-tailed)	0.009	.	0.000	0.002	0.017	0.005
VFQ Mental Health Score	Correlation Coefficient	**.413***	**.967****	1.000	**.682****	**-.530****	**-.550****
	Sig. (2-tailed)	0.045	0.000	.	0.000	0.008	0.005
VFQ Composite Score	Correlation Coefficient	**0.393**	**.610****	**.682****	1.000	-0.274	-0.356
	Sig. (2-tailed)	0.057	0.002	0.000	.	0.195	0.088
FCQ Vision Score	Correlation Coefficient	**-0.178**	**-.483***	**-.530****	-0.274	1.000	**.679****
	Sig. (2-tailed)	0.404	0.017	0.008	0.195	.	0.000
FCQ Composite Score	Correlation Coefficient	**-0.359**	**-.556****	**-.550****	-0.356	**.679****	1.000
	Sig. (2-tailed)	0.085	0.005	0.005	0.088	0.000	.

* Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

Table 2b. Spearman Correlation between $VFQ_{Mental\ Health}$ Score components and $SDSCA_{Composite}$ Score in the Type 1 Diabetes Group (N = 24).

Spearman's rho		SDSCA Composite Score	$VFQ_{Item\ 3}$	$VFQ_{Item\ 21}$	$VFQ_{Item\ 22}$	$VFQ_{Item\ 25}$	$VFQ_{Item\ A12}$	VFQ Mental Health Score
SDSCA Composite Score	Correlation Coefficient	1.000	**.521****	0.025	0.020	0.066	-0.110	**.413***
	Sig. (2-tailed)	.	0.009	0.908	0.926	0.758	0.609	0.045
$VFQ_{Item\ 3}$	Correlation Coefficient	**.521****	1.000	**.565****	**.565****	**.472***	0.363	**.967****
	Sig. (2-tailed)	0.009	.	0.004	0.004	0.020	0.082	0.000
$VFQ_{Item\ 21}$	Correlation Coefficient	0.025	**.565****	1.000	**.993****	**.829****	**.703****	**.716****
	Sig. (2-tailed)	0.908	0.004	.	0.000	0.000	0.000	0.000
$VFQ_{Item\ 22}$	Correlation Coefficient	0.020	**.565****	**.993****	1.000	**.835****	**.710****	**.719****
	Sig. (2-tailed)	0.926	0.004	0.000	.	0.000	0.000	0.000
$VFQ_{Item\ 25}$	Correlation Coefficient	0.066	**.472***	**.829****	**.835****	1.000	**.816****	**.646****
	Sig. (2-tailed)	0.758	0.020	0.000	0.000	.	0.000	0.001
$VFQ_{Item\ A12}$	Correlation Coefficient	-0.110	0.363	**.703****	**.710****	**.816****	1.000	**.551****
	Sig. (2-tailed)	0.609	0.082	0.000	0.000	0.000	.	0.005
VFQ Mental Health Score	Correlation Coefficient	**.413***	**.967****	**.716****	**.719****	**.646****	**.551****	1.000
	Sig. (2-tailed)	0.045	0.000	0.000	0.000	0.001	0.005	.

* Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

Table 2c. Significant and non-Significant Spearman Correlations of Interest for the Type 2 Diabetic Group (N = 69)

Spearman's rho		SDSCA Composite score	VFQ Item 3	VFQ Mental Health Score	VFQ Composite Score	FCQ Vision Score	FCQ Composite Score
SDSCA Composite score	Correlation Coefficient	1.000	**-0.153**	**-0.173**	**0.022**	**0.131**	**0.012**
	Sig. (2-tailed)	.	0.210	0.156	0.861	0.285	0.924
VFQ Item 3	Correlation Coefficient	**-0.153**	1.000	**.889****	**.446****	**-.596****	**-.636****
	Sig. (2-tailed)	0.210	.	0.000	0.000	0.000	0.000
VFQ Mental Health Score	Correlation Coefficient	**-0.173**	**.889****	1.000	**.633****	**-.517****	**-.560****
	Sig. (2-tailed)	0.156	0.000	.	0.000	0.000	0.000
VFQ Composite Score	Correlation Coefficient	**0.022**	**.446****	**.633****	1.000	**-.343****	**-.372****
	Sig. (2-tailed)	0.861	0.000	0.000	.	0.004	0.002
FCQ Vision Score	Correlation Coefficient	**0.131**	**-.596****	**-.517****	**-.343****	1.000	**.815****
	Sig. (2-tailed)	0.285	0.000	0.000	0.004	.	0.000
FCQ Composite Score	Correlation Coefficient	**0.012**	**-.636****	**-.560****	**-.372****	**.815****	1.000
	Sig. (2-tailed)	0.924	0.000	0.000	0.002	0.000	.

* Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

Table 2d. Significant and non-Significant Spearman Correlations of Interest for the Unknown Diabetes Type Group (N = 7)

Spearman's rho		SDSCA Composite Score	VFQ Item 3	VFQ Mental Health Score	VFQ Composite Score	FCQ Vision Score	FCQ Composite Score
SDSCA Composite Score	Correlation Coefficient	1.000	**-0.468**	**-0.099**	**-0.036**	**0.182**	**0.144**
	Sig. (2-tailed)	.	0.290	0.834	0.939	0.696	0.758
VFQ Item 3	Correlation Coefficient	**-0.468**	1.000	**.774***	0.225	-0.686	-0.576
	Sig. (2-tailed)	0.290	.	0.041	0.628	0.089	0.176
VFQ Mental Health Score	Correlation Coefficient	**-0.099**	**.774***	1.000	0.571	**-.903****	**-.915****
	Sig. (2-tailed)	0.834	0.041	.	0.180	0.005	0.004
VFQ Composite Score	Correlation Coefficient	**-0.036**	0.225	0.571	1.000	-0.491	-0.577
	Sig. (2-tailed)	0.939	0.628	0.180	.	0.263	0.175
FCQ Vision Score	Correlation Coefficient	**0.182**	-0.686	**-.903****	-0.491	1.000	**.963****
	Sig. (2-tailed)	0.696	0.089	0.005	0.263	.	0.000
FCQ Composite Score	Correlation Coefficient	**0.144**	-0.576	**-.915****	-0.577	**.963****	1.000
	Sig. (2-tailed)	0.758	0.176	0.004	0.175	0.000	.

* Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

Table 2e. Significant and non-Significant Spearman Correlations of Interest for all Subjects Combined (N=100)

Spearman's rho		SDSCA Composite Score	VFQ Item 3	VFQ Mental Health Score	VFQ Composite Score	FCQ Vision Score	FCQ Composite Score
SDSCA Composite Score	Correlation Coefficient	1.000	**-0.058**	**-0.068**	**0.082**	**0.089**	**-0.035**
	Sig. (2-tailed)	.	0.565	0.503	0.419	0.381	0.727
VFQ Item 3	Correlation Coefficient	**-0.058**	1.000	**.907****	**.491****	**-.585****	**-.593****
	Sig. (2-tailed)	0.565	.	0.000	0.000	0.000	0.000
VFQ Mental Health Score	Correlation Coefficient	**-0.068**	**.907****	1.000	**.657****	**-.549****	**-.560****
	Sig. (2-tailed)	0.503	0.000	.	0.000	0.000	0.000
VFQ Composite Score	Correlation Coefficient	**0.082**	**.491****	**.657****	1.000	**-.355****	**-.373****
	Sig. (2-tailed)	0.419	0.000	0.000	.	0.000	0.000
FCQ Vision Score	Correlation Coefficient	**0.089**	**-.585****	**-.549****	**-.355****	1.000	**.806****
	Sig. (2-tailed)	0.381	0.000	0.000	0.000	.	0.000
FCQ Composite Score	Correlation Coefficient	**-0.035**	**-.593****	**-.560****	**-.373****	**.806****	1.000
	Sig. (2-tailed)	0.727	0.000	0.000	0.000	0.000	.

* Correlation is significant at the 0.05 level (2-tailed).

**Correlation is significant at the 0.01 level (2-tailed).

Table 3a. Linear Regression Analysis - Relationship between $VFQ_{Mental\ Health}$, $VFQ_{Item\ 3}$, $VFQ_{Composite}$, FCQ_{Vision}, $FCQ_{Composite}$ Scores (as Independent Variables) and the $SDSCA_{Composite}$ Score (as the Dependent Variable)

Independent Variables	R square	Regression Coefficient (B)	Standardized Regression Coefficient (B_s)	Significance (2 tailed)
Type 1 DM				
$VFQ_{Mental\ Health}$	0.059	0.092	0.242	0.254
$VFQ_{Item\ 3}$	0.231	0.118	0.481	**0.017***
$VFQ_{Composite}$	0.041	0.091	0.203	0.340
FCQ_{Vision}	0.021	-0.043	-0.144	0.501
$FCQ_{Composite}$	0.089	-0.131	-0.298	0.157
Type 2 DM				
$VFQ_{Mental\ Health}$	0.030	-0.188	-0.172	0.157
$VFQ_{Item\ 3}$	0.029	-0.092	-0.169	0.164
$VFQ_{Composite}$	0.011	-0.140	-0.106	0.385
FCQ_{Vision}	0.015	0.064	0.122	0.316
$FCQ_{Composite}$	0.000	0.004	0.006	0.959
All DM groups				
$VFQ_{Mental\ Health}$	0.013	-0.100	-0.112	0.266
$VFQ_{Item\ 3}$	0.012	-0.052	-0.108	0.283
$VFQ_{Composite}$	0.002	-0.050	-.047	0.641
FCQ_{Vision}	0.009	0.046	0.096	0.341
$FCQ_{Composite}$	0.000	-0.004	-0.006	0.953

Dependent variable: $SDSCA_{Composite}$ Score

Table 3b. Multiple Regression Analysis - Effect of Fear of Other Diabetes Complications on the Relationship between Concern for Overall Eyesight and Self-care Behavior (Type 1 Diabetes Group only).

Variable	R square	Regression coefficient (B)	Standardized Regression Coefficient (B_a)	Significance (2 tailed)
VFQ Items 21,22,25,A12	0.357	0.155	0.630	0.018*
$FCQ_{Long\ term}$	0.240	0.105	0.425	0.069
FCQ_{Vision}	0.243	0.134	0.543	0.022*
FCQ_{Heart}	0.247	0.108	0.439	0.040*
FCQ_{Kidney}	0.242	0.125	0.507	0.017*
FCQ_{Stroke}	0.285	0.109	0.442	0.028*
$FCQ_{Blood\ Glucose}$	0.252	0.111	0.450	0.030*
$FCQ_{Circulation}$	0.275	0.093	0.378	0.083
$FCQ_{Composite}$	0.237	0.108	0.439	0.056

Independent Variable: $VFQ_{Item\ 3}$ Score

Dependent Variable: $SDSCA_{Composite}$ Score

*Relationship between $VFQ_{Item\ 3}$ Score and $SDSCA_{Composite}$ Score remains statistically significant when indicated continuous variables are controlled for.

Table 4. ANCOVA - Determining the Effect of Confounding Variables on the Association between $VFQ_{Item\ 3}$ scores and $SDSCA_{Composite}$ Scores.

Factor	F ratio (df_M, df_R)	R^2_{model} (η^2_{model})	$\eta^2_{VFQ\_3}$	Effect size (r)	*P*
None	6.620 (1,22)	0.231	0.231	0.481	0.017*
Age	6.198 (1,20)	0.290	0.220	0.486	0.022*
Gender	6.646 (1,21)	0.250	0.237	0.490	0.018*
Employment Status[a]	2.973 (1,19)	0.342	0.103	0.368	0.101
Marital Status	6.162 91,21)	0.232	0.225	0.476	0.002*
Health Insurance	4.980 (1,16)	0.409	0.184	0.489	0.040*
Years of DM	6.329 (1,21)	0.249	0.166	0.481	0.020*
Type of Medication	6.756 (1,20)	0.510	0.166	0.502	0.017*
Diabetic Retinopathy	4.274 (1,21)	0.275	0.148	0.411	0.051
Laser Therapy for DR	4.650 (1,21)	0.241	0.168	0.425	0.043*
Presbyopia (Glasses for Near Vision)	9.441 (1,21)	0.351	0.292	0.557	0.006*
All 10 factors	0.253 (1,4)	0.877	0.008	0.244	0.641
Macular Degeneration	7.573 (1,21)	0.267	0.265	0.515	0.012*
Myopia (Glasses needed for Distant Vision)	6.407 (1,21)	0.389	0.187	0.483	0.019*
Cataract	6.933 (1,21)	0.262	0.243	0.498	0.016*
Glaucoma	8.699 (1,21)	0.335	0.276	0.541	0.008*
Cataract Surgery	6.489 (1,21)	0.236	0.236	0.485	0.019*
All 8 eye-related factors	8.146 (1,14)	0.692	0.179	0.606	0.013*

F-ratio: Ratio of the average variability in the data that each respect model can explain to the average variability unexplained by the same model
η^2_{model} : Total variance of each respective model
$\eta^2_{VFQ\_3}$: Proportion of variance in $SDSCA_{Composite}$ score attributable to $VFQ_{Item\ 3}$ score in each respective model
Effect size (r): Effect size of $VFQ_{Item\ 3}$ score in each respective model
P: Statistical significance of the relationship between $VFQ_{Item\ 3}$ and $SDSCA_{Composite}$ scores in each respective model
Dependent Variable: $SDSCA_{Composite}$ Score
Independent Variable: $VFQ_{Item\ 3}$ Score
*Relationship between $SDSCA_{Composite}$ score and $VFQ_{Item\ 3}$ score remains statistically significant with the indicated categorical variables are adjusted for.
[a]Levene's test of equality of variances not met.

Table 5a. Relationship Between HgA1c and $SDSCA_{Composite}$, $FCQ_{Composite}$, FCQ_{Vision}, $VFQ_{Mental\ Health}$ and $VFQ_{Composite}$ Scores

	F-ratio$_{Combined}$ (df_M, df_R)	**Sig. (2-tailed)**	**F-ratio$_{Linear}$ (df_M, df_R)**	**Sig. (2-tailed)**
Type 1 DM				
$SDSCA_{Composite}$	0.319 (4,15)	0.861	0.106 (1,15)	0.749
$FCQ_{Composite}$	0.310 (4,15)	0.867	0.003 (1,15)	0.957
FCQ_{Vision}	0.760 (4, 15)	0.567	1.76 (1,15)	0.205
$VFQ_{Mental\ Health}$	1.02 (4,15)	0.430	0.352 (1, 15)	0.562
$VFQ_{Composite}$	1.72 (4,15)	0.198	0.353 (1, 15)	0.561
Type 2 DM				
$SDSCA_{Composite}$	0.994 (4,53)	0.419	0.234 (1,53)	0.631
$FCQ_{Composite}$	5.94 (4,53)	0.001*	7.80 (1,53)	0.007*
FCQ_{Vision}	5.06(4,53)	0.002*	7.56 (1,53)	0.008*
$VFQ_{Mental\ Health}$	1.25 (4,53)	.300	0.443 (1,53)	0.509
$VFQ_{Composite}$	0.682 (4,53)	.607	0.394 (1,53)	0.533
All Groups Combined				
$SDSCA_{Composite}$	0.680 (4, 79)	0.608	0.141 (1, 79)	0.708
$FCQ_{Composite}$	2.601 (4, 79)	0.042*	2.994 (1, 79)	0.087
FCQ_{Vision}	1.58 (4, 79)	0.188	0.835 (1, 79)	0.364
$VFQ_{Mental\ Health}$	0.621 (4, 79)	0.649	0.847 (1, 79)	0.360
$VFQ_{Composite}$	0.267 (4, 79)	0.898	0.832 (1, 79)	0.364

*Statistically Significant

Table 5b. Effect sizes of Relationships between FCQ Composite and Subscale Scores and HgA1c levels for the Type 2 Diabetic group and all Groups Combined.

FCQ Subscale Score	$F\text{-ratio}_{Combined}$ (df_M, df_R, sig)	$F\text{-ratio}_{Linear}$ (df_M, df_R, sig)	Effect size (ω)
Type 2 DM			
$FCQ_{Composite}$	5.942 (4, 53, 0.003*)	7.80 (1, 53, 0.007*)	0.504*
$FCQ_{Blood\ Glucose}$	5.88 (4, 53, 0.001*)	9.60 (1, 53, 0.003*)	0.502*
FCQ_{Vision}	5.06 (4, 53, 0.002*)	7.56 (1, 53, 0.008*)	0.468*
FCQ_{Stroke}	5.00 (4, 53, 0.002*)	5.47 (1, 53, 0.023*)	0.465*
$FCQ_{Long\ Term}$	4.67 (4, 53, 0.003*)	5.78 (1, 53, 0.020*)	0.449*
FCQ_{Heart}	4.80 (4, 53, 0.002*)	5.88 (1, 53, 0.019*)	0.445*
FCQ_{Kidney}	2.88 (4, 53, 0.031*)	3.77 (1, 53, 0.058)	0.339*
$FCQ_{Circulation}$	2.00 (4, 53, 0.108)	1.03 (1, 53, 0.314)	0.254
All DM Groups			
$FCQ_{Composite}$	2.60 (4, 79, 0.042*)	2.99 (1, 79, 0.087)	0.283*
$FCQ_{Blood\ Glucose}$	3.09 (4, 79, 0.020*)	5.34 (1, 79, 0.023*)	0.323*
FCQ_{Stroke}	4.83 (4, 79, 0.002*)	1.81 (1, 79, 0.182)	0.437*

*Statistically Significant

Table 5c. Planned Contrast Results for Comparison of FCQ Composite and Subscale Scores Between HgA1c Categories in the Type 2 Diabetes Group and All Groups Combined.

FCQ Subscale Score	Contrast[a]	Value of Contrast	Std. Error	t	df_R	Sig. (2-tailed)	Contrast Effect size (r)
Type 2 DM							
$FCQ_{Long\ term}$	**1**	83.83	46.44	1.805	53	0.077	0.241
	4	42.54	12.06	3.527	53	0.001*	0.436*
FCQ_{Vision}	**1**	105.39	52.44	2.009	53	0.050*	0.266*
	4	52.36	13.62	3.843	53	<0.001*	0.467*
FCQ_{Heart}	**1**	96.61	50.38	1.918	53	0.061	0.255
	4	47.98	13.09	3.667	53	0.001*	0.450*
FCQ_{Kidney}	**1**	100.20	57.51	1.742	53	0.087	0.233
	4	38.27	14.94	2.562	53	0.013*	0.332*
FCQ_{Stroke}	**1**	88.75	46.84	1.895	53	0.064	0.252
	4	45.79	12.17	3.763	53	<0.001*	0.459*
$FCQ_{Blood\ Glucose}$	**1**	118.29	50.59	2.338	53	0.023*	0.306*
	4	53.37	13.14	4.062	53	<0.001*	0.487*
$FCQ_{Composite}$	**1**	89.17	41.43	2.153	53	0.036*	0.284*
	4	44.85	10.76	4.168	53	<0.001*	0.497*
All DM Groups							
$FCQ_{Composite}$	**1**	48.7	37.7	1.290	79	0.201	0.144
	4	25.9	9.32	2.775	79	0.007*	0.298*
FCQ_{Stroke}	**1**	40.50	40.94	0.989	79	0.326	0.111
	4	38.16	10.12	3.772	79	<0.001*	0.391*
$FCQ_{Blood\ Glucose}$	**1**	80.13	47.85	1.675	79	0.098	0.185
	4	33.18	11.82	2.806	79	0.006*	0.301*

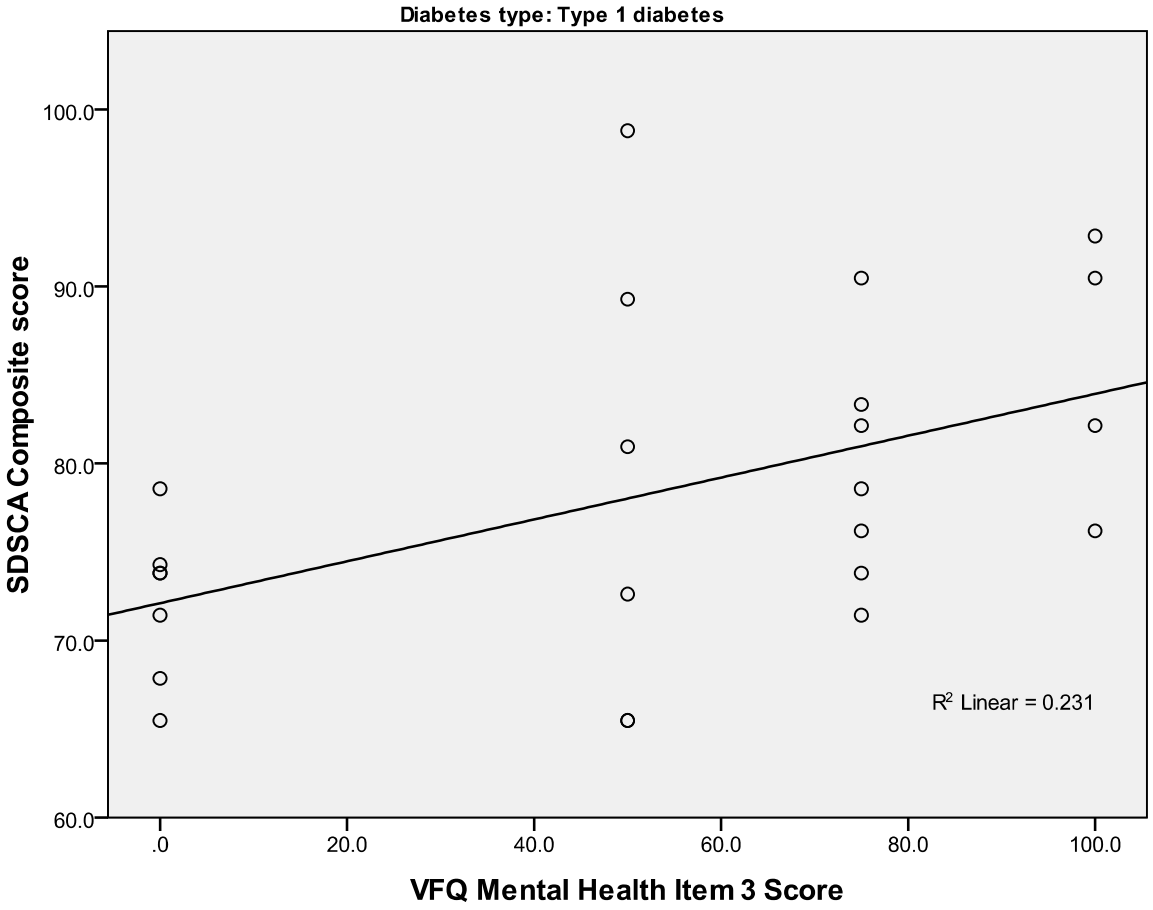
* Statistically significant

[a]**Contrast Coefficients**

Contrast	What was your most recent HbA1c level?				
	<5.0 - 5.9	6.0 - 6.9	7.0 - 7.9	8.0-9.0	>9.0
1	-4	1	1	1	1
2	0	-3	1	1	1
3	0	0	-2	1	1
4	0	0	0	-1	1

8. Figures

Figure 1. Linear Regression Relationship Between $VFQ_{Item\ 3}$ and $SDSCA_{Composite}$ Score for the Type 1 Diabetes Group



9. APPENDIX: QUESTIONNAIRES

I. Demographic Information Sheet

Please complete the following questions as best you can to help us learn more about who you are. Note that none of the information you provide will be shared with unauthorized individuals. Thank you for your participation.

1. Have you participated in this study before?
   a. Yes
   b. No

   If 'Yes' please return the questionnaire packet to the individual who gave it to you.

2. What is your age? _____years.

3. What is your gender?
   a. Male
   b. Female

4. What language do you speak most in your home?
   a. English
   b. Spanish
   c. Other (please specify):_____

5. What is the highest level of formal education you have completed?
   a. Elementary school
   b. High school or equivalent
   c. Vocation/Technical School (2 years)
   d. Some College
   e. Bachelor's Degree (4 years of College)
   f. Master's Degree
   g. Doctoral Degree or equivalent
   h. Professional Degree (MD, JD etc)
   i. Other (please specify):_____

6. What is your race?
   a. African American
   b. Asian
   c. Caucasian
   d. Hispanic
   e. Multi-racial
   f. Other (please specify):_____

7. How would you describe your current employment status?
    a. Employed (full time)
    b. Employed (part time)
    c. Unemployed (but job hunting)
    d. Unemployed (not job hunting)
    e. Disabled (unable to work)
    f. Retired

8. What is your yearly income level?
    a. <$30,000
    b. $30,000 - $60,000
    c. $60,000 - $100,000
    d. $100,000 and greater

9. What is your current marital status?
    a. Single
    b. Married
    c. Divorced
    d. Separated
    e. Widowed
    f. Civil union
    g. Living with another

10. What kind of health insurance do you have (*Please circle one*)?
    a. Medicare only
    b. Medicaid only
    c. Private only
    d. Medicare and Medicaid
    e. Medicare and Private
    f. Medicaid and Private
    g. None/self pay

II. Health Information Sheet

Please complete this questionnaire as best you can to help us understand more about your health. Note that none of the information you provide will be shared with unauthorized individuals. Thank you for your participation.

1. What type of diabetes do you have?
   a. Type 1 Diabetes
   b. Type 2 Diabetes
   c. Gestational Diabetes
   d. Other (*Please specify*):_____
   e. Don't know

2. When were you first told you have diabetes? (*Circle one*)
   Less than 5 years ago/5-10 years ago/10-20 years ago/More than 20 years ago

3. Are you using any medication for diabetes? Yes No Don't know

4. If you answered 'Yes' to question (3), what kind of medication are you using? (*Circle all that apply*)
   a. Pills/tablets
   b. Injection (Insulin)
   c. Pump (Insulin)
   d. Other (*Please Specify*):_____
   e. Don't know

5. What was your most recent HbA1c level (within the past 2-3 months)?
   a. < 5.0
   b. 5.0 – 5.9
   c. 6.0 – 6.9
   d. 7.0 – 7.9
   e. 8.0 – 9.0
   f. > 9.0
   g. Don't know

6. Have you ever been told you have kidney problems because of diabetes? Yes No Don't know

7. If you answered 'Yes' to question (6) please answer the following:
   a. Are you on dialysis? Yes No Don't know

   b. Have you ever received a kidney transplant? Yes No Don't know

8. Have you ever been told you have diabetic retinopathy or diabetic eye Yes No Don't know

disease?

a. If 'Yes' have you ever had laser treatments for your diabetic eye disease? Yes No Don't know

9. Do you wear glasses to help you see things that are far away? Yes No Don't know

10. Do you wear glasses to help you see things up close? Yes No Don't know

11. Have you ever been told you have macular degeneration? Yes No Don't know

12. If you answered 'Yes' to question (11), have you received or do you use any of the following treatments? (*Circle all that apply*)
   a. Vitamins (taken by mouth)
   b. Injections into the eye
   c. Laser therapy
   d. Other (Please Specify): _____
   e. Don't know

13. Have you ever been told you have cataracts or clouded eye lenses? Yes No Don't know

14. If you answered 'Yes' to question (13), have you ever had surgery to have the cataracts removed? Yes No Don't know

15. Have you ever been told you have glaucoma or high eye pressure? Yes No Don't know

16. If you answered 'Yes' to question (15), have you received or do you use any of the following treatments? (*Circle all that apply*)
   a. Eye drops
   b. Surgery
   c. Laser therapy
   d. Other (*Please specify*):_____
   e. Don't know

17. When was your last eye examination? (*circle one)*
   a. I have never had an eye exam
   b. Within the last year
   c. 2 – 5 years ago
   d. Greater than 5 years ago
   e. I cannot remember

18. Have you ever had an eye examination that included having eye drops put in your eyes to dilate your pupils? Yes No Don't know

19. Have you ever had a stroke? Yes No Don't know

20. Have you ever been told you have heart disease? Yes No Don't know

21. If you answered 'Yes' to question (20) please answer the following:

a. Have you ever had a heart attack? Yes No Don't know

b. Do you experience chest pain when you exercise or walk long distances? Yes No Don't know

22. Have you ever been told you have poor circulation? Yes No Don't know

23. If you answered 'Yes' to question (19) please answer the following:

a. Do you have sores on your legs/feet that do not heal? Yes No Don't know

b. Has any part of your body been amputated because of poor circulation? Yes No Don't know

24. Does anyone in your family have diabetes? Yes No Don't know

25. If you answered 'Yes' to question (24) please answer the following:

a. Please specify how this (these) family member(s) is(are) related to you (e.g. mother, brother, sister etc) :_____

b. Has (have) this (these) family members experienced any of the following diabetes complications?
   i. Heart disease
   ii. Kidney disease
   iii. Diabetic retinopathy/diabetic eye disease
   iv. Stroke
   v. Blindness
   vi. Amputation of a limb
   vii. Other (*Please specify*): _____
   viii. Don't know

III. Summary of Diabetes Self-Care Activities

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

1. How many of the last SEVEN DAYS have you followed a healthy eating plan?
   0 1 2 3 4 5 6 7

2. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?
   0 1 2 3 4 5 6 7

3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?
   0 1 2 3 4 5 6 7

4. On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?
   0 1 2 3 4 5 6 7

Exercise

5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).
   0 1 2 3 4 5 6 7

6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?
   0 1 2 3 4 5 6 7

Blood Sugar Testing

7. On how many of the last SEVEN DAYS did you test your blood sugar?
   0 1 2 3 4 5 6 7

8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?
   0 1 2 3 4 5 6 7

Foot Care

9. On how many of the last SEVEN DAYS did you check your feet?
   0 1 2 3 4 5 6 7

10. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?
0 1 2 3 4 5 6 7

Smoking

11. Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?
0. No
1. Yes.

If *Yes*, how many cigarettes did you smoke on an average day?
Number of cigarettes:

Medications

12. On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?
0 1 2 3 4 5 6 7

IV. Fear of complications questionnaire (FCQ)

*This questionnaire is designed to help us understand how you feel about your Diabetes and how it affects you, particularly in the **long-term**. Please answer the following questions as honestly as possible. Your answers will be kept in strictest confidence.*

1. I feel afraid of long-term complications of Diabetes

Very **Moderately** **A little** **Not at all**

2. I worry about losing my eyesight because of Diabetes

All the time **Frequently** **Occasionally** **Never**

3. I worry that having Diabetes increases my chances of heart disease

All the time **Frequently** **Occasionally** **Never**

4. I am afraid I will need a kidney transplant one day

Very **Moderately** **A little** **Not at all**

5. I am afraid of developing long-term complications as a result of frequent high blood sugars

All the time **Frequently** **Occasionally** **Never**

6. I am afraid that I may need kidney dialysis one day

Never **Occasionally** **Frequently** **Constantly**

7. I am afraid that I will develop kidney problems one day

All the time **Frequently** **Occasionally** **Never**

8. How often do you think about long-term complications of Diabetes?

Hardly ever **Occasionally** **Frequently** **All the time**

9. I worry that I might be at a higher risk for having a stroke

All the time **Frequently** **Occasionally** **Never**

10. Do you ever worry about your future health?

Not at all **Occasionally** **Frequently** **All the time**

11. I worry that the Diabetes Specialist will find something wrong with my eyes

Not at all **Occasionally** **Frequently** **Constantly**

12. Do you worry about future problems when your blood sugars are erratic?

Not at all **Occasionally** **Frequently** **All the time**

13. I am scared that Diabetes could affect my feet

Very **Moderately** **A little** **Not at all**

14. I'm scared of having a heart attack in the future

Not at all **A little scared** **Moderately scared** **Very scared**

15. I worry about developing problems with circulation

Never **Occasionally** **Frequently** **All the time**

V. Visual Functioning Questionnaire (VFQ)

PB/IA

National Eye Institute Visual Functioning Questionnaire - 25 (VFQ-25)

version 2000

(INTERVIEWER ADMINISTERED FORMAT)

January 2000

- 1 - ***version 2000***

Instructions:

I'm going to read you some statements about problems which involve your vision or feelings that you have about your vision condition. After each question I will read you a list of possible answers. Please choose the response that best describes your situation.

Please answer all the questions as if you were wearing your glasses or contact lenses (if any).

Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about vision problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses for a particular activity, please answer all of the following questions as though you were wearing them.

Visual Functioning Questionnaire - 25

PART 1 - GENERAL HEALTH AND VISION

1. In general, would you say your overall health is*:

(Circle One)

READ CATEGORIES:

Excellent 1
Very Good..... 2
Good..... 3
Fair..... 4
Poor..... 5

2. At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor or are you completely blind?

(Circle One)

READ CATEGORIES:

Excellent 1
Good..... 2
Fair..... 3
Poor..... 4
Very Poor 5
Completely Blind..... 6

*** Skip Question 1 when the VFQ-25 is administered at the same time as the SF-36 or RAND 36-Item Health Survey 1.0**

3. How much of the time do you worry about your eyesight?

(Circle One)

READ CATEGORIES:

None of the time..... 1
A little of the time..... 2
Some of the time..... 3
Most of the time 4
All of the time? 5

4. How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)? Would you say it is:

(Circle One)

READ CATEGORIES:

None 1
Mild..... 2
Moderate 3
Severe, or..... 4
Very severe?..... 5

PART 2 - DIFFICULTY WITH ACTIVITIES

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity.

5. How much difficulty do you have reading ordinary print in newspapers? Would you say you have:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

6. How much difficulty do you have doing work or hobbies that require you to <u>see well up close</u>, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

7. Because of your eyesight, how much difficulty do you have <u>finding something on a crowded shelf</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

8. How much difficulty do you have <u>reading street signs or the names of stores?</u>
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

9. Because of your eyesight, how much difficulty do you have <u>going down steps, stairs, or curbs in dim light or at night</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

10. Because of your eyesight, how much difficulty do you have <u>noticing objects off to the side while you are walking along</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

11. Because of your eyesight, how much difficulty do you have <u>seeing how people react to things you say</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

12. Because of your eyesight, how much difficulty do you have <u>picking out and matching your own clothes</u>?

(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

13. Because of your eyesight, how much difficulty do you have <u>visiting with people in their homes, at parties, or in restaurants</u> ?

(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

14. Because of your eyesight, how much difficulty do you have <u>going out to see movies, plays, or sports events</u>?

(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

15. Now, I'd like to ask about driving a car. Are you currently driving, at least once in a while?

(Circle One)

Yes ..... 1 *Skip To Q 15c*

No..... 2

15a. IF NO, ASK: Have you never driven a car or have you given up driving?

(Circle One)

Never drove ..... 1 *Skip To Part 3, Q 17*

Gave up..... 2

15b. IF GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

(Circle One)

Mainly eyesight ..... 1 *Skip To Part 3, Q 17*

Mainly other reasons ..... 2 *Skip To Part 3, Q 17*

Both eyesight and other reasons ... 3 *Skip To Part 3, Q 17*

15c. IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have:

(Circle One)

No difficulty at all 1
A little difficulty 2
Moderate difficulty 3
Extreme difficulty 4

16. How much difficulty do you have <u>driving at night</u>? Would you say you have: (READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Have you stopped doing this because of your eyesight 5
Have you stopped doing this for other reasons or are you not interested in doing this 6

16a. How much difficulty do you have <u>driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic</u>? Would you say you have:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Have you stopped doing this because of your eyesight 5
Have you stopped doing this for other reasons or are you not interested in doing this 6

PART 3: RESPONSES TO VISION PROBLEMS

The next questions are about how things you do may be affected by your vision. For each one, I'd like you to tell me if this is true for you <u>all</u>, <u>most</u>, <u>some</u>, <u>a little</u>, or <u>none</u> of the time.

(Circle One On Each Line)

READ CATEGORIES:	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
17. <u>Do you accomplish less</u> than you would like because of your vision?	**1**	**2**	**3**	**4**	**5**
18. <u>Are you limited</u> in how long you can work or do other activities because of your vision?	**1**	**2**	**3**	**4**	**5**
19. How much does pain or discomfort <u>in or around your eyes</u>, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say:	**1**	**2**	**3**	**4**	**5**

- 10 - ***version 2000***

For each of the following statements, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you are not sure.

(Circle One On Each Line)

READ CATEGORIES:	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
20. I stay home most of the time because of my eyesight.....	1	2	3	4	5
21. I feel frustrated a lot of the time because of my eyesight ….	1	2	3	4	5
22. I have much less control over what I do, because of my eyesight.	1	2	3	4	5
23. Because of my eyesight, I have to rely too much on what other people tell me. .	1	2	3	4	5
24. I need a lot of help from others because of my eyesight.....	1	2	3	4	5
25. I worry about doing things that will embarrass myself or others, because of my eyesight.....	1	2	3	4	5

- 11 - ***version 2000***

SUBSCALES: WELL-BEING/DISTRESS (#A12)

The next questions are about how you deal with your vision. For each statement, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you don't know.

(Circle One On Each Line)

READ CATEGORIES:	**Definitely True**	**Mostly True**	**Not Sure**	**Mostly False**	**Definitely False**
A12. I am often irritable because of my eyesight.	**1**	**2**	**3**	**4**	**5**

That's the end of the interview. Thank you very much for your time and your help.

10. References

1. CDC National Diabetes Fact Sheet, 2007 (http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf). **Accessed June 2009**.

2. Moss, S.E., Klein, R., and Klein, B.E. 1998. The 14-year incidence of visual loss in a diabetic population. *Ophthalmology* **105**:998-1003.

3. Anonymous 1993. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group *N. Engl. J. Med.* **329**:977-986.

4. Nathan, D.M., Cleary, P.A., Backlund, J.Y., Genuth, S.M., Lachin, J.M., Orchard, T.J., Raskin, P., Zinman, B., and Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. 2005. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes *N. Engl. J. Med.* **353**:2643-2653.

5. Saydah, S.H., Fradkin, J., and Cowie, C.C. 2004. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA* **291**:335-342.

6. Klein, R., and Klein, B.E. 1995. Vision Disorders in Diabetes. In *National Diabetes Data Group: Diabetes in America.* 2nd edition. National Institutes of Health. Bethesda, MD. 293-338.

7. Zhang, X., Gregg, E.W., Cheng, Y.J., Thompson, T.J., Geiss, L.S., Duenas, M.R., and Saaddine, J.B. 2008. Diabetes mellitus and visual impairment: National health and nutrition examination survey, 1999-2004. *Arch. Ophthalmol.* **126**:1421-1427.

8. Kempen, J.H., O'Colmain, B.J., Leske, M.C., Haffner, S.M., Klein, R., Moss, S.E., Taylor, H.R., Hamman, R.F., West, S.K., Wang, J.J. et al. 2004. The Prevalence of Diabetic Retinopathy among Adults in the United States. *Arch. Ophthalmol.* **122**:552-563.

9. Roy, M.S., Klein, R., O'Colmain, B.J., Klein, B.E.K., Moss, S.E., and Kempen, J.H. 2004. The Prevalence of Diabetic Retinopathy among Adult Type 1 Diabetic Persons in the United States. *Arch. Ophthalmol.* **122**:546-551.

10. Saaddine, J.B., Honeycutt, A.A., Narayan, K.M.V., Zhang, X., Klein, R., and Boyle, J.P. 2008. Projection of diabetic retinopathy and other major eye diseases among people with diabetes mellitus: United States, 2005-2050. *Arch. Ophthalmol.* **126**:1740-1747.

11. Bernbaum, M., Albert, S.G., and Duckro, P.N. 1988. Psychosocial profiles in patients with visual impairment due to diabetic retinopathy. *Diabetes Care* **11**:551-557.

12. Cox, D.J., Kiernan, B.D., Schroeder, D.B., and Cowley, M. 1998. Psychosocial sequelae of visual loss in diabetes. *Diabetes Educ.* **24**:481-484.

13. Lloyd, A., Nafees, B., Gavriel, S., Rousculp, M.D., Boye, K.S., and Ahmad, A. 2008. Health utility values associated with diabetic retinopathy. *Diabet. Med.* **25**:618-624.

14. Sharma, S., Oliver-Fernandez, A., Liu, W., Buchholz, P., and Walt, J. 2005. The impact of diabetic retinopathy on health-related quality of life. *Curr. Opin. Ophthalmol.* **16**:155-159.

15. Klein, R., Moss, S.E., Klein, B.E., Gutierrez, P., and Mangione, C.M. 2001. The NEI-VFQ-25 in people with long-term type 1 diabetes mellitus: the Wisconsin Epidemiologic Study of Diabetic Retinopathy. *Arch. Ophthalmol.* **119**:733-740.

16. Lamoureux, E.L., Hassell, J.B., and Keeffe, J.E. 2004. The impact of diabetic retinopathy on participation in daily living. *Arch. Ophthalmol.* **122**:84-88.

17. Coyne, K.S., Margolis, M.K., Kennedy-Martin, T., Baker, T.M., Klein, R., Paul, M.D., and Revicki, D.A. 2004. The impact of diabetic retinopathy: Perspectives from patient focus groups. *Fam. Pract.* **21**:447-453.

18. Hendricks, L.E., and Hendricks, R.T. 1998. Greatest fears of type 1 and type 2 patients about having diabetes: implications for diabetes educators. *Diabetes Educ.* **24**:168-173.

19. Luckie, R., Leese, G., McAlpine, R., MacEwen, C.J., Baines, P.S., Morris, A.D., Ellis, J.D., and DARTS/MEMO Collaboration. 2007. Fear of visual loss in patients with diabetes: results of the prevalence of diabetic eye disease in Tayside, Scotland (P-DETS) study. *Diabet. Med.* **24**:1086-1092.

20. Anderson, R.M., Wolf, F.M., Musch, D.C., Fitzgerald, J.T., Johnson, M.W., Nwankwo, R.B., Robins, L.S., Oh, M.S., and Gillard, M.L. 2002. Conducting community-based, culturally specific, eye disease screening clinics for urban African Americans with diabetes. *Ethnicity and Disease* **12**:404-410.

21. Bouligny, R.P., McGregor, G.P., and Chisholm, L. 1996. Diabetic eye disease in a rural setting: The West Virginia diabetic eye care project. *Invest. Ophthalmol. Visual Sci.* **37**.

22. Moss, S.E., Klein, R., and Klein, B.E. 1995. Factors associated with having eye examinations in persons with diabetes. *Arch. Fam. Med.* **4**:529-534.

23. Lewis, K., Patel, D., Yorston, D., and Charteris, D. 2007. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. *Ophthalmic Epidemiol.* **14**:375-380.

24. Hartnett, M.E., Key, I.J., Loyacano, N.M., Horswell, R.L., and DeSalvo, K.B. 2005. Perceived barriers to diabetic eye care: Qualitative study of patients and physicians. *Arch. Ophthalmol.* **123**:387-391.

25. Walker, E.A., Basch, C.E., Howard, C.J., Zybert, P.A., Kromholz, W.N., and Shamoon, H. 1997. Incentives and barriers to retinopathy screening among African-Americans with diabetes. *J. Diabetes Complications.* **11**:298-306.

26. Muñoz, B., O'Leary, M., Fonseca-Becker, F., Rosario, E., Burguess, I., Aguilar, M., Fickes, C., and West, S.K. 2008. Knowledge of diabetic eye disease and vision care guidelines among hispanic individuals in Baltimore with and without diabetes. *Arch. Ophthalmol.* **126**:968-974.

27. Oehler-Giarratana, J., and Fitzgerald, R.G. 1980. Group therapy with blind diabetics. *Arch. Gen. Psychiatry* **37**:463-467.

28. Mangione, C.M. 2000. National Eye Institute 25-Item Visual Function Questionnaire. *NEI-VFQ Scoring Algorithm*.

29. Taylor, E.P., Crawford, J.R., and Gold, A.E. 2005. Design and development of a scale measuring fear of complications in type 1 diabetes. *Diabetes. Metab. Res.* **21**:264-270.

30. Toobert, D.J., Hampson, S.E., and Glasgow, R.E. 2000. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care* **23**:943-950.

31. Gwira, J.A., Vistamehr, S., Shelsta, H., Bashford, K., Forster, S., Palmisano, P., Shafranov, G., and Shields, M.B. 2006. Factors associated with failure to follow up after glaucoma screening: a study in an African American population. *Ophthalmology* **113**:1315-1319.

32. Cusick, M., SanGiovanni, J.P., Chew, E.Y., Csaky, K.G., Hall-Shimel, K., Reed, G.F., Caruso, R.C., and Ferris, F.L.,3rd. 2005. Central visual function and the NEI-VFQ-25 near and distance activities subscale scores in people with type 1 and 2 diabetes. *Am. J. Ophthalmol.* **139**:1042-1050.

33. Selby, J.V., Swain, B.E., Gerzoff, R.B., Karter, A.J., Waitzfelder, B.E., Brown, A.F., Ackermann, R.T., Duru, O.K., Ferrara, A., Herman, W. et al. 2007. Understanding the gap between good processes of diabetes care and poor intermediate outcomes: Translating Research into Action for Diabetes (TRIAD) *Med. Care* **45**:1144-1153.

34. Gillard, M.L., Nwankwo, R., Fitzgerald, J.T., Oh, M., Musch, D.C., Johnson, M.W., and Anderson, R. 2004. Informal diabetes education: impact on self-management and blood glucose control *Diabetes Educ.* **30**:136-142.

35. Duke, S.A., Colagiuri, S., and Colagiuri, R. 2009. Individual patient education for people with type 2 diabetes mellitus *Cochrane Database Syst. Rev.* **(1)**:CD005268.

36. Peyrot, M., and Rubin, R.R. 1994. Modeling the effect of diabetes education on glycemic control *Diabetes Educ.* **20**:143-148.

37. Panja, S., Starr, B., and Colleran, K.M. 2005. Patient knowledge improves glycemic control: is it time to go back to the classroom? *J. Investig. Med.* **53**:264-266.

38. Eiser, J.R., Eiser, C., Riazi, A., Taylor, D.J., Hammersley, S., and Tooke, J.E. 2001. Screening for diabetic retinopathy is well received by patients and may improve self-management intentions *Diabet. Med.* **18**:835-841.

39. Shah, B.R., and Booth, G.L. 2009. Predictors and effectiveness of diabetes self-management education in clinical practice *Patient Educ. Couns.* **74**:19-22.

40. Bodenheimer, T., Wagner, E.H., and Grumbach, K. 2002. Improving primary care for patients with chronic illness *JAMA* **288**:1775-1779.

41. Grumbach, K., and Bodenheimer, T. 2002. A primary care home for Americans: putting the house in order *JAMA* **288**:889-893.

42. Bodenheimer, T., Wagner, E.H., and Grumbach, K. 2002. Improving primary care for patients with chronic illness: the chronic care model, Part 2 *JAMA* **288**:1909-1914.

43. Bodenheimer, T., Lorig, K., Holman, H., and Grumbach, K. 2002. Patient self-management of chronic disease in primary care *JAMA* **288**:2469-2475.

44. Singh, D. 2005. Transforming Chronic Care: Evidence about improving care for people with long-term conditions(http://www.hsmc.bham.ac.uk/research/transforming_chronic_care.shtml). **Accessed January 2010**.

45. Anstiss, T. 2009. Motivational interviewing in primary care *J. Clin. Psychol. Med. Settings* **16**:87-93.

46. Miller, R.W., and Rollnick, S. 2002. *Motivational Interviewing.* 2nd edition. Guilford Press. New York.

47. Rollnick, S., Miller, W., and Butler, C. 2007. *Motivational Interviewing in Health Care: Helping Patients Change Behavior.* Guilford Press. New York.

48. Channon, S.J., Huws-Thomas, M.V., Rollnick, S., Hood, K., Cannings-John, R.L., Rogers, C., and Gregory, J.W. 2007. A multicenter randomized controlled trial of motivational interviewing in teenagers with diabetes *Diabetes Care* **30**:1390-1395.

49. Brug, J., Spikmans, F., Aartsen, C., Breedveld, B., Bes, R., and Fereira, I. 2007. Training dietitians in basic motivational interviewing skills results in changes in their counseling style and in lower saturated fat intakes in their patients *J. Nutr. Educ. Behav.* **39**:8-12.

50. Kramer, J.R., Ledolter, J., Manos, G.N., and Bayless, M.L. 2000. Stress and metabolic control in diabetes mellitus: methodological issues and an illustrative analysis *Ann. Behav. Med.* **22**:17-28.

51. Riazi, A., Pickup, J., and Bradley, C. 2004. Daily stress and glycaemic control in Type 1 diabetes: individual differences in magnitude, direction, and timing of stress-reactivity *Diabetes Res. Clin. Pract.* **66**:237-244.

52. Lloyd, C.E., Dyer, P.H., Lancashire, R.J., Harris, T., Daniels, J.E., and Barnett, A.H. 1999. Association between stress and glycemic control in adults with type 1 (insulin-dependent) diabetes *Diabetes Care* **22**:1278-1283.

53. Surwit, R.S., van Tilburg, M.A., Zucker, N., McCaskill, C.C., Parekh, P., Feinglos, M.N., Edwards, C.L., Williams, P., and Lane, J.D. 2002. Stress management improves long-term glycemic control in type 2 diabetes *Diabetes Care* **25**:30-34.

54. National Diabetes Information Clearing House: Race and Ethnic Difference in Prevalence of Diagnosed Diabetes (http://diabetes.niddk.nih.gov/DM/PUBS/statistics/#race). **Accessed February 2010**.

55. US Census Bureau State and County Quick Facts (http://quickfacts.census.gov/qfd/states/09/09009.html). **Accessed February 2010**.

56. Ciechanowski, P.S. 2000. Depression and Diabetes: Impact of Depressive Symptoms on Adherence, Function, and Costs *Arch. Intern. Med.* **160**:3278 - 3285.

57. Zigmond, A.S., and Snaith, R.P. 1983. The hospital anxiety and depression scale *Acta Psychiatr. Scand.* **67**:361-370.

58. Osborn, C.Y., and Egede, L.E. 2009. Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC) *Patient Educ. Couns.*

59. Dunn, S.M., Bryson, J.M., Hoskins, P.L., Alford, J.B., Handelsman, D.J., and Turtle, J.R. 1984. Development of the diabetes knowledge (DKN) scales: forms DKNA, DKNB, and DKNC *Diabetes Care* **7**:36-41.

60. Fitzgerald, J.T., Funnell, M.M., Hess, G.E., Barr, P.A., Anderson, R.M., Hiss, R.G., and Davis, W.K. 1998. The reliability and validity of a brief diabetes knowledge test *Diabetes Care* **21**:706-710.