Health-Related Quality of Life, Nutrition Hassles, and Glycosylated Hemoglobin Assessment in People with Type II Diabetes Mellitus.

by

Ann A. Ward

A THESIS

Presented to the Department of Behavioral Neuroscience

and the Graduate Council of

Oregon Health Sciences University

in partial fulfillment of

the requirements for the degree of

Master of Science

March, 1997

School of Medicine
Oregon Health Sciences University

CERTIFICATE OF APPROVAL

This is certify that the M.S. thesis of

Ann A. Ward

has been approved

[redacted]
Professor in charge of thesis

[redacted]
Member

[redacted]
Member

[redacted]
Member

[redacted]
Member

[redacted]
Associate Dean for Graduate Studies

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF TABLES

LIST OF ABBREVIATIONS

ADA	American Diabetes Association
DCCT	Diabetes Control and Complications Trial
DCP	Diabetes Care Profile
DDHS	Diabetes Daily Hassles Scale
DQOL	Diabetes Quality of Life Scale
HbA1c	Glycosylated Hemoglobin A1c
HRQOL	Health Related Quality of Life
LOT	Life Orientation Test
NDDG	National Diabetes Data Group
NHQ	Nutrition Hassles Questionnaire
QWB	Quality of Well-Being Scale
SF-36	Medical Outcomes Study Short-Form 36
Type II DM	Type II Diabetes Mellitus
UKPDS	UK Prospective Diabetes Study

ACKNOWLEDGMENTS

First and foremost I would like to thank Dan Hatton for all of his support during my graduate career. Dan is a wonderful, caring person and I feel privileged to have him as my advisor. I would also like to thank my committee members; Chris Cunningham, Jeri Janowsky, Matt Riddle, and Jill Metz for their support, time, and helpful feedback. Many thanks also go to Nancy Perrin for her exceptional statistical advice.

On a more personal note, I would like to thank Sarah Coste, Jennifer Buckman, Christina Lessov, Nancy Bormann, Julie Broadbent, Deb Finn, Shelly Dickinson, Julia Chester, and especially ***the Ging*** for listening, caring, laughing, hugging, and passing me the kleen-ex when necessary. I will always be grateful for the love and support you have all given me. I would also like to thank Yue Qi for his kindness and unyielding willingness to make pot-stickers for me. A great big thank you goes to Sue Down, Christopher G. Ward, Jean Sauve and Lee Sage for their loving friendship throughout the many years, and for believing in me even when I didn't believe in myself. Finally, this thesis is dedicated to Scott W. Stanyar, a dear friend with Type II Diabetes Mellitus whose positive impact on my quality of life is immeasurable.

ABSTRACT

The health of an individual is characterized by more than the absence of disease. Psychological, emotional, and social functioning, as well as physical functioning and somatic sensations are important aspects of health. The assessment of Health-Related Quality of Life (HRQOL) is a method used to measure the impact of physical disease on the individual's sense of well being in each of these areas. The primary purpose of the present study was to measure HRQOL in patients with Type II Diabetes Mellitus using generic, diabetes-specific and nutrition-specific HRQOL instruments and to determine which instrument or combination of instruments best predicted blood sugar levels as indexed by glycosylated hemoglobin. An additional goal of this study was to assess the psychometric properties of a nutrition-specific HRQOL instrument.

Health-Related Quality of Life was measured in this cross-sectional study by two generic (Medical Outcomes Study Short-Form 36 and Quality of Well-Being Scale), two disease-specific (Diabetes Daily Hassles Scale and Diabetes Quality of Life Scale), and one nutrition-specific HRQOL (Nutrition Hassles Questionnaire) instruments. Demographic, life orientation, and adherence questionnaires were administered to gather background information. One hundred thirty-six patients with Type II Diabetes Mellitus were recruited from diabetes education centers, health clinics, and support groups, in the Portland metropolitan area. Finger stick blood samples for measuring glycosylated hemoglobin were acquired at the time of recruitment.

The findings of low to moderate HRQOL subscale scores indicates that subjects in the present study do not perceive disease-related decrements in the quality of their lives. Factor analysis of the subscales from each of the HRQOL instruments showed that generic, diabetes-specific and nutrition-related instruments are measuring different aspects of HRQOL. Outcomes on the Medical Outcomes Study Short-Form 36 were significantly related to glycosylated hemoglobin ($p < .01$) as was the Insulin subscale from the Diabetes Daily Hassles Scale. None of the other instruments or combination of instruments was significantly associated with HbA1c, indicating that only a small relationship exists between perceived HRQOL and glycemic control. The nutrition-related HRQOL instrument proved to have good internal consistency, construct reliability, and convergent validity.

Taken together, these results suggest that a comprehensive view of HRQOL may be attained by the use of more than one form of HRQOL measurement. Assessing generic, diabetes-specific, and nutrition-related HRQOL could give a detailed view of HRQOL among people with Type II Diabetes Mellitus. Lastly, little evidence was found for a strong relationship between perceived HRQOL and glycemic control.

INTRODUCTION

Diabetes Mellitus is a metabolic disorder effecting between 8 and 14 million people in the United States alone (Harris, 1995; Harris, Hadden, Knowler, & Bennett, 1987). Of these people, approximately 70 to 95 percent have Type II Diabetes Mellitus (Type II DM) (Harris, 1995; Riddle, 1993). Type II DM is primarily a syndrome of the middle-age to aged adult population and is thought to be the leading cause of disability in adults age 45 and older (Rubin & Peyrot, 1992). Type I DM, by comparison, has an earlier age of onset ($<$ 30 years old) and is thought to have a different etiology. Diagnostic characteristics of Type II DM includes poor metabolic control as measured by repeated fasting plasma hyperglycemia ($>$ 140 mg/dl), plasma glucose at or above 200 mg/dl after repeated oral glucose tolerance testing and elevated percent glycosylated hemoglobin ($>$ 6%), as well as glycosuria, hyperinsulinemia, polydipsia, polyuria, polyphagia, weight loss, and fatigue (American Diabetes Association [ADA], 1995; Expert Committee of the Canadian Diabetes Advisory Board, 1992; National Diabetes Data Group [NDDG], 1979).

The etiology of Type II DM is not fully understood yet it is thought to have genetic as well as environmental influences. The commonly agreed upon etiology of Type II DM is insulin resistance at the receptor level together with reduced function of insulin producing beta cells due to chronic hyperinsulinemia (NDDG, 1979, 1995; Polonsky, Sturis, & Bell, 1996; Taylor, Accili, & Imai, 1994). Molecular techniques have been used to identify genetic abnormalities involved in the disorders of insulin

resistance, including Type II DM. Genes thought to be involved in the etiology of Type II DM include genes coding for the insulin receptor, glucose transporters, insulin receptor protein kinases and nuclear regulatory proteins, glycogen synthase and glucokinase related enzymes, as well as pancreatic beta-cell electrophysiologic mediators (Brunetti, Brunetti, Foti, Accili, & Goldfine, 1996; Ghosh & Schork, 1996; Iwasaki et al., 1996; Kahn, 1994; Taylor, 1992).

Environmental factors thought to work in concert with a genetic predisposition to Type II DM onset include sedentary life style (little physical activity, work or recreationally related), poor nutritional habits, and obesity (for a review, see Rewers & Hamman, 1995). Evidence for a relationship between these lifestyle factors and Type II DM exists from epidemiological and tertiary prevention studies (studies assessing treatment effect on the prevention or delay of diabetes complications) (Helmrich, Ragland, Leung, & Paffenbarger, 1991; King, & Kriska, 1992). For example, an epidemiological study assessing population attributable risk calculated dramatic decreases in diabetes related mortality with increased physical activity (Powell & Blair, 1994). In addition evidence for a proposed role of poor nutrition and obesity in the etiology of Type II DM stems from studies looking at the amelioration of progression of the disease by nutritional and weight loss treatments. Indeed, it is thought that weight loss alone is associated with increased peripheral insulin sensitivity, increased insulin release from pancreatic beta-cells, and a decrease in lipid metabolism abnormalities (Eriksson & Lindgarde, 1991; Fitz, Sperling, & Fein, 1983; Garg, Grundy, & Koffler, 1992; Henry, Wallace, & Olefsky, 1986; Wing, Epstein, Nowalk,

Koeske, & Hagg, 1985; for review see Rewers & Hamman, 1995). Thus, adherence to a nutritional regimen, potentially leading to weight loss, may lead to normal or near normal glycemic control. An intensive prospective nutritional intervention trial in Northern Ireland supports this notion (Hadden et al., 1986). High adherence rates to a stringent nutritional regimen for a period of six years, yielding significant weight loss, was highly associated with significant decreases in challenged plasma glucose concentrations. However, the success of this study is somewhat of an anomaly among nutrition interventions, as diet is notoriously the most poorly adhered to aspect of the diabetic regimen (Burroughs, Pontious, & Santiago, 1993; Kravits et al., 1993; Polly, 1992).

Initial treatment recommendations in Type II DM involve lifestyle modifications which increase metabolic control such as dietary restriction, weight loss, initiation of an exercise regimen, and other lifestyle modifications such as smoking cessation (ADA, 1995; Expert Committee of the Canadian Diabetes Advisory Board, 1992; Zimmerman & Service, 1988). Dietary modifications relevant to the treatment of Type II DM include low fat and moderate protein and high carbohydrate consumption. Upon determining the efficacy of the initial behavioral treatment approaches, plasma glucose lowering agents such as sulfonylureas, biguanides, or insulin may be recommended (ADA, 1995; NDDG, 1979; 1995; Riddle, 1993, Rodger, 1991; Wolffenbuttel, & van Haeften, 1995; Zimmerman & Service, 1988). Further, recombinant human insulin-like growth factor one (rhIGFI), which shares structural and functional homology with insulin and is thought to stimulate glucose uptake in peripheral tissue through its action

at the IGFI receptor, is now used experimentally in some insulin-resistant patients (Hussain et al., 1993; Kolaczynksi & Caro, 1994; Zenobi, Jaeggi-Groisman, Riesen, Roder, & Froesch, 1992). Findings from insulin and rhIGFI studies have shown them to be appropriate and efficacious treatment approaches, in some cases even yielding a general sense of satisfaction and well-being from patients (Taylor, Foster, Kyne-Grzebalski, & Vanderpump, 1994).

Even though there is no one prophylactic for Type II DM, or cure, medical complications can be prevented with appropriate metabolic control. In a study of people living with Type I DM, the Diabetes Control and Complications [DCCT] Trial research group showed evidence for the decreased progression and prevalence of diabetes complications in patients who were in good metabolic control (e.g., plasma glucose concentration below or near 140 mg/dl and percent glycosylated hemoglobin $<7\%$), (DCCT, 1986, 1987, 1988). This hypothesized relationship between blood glucose regulation and diabetes related complications is presently being tested among people with Type II DM (UK Prospective Diabetes Study Group [UPKDS], 1991, 1995). Results from this study are, at this time, inconclusive as the project will not be completed until 1998. However, it is possible that maintaining good metabolic control by adherence to nutritional and lifestyle modifications, as well as drug regimens, will decrease the progression of diabetes-related complications among people with Type II DM.

Unfortunately, even after initial treatment, metabolic control may remain severely compromised. If nutritional, behavioral, and medicinal treatments are not

successful in maintaining near normal metabolic control, within 10 to 15 years one of several debilitating medical conditions may ensue (Riddle, 1993). Some of the complications associated with Type II DM include sexual dysfunction, retinopathy, central and peripheral neuropathy, renal failure, micro and macro angiopathy, as well as learning and memory deficits (Kurtz, 1989; Polly, 1992; Schafer, Glasgow, McCaul & Dreher, 1983; Shenkel, Rogers, Perfetto & Levin, 1985; Wooldridge, Wallston, Graber, Brown & Davidson, 1992). Moreover, it is estimated that mortality from cardiovascular complications associated with diabetes accounts for between 40% - 75% of deaths among people with Type II DM (Geiss et al., 1993; Uusitupa, Niskanen, Siitonen, Voutilainen, & Pyorala, 1993). For a review of the proposed physiologic basis for a relationship between diabetes and vascular disease see Sowers & Epstein (1995).

Clearly, a physiological parameter such as metabolic control is an important clinical outcome measure, particularly as it may relate to the debilitating conditions associated with Type II DM. Yet, overall health is defined as more than the absence of physical dysfunction; it is also thought to be comprised of physical, psychological/emotional, and social well-being (World Health Organization, 1947). As such, the health goals for the treatment of a chronic condition, such as Type II DM, is to decrease the incidence of comorbidities and dysfunction, and to increase well-being and functionality within the context of patients' daily lives (Davis, Hess, Van Harrison, & Hiss, 1987; Stewart et al., 1989). Therefore, precise measures of how patients perceive the impact of living with Type II DM on their daily functioning, psychological

and emotional well-being, and social satisfaction need to be addressed. An increasingly used method of ascertaining the impact of a disease on personal well-being is to measure Health-Related Quality of Life (HRQOL) (Aaronson, 1989; Bergner, 1985; Cox, Fitzpatrick, Gore, Spiegelhalter, Fletcher, & Jones, 1992; Guyatt, Krishner, & Jaeschke, 1992; Kaplan, 1990; Patrick & Deyo, 1989; Stewart et al., 1989).

HRQOL is a multidimensional construct and has been defined by researchers in many different ways (Bech, 1987; Cox, Fitzpatrick, Gore, Spiegelhalter, Fletcher & Jones, 1992; Testa, 1987; Revicki, 1990). Fortunately, a general consensus on the dimensions of HRQOL in the behavioral medicine literature has been tentatively reached. Four fundamental quantifiable dimensions generally agreed upon are: 1) physical well-being, 2) mental well-being, 3) social support and satisfaction, and 4) somatic sensations related to the symptoms and/or treatment of a disease (Aaronson, 1989; Schipper, Clinch & Powell, 1990; Spilker, 1990). These four dimensions are thought to encompass health-specific aspects of quality of life, as opposed to more general quality of life concepts such as satisfaction related to career and place in community (Flanagan, 1982).

HRQOL dimensions are typically measured as either generic HRQOL or disease-specific HRQOL. Instruments designed to measure generic and disease-specific HRQOL have been widely used and statistically evaluated in the behavioral medicine literature (Aaronson, 1989; Bech, 1987; Cox et al., 1992; Kaplan & Bush, 1982; Given, Given, Gallin, & Condon, 1983; Guyatt, Bombardier, & Tugwell, 1986; Guyatt, Feeny, & Patrick, 1993; Guyatt, Veldhuyzen Van Zanten, Feeny, & Patrick,

1989; Lydick & Epstein, 1993; Testa, 1987). In general, generic HRQOL instruments are designed to measure the four broad dimensions of HRQOL as they relate to many different physical impairments, patient populations, and disease states. These instruments have a broad application that includes comparisons between individuals with and without disease, comparisons within the context of severity of a disease, and across demographic strata. These instruments have also been shown to be useful in the evaluation of the impact of different treatment approaches on HRQOL. Examples of generic HRQOL instruments include the Medical Outcome Study Short Form 36 [SF-36] (Ware & Sherbourne 1992), the Quality of Well-Being Scale [QWB] (Kaplan, Bush, & Berry, 1976), the Sickness Impact Profile (Bergner, Bobbitt, Carter, & Gilson, 1981), and the Nottingham Health Profile (Hunt et al., 1980). Examples of the broad disease categories in which the SF-36 and the QWB have been used to assess generic HRQOL include: AIDS, Cystic Fibrosis, Arthritis, (Kaplan et al., 1995; Kaplan, Anderson, Wu, Mathews, Kozin, & Orenstein, 1989, Orenstein & Kaplan, 1991) Type II DM (Jacobson, de Groot, & Samson, 1994; Kaplan, Hartwell, Wilson, & Wallace, 1987; Nerenz, Repasky, Whitehouse, Kahkonen, 1992; Weinberger et al., 1994) Type I DM, (Stewart et al., 1989) Epilepsy, Hypertension, Heart Disease, Depressive Disorders, Asthma, and Gastrointestinal Disorders (Vickrey, Hays, Rausch, Sutherling, Engel Jr., & Brook, 1994). For classification and reviews of generic HRQOL measurement approaches see Aaronson (1989), Guyatt, Veldhuyzen Van Zanten, & Patrick (1989) and Patrick & Deyo (1989).

Disease-specific instruments are designed to assess perceived HRQOL as it relates to the physical symptoms, psychological states, social functioning, and treatment effects associated with a specific disease. These types of instruments are not applicable across disease groups as are generic instruments. The usefulness of disease-specific instruments is that they measure the impact of disease on aspects of HRQOL that are of interest to clinicians as well as to the patients. For example, a chronic lung disease-specific instrument measures the effect of symptoms such as dyspenea, daily functioning decrements, fatigue, and emotionality on HRQOL among individuals suffering from this disease (Guyatt, Berman, Townsend, Pugsley, & Chambers, 1987). Thus, one advantage to using disease-specific HRQOL instruments is that they are often responsive to clinically important endpoints. Disease-specific HRQOL has been assessed in a number of chronic illnesses including Type I DM, Cancer, AIDS, Hypertension, Chronic Obstructive Pulmonary Disease, Rheumatoid Arthritis, and Inflammatory Bowel Disease. Specific studies and reviews can be found in Dimsdale & Baum (1995) and Spilker (1990).

Generic and disease-specific HRQOL instruments can be quantified as either total profile scores or as the individual components comprising the instrument (e.g., subscales). For example, the generic HRQOL instrument the Sickness Impact Profile is comprised of 12 categories that can either be scored separately or in conjunction with one another to give an overall profile score (Bergner, Bobbitt, Carter, & Gilson, 1981). The advantage of using the profile approach is that only one HRQOL instrument is needed to obtain a "global" assessment of HRQOL. On the other hand, assessment of

the individual components of HRQOL may yield a quantification that is more sensitive to alterations in clinical outcomes (Patrick & Deyo, 1989).

A small number of studies have assessed generic HRQOL among people with Type II DM. Two of these studies investigated the relationship between metabolic control and generic HRQOL (Nerenz, Repasky, Whitehouse, & Kahkonen, 1992; Weinberger, et al., 1994). One study was designed to assess both the relationship between metabolic control and generic HRQOL as well as treatment impact (Kaplan, Hartwell, Wilson, & Wallace, 1987). One study compared generic HRQOL and metabolic control between people with Type I DM and Type II DM (Mayou, Bryant, & Turner, 1990), and two studies compared generic HRQOL among people living with diabetes to generic HRQOL among different disease populations (Stewart et al., 1989; Vickrey, Hays, Rausch, Sutherling, Engel, & Brook, 1994). In general, these studies show that all measurable dimensions of generic HRQOL are relevant in the assessment of HRQOL of people living with Type II DM.

Although the dimensions of generic HRQOL important to people living with Type II DM are beginning to emerge, the relationship between these dimensions and important physiologic outcomes (e.g. metabolic control) remains unclear. Indeed, some of the studies cited above have shown no association between generic HRQOL measures and metabolic control, as measured by glycosylated hemoglobin A1c [HbA1c] (Weinberger et al., 1994), whereas others suggest a strong relationship among these variables (Kaplan, Hartwell, Wilson & Wallace, 1987; Nerenz, Repasky, Whitehouse, & Kahkonen, 1992). One possible reason for this discrepancy may lie in the choice of

HRQOL instruments. For example, Kaplan, Hartwell, Wilson & Wallace (1987) observed a high degree of association between the generic HRQOL QWB scale and HbA1c among people with Type II DM. In contrast, Weinberger et al., (1994) showed no association between the generic SF-36 HRQOL instrument and HbA1c (Ware & Sherbourne, 1992; McHorney, Ware, Lu & Sherbourne, 1994; Weinberger et al., 1994). Whereas, Nerenz et al. (1992) showed a modest degree of correlation between the SF-36 and HbA1c (Nerenz, Repasky, Whitehouse, & Kahkonen, 1992). The use of a responsive diabetes-specific HRQOL instrument may clarify the relationship between HRQOL and metabolic control.

Studies assessing disease-specific HRQOL among people with Type II DM are much less prevalent than those using generic instruments. One explanation for this could be that only recently have diabetes-specific measures of HRQOL been developed. Two diabetes-specific HRQOL instruments are presently available. The Diabetes Quality of Life Scale [DQOL], was developed for the DCCT by the DCCT Research Group (1986, 1987, 1988). This instrument has been psychometrically tested and was found to be reliable and valid among people with Type I DM. Although evaluation of this instrument among people with Type II DM has begun (Jacobson, de Groot, & Samson, 1994) further reliability and validity assessment is needed to support its use in this population. The Diabetes Daily Hassles Questionnaire [DDHS] (Meisler & Carey, 1991) was recently developed specifically to assess disease-specific HRQOL among people with Type II DM. This instrument assesses hassles related to medication taking,

daily functioning, and worries associated with living with Type II DM. As with the DQOL scale, reliability and validity testing of this instrument is needed.

Few studies exist that have investigated the relationship between disease-specific HRQOL instruments and metabolic control among people with Type II DM. One study found a significant correlation between disease-specific HRQOL and HbA1c (Davis, Hess, Van Harrison, & Hiss, 1987). Furthermore, only two studies have addressed specific components of the Type II DM treatment regimen such as diet, exercise, and insulin administration and their relationship to HbA1c (Hatton et al., 1996; Meisler & Carey, 1991). In a pilot study testing the DDHS, a disease-specific HRQOL instrument that assesses hassles related to specific component of the diabetes regimen, no association between HbA1c and these hassles was found (Meisler, & Carey, 1991). In contrast, Hatton et al. (1996) found significant relationships between diet, nutrition-related affect, nutritional health perceptions, generic HRQOL, and HbA1c among people with a Type II DM (Hatton et al., 1996). In sum, the recent creation of disease-specific and nutrition-specific HRQOL instruments may account for the increase in the investigation of such relationships.

The Nutrition Hassles Questionnaire (See Instrument Description in Appendix C) was developed specifically to address nutrition-specific HRQOL issues (Ward & Hatton, 1995). Measurement of nutrition-specific HRQOL is of interest as many barriers to adherence to nutritional aspects of the diabetic regimen have been identified. Some of the psychological and psychosocial barriers to adherence include attitudes toward perceived efficacy of dietary modifications, food-related social environments,

lack of understanding proposed modifications, social and family support, tendencies toward social norms, problem solving capabilities, health locus of control, perceived medical support, self-control, self-efficacy, health-beliefs, depression, and stress (Ary, Toobert, Wilson, & Glasgow, 1986; Hampson, Glasgow, & Toobert, 1990; Kavanagh, Gooley, & Wilson, 1993; Toobert & Glasgow, 1991; Schafer, McCaul, & Glasgow, 1986; Wilson, Ary, Biglan, Glasgow, Toobert, & Campbell, 1986; Wooldridge, Wallston, Graber, Brown, & Davidson, 1992). This list of barriers to adherence suggests that nutritional modifications may impact perceived quality of life and therefore negatively impact adherence perhaps leading to poor metabolic control. Thus, assessment of the nutrition-specific HRQOL among people with a chronic illness that demands rigorous nutritional and lifestyle modifications would be of interest. As people with Type II DM are a heterogeneous group, individualizing treatment has been suggested to be the only way to attain acceptable levels of adherence, hence the only way to prevent disability due to diabetes complications (Anderson & Gustafson, 1989; Ary, Toobert, Wilson, & Glasgow, 1986). Therefore, identifying relevant hassles among individual patients could aid in the individualization of treatment among patients with Type II DM. Lastly, given the hypothesized importance of the relationship between metabolic control and advanced diabetes complications, identification of all HRQOL constructs associated with or predictive of metabolic control would be of importance. This would include nutrition-specific HRQOL constructs. However, the Nutrition Hassles Questionnaire is a newly developed instrument and reliability and validity testing are needed to assess its psychometric properties (Jaeschke & Guyatt,

1990; Guyatt & Jaeschke, 1990). Initial psychometric testing of this instrument has been done (see Appendix C), yet convergent validity and continued construct reliability must be tested.

In conclusion, health is composed of several interwoven components. These components include measurable physiologic outcomes as well as the many dimensions comprising HRQOL. In order to accurately measure health, it would seem necessary to measure all aspects of it. Measurement tools are available to measure both physiologic and HRQOL aspects of health, among people with Type II DM. Indeed, generic, diabetes-specific, and nutrition-specific HRQOL instruments are available. However, further research is required to investigate the relationship among different HRQOL measurement strategies and their relationship to metabolic control among people with Type II DM.

Therefore, the present thesis was designed to assess three specific aims. These three aims were further broken down into individual, testable components with related hypotheses as follows:

Specific Aim #1:

To comprehensively quantitate HRQOL among people living with a chronic disease that is thought to impact all aspects of health.

a) Identification of similarities and differences among HRQOL constructs measured by generic, diabetes-specific, and nutrition-specific HRQOL instruments.

It was of interest to determine the concepts within the four domains of HRQOL (physical, psychological/emotional, social and somatic well-being) that were measured.

It was hypothesized that generic, disease-specific and nutrition-specific HRQOL instruments would measure slightly different concepts within the larger domains of HRQOL.

b) Determination of a predictive relationship between subscales comprising the NHQ and those subscales comprising the other HRQOL instruments.

It was of interest to determine how the subscales comprising the NHQ were related to the subscales comprising the four HRQOL instruments. The specific hypothesis was that the subscales of the NHQ would be significantly predictive of variance within the individual subscales measuring HRQOL.

Specific Aim #2:

Determination of how HRQOL relates to a HbA1c.

a) Determination of the predictive relationship of generic, diabetes-specific, and nutrition-specific HRQOL constructs on HbA1c.

The specific hypotheses related to this aim was that HRQOL subscales would be significantly correlated with HbA1c and significantly predictive of variance within this parameter.

Specific Aim #3:

To assess the psychometric properties of the NHQ.

a) Assessment of the convergent validity of the NHQ.

b) Determination of the internal consistency reliability of the NHQ.

This final aim was measured in two ways. First, evidence for the convergent validity of the NHQ was hypothesized to exist and be exemplified by significant

correlations between the subscales comprising the NHQ and a priori selected items from the Diabetes Care Profile [DCP] (Davis, Hiss, Van Harrison, & Hess, 1987; Hess, Davis, & Van Harrison, 1986), DDHS, and DQOL. Second, internal consistency reliability, measured as high Cronbach's alpha coefficients, was hypothesized to exist for the NHQ and its seven subscales.

Although other studies have addressed different aspects of these aims individually, this thesis is unique in that it looked at a variety of HRQOL instruments and attempted to associate the measured HRQOL variables with a measurement of metabolic control. Furthermore, this thesis specifically addressed issues of nutrition-specific HRQOL among people living with a chronic disease in which an intensive nutritional regimen is often prescribed.

METHODS

Subjects & Recruitment

Fifty-five men and 107 women (total N = 162) with Type II DM were recruited from nine Portland area health-care, educational, or support group settings; specifically, the Providence Health Care System in the greater Portland area, and regional senior centers or an American Diabetes Association support group. Thus, potential subjects were approached either during a routine physician visit, a support group meeting, or during a diabetes life-skills education class. Table 1 contains specific recruitment locations names and types. Subjects in all but two settings were approached as a group. The Providence Endocrine Clinic and Ambulatory Care Clinic patients were asked to participate on an individual basis during regularly scheduled check-ups with their physicians. Verbal recruitment method was the same for both recruitment approaches. A standard recruitment script can be found in Appendix A. Verbal consent to be approached by a researcher was acquired from all potential subjects prior to introduction to the researcher. Upon verbal recruitment and agreement to participate, questionnaire packets were given to subjects. Subjects were then asked to carefully read and sign the consent form (See Appendix B) and return it along with the completed questionnaire packet in the self-addressed stamped envelope provided by the researcher. Blood samples were taken following verbal consent from patients.

Subjects who did not return questionnaire packets by mail within 10 days from enrolling in the study were called and asked to return the packet as soon as possible.

Table 1. Recruitment site information: Site, type of recruitment setting and number of subjects from each site.

Recruitment Site	Type of Recruitment Setting	Mean Age ± SEM	Number of Subjects
Providence Portland Diabetes Treatment Center	Educational	57±1.93	35
St. Vincent's Diabetes Treatment Center	Educational	57±2.18	27
Providence Newberg Diabetes Treatment Center	Educational	66±2.03	30
Providence Milwaukie Diabetes Treatment Center	Educational	59±8.84	3
American Diabetes Association	Support	60.5±4.23	8
Elsie Stuhr Senior Center	Support	67±2.80	7
Milwaukie Senior Center	Support	72±3.81	7
Providence Portland Endocrine Clinic	Medical	63.5±3.12	4
Providence Portland Ambulatory Care Clinic	Medical	58.6±2.47	15

Inclusion Criteria

Inclusion criteria were: 1) diagnosis of Type II DM, 2) absence of memory or cognitive deficits (as indicated by physician, nurse, diabetes educator, or support group coordinator), 3) English as the first language, and 4) the ability to read and write. Verbal acknowledgment of diagnosis of Type II DM from the subjects' physician, nurse, diabetes educator, or support group coordinator was sufficient evidence of diagnosis. These inclusion criteria are similar to those used by other researchers of diabetes HRQOL (Burkhardt, Woods, Schultz, & Ziebarth, 1989; Jacobson, de Groot, & Samson, 1994; Nerenz, Repasky, Whitehouse, & Kahkonen, 1992).

Blood Sampling

Subjects chose the finger that was to receive the lancet stick and it was sterilized with a 2 ply alcohol pad, 70% isopropyl alcohol solution (Baxter Corporation, Deerfield, IL). Approximately 4μl of blood were taken from the sterilized finger. A Glucolet 2 lancet system (Bayer Corporation, Elkhart, IN) was used to make a small puncture wound on either the medial or lateral side of the tip of the designated finger. Blood samples were collected and stored in heparinized soda lime glass microhematocrit capillary tubes (Baxter Healthcare Corporation, Deerfield, IL). Blood samples were taken by one of three methods: 1) the researcher performed the finger stick, 2) the subject performed the finger stick, or 3) the clinic nurse or licensed diabetes educator performed the finger stick. Microhematocrit tubes containing blood samples were capped at both ends by Seal-Ease tube sealer (Becton Dickinson and

Company, Rutherford, NJ). Blood samples were stored at $+2^{\circ}$ C for no more than 5 days before HbA1c analyses were performed.

HbA1c Assay

HbA1c was chosen as the measure of glucose control in the present study as it is thought to be the best stable measure of this parameter and is often used in the literature (Gabbay, Hasty, Breslow, Ellison, Bunn, & Gallop, 1977; Nathan, Singer, Hurxthal, & Goodson, 1984). Microhematocrit tubes were scratched with a small round file and broken at the scratch point. A 23 gauge Monoject polypropylene hub hypodermic needle connected to an air filled 1.0 cc tuberculin syringe (Sherwood Medical, St. Louis, MO) was inserted through the tube seal and the blood sample was squirted into a medium size polystyrene cup (VWR Scientific, San Francisco, CA). Approximately 1μl of blood was suctioned into a Hemoglobin A1c reagent cartridge (Bayer Corporation, Elkhart, IN). The reagent cartridge was loaded into the Ames DCA 2000 mass spectrometry analyzer (Bayer Corporation, Elkhart, IN). HbA1c values were then recorded by subject identification number to be later matched with demographic and QOL data.

Instruments

One demographic form, one pessimism/optimism questionnaire, one nutritional hassles HRQOL instrument, one adherence and care profile, two generic and two diabetes-specific HRQOL instruments comprised the questionnaire packets given to subjects. Table 2 contains the names and citations for each instrument.

Table 2. Instrument names, abbreviations and references.

Instrument	Reference
Nutrition Hassles Questionnaire (NHQ)	Ward & Hatton (1995)
Medical Outcomes Study Short-Form 36 (SF-36)	Ware & Sherbourne (1992)
Quality of Well-Being Scale (QWB)	Kaplan, Bush, & Berry (1976)
Diabetes Quality of Life Scale (DQOL)	DCCT (1986, 1987, 1988)
Diabetes Daily Hassles Scale (DDHS)	Meisler & Carey (1991)
Diabetes Care Profile (DCP)	Davis, Hiss, Van Harrison, & Hess (1987) Hess, Davis, & Van Harrison (1986)
Life Orientation Test (LOT)	Scheier, Carver, & Bridges (1994)
Demographic Form	Ward & Hatton (personal communication, 1995)

Appendix C contains all instruments and rationale behind the use of each. A brief rationale for the use of each questionnaire follows. The demographic form was included in the present study to obtain gender, age, employment, and marital status information. This four page demographic form was also used to document duration of diabetes, body weight perceptions and nutritional restrictions. The DCP (Davis, Hess, Van Harrison, & Hiss, 1987; Hess, Davis & Van Harrison, 1986) was chosen for the present study as it provides a comprehensive assessment of severity of diabetes, prescribed medical regimens and adherence; all of which could be useful as predictor variables or covariates. The Life Orientation Test (LOT) (Scheier, Carver, & Bridges, 1994) was included in the present study to control for optimistic versus pessimistic life orientations that could potentially confound perceptions of quality of life. The NHQ (Ward & Hatton, 1995; Hatton et al., 1996) was used to assess the predictive power on other measurable aspects of HRQOL and HbA1c, as well as to determine its convergent validity and internal reliability. The DQOL (DCCT, 1986, 1987, 1988) was included because it is thought to be the best disease-specific instrument presently available to measure HRQOL among people with Diabetes Mellitus (Jacobson, de Groot, & Samson, 1994, 1995). The DDHS (Meisler & Carey, 1991) was included as it addresses disease-specific hassles related to living with diabetes that the DQOL does not measure. The SF-36 (Ware & Sherbourne, 1992) and a new, self-administered version of the QWB (Kaplan, Bush & Berry, 1976) were included to assess global health-related quality of life. The SF-36 and the QWB are often the only measures used in the assessment of generic HRQOL and are considered to be reliable and valid

instruments (Kaplan, Bush, & Berry, 1976; McHorney, Ware, Lu, & Sherbourne, 1994; McHorney, Ware, & Raczek, 1993; Ware & Sherbourne, 1992). An important difference between the two generic instruments is that the QWB assesses physical symptoms of illness and functioning deficits in more detail than does the SF-36. The QWB and SF-36 were also chosen in order to add clarity to the contradictory literature regarding the relationship among these instruments and HbA1c. In general, these instruments were chosen for their unique HRQOL measurement abilities, as well as their use in assessing the convergent validity of the NHQ. All instruments consisted of fill in the blank or multiple choice, Likert-response options.

Data Entry

Subjects were assigned identification numbers in order to compare HbA1c with QOL results in a blind fashion. Subjects' names did not appear on either the demographic material or the QOL instruments. Demographic information and questionnaire responses were entered into the Microsoft Access for Windows (version 7.0) database on a Pentium P75t PC computer system. Data were transferred to the Statistical Package for the Social Sciences (SPSS) statistical program. In general items were scored according to procedures provided by the authors of the individual questionnaires with two exceptions. First, scores on several items were reversed so a uniform scoring motif was designed. This scoring approach yielded HRQOL data in which low scores indicated good HRQOL and high scores indicated poor HRQOL or in some cases, many hassles. Second, an index type of scoring method was devised for the QWB which is addressed in Appendix C. Data were reviewed for missing and out

of range data points. Data outside of one standard deviation of the mean for any one subscale were checked to see if they were randomly distributed across age and recruitment site. To account for random missing data, average subscale scores were calculated for each subject and subsequently used for all statistical analyses [e.g. sum(subscale items)/number of subscale items completed]. Averaged scores were not calculated for subscales in which response options were categorical. These response options were given dummy codes of 0 and 1, respectively. Data screening techniques and handling of missing data were similar to methods described in Tabachnick & Fidell (1989).

Statistical Analyses

Multivariate Analyses of Variance [MANOVA] and ANOVAs were used to determine if differences existed on subscales of the HRQOL instruments among recruitment sites, age, gender, duration of diabetes, disability, and insulin strata. To assess the relationship between subscales comprising disease-specific HRQOL instruments, generic HRQOL instruments and the NHQ, a principle axis-factoring, direct oblimin (oblique) rotation factor analysis was performed. Several simultaneous multiple regressions were done to determine the predictive nature of the NHQ subscales on subscales comprising the HRQOL instruments. Hierarchical multiple regression analyses were used to assess the predictive nature of the subscales comprising HRQOL on HbA1c. Lastly, individual Pearson's Product Moment Correlation Coefficients were calculated to assess the convergent validity of the NHQ with a priori selected items from the DCP, the DDHS, and the DQOL scale. The specific instrument and

item numbers used for comparisons can be found in Table 3. These items were chosen for their nutrition-related content as no one subscale within these three instruments measured nutrition-specific constructs.

Internal consistency reliability of all questionnaires was assessed using Cronbach's Alpha Coefficient (Cronbach, 1951). These statistical procedures were thought to be appropriate for the purposes of this study as they are similar to those used by other investigators in similar studies (Jacobson, de Groot, & Samson, 1994; Mayou, Bryant, & Turner, 1990; Weinberger et al., 1994). For reviews on the assumptions, and specific methodology see Cronbach (1951), Hays (1988), Kim & Mueller (1978), Pedhazur (1982), and Tabachnick & Fidell (1989).

Table 3. Instrument items chosen a priori for convergent validity testing of the NHQ.

NHQ Subscale	Other Instruments	Item Number	Proposed Direction of Correlation
Nutritional Complexities	DCP	8, 9	+
	DQOL	1	+
	DDHS	2	+
Vigilance	DCP	50, 52, 55, 56, 57, 60	+
	DDHS	13, 14, 19	+
Monitoring Nutrients	DCP	35, 36, 37, 38, 39, 40, 41, 42, 47, 49	+
Social Hassles	DCP	10, 11b,c,g,i, 1 106f, 104a	+ -
	DQOL	4, 13, 16, 24,33	+
	DDHS	3, 15, 30	+
Planning & Preparation	DDHS	25	+
Dysphoria	DCP	16, 29 17, 21	+ -
	DQOL	3, 11	+
Control	DCP	11e,f,h, 24a, b,c, 26, 27 19, 48	+ -
	DDHS	16	+

RESULTS

One-hundred and sixty-two people agreed to participate in the present study. Of this group, 136 people returned completed questionnaires. Return rate was 82%. Of the non-responders, 8 were male and 18 were female. Thus, HRQOL analyses were performed on data from 136 people. Of those who did respond, 47 were male and 89 were female. Overall, mean age was 60.8 ± 11.58 years (range 31 - 84), and mean duration of diabetes was 6.2 ± 7.13 years (range 1 - 34). Demographic information can be found in Table 4.

Stratification Analyses

HRQOL differences among recruitment sites were hypothesized to exist as significant age differences among the recruitment groups were revealed by use of an ANOVA ($F(8,127) = 3.081$, $p = 0.003$). Post-hoc Tukey's Honestly Significant Difference (HSD) revealed that subjects recruited from the Milwaukie Senior Center (mean age = 72 $\pm$ SEM 3.82) were significantly older than subjects recruited from the Providence Portland (57 $\pm$ 1.93) and St. Vincent's (57 $\pm$ 2.18) Diabetes Treatment Centers. Furthermore, subjects recruited from the Newberg Diabetes Treatment Center (66 $\pm$ 2.08) were significantly older than subjects recruited from the Providence Portland Diabetes Treatment Center (57 $\pm$ 1.93). The data also showed recruitment site differences, as tested by ANOVAs, existed on one subscale of the QWB. Scores on the Physical Activity subscale was significantly different among sites ($F(8,126) = 2.05$, $p = 0.046$).

Table 4. Demographic information.

N - Recruited	162
N - Returned HRQOL Packet	136
Non-Responders:	
Male	8
Female	18
Responders:	
Male	47
Female	89
Mean Age (years)	60.8
Age Range (years)	31-84
Mean Duration of Diabetes (years)	6.2
Duration Range (years)	1-34

Post-hoc Tukey's HSD revealed that the Providence Portland Ambulatory Care Clinic (mean score = 3.61$\pm$ SEM 0.63) group was different from the Providence Portland (1.75$\pm$.241) and St. Vincent's (1.71$\pm$.32) Diabetes Treatment Center subjects on this subscale.

Means and SEMs for each recruitment site can be found in Table 5. Possible interpretations can be found in the discussion. Fifteen subjects were recruited from Providence Portland Endocrine Clinic, 35 subjects were recruited from the Providence Portland Diabetes Treatment Center, and 27 from St. Vincent's Diabetes Treatment.

The effect of age stratification (group 1 = 30 to 49; group 2 = 50 - 59; group 3 = 60-69; group 4 = 70-79; group 5 = 80-84), on the subscales comprising the HRQOL instruments was assessed by the use of ANOVAs. Results showed significant age group differences on some of the subscales comprising the NHQ and the DDHS. NHQ subscales included Complexities ($F(4,131) = 3.55$, $p = 0.009$), Control ($F(4,131) = 4.03$, $p = 0.004$), Planning and Preparation ($F(4,131) = 3.74$, $p = 0.006$), and Social Hassles ($F(4,131) = 3.62$, $p = 0.008$). The two subscales from the DDHS that accounted for the age group differences on this questionnaire were Physical Disability ($F(4,131) = 2.60$, $p = 0.040$) and Weight ($F(4,131) = 4.33$, $p = 0.003$). Post-hoc Tukey's HSD analyses revealed that age groups 4 (70-79) were different from age groups 3 (60-69) and 5 (80-84) on the Complexities subscale, whereas age group 4 was different from age groups 1(30-49) and 2(50-49) on the Control subscale.

Table 5. Recruitment site means $\pm$ SEMs on the Physical Activity subscale of the QWB.

Recruitment Site	Physical Activity Subscale Mean ± SEM
Providence Portland Diabetes Treatment Center	1.75 ± 0.24
St. Vincent's Diabetes Treatment Center	1.71 ± 0.32
Providence Newberg Diabetes Treatment Center	2.15 ± 0.36
Providence Milwaukie Diabetes Treatment Center	1.67 ± 0.67
American Diabetes Association	1.88 ± 0.52
Elsie Stuhr Senior Center	1.67 ± 0.31
Milwaukie Senior Center	2.41 ± 0.70
Providence Portland Endocrine Clinic	1.00 ± 0.00
Providence Portland Ambulatory Care Clinic	3.61 ± 0.63

Age group 4 was different from age group 3 and 2 on the Planning and Preparations subscale whereas age group 4 was different from age groups 1, 2, and 3 on the Social Hassles subscale. Lastly, age group four was different from age group 2 on the Physical Disability subscale, whereas age group 4 was different from age groups 2 and 3 on the Weight subscale. In all cases the mean for age group 4 was lower than for the others. This indicates that the 70-79 year old subjects perceived fewer hassles on some subscales than did younger subjects. Means and SEMs for each subscale can be found in Table 6. Age group 1 consisted of 26 people, age group 2 consisted of 32 people, age group 3 consisted of 40 people, age group 4 consisted of 33 people, and age group 5 consisted of 5 people.

The effect of gender on the subscales comprising the HRQOL instruments was assessed by the use of ANOVAs. Results showed significant gender differences on some of the subscales comprising the SF-36, the QWB, and the DDHS. Subscales from the SF-36 that were significantly different between men and women were Bodily Pain ($F(1,134) = 6.45$, $p = 0.01$), Physical Functioning ($F(1,134) = 7.92$, $p = 0.006$), Role Functioning due to Emotional Problems ($F(1,129) = 6.88$, $p = 0.009$), Role Functioning due to Physical Problems ($F(1,131) = 6.90$, $p = 0.009$), Social Functioning ($F(1,134) = 6.54$, $p = 0.011$) and Vitality ($F(1,133) = 9.38$, $p = 0.003$). Subscales from the QWB scale shown to be different between men and women were Physical Activity ($F(1,133) = 7.29$, $p = 0.007$) and Symptoms ($F(1,134) = 11.60$, $p = 0.0009$). Lastly, subscales from the DDHS that were different between men and women were Medical and Social Concerns ($F(1.134) = 3.99$, $p = 0.047$) and Weight

Table 6. Age group means ± SEMs for the Complexities, Control, Planning and Preparation, Social Hassles, Physical Disability, and Weight subscales.

Age Group	Complexities	Control	Planning & Preparation	Social Hassles	Physical Disability	Weight
1 (30-49)	2.45 ± 0.29	**2.30 ± 0.27**	1.52 ± 0.26	**1.70 ± 0.22**	1.03 ± 0.12	1.61 ± 0.20
2 (50-59)	2.04 ± 0.26	**2.5 ± 0.27**	**1.74 ± 0.28**	**1.62 ± 0.21**	**1.44 ± 0.19**	**2.01 ± 0.22**
3 (60-69)	**2.18 ± 0.24**	2.19 ± 0.26	**1.44 ± 0.20**	**1.54 ± 0.21**	1.22 ± 0.15	**1.71 ± 0.18**
4 (70-79)	**1.23 ± 0.18***	**1.27 ± 0.18***	**0.62 ± 0.14***	**0.76 ± 0.12***	**0.79 ± 0.13***	**1.01 ± 0.14**
5 (80-84)	**2.33 ± 0.35**	1.40 ± 0.29	1.45 ± 0.26	1.54 ± 0.48	1.10 ± 0.19	0.90 ± 0.25

* indicates group that was the source of the difference from the other bolded groups

($F(1,134) = 4.28$, $p = 0.04$). In all cases the mean subscale scores for women were lower than those for men. This indicates that the women perceived more of an impact on their HRQOL, as measured by these subscales, than did men. Means and SEMs for each subscale can be found in Table 7.

The effect of duration of diabetes stratification (group 1 = 1 year; group 2 = 2-9 years; group 3 = 10-19 years; group 4 = 20-34 years), on the subscales comprising the HRQOL instruments was assessed by the use of ANCOVAs, with age as a covariate. No effects of duration of diabetes on any subscale of the HRQOL instruments were observed.

All subsequent statistical analyses are collapsed across recruitment sites, age groups as well as gender. The observed recruitment site and age differences were controlled for in all relevant analyses, as were gender and duration of diabetes.

HRQOL - General Findings

Averaged score distributions for each subscale indicated that subjects reported good HRQOL. HRQOL is considered to be good as subscale means are at or below the middle value of the range of possible responses. Subscale means, standard error of the means, and ranges can be found in Table 8.

Effects of Disability Status and Insulin Use on HRQOL

To determine the effects on HRQOL of grouping subjects according to disability status, Multivariate Analyses of Covariance (MANCOVA), with age as a covariate, were performed for each of the HRQOL instruments.

Table 7. Subscale score means ± SEMs by gender.

Instrument Subscale	MEN Mean ± SEM	WOMEN Mean ± SEM	p Value
SF-36			
Bodily Pain	2.09 ± 0.017	2.60 ± 0.12	0.012
Role - Emotional	0.5 ± 0.15	1.04 ± 0.13	0.009
Role - Physical	1.13 ± 0.22	1.92 ± 0.18	0.009
Social Function	1.52 ± 0.11	1.95 ± 0.11	0.01
Vitality	3.00 ± 0.14	3.62 ± 0.13	0.03
Physical Function	1.43 ± 0.06	1.71 ± 0.06	0.006
General Health	2.54 ± 0.12	2.80 ± 0.09	0.09
Mental Health	2.17 ± 0.12	2.45 ± 0.99	0.09
QWB			
Physical Activity	1.49 ± 0.14	2.33 ± 0.21	0.007
Symptoms	1.55 ± 0.08	2.08 ± 0.10	0.0009
Social Activity	1.43 ± 0.19	1.83 ± 0.20	0.19
Mobility	2.95 ± 0.11	3.09 ± 0.09	0.33
DDHS			
Med/Soc Concerns	0.67 ± 0.11	0.95 ± 0.08	0.47
Weight	1.29 ± 0.17	1.70 ± 0.11	0.04
Insulin	0.51 ± 0.08	0.64 ± 0.06	0.22
Physical Disability	1.01 ± 0.13	1.19 ± 0.09	0.26
DQOL			
Diabetes Worry	1.86 ± 0.11	1.99 ± 0.07	0.28
Impact	1.85 ± 0.07	1.99 ± 0.05	0.08
Satisfaction	2.74 ± 0.09	2.87 ± 0.06	0.23
Soc/Voc Worry	1.65 ± 0.11	1.88 ± 0.09	0.13
NHQ			
Complexities	1.74 ± 0.17	1.51 ± 0.16	0.16
Control	1.84 ± 0.22	2.14 ± 0.15	0.27
Dysphoria	1.38 ± 0.17	1.69 ± 0.14	0.17
Monitoring	1.42 ± 0.21	1.66 ± 0.15	0.36
Plan & Prep	1.10 ± 0.15	1.45 ± 0.15	0.14
Social	1.35 ± 0.17	1.43 ± 0.12	0.68
Vigilance	1.33 ± 0.19	1.49 ± 0.14	0.49

Table 8. Subscale score means ± SEMs and ranges for all subscales of all HRQOL instruments.

Instrument Subscale	Mean	SEM	Minimum	Maximum	N
Lot (Total)	2.43	0.06	1.0	5.0	136
NHQ					
Complexities	1.98	0.12	0.00	6.00	136
Control	2.04	0.13	0.00	6.00	136
Dysphoria	1.58	0.11	0.00	5.17	136
Monitoring	1.57	0.12	0.00	6.00	135
Planning and Preparation	1.33	0.11	0.00	6.00	136
Social Hassles	1.40	0.10	0.00	4.57	136
Vigilance	1.44	0.11	0.00	5.80	136
SF-36					
Bodily Pain	2.42	0.10	1.00	5.50	136
Vitality	3.40	0.10	1.25	6.00	135
Social Functioning	1.80	0.08	1.00	4.50	136
Role Functioning - Physical	1.62	0..15	1.00	2.00	133
Role Functioning - Emotional	0.85	0.10	1.00	2.00	131
Physical Functioning	1.62	0.05	1.00	3.00	136
Mental Health	2.35	0.08	1.00	5.80	135
General Health	2.71	0.07	1.20	5.00	136
QWB					
Mobility	3.04	0.07	1.00	5.80	136
Social Activity	1.69	0.15	1.00	9.00	134
Physical Activity	2.04	0.15	1.00	8.00	135
Symptoms	1.90	0.08	1.00	5.24	136
DDHS					
Weight	1.56	0.10	0.00	4.67	136
Physical Disability	1.13	0.08	0.00	3.82	136
Medical & Social Concerns	.85	0.07	0.00	3.77	136
Insulin	0.59	0.05	0.00	3.50	136
DQOL					
Diabetes Worry	1.95	0.06	1.00	5.00	135
Social & Vocational Worry	1.80	0.07	1.00	4.67	135
Satisfaction	2.83	0.05	1.47	4.29	136
Impact	1.95	0.04	1.06	3.33	135

Note: Low subscale scores = good perceived HRQOL

Disability stratification was based on responses from a disability item from the DCP that asks the following: "How often has your diabetes kept you from doing your normal daily activities during the past year (e.g. couldn't: go to work, work around the house, go to school, visit friends)?". Response options ranged from never to always on a 5 point Likert scale. A dummy code of 0 was given to those who indicated no disability (never) while a dummy code of 1 was given to those who indicated some disability (rarely - always).

MANCOVAs revealed that on all five of the HRQOL instruments people reporting some disability reported lower HRQOL than people reporting no disability; NHQ, ($F(1,125) = 2.55$, $p = 0.017$), SF-36 ($F(1,119) = 4.21$, $p < 0.001$), QWB ($F(1,124) = 5.59$, $p < 0.001$), DQOL ($F(1,125) = 7.66$, $p < 0.001$), and DDHS ($F(1,126) = 5.24$, $p = 0.001$). Disability strata differences for each of the significant subscales can be found in Figures 1-6. All subscale means for each disability strata can be found in Table 9. Subscales from the NHQ that accounted for the significant difference between disability strata were Monitoring ($p = 0.027$), Social Hassles ($p = 0.002$), Vigilance ($p = 0.047$), and Planning and Preparation ($p = 0.002$). All subscales from the SF-36 accounted for the difference between disability strata. The significance values for these subscales were Bodily Pain ($p = 0.004$), General Health ($p = 0.001$), Mental Health $p < 0.001$), Physical Functioning ($p = 0.048$), Role Functioning due to Emotional Problems ($p < 0.001$), Role Functioning due to Physical Problems ($p < 0.001$), Social Functioning ($p < 0.001$), and Vitality ($p < 0.001$).

Table 9. Disability strata means ± SEMs for subscales from each HRQOL instruments.

HRQOL Instrument Subscale	No Disability (N=86) Mean ± SEM	Some Disability (N=43) Mean ± SEM
NHQ		
Monitoring	1.34 ± 0.14	1.93 ± 0.24*
Planning and Preparation	1.02 ± 0.11	1.81 ± 0.23**
Social Hassles	1.16 ± 0.10	1.89 ± 0.22**
Vigilance	1.24 ± 0.12	1.75 ± 0.25*
Dysphoria	1.45 ± 0.13	1.77 ± 0.20
Complexities	1.76 ± 0.14	2.34 ± 0.23
Control	1.89 ± 0.15	2.31 ± 0.24
SF-36		
Role Functioning - Emotional	0.52 ± 0.10	1.40 ± 0.20**
Role Functioning - Physical	1.19 ± 0.17	2.48 ± 0.26**
Social Functioning	1.54 ± 0.09	2.23 ± 0.15*
Physical Functioning	1.55 ± 0.06	1.73 ± 0.09**
Mental Health	2.14 ± 0.09	2.70 ± 0.14**
Bodily Pain	2.20 ± 0.12	2.77 ± 0.16**
General Health	2.52 ± 0.09	3.04 ± 0.11**
Vitality	3.15 ± 0.12	3.85 ± 0.16**
QWB		
Social Activity	1.31 ± 0.12	2.19 ± 0.33**
Symptoms	1.64 ± 0.07	2.35 ± 0.16**
Mobility	2.99 ± 0.08	3.05 ± 0.13
Physical Activity	1.81 ± 0.17	2.47 ± 0.31
DQOL		
Social and Vocational Worry	1.69 ± 0.09	2.01 ± 0.13*
Impact	1.81 ± 0.04	2.24 ± 0.08**
Diabetes Worry	1.87 ± 0.07	2.17 ± 0.12*
Satisfaction	2.70 ± 0.06	3.08 ± 0.08**
DDHS		
Insulin	0.47 ± 0.05	0.80 ± 0.10**
Medical and Social Concerns	0.68 ± 0.07	1.15 ± 0.13**
Physical Disability	0.86 ± 0.08	1.54 ± 0.14**
Weight	1.35 ± 0.11	1.91 ± 0.18**

* $p < 0.05$

** $p < 0.01$

Data indicating disability status were missing for 7 people.

Figure 1. NHQ subscale differences between disability strata.

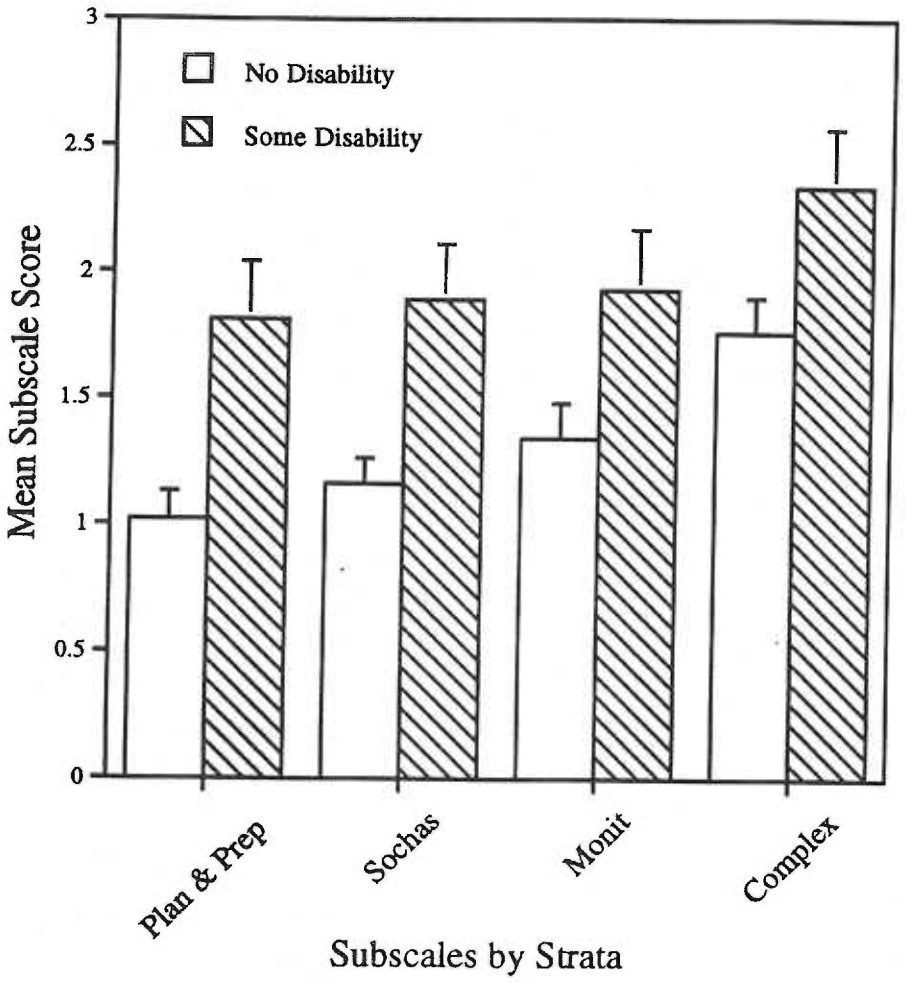

NHQ by Disability Strata
No Disability
Some Disability
Mean Subscale Score
3
2.5
2
1.5
1
0.5
0
Plan & Prep
Sochas
Monit
Complex
Subscales by Strata

Figure 2. SF-36 subscale differences between disability strata.

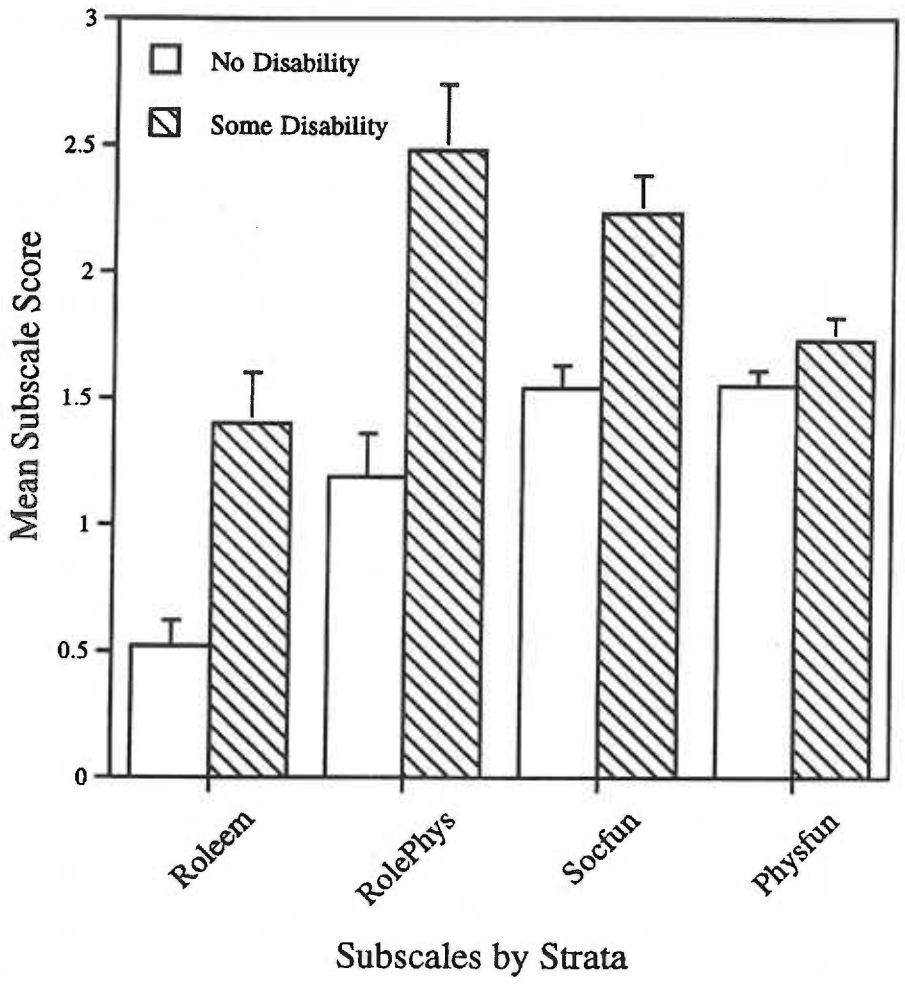

SF-36 by Disability Strata
No Disability
Some Disability
Mean Subscale Score
3
2.5
2
1.5
1
0.5
0
Roleem
RolePhys
Socfun
Physfun
Subscales by Strata

Figure 3. SF-36 subscale differences between disability strata (contd.).

SF-36 by Disability Strata

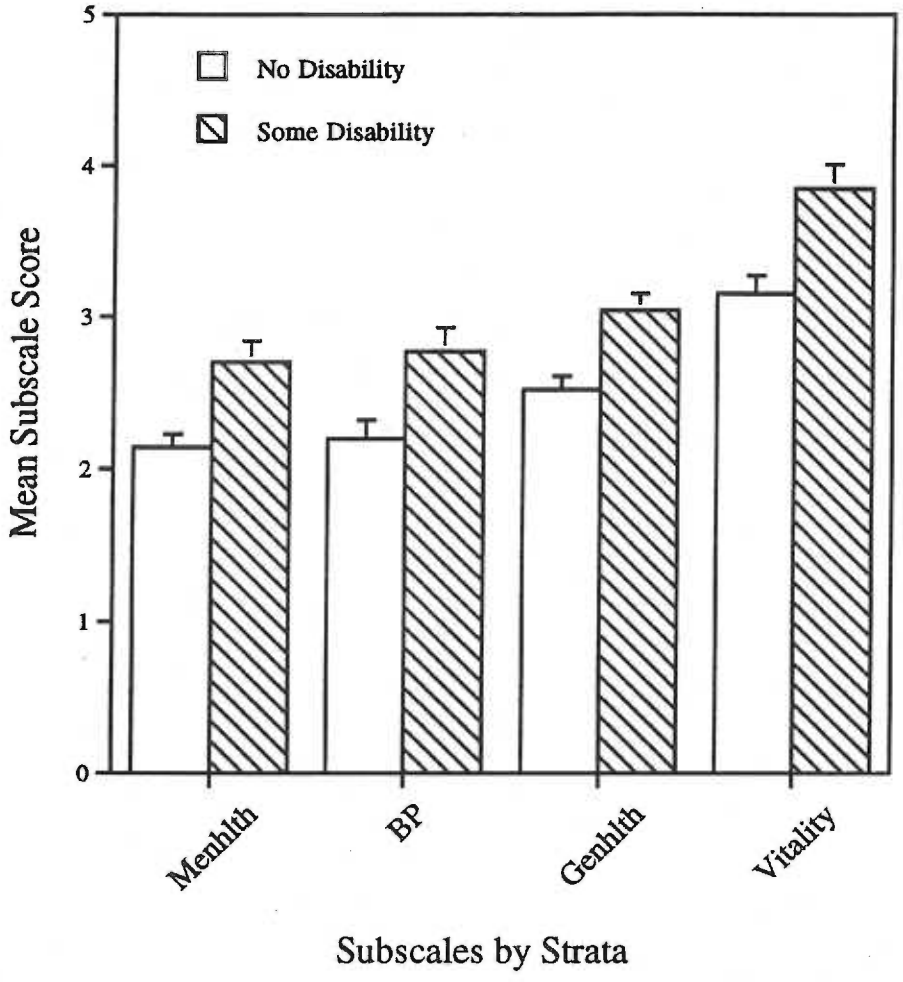


Figure 4. QWB subscale differences between disability strata.

QWB by Disability Strata

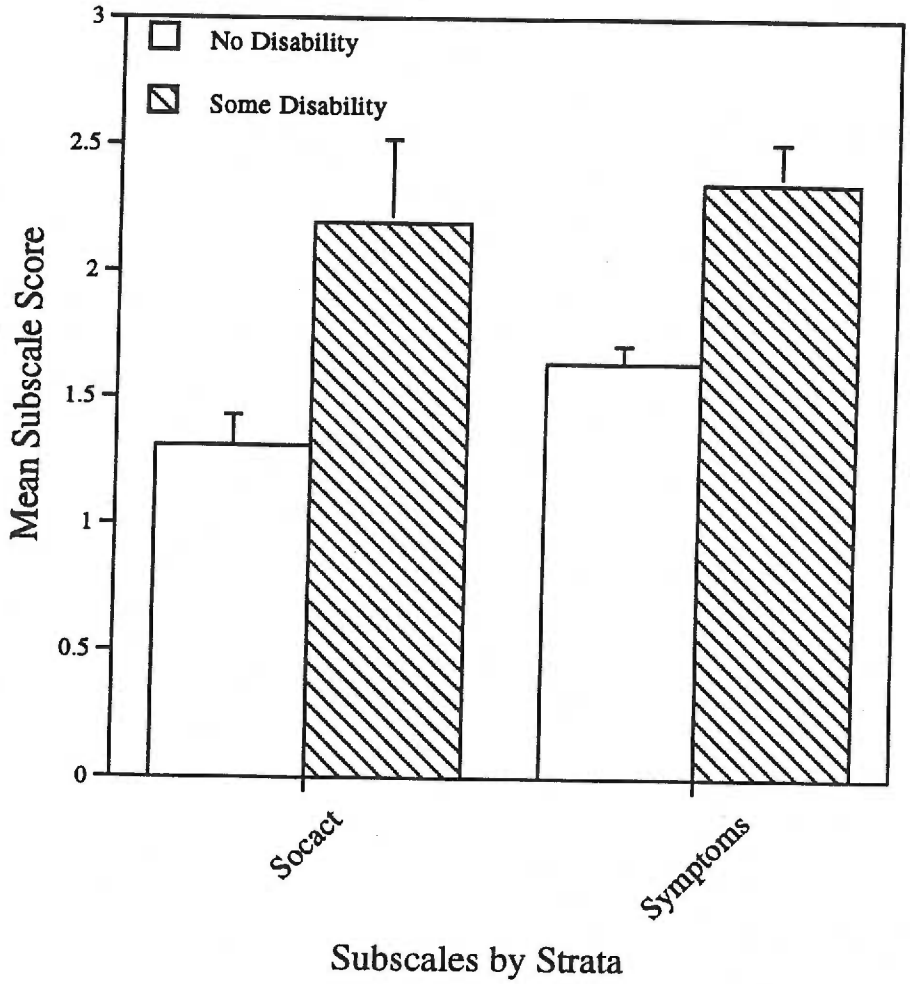


Figure 5. DQOL subscale differences between disability strata.

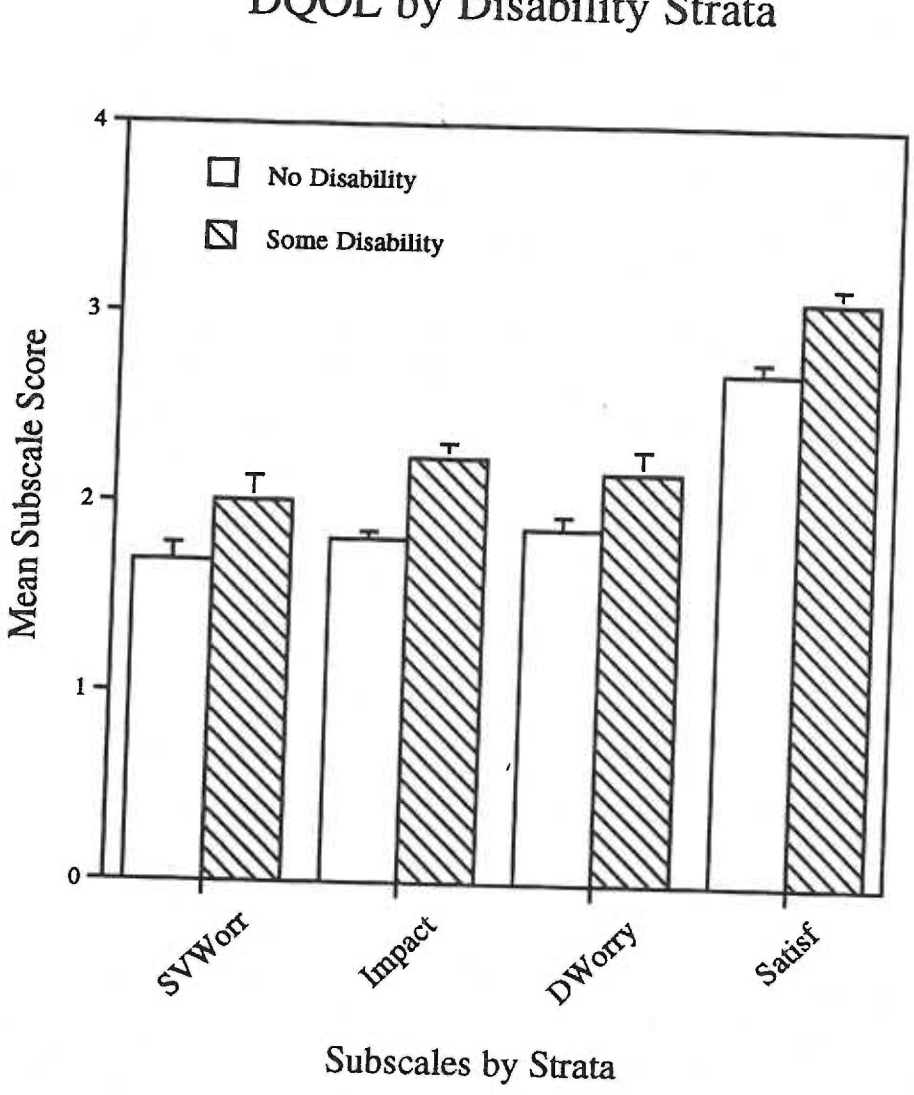
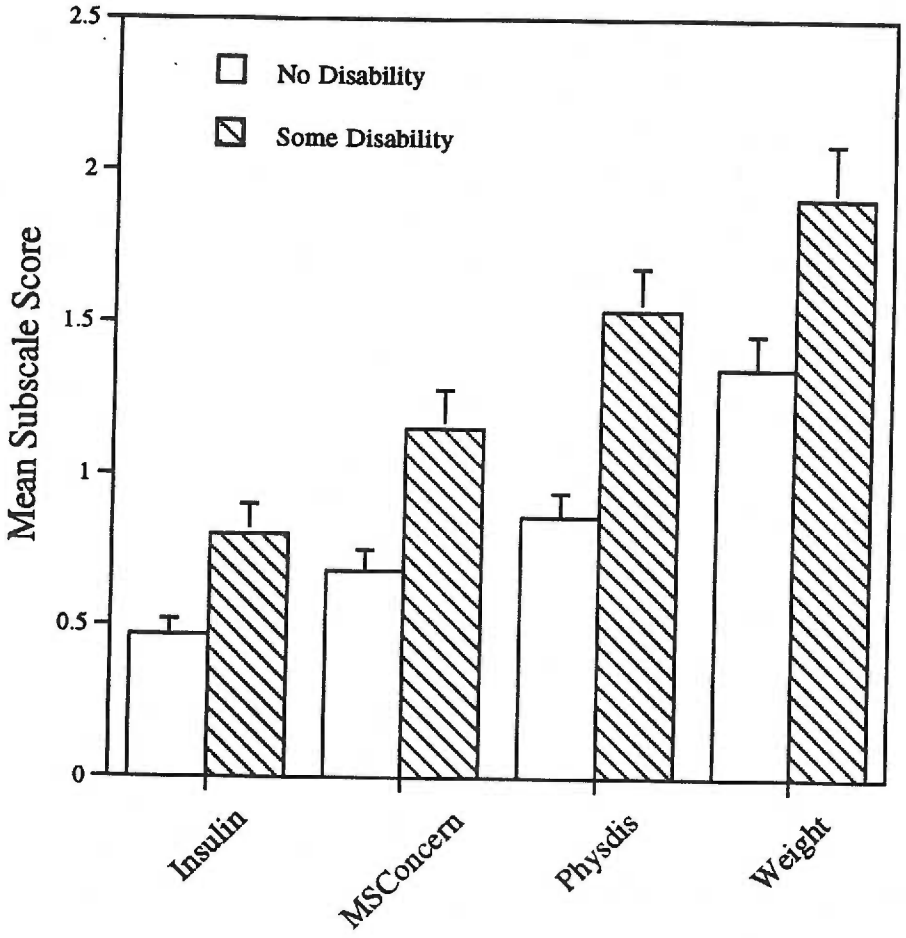

DQOL by Disability Strata
No Disability
Some Disability
Mean Subscale Score
4
3
2
1
0
SVWorr
Impact
DWorry
Satisf
Subscales by Strata

Figure 6. DDHS subscale differences between disability strata.

DDHS by Disability Strata



Subscales by Strata

The two QWB subscales that accounted for the observed differences between disability strata were Symptoms ($p < 0.001$), and Social Activities ($p = 0.003$). All of the subscales from the DQOL and DDHS instruments were responsible for the observed strata differences. Subscales significance values for DQOL subscales were Satisfaction ($p = 0.001$), Impact ($p < 0.001$), Diabetes Worry ($p = 0.025$), and Social and Vocational Worry ($p = 0.051$). Significance values for DDHS subscales were Physical Disability ($p < 0.001$), Medical and Social Concerns ($p = 0.001$), Insulin ($p = 0.003$), and Weight ($p = 0.010$). These results suggest that people who indicated some disability perceived poorer HRQOL than those who had no disability.

To determine the effects of insulin taking on HRQOL, Multivariate Analyses of Covariance (MANCOVA), with age as a covariate, were performed for each of the HRQOL instruments. A dummy code of 0 was given to those who indicated they were on insulin while a dummy code of 1 was given to those who indicated they were not on insulin). MANCOVAs revealed insulin strata differed on two of the five HRQOL instruments; the SF-36 ($F(1,124) = 2.46$, $p = 0.017$), and the DQOL ($F(1,130) = 3.85$, $p = 0.005$). All subscale means for each insulin strata can be found in Table 10. Insulin strata differences for significant subscales can be found in Figures 7-8. Subscales from the SF-36 that were significantly different between those who were on versus not on insulin included Bodily Pain ($p = 0.017$), General Health ($p = 0.025$), Physical Functioning ($p = 0.002$), Role Functioning due to Emotional Problems ($p = 0.006$), Role Functioning due to Physical Problems ($p = 0.006$), and Vitality ($p = 0.001$). Subscales comprising the DDHS that were different between insulin strata

included Insulin ($p < 0.001$), and Physical Disability ($p = 0.028$). These results suggest that people who indicated being on insulin perceived their HRQOL as poorer than those who were not on insulin.

No recruitment site, age group, gender, duration of diabetes, disability status, or insulin status differences were found for the LOT.

HRQOL Factors

Specific Aim #1, to comprehensively quantitate HRQOL among people living with a chronic disease that is thought to impact all aspects of health, and its related hypothesis that generic, disease-specific and nutrition-specific HRQOL instruments would measure slightly different concepts within the larger domains of HRQOL, was tested by use of factor analysis.

A five factor model accounting for 68.8% of the variance was identified by use of a principle-axis factoring, direct oblimin (oblique) rotation factor analysis. However, three subscale variables had low factor loadings (<0.40). These three subscale variables Symptoms (QWB), Medical and Social Concerns (DDHS), and Physical Disability (DQOL) were eliminated from the second factor analysis. The subsequent factor analysis identified five factors with eigenvalues greater than 1 were and high communalities (> 0.44) that accounted for 69% of the variance.

Table 10. Insulin strata means and SEMs for subscales from the HRQOL instruments.

HRQOL Instrument Subscale	On Insulin (N= 41) Means SEM	Not on Insulin (N = 92) Mean SEM
SF-36		
Bodily Pain	2.77 ± 0.20	2.24 ± 0.11*
General Health	2.94 ± 0.14	2.58 ± 0.08*
Mental Health	2.51 ± 0.18	2.2 ± 70.09
Physical Functioning	1.82 ± 0.10	1.52 ± 0.06**
Role Functioning - Emotional	1.22 ± 0.20	0.64 ± 0.11**
Role Functioning - Physical	2.17 ± 0.29	1.38 ± 0.16
Social Functioning	2.02 ± 0.15	1.71 ± 0.10
Vitality	3.91 ± 0.20	3.17 ± 0.11**
QWB		
Symptoms	2.02 ± 0.14	1.86 ± 0.09
Mobility	3.17 ± 0.12	2.95 ± 0.09
Physical Activity	2.44 ± 0.29	1.89 ± 0.18
Social Activity	1.73 ± 0.30	1.69 ± 0.18
DDHS		
Insulin	0.84 ± 0.09	0.49 ± 0.06**
Physical Disability	1.37 ± 0.16	1.02 ± 0.08*
Medical and Social Concerns	1.03 ± 0.14	0.77 ± 0.07
Weight	1.63 ± 0.18	1.54 ± 0.12
DQOL		
Satisfaction	3.01 ± 0.10	2.76 ± 0.06
Impact	2.07 ± 0.08	1.89 ± 0.05
Diabetes Worry	2.10 ± 0.11	1.87 ± 0.07
Social and Vocational Worry	2.07 ± 0.15	1.68 ± 0.08
NHQ		
Complexities	2.07 ± 0.24	1.92 ± 0.14
Control	2.11 ± 0.23	2.04 ± 0.15
Dysphoria	1.60 ± 0.21	1.59 ± 0.13
Monitoring	1.75 ± 0.26	1.53 ± 0.14
Planning and Preparation	1.44 ± 0.19	1.29 ± 0.14
Social Hassles	1.63 ± 0.20	1.33 ± 0.12
Vigilance	1.62 ± 0.23	1.38 ± 0.13

* $p < 0.05$

** $p < 0.01$

Data indicating insulin taking status were missing for 3 people

Figure 7. SF-36 subscale differences between insulin strata.

SF-36 by Insulin Strata

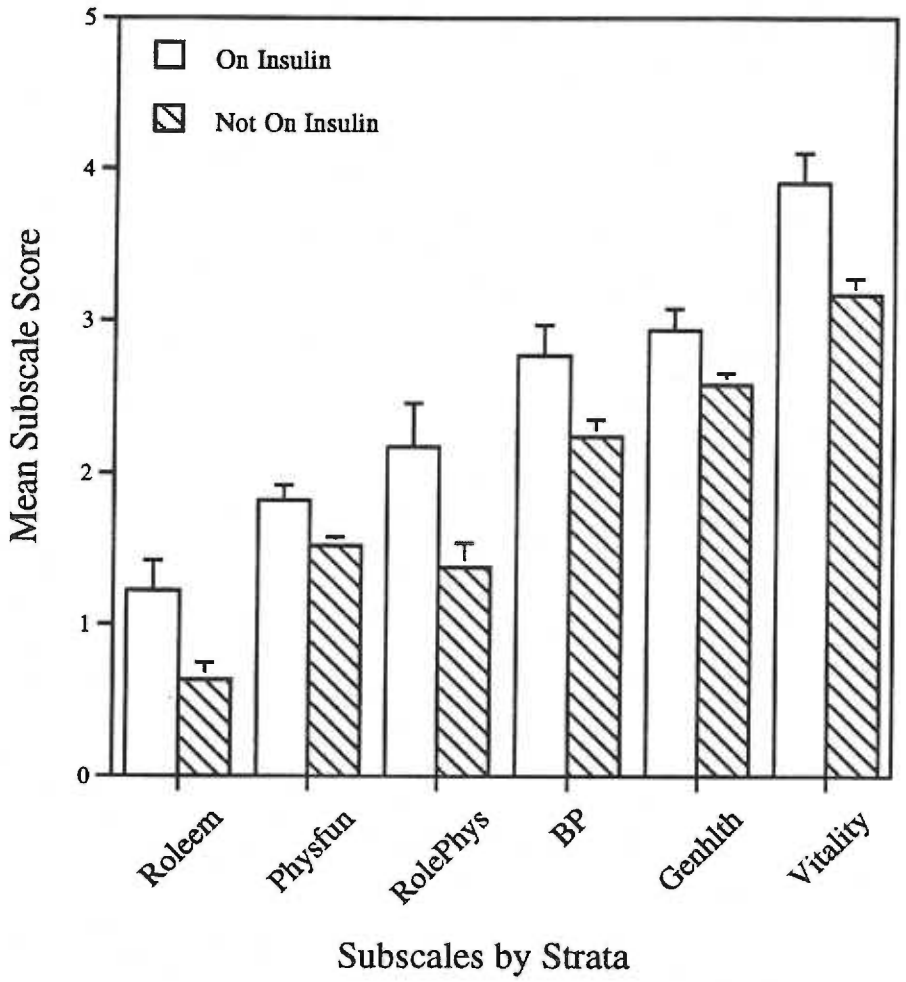
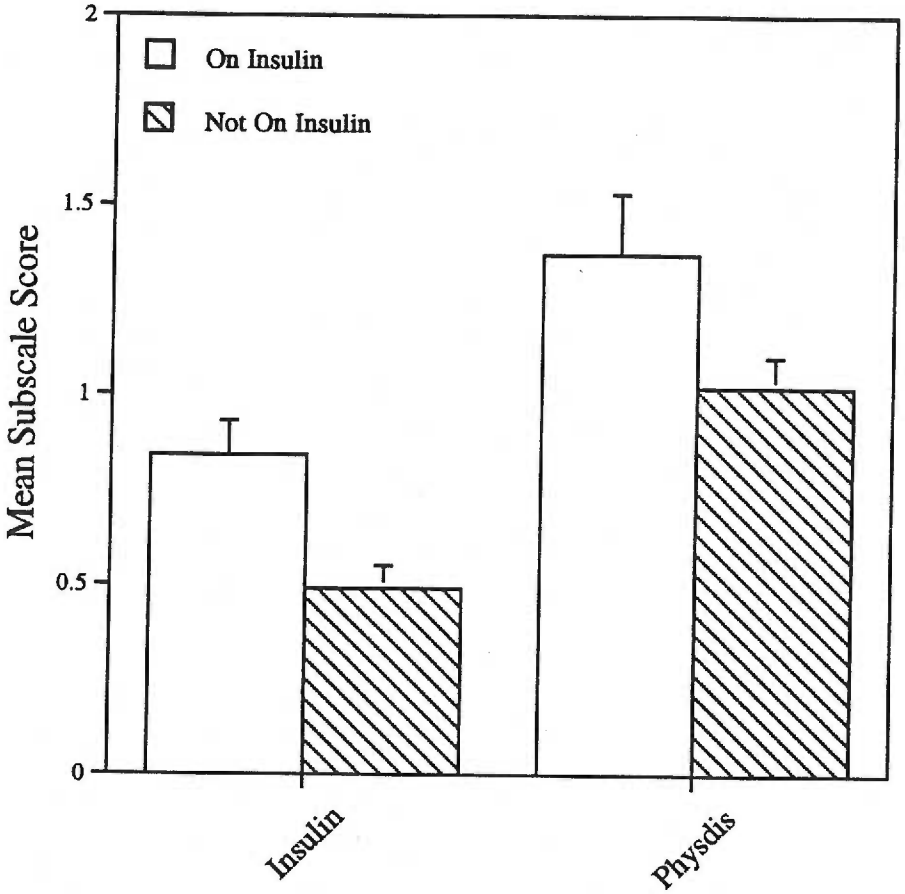


Figure 8. DDHS subscale differences between insulin strata.

DDHS by Insulin Strata



Subscales by Strata

Table 11. Factor analysis results: Five factors and subscale loadings

Variables (Subscales)	Factor 1 (Well-Being)	Factor 2 (Physical Ability)	Factor 3 (Psychological Impact)	Factor 4 (Social Impact)	Factor 5 (Nutrition Hassles)
General Health	.57091*	.23436	.12000	-.02718	.03694
Mental Health	.69417*	-.10028	-.01495	.23871	.07927
Role - Emotional	.45009*	.33835	-.00734	-.02989	.18055
Vitality	.58667*	.21930	.11929	.00249	.02920
Diabetes Worry	-.06804	-.00576	.66047*	.03161	-.01412
Impact	.06294	.09000	.74310*	-.00540	.07005
Satisfaction	.17533	-.09066	.55790*	-.05557	.06458
Social and Vocational Worry	-.10732	.02719	.78683*	.02312	-.04293
Bodily Pain	.17341	.56513*	.03912	.12242	.03869
Mobility	-.06593	.48704*	-.01521	-.03198	.02795
Physical Activity	-.01309	.70611*	.04409	.23419	-.04194
Physical Functioning	.16471	.77624*	.02884	.06202	-.01308
Role Physical	.25258	.63121*	.15667	-.01296	-.01179
Complexities	.04357	-.01088	-.04442	.15038	.64443*
Control	.10995	-.09181	-.00086	.00341	.79132*
Dysphoria	-.02891	.01438	.02463	-.03046	.82067*
Monitoring	-.00044	.11520	-.00144	-.12999	.83383*
Planning and Preparation	-.03989	-.11716	.03427	.19053	.78134*
Social Hassles	-.04139	.01044	.09119	-.08163	.84894*
Vigilance	-.08514	.07711	-.04410	.02829	.88057*
Weight	.31526	-.03876	.07520	.06493	.54571*
Insulin	.09468	-.06958	.08563	.60022*	.18500
Social Activity	-.04725	.20723	-.01922	.89015*	-.02331
Social Functioning	.33270	.20202	.11165	.43579*	.01133

* Indicate high or "significant" factor loadings ($\geq$ 0.40).

All subscale variables loaded greater than 0.40 on one, and only one, factor (See Table 11). Interpretation of the subscale variables loading on each factor yielded the following factor titles: 1) Nutrition Hassles, 2) Well-Being, 3) Psychological Impact, 4) Social Impact, and 5) Physical Ability. All but the Nutrition Hassles and Physical Ability factors were correlated with one another (r's = .2830 - .4188).

Specific Aim #1, to comprehensively quantitate HRQOL among people living with a chronic disease that is thought to impact all aspects of health, and the related hypothesis that the subscales of the NHQ would be significantly predictive of variance within the individual subscales measuring HRQOL, was tested by the use of twenty simultaneous multiple regressions. These analyses are summarized in Table 12.

Findings showed the nutrition hassles subscales to be significantly ($p < 0.01$) predictive of 13 out of 20 HRQOL subscales; in one case accounting for as much as 55% of the variance within a subscale. Due to the large number of statistical tests performed, only p values less than 0.01 were considered significant.

HbA1c

Glycosylated hemoglobin A1c values were available for 108 of the 136 subjects. On several occasions, the mass spectrometry analyzer malfunctioned, resulting in a loss of a sample. As only a small amount of blood (approximately 4μl) was collected from each subject, it was unusual that enough blood was available for more than one HbA1c analysis attempt. The mean HbA1c value was 7.9 mg/dl (SEM = 0.16) and values ranged from 5.3 to 12.8 mg/dl. This mean value falls within what is considered acceptable for people living with Type II DM (ADA, 1995).

Table 12. Simultaneous Regression Analyses of NHQ subscales on subscales from the other HRQOL instruments

Instrument Subscale	F Value	df	P Value	% Variance Accounted For
DDHS				
Weight	22.67	7,127	<.001	55.0%
Physical Disability	10.07	7,127	<.001	35.7%
Medical and Social Concerns	7.94	7,127	<.001	30.4%
Insulin	5.73	7,127	<.001	24.0%
DQOL				
Satisfaction	2.34	7,127	NS	11.4%
Impact	3.78	7,126	<.001	17.4%
Diabetes Worry	0.864	7,126	NS	5.0%
Social Vocational Worry	1.16	7,126	NS	6.0%
QWB				
Symptoms	6.24	7,127	<.001	25.6%
Mobility	0.498	7,127	NS	3.0%
Physical Activity	0.899	7,126	NS	5.0%
Social Activity	3.00	7,125	<.01	14.4%
SF-36				
Physical Functioning	1.90	7,127	NS	9.5%
Social Functioning	4.03	7,127	<.001	18.2%
Role Functioning - Physical	1.81	7,126	NS	9.2%
Role Functioning - Emotional	6.42	7,123	<.001	26.8%
Bodily Pain	2.74	7,127	=0.011	13.1%
General Health	3.19	7,127	=0.003	25.4%
Mental Health	6.15	7,126	<0.001	25.5%
Vitality	3.087	7,126	=0.004	14.6%

To assess Specific Aim #2, determination of how HRQOL relates to a HbA1c, and the related hypothesis that HRQOL subscales would be significantly correlated with HbA1c and significantly predictive of variance within this parameter, a hierarchical multiple regression technique was used.

The HRQOL factors, when regressed on HbA1c, showed no predictive ability (hierarchical multiple regression results shown in Table 13). A set of control variables consisting of age, duration of diabetes, gender, recruitment group, and LOT score, were added to the regression equation prior to the five HRQOL factor sets. As with the global constructs, none of the control variables were significantly predictive of HbA1c.

A simultaneous multiple regression analysis was performed using HbA1c as the criterion and only those subscales shown to be correlated with HbA1c in the initial hierarchical regression as predictors (See Table 14). Results from this analysis indicated that the Role Functioning Due to Physical Problems, Vitality, and Insulin subscales were significantly predictive of HbA1c, accounting for 19% of the variance in this parameter ($F(6,95) = 3.69$, $p = 0.0024$).

Lastly, to test the possible confounding effect of grouping subscales according to HRQOL factors instead of as grouped in the HRQOL instruments, a series of simultaneous multiple regression analyses were performed. Findings from these analyses revealed the SF-36 was significantly predictive of 17.8% of the variance in HbA1c ($F(8,96) = 2.59$, $p = 0.01$) (See Table 15).

Table 13. Multiple regression statistics from HRQOL factors regressed on HbA1c.

Control Variables and Factors	R^2	ΔR^2	F	ΔF
Recruitment Site	0.0640	*	0.7693	*
Demographics	0.1001	0.0361	0.8799	0.1106
Lot	0.1018	0.0002	0.8131	0.0668
Nutrition Hassles	0.1461	0.0444	0.6675	0.1456
Well-Being	0.2327	0.0866	0.9351	0.2676
Social Impact	0.2499	0.0172	0.8762	0.0589
Physical Ability	0.3552	0.1053	1.1364	0.2602
Psychological Impact	0.3960	0.0408	1.1289	0.0075

Table 14. Multiple regression statistics from those subscales correlated with HbA1c, regressed on HbA1c.

Subscale (Instrument)	Correlation	Variable β Weights	Variable t- value	Variable t-value Significance
Vitality (SF-36)	+0.16	+0.3302	2.731	0.0075*
Role Functioning - Physical (SF-36)	-0.12	-0.3335	-2.780	0.007*
Insulin (DDHS)	+0.21	+0.2121	2.013	0.0470*
Duration of Diabetes	+0.13	+0.1209	1.255	0.2125
Mobility (QWB)	-0.13	-0.1238	-1.291	0.1998
Impact (DQOL)	-0.11	-0.1464	-1.424	0.1577

Table 15. Multiple regression statistics from SF-36 subscales regressed on HbA1c.

Subscale (Variable)	Correlation	Variable β Weights	Variable t- value	Variable t-value Significance
Mental Health	-0.0639	0.2592	-2.814	0.0059*
Role - Physical	-0.1438	0.1595	-2.741	0.0073*
Vitality	+0.1454	0.5576	3.761	0.0003*
Bodily Pain	-0.0010	0.1143	0.944	0.3477
General Health	-0.0068	0.0260	0.199	0.8425
Social Function	+0.0011	0.1523	1.114	0.2679
Role - Emotional	-0.0237	0.1368	0.940	0.3495

* = Significant values

Subscales that accounted for the predictive capabilities of the SF-36 were Vitality ($p = 0.003$), Mental Health ($p = 0.006$), and Role Functioning due to Physical Problems ($p = 0.0073$).

Psychometric Properties of the NHQ

To assess Specific Aim #3, to assess the psychometric properties of the NHQ, and the related hypothesis that evidence for the convergent validity of the NHQ would exist as significant correlations between the subscales comprising the NHQ and a priori selected items from the DCP, DDHS, and DQOL, Pearson's Product Moment Correlation Coefficients were calculated. The results of these analyses are shown in Table 16. In sum, 9 out of 17 of the correlations were significant in the predicted direction at the $p < 0.01$ level, providing good evidence for convergent validity. Due to the large number of correlations calculated, only p values of less than 0.01 were considered significant.

Secondly, this final aim was assessed by investigation into the internal consistency reliability of the NHQ. It was hypothesized that high Cronbach's Alpha Coefficients would exist for the NHQ and its seven subscales.

Internal consistency reliability for the NHQ as a whole was high ($\alpha = 0.9307$), as it was for the individual subscales, Complexities ($\alpha = 0.8342$), Control ($\alpha = 0.8485$), Dysphoria ($\alpha = 0.8495$), Monitoring ($\alpha = 0.8582$), Planning and Preparation ($\alpha = 0.8721$), Social ($\alpha = 0.8103$), and Vigilance ($\alpha = 0.7751$). Alpha coefficients for the other instruments can be found in Appendix C with the instrument descriptions.

Table 16. Pearson's correlation analyses assessing the convergent validity of the NHQ.

Hassles Subscale	Other Instruments	Item Number	Proposed Direction	Correlation (Direction)	Significance Value	**
Nutritional Complexities	DCP	8, 9	+	+0.1362	p = 0.119	
	DQOL	1	+	-0.0055	p = 0.949	
	DDHS	2	+	+0.3987	p < 0.001	**
Vigilance	DCP	50, 52, 55, 56, 57, 60	+	-0.0253	p = 0.771	
	DDHS	13, 14, 19	+	+0.5946	p < 0.001	**
Monitoring Nutrients	DCP	35, 36, 37, 38, 39, 40, 41, 42, 47, 49	+	+0.1705	p = 0.048	
Social Hassles	DCP	10, 11b,c,g,i, 106f	+	+0.2550	p = 0.003	**
		104a	-	-0.2661	p = 0.003	**
	DQOL	4, 13, 16, 24,33	+	+0.3474	p < 0.001	**
	DDHS	3, 15, 30	+	+0.5422	p < 0.001	**
Planning and Preparation	DDHS	25	+	-0.0335	p = 0.699	
Dysphoria	DCP	16, 29	+	+0.4079	p < 0.001	**
		17, 21	-	-0.3762	p < 0.001	**
	DQOL	3, 11	+	+0.0320	p = 0.712	
Control	DCP	11e,f,h, 24a, b,c, 26, 27	+	-0.1520	p = 0.077	
		19, 48	-	-0.1188	p = 0.168	
	DDHS	16	+	+0.9999	p < 0.001	**

** $p < 0.01$

DISCUSSION

The present study was designed to comprehensively measure HRQOL among people with Type II DM. This assessment employed two generic, two diabetes-specific, and a nutrition-specific HRQOL instruments. A second goal of this study was to determine if subscales comprising HRQOL could significantly predict variance within a physiological measurement of metabolic control; HbA1c. Lastly, the convergent validity and internal reliability of the NHQ was addressed.

This study yielded several interesting results. First, it was found that the variables of recruitment site, age, gender, disability status and insulin taking status had a significant impact on HRQOL outcomes. Second, HRQOL in the present population was perceived as good. On average, scores on the subscales comprising HRQOL instruments were distributed between the low and middle areas of the possible range (See Table 7). Third, factor analytic techniques revealed that five HRQOL factors exist based on the subscales from the generic, disease-specific, and nutrition-specific instruments. These findings suggest that the use of generic, disease-specific and nutrition-specific instruments in the assessment of HRQOL is complementary rather than redundant. In other words, constructs measured by generic instruments are not the same as those measured by disease-specific and nutrition-specific HRQOL instruments. In addition, subscales comprising a newly developed nutrition-specific HRQOL instrument, the NHQ, is predictive of other HRQOL subscales. Also of interest was that little association was found between HRQOL and HbA1c. At the factor level, HRQOL was not predictive of HbA1c, yet some of the subscales comprising the

generic SF-36 were significantly predictive of variance within this parameter. Further, subscales shown to have moderate correlations with HbA1c were significantly predictive of a small portion of the variance in this parameter. Lastly, evidence for high convergent validity and internal reliability of the NHQ was found.

Stratification Analyses

Several demographic variables were highly associated with HRQOL. Demographics important in HRQOL outcomes were recruitment site, age and gender. Recruitment site differences existed on 1 out of 27 HRQOL subscales. This subscale was the Physical Activity subscale from the QWB. Evaluation of the recruitment site means for the Physical Activity subscale indicate that the fifteen subjects recruited from the Providence Portland Ambulatory Care Clinic reported significantly poorer perceived HRQOL than did subjects recruited from the Providence Portland and St. Vincent's Diabetes Treatment Centers. However, this recruitment site was not different from the other sites on demographic variables of age, duration of diabetes, insulin taking, or disability ratings. One possible explanation for this observed site difference may stem from marital status, education level, income, and support group involvement of subjects in the Providence Portland Ambulatory Care Clinic. It has been suggested that these factors may play a role in perceived severity of Type II DM (Jacobson, de Groot, & Samson, 1994; Weinberger et al., 1994). Thus, to avoid any confounding effects of these variables on outcomes of interest, it is suggested that future studies control for these variables.

Age differences on six HRQOL subscales were observed. Age group 4 (70-79 years) was the source of the difference in all analyses. Mean differences indicated that people between 70 and 79 years of age perceive significantly fewer nutrition hassles than those younger than themselves. Specifically, people in this age group perceived fewer nutrition hassles related to dietary control over diet, planning and preparation and social hassles than did younger subjects in this study. Furthermore, subjects in their 70s perceive fewer diabetes-related hassles than do some of the younger age groups. Specifically, these subjects reported fewer hassles related to Physical Disability and Weight than did subjects in their 50s and 60s. Interestingly, subjects in their 70s also perceived fewer dietary complexity hassles than did people in the 60s and 80s. One possible explanation for these findings is that older people with Type II DM may have had the disease longer than younger study participants and have become accustomed to the nutrition and diabetes-related hassles that accompany treatment approaches. This explanation may not be sufficient however, as the five people in the oldest age strata (80-84 years of age) perceived more dietary complexity hassles than did people in their 70s. Another possible explanation is that age group 4 may consist of people residing in assisted living or senior apartment facilities where meals are prepared by a central kitchen, thus decreasing nutrition-related hassles. Additionally, in assisted living situations physical disability and weight hassles may not be as prevalent as shopping and social activities are somewhat centrally located and easy to get to. Given these possibilities, further investigation into demographic variables other than age that may make age group 4 unique is warranted.

The demographic variable of gender was found to significantly influence responses on several HRQOL subscales. In general women tended to perceive more bodily pain and symptoms, more difficulties with physical, role, and social functioning, and less perceived vitality than did men. One possible explanation for these findings is that women traditionally report more physical dysfunction than do men. However, a recent review of the gender and health literature has suggested a complex relationship between other demographic variables and gender that impacts how men and women view different symptoms and role functioning difficulties (Anson, Paran, Neumann, & Chernichovsky, 1993; Macintyre, Hunt, & Sweeting, 1996; Wool & Barsky, 1994). In sum, it may be a combination of variables (gender, perceived happiness with life, role burden, etc.) that is responsible for the observed HRQOL gender differences. Alternatively, the fact that there were nearly twice as many women as men in the present sample may be the source of these differences.

No effect of duration of diabetes on perceived HRQOL was observed. It is probable that no differences were observed as age was used as a covariate in this analysis. In other words, it is suspected that age is integrally related to the perceived HRQOL among people with Type II DM, more so than is duration of diabetes. Thus, as was done in this study, future work assessing HRQOL among people with Type II DM should include age as a control variable.

HRQOL - General Findings

HRQOL in the present population was perceived as good. Mean scores for each of the HRQOL subscales were below the middle of the possible range of scores indicating that the present study population perceives little to no negative HRQOL

impact of living with diabetes. This finding is consistent with results from other studies assessing HRQOL among older adults living with Type II DM (Mayou, Bryant, and Turner, 1990; Vickrey et al., 1994). The Mayou et al.(1990) study assessed generic HRQOL in a number of patients participating in the UK Prospective Diabetes Study of treatment approaches, physiologic and generic HRQOL (UKPDS, 1983). Findings from this report indicate that their sample, in general, reported few decrements in HRQOL as measured by social and role functioning, psychological well-being, and physical complications. In addition, Vickrey et al. (1994) found that people living with Type II DM rate certain aspects of their generic HRQOL better than do people with other chronic illnesses, such as epilepsy, heart disease, and depression. Thus, it seems to be a consistent finding that people living with Type II DM report little significant impact on their perceived HRQOL.

An alternative explanation for the present findings is that all of the subjects within this study population were involved in a socially supportive environment. This included support groups, educational settings, or regular physician visits. Participation in supportive environments with a consistent social network has been shown to positively impact certain aspects of perceived quality of life for older people living with Type II DM (Gilden, Hendryx, Clar, Casia, & Singh 1992; Kaplan & Hartwell, 1987). If subjects had been found through a medical registry or comprised a community sample, there may not have been such a high potential for demand characteristics. It is also possible that the instruments employed in the present study may have been insensitive to HRQOL issues among this specific sample of people with Type II DM. Further, because all of the subjects were ambulatory, their perceived HRQOL may have

been better than people who are in care facilities or disabled due to complications. Support for this possibility comes from studies which looked at HRQOL among a number of disease populations. These studies showed that people with Type II DM rate HRQOL better than people with a debilitating, function-limiting chronic disease (Cassileth et al., 1984; Stewart et al., 1989, Vickrey et al., 1994)..

Lastly, it may be the case that people with Type II DM do not perceive their HRQOL as poorly as do researchers, physicians, and significant others. There is a considerable literature on the disagreement between proxy and patient ratings of the patients' health status and HRQOL (Epstein et al., 1989; for review see Sprangers & Aaronson, 1992). More specifically it has been shown that people living with Type II DM rate their HRQOL better than do their physicians (Pearlman & Uhlmann, 1988).

In sum, the present findings must be viewed with caution as perceived HRQOL among this subject population may be skewed due to the potential insensitivity of the instruments used, the degree of ambulation and social support , as well as the relatively normal average level of glucose control observed.

Effects of Disability Status and Insulin Use on HRQOL

Significant differences between people reporting some disability and those reporting no disability were observed for all five of the HRQOL instruments, but not for the LOT. Mean subscale values for the groups indicated that people reporting some disability perceived a significantly poorer HRQOL perception than did people reporting no disability. In sum, people reporting some disability perceived more nutrition related hassles, poor role and physical functioning, poor overall health and feelings of vitality

and difficulties in social interactions as compared to people with no disability. As can be observed, all four of the HRQOL domains (physical, psychological/emotional, social, and somatic well-being) are perceived to be worse among patients reporting some diabetes-related disability compared with those patients who reported no disability.

These findings suggest that not only do people with diabetes-related disability have poor physical health, their HRQOL is also negatively impacted. Therefore, in the larger conception of health, physical, mental, and social well-being, people reporting some diabetes-related disability can be considered to be in poor health. While this may be obvious to the patient as well as the clinician, this is the first study to assess HRQOL in a comprehensive manner among people with Type II DM. Although the Medical Outcomes Study (Stewart et al., 1989) assessed generic HRQOL in a comprehensive manner, no disease-specific instruments were employed and no delineation was made between people with Type I and Type II DM.

People reporting taking insulin perceived poorer HRQOL on a small number of subscales as compared to people reporting not taking insulin. People on insulin perceived more bodily pain, worse general health and physical functioning, more decrements in functioning due to emotional and physical problems, and less perceived vitality than did subjects who were not taking insulin. Intuitively this makes sense when the course of treatment is considered. At diagnosis, patients are initially treated with dietary and lifestyle modifications. Later, an oral glucose-lowering agent may be prescribed if glucose control fails to meet clinical goals. Lastly, insulin is prescribed,

often for those who have failed in meeting clinically desirable endpoints through other methods (Fertig, Simmons, & Martin, 1995). Thus, it is reasonable to assume that people requiring insulin are those who are severely metabolically compromised, have had diabetes for a long time, and have some diabetes-related disabilities. In addition, the present findings suggest that other aspects of health, namely HRQOL, may be detrimentally impacted among this subgroup if people with Type II DM.

HRQOL Factors

Five global HRQOL factors were identified by factor analytic techniques (Harman, 1970). Subscales comprising the generic, disease-specific and nutrition-specific HRQOL instruments combined in such a way as to create the following factors: 1) Nutrition Hassles, 2) Well-Being, 3) Physical Ability, 4) Psychological Impact, and 5) Social Impact.

The Nutrition Hassles factor included all seven of the NHQ subscales as well as the Weight subscale from the DDHS. Inherent in the factor analytic approach is that the subscales that load on a given factor are highly correlated with one another and the factors that they measure (Harman, 1970). Thus, the inclusion of all seven of the NHQ subscales is evidence for the cohesiveness and reliability of this instrument (Dunn, 1989; Durkin et al., 1995; Harman, 1970; Kim & Mueller, 1978; Lord & Novick, 1968). The inclusion of the Weight subscale in this factor indicates that this subscale is highly correlated with those subscales comprising the NHQ. The Weight subscale consists of several hassle items that are consistent with the overall concept of nutrition hassles, (e.g., being offered food you shouldn't eat, eating when you're supposed to, difficulty adhering to diet, and planning meals and/or snacks). In sum, the Nutrition

Hassles factor is assessing nutrition hassles relating to dietary modifications that are related to HRQOL among people with Type II DM.

The Well-Being factor is comprised of four subscales all of which are from the SF-36 suggesting that this is a reliable instrument (Dunn, 1989). These generic HRQOL subscales include such concepts as General Health, Mental Health, Role Functioning due to Emotional Problems, and Vitality. These four subscales measure overall well-being as it relates to physical and emotional health.

The Physical Ability factor consists of subscales from the SF-36 and the QWB, the two generic HRQOL instruments used in the present study. The subscales that comprise this factor include Bodily Pain, Mobility, Physical Activity, Physical Functioning, and Role Functioning due to Physical Factors. These subscales all relate to physical well-being and functioning.

Subscales loading high on the Psychological Impact factor include the Diabetes Worry, Impact, Satisfaction, and Social/Vocational Worry subscales from the disease-specific DQOL. As with the NHQ and SF-36, these results suggest reliability among the DDHS subscales.

Lastly, the Social Impact construct consisted of subscales from both generic and disease-specific instruments. These subscales were Social Activities (QWB), Social Functioning (SF-36), and Insulin (DDHS). Items within the Insulin subscale of the DDHS encompass hassles regarding remembering to take insulin, blood sugar testing, low blood sugar, and coordinating insulin taking and exercising. The high correlation between this subscale and the two social subscales, suggests that in people with Type II DM the use of insulin is highly related to social functioning and activities. High

positive correlations among these three subscales indicate that as hassles related to taking insulin and blood sugar testing increase, social interactions and functioning become more problematic. This finding, although alluded to in a previous study looking at the relationship between psychosocial variables and diabetic regimen adherence (Ary, Toobert, Wilson, & Glasgow, 1986), has not been previously quantified.

Three subscales were not included in the final factor analysis. This may be due to the unique concepts that these subscales measure. The Symptoms subscale, from the QWB, may not have loaded on any one factor because no other subscales within the HRQOL factors specifically assessed a broad range of symptoms. Alternatively, it may be that the scoring method employed for this instrument decreased the ability of this subscale to correlate with any others. This rationale seems unlikely considering the other QWB subscales showed strong factor loadings.

It is possible that the Medical and Social Concerns subscale, from the DDHS, may be measuring more than one underlying HRQOL concept (e.g., medical as well as social concerns) which would decrease the ability of this subscale to load on any one of the identified factors (Meisler & Carey, 1991). By potentially measuring more than one concept, the subscale may be unstable (correlations and shared variance among items would be low) and would therefore not be strongly correlated with other subscales.

Lastly, the fact that the Physical Disability subscale, from the DDHS, did not load on the Physical Ability factor is, on the surface, more difficult to explain.

However, when the hassle items comprising this subscale are considered (troubling thoughts about your health, thoughts about death, getting enough exercise, trouble with sexual functioning, pain or numbness, limitations on your recreational...work activities, and feeling thirsty all the time), it is clear that these items could have been associated with more than one of the HRQOL factors.

Overall, the factors show very little overlap among subscales comprising generic, disease-specific, and nutrition-specific HRQOL instruments. This is a novel finding in that no previous studies have used factor analytic methods to specifically address the possibility of overlap among the constructs measured by generic and diabetes-specific HRQOL instruments. Several researchers have proposed the value of measuring both generic and disease specific HRQOL instruments within a disease population, yet the relatedness of constructs measured by these types of instruments has not been addressed (Aaronson, 1989; Cox, et al., 1992; Guyatt, Feeny, & Patrick, 1991, 1993; Guyatt, Veldhuyzen Van Zanten, Feeny, & Patrick, 1989; Patrick & Deyo, 1989). Thus, the present study is unique in its comprehensive assessment of the relatedness of HRQOL constructs. This assessment is considered comprehensive in that not only were two generic, two disease-specific, and one nutrition-specific HRQOL instruments employed, but a sophisticated statistical technique was used to determine the relationships among subscales comprising each. The advantage to using the factor analytic approach employed in this study was that all of the variance within the subscales can be accounted for and used in the measurement of the relationship among subscales. Thus, the common and unique variance associated with the subscales can be accurately measured (Harman, 1970; Kim & Mueller, 1978). Indeed the usefulness of

this method has been shown by De Conno et al. (1994) in a comparison of six cancer pain measures.

Moreover, the method employed in the present study to assess construct overlap among generic and disease-specific HRQOL is much more complete than the correlational technique used in either the Jacobson, de Groot, & Samson (1994) study among people with Type II DM, or the studies looking at such construct relationships in other disease populations (Aaronson, 1989; de Boer, Wijker, Speelman, & Haes, 1996; Drossman, Patrick, Mitchell, Zagami, & Appelbaum, 1989; Kressin, Spiro, Bosse, Garcia, & Kazis, 1996; Laupacis, Wong, Churchill, et al., 1991). Unlike the comprehensive assessment of variance within subscales offered by the factor analytic method, the Pearson's Correlation Coefficients utilized by these studies only considers the variance associated with the two subscales of comparison.

In sum, there appears to be little overlap among HRQOL construct measured by generic, disease-specific and nutrition-specific HRQOL instruments. These results support the findings of Jacobson, de Groot, & Samson (1994) study that showed moderate Pearson's Product Moment Correlation Coefficients among the subscales comprising the SF-36 and the DQOL. However, it would be appropriate to further test the factor structure found in the present study in another sample of people with Type II DM. If, as presently shown, there is little overlap among generic, disease-specific HRQOL instruments, the continued use of both types of instruments in HRQOL assessment studies would be highly suggested. Further, by replicating the present study in a different population, the validity and generalizability of the present findings could be elucidated.

In order to comprehensively assess HRQOL among people with Type II DM, it was deemed important to understand how a new HRQOL measurement tool related to well-established HRQOL instruments. Thus, the NHQ, comprised of seven subscales, was regressed on each of the HRQOL subscales. Subscale level analyses were used as it was of interest to determine the predictive nature of nutrition-specific quality of life on specific dimensions of HRQOL. These regressions showed that the NHQ was indeed predictive of HRQOL as measured by these instruments. The NHQ, as a whole, predicted a significant proportion of the variance in 13 out of 20 HRQOL subscales. Subscales in which a significant proportion of the variance was predicted by the NHQ were: Vitality (SF-36), Mental Health (SF-36), General Health (SF-36), Bodily Pain (SF-36), Role Functioning due to Emotional Problems (SF-36), Social Functioning (SF-36), Insulin (DDHS), Medical and Social Concerns (DDHS), Physical Disability (DDHS), Weight (DDHS), Social Activity (QWB), Symptoms (QWB), and Impact (DQOL). As can be observed, the four generally agreed upon domains of HRQOL (physical, psychological/emotional, social, and somatic well-being) are included in the list of criterion predicted by the NHQ (Schipper, Clinch, & Olweny, 1996; Spilker, 1990). Thus, although this is not an all inclusive list of HRQOL subscales used in the present study, the NHQ can still be thought of as predictive of different components of HRQOL.

The importance of this finding can be found in the proposed use of the NHQ. As nutritional modifications are commonly used as a treatment strategy among people with Type II DM the benefits of using the NHQ may be two-fold. Administering this

instrument to those patients prescribed nutritional modification can aid in the determination of the perceived hassles associated with dietary interventions. Once these hassles are quantified, a team effort, (e.g. the physician, nurse, dietitian, diabetes educator, and patient) could be employed to alleviate these hassles perhaps leading to better adherence and better health outcomes. Further, as this instrument is predictive of other aspects of HRQOL, it may be reasonable to use this brief, self-administered instrument as a warning signal for the need for further HRQOL assessment among some patients. Lastly, data obtained from future studies designed to determine the relationship between the NHQ and dietary adherence, may show the NHQ to be useful in predicting future adherence among those newly prescribed nutritional modifications.

HbA1c

The HRQOL factors showed no predictive capabilities when regressed on HbA1c. However, four of the HRQOL subscales as well as one demographic variable were found to be correlated with HbA1c and were subsequently regressed on HbA1c in a simultaneous fashion. The results of this analysis showed that the Insulin, Vitality, and Role Functioning due to Physical Problems accounted for 18% of the variance in HbA1c. Lastly, the SF-36, comprised of eight HRQOL subscales, was significantly predictive of 17.8% of the variance in HbA1c.

The lack of significant predictability by the subscales grouped as HRQOL factors is likely due to the large degree of multicollinearity among factor subscales. Multicollinearity refers to the intercorrelations among the predictors in the multiple regression paradigm. Multicollinearity occurs because of the high degree of overlap of

variance among highly correlated variables. This then can lead to the observation of a high error variance within sets of predictor variables and a low predicted amount of variance within the criterion. For methods on the diagnosis and management of multicollinearity see Hays (1988), Licht (1995), Pedhazur (1982), and Tabachnick and Fidell (1989).

Another possible reason for the observed lack of predictability is the relatively small sample size used for these analyses. Although the sample size of the present study was large enough to meet the minimum criteria of 5 subjects per independent variable in the regression equation (Tabachnick & Fidell, 1989), this may have not been a sufficient case to IV ratio. Therefore, future research in this area should adjust sample size accordingly to avoid the present shortcomings.

The finding that five subscales and one demographic variable, when regressed simultaneously, were predictive of HbA1c may be due to the elimination of the confounding effects of multicollinearity with the disintegration of the construct subscale groupings. Individual t-test analyses within the regression model showed that three of these five subscales were responsible for the observed predictability. These three subscales were Role Functioning Due to Physical Problems, Vitality subscales (both from the SF-36), and the Insulin subscale from the DDHS. Correlations between these subscales and HbA1c indicate a complex relationship. The Role Functioning Due to Physical Problems subscale was negatively correlated with HbA1c whereas the Vitality and Insulin subscales were positively correlated. These findings suggest that as glucose control is diminished, indicated by high HbA1c values, role functioning increases, indicated by low Role - Physical scores. Conversely, as glucose control improves, role

functioning decreases. One interpretation of these findings is that people who are physically disabled by their diabetes are on a stringent glucose lowering regimen. In other words, progression of the pathology associated with diabetes, thus diminished role functioning, may increase the necessity for more intensive efforts to achieve near average glucose control. Therefore, a future direction for this line of research would be a longitudinal study assessing the clinical relationship between intensified efforts to attain glucose control and role functioning status. Alternatively, a case-control strategy may be employed in that medical records of people with and without disability due to diabetes complications could be reviewed for alterations treatment strategy coinciding with changes in disability.

Further, these results indicate that as glucose control decreases, subjects perceive less Vitality and more hassles related to Insulin treatment. Conversely, as glucose control increases, higher levels of Vitality and fewer Insulin treatment hassles are perceived. One interpretation of these relationships is that people perceiving little to no hassles associated with insulin taking, may adhere to their insulin regimen with the outcome of good glucose control and higher feelings of vitality. Alternatively, if a large degree of hassles related to insulin taking is perceived, adherence to this treatment variable may be poor, leading to decreased insulin taking and diminished feelings of vitality.

Interestingly, the original questionnaires that yielded these subscales, the SF-36 and the DDHS, have shown little correlation with HbA1c in other studies. In one study the SF-36 has been shown to be correlated with HbA1c (Nerenz, Repasky, Whitehouse, & Kahkonen, 1992;), whereas another study found no such relationship (Weinberger et

al., 1994). Furthermore, the DDHS has not been significantly correlated with HbA1c. Pilot work on the DDHS showed that in a sample of 120 people with Type II DM the DDHS as a whole was non-significantly correlated with HbA1c (Meisler & Carey, 1991).

The current study found the subscales comprising the SF-36 to be predictive of a significant proportion of the variance within HbA1c. Although this finding supports the correlational work of Nerenz, Repasky, Whitehouse, & Kahkonen. (1992), it is in stark contrast to the findings of Weinberger et al. (1994). Nerenz (1992), showed high correlations between SF-36 subscales and glycosylated hemoglobin A1c. Unfortunately, no correction for multiple correlational analyses were used, so the Nerenz findings must be interpreted with care. Weinberger et al. (1994), using a multiple regression technique similar to that used in the current study, found no significant predictability of the SF-36 subscales on HbA1c. However, the Weinberger et al. (1994) study included a number of predictor variables that may have masked the ability of the SF-36 to predict HbA1c. These predictor, or control variables, were insulin use, number of diabetic complications, completion of high school, and a number of self-reported signs or symptoms of hypoglycemia. As stated previously, duration of diabetes, although slightly correlated with HbA1c values in the current study, was not itself predictive of HbA1c. Results from the current study suggest that inclusion of such a variable may mask the ability of SF-36 subscales to be predictive of variance within HbA1c. It would be of interest to reanalyze the data from the current study, controlling for the predictors used in the Weinberger et al. (1994) analysis. Although

these data are available for the present sample, these analyses are beyond the scope of the present study and will be addressed in future work.

Individual t-tests performed within the regression model indicated that 3 of 8 subscales comprising the SF-36 were responsible for this instruments predictive capabilities. These three subscales were Role Functioning due to Physical Problems, Vitality, and Mental Health. The intricate relationship between Role - Physical, Vitality and HbA1c has already been considered. Much like the Role - Physical subscale, the Mental Health subscale was negatively correlated with HbA1c. Thus, as HbA1c values increased, indicating poor glucose control, Mental Health values decreased, indicating good perceived mental health. Conversely, as HbA1c values decreased, indicating good glucose control, Mental Health values increased, indicating poor perceived mental health. One possible interpretation from these data is that patients perceiving role functioning impairment are also be experiencing decrements in their mental health. Further, as stated previously, role functioning disability may then lead to increased efforts to attain better glucose control on both the part of patients and clinicians, with the goal being to alleviate the negative mental health state as well as stop the progression of the debilitating physical problems. Again, a longitudinal or case-control study may help in further clarifying the nature of these relationships.

Psychometric Properties of the NHQ

Evidence for convergent validity of the NHQ was found in highly significant Pearson's Product Moment Correlation Coefficients between NHQ subscales and a priori selected items from three of the instrument used in the present study (See Table 16). These items were thought to be, at least in part, conceptually relevant to the NHQ

and were used for this analysis as no "gold standard" for assessing nutrition-specific hassles exists (support for this methodology can be found in Guyatt, Bombardier, & Tugwell, 1986; and Lord and Novick, 1968). Furthermore, no one subscale within the HRQOL instruments was thought to assess nutrition related hassles, thus analysis at the item level was chosen. The a priori chosen items used to assess convergent validity of the subscales within the NHQ ranged from changes in medication due to hypo- or hyperglycemic events to how often diet interferes with social and leisure activities. The findings indicate that the constructs being measured by the NHQ subscales are consistent with the developmental goals for this instrument. That is, these subscales are measuring the constructs they were designed to measure.

The internal consistency reliability of the NHQ was assessed by use of Cronbach's alpha coefficient (Cronbach, 1951). Both the total instrument and the individual subscale alpha coefficients were high, indicating good internal consistency reliability. Internal consistency reliability is an important aspect of the psychometric soundness of an instrument. This coefficient yields information regarding how well an instruments retains its ability to measure individual concepts, in a cohesive manner, among different populations and testing situations. In previous studies with different disease populations the NHQ was shown to have good internal reliability, again adding to the psychometric stability of this instrument (Hatton, Haynes, Oparil, et al., 1996).

Summary

In order to comprehensively assess HRQOL among people with Type II DM, the present study measured HRQOL concepts from generic, disease-specific, and nutrition-specific HRQOL instruments. On average, subjects in this study perceived little decrement in their HRQOL as indicated by low average subscale scores. Upon relating concepts measured by these instruments to one another, it became clear that different concepts within the four HRQOL domains are being measured by the different genre of instruments. Among the sample population of people with Type II DM, generic instruments appeared to be measuring physical/functional aspects of HRQOL, whereas disease-specific instruments measured psychological/emotional aspects of living with diabetes. The nutrition-specific instrument as well measured it's own "treatment-related" aspects of HRQOL. Further, the nutrition-specific HRQOL components were significantly predictive of several of subscales comprising the other HRQOL concepts. Although the subscales measuring HRQOL were related with one another, in fact predictive of one another in some cases, there was little association with metabolic control as measured by HbA1c. In fact, out of the 27 subscales comprising the different measurable aspects of HRQOL, only four subscales were predictive of a significant proportion of the variance within HbA1c. Lastly, strong evidence for the convergent validity and internal consistency reliability of the NHQ, a newly developed nutrition-specific HRQOL instrument, was found.

Conclusions

Although the present study has limited generalizability, the data provide important stepping stones for future research. The present findings indicate that a useful approach to the comprehensive measurement of HRQOL would be to use generic and disease-specific HRQOL instruments. Furthermore, if the subject population of interest has also been prescribed nutritional modifications as a strategy for attaining good glucose control, the psychometrically sound NHQ should also be employed. A further use of the NHQ could be to serve as a marker for the need to assess other aspects of HRQOL. Taken together, these instruments could provide a more comprehensive assessment of HRQOL than either approach alone.

The present findings provide additional evidence that physiologic indicators of disease may bear little association with the patient's subjective experience of the disease (for review see Kaplan, 1990; Guyatt, Kirshner, & Jaeschke, 1992). Since the subjective experience of the disease and relief from symptoms may be of greatest importance to the patient, this schism between physiologic endpoints and HRQOL measurement strongly suggests that both types of measurements are necessary in order to adequately assess health and treat disease.

Lastly, the current data suggest that a new, brief, HRQOL questionnaire that assesses both generic and disease-related HRQOL can be devised. By culling the questionnaire items, and keeping only some of the redundant subscales within HRQOL factors, a brief, yet comprehensive HRQOL instrument could be developed for use among people with Type II DM. This brief questionnaire, once psychometrically tested, could then be used in conjunction with the NHQ. The usefulness of this

approach would be to give members of a health-care team (physician, nurse, dietitian, diabetes educator, and patient) a "global" perspective on the patients HRQOL with a minimum amount of respondent burden. In other words, a relatively brief HRQOL questionnaire and the NHQ could provide information relevant to all members of a health-care team thus allowing them to provide the best possible treatment approach for individual patients.

APPENDIX A

Recruitment script

My name is Ann Ward, and I am a researcher at Oregon Health Sciences University. I am conducting a study assessing quality of life among people living with Type II Diabetes Mellitus. The purpose of this study is to determine how quality of life is impacted by living with diabetes. Quality of life, defined in many ways, can often be looked at as how a chronic illness impacts physical well-being, mental or emotional well-being, social functioning, and bodily sensations. Thus, I would like to know how living with diabetes has impacted, or not impacted, these aspects of your life. For, example are you physically able to do the same things you do now, with diabetes, as you were before you had diabetes? Do you sometimes feel you cannot participate in social gatherings that involve food, because you don't think you should eat some of the things that are presented.

To measure quality of life, I have a questionnaire packet to send home with you that you may mail back to me in the self-addressed stamped envelope that I have enclosed with the questionnaires. This packet takes approximately two hours to complete, and I would ask that you return it to me within a week.

A second part of this study is to determine if there is a relationship between glycosylated hemoglobin A1c, which is a stable measure of your blood sugar over past 6 to 8 weeks, and quality of life. Identifying a relationship between these variables is important in determining if there is a connection between metabolic control and psychological measures. If there is a relationship, third party providers could potentially become more interested in reviewing quality of life measurements along with physiological parameters.

The ultimate goal for the information obtained in this study is to help the medical community to better understand what it is like for people to live with Type II Diabetes Mellitus. With the hope that with better understanding more individualized treatment approaches that fit individual needs can be developed.

You should know that participation in this study is in no way involved with your continued care (education or support group status) here. Your participation is completely voluntary. Although I can not give you money for participating in this study, I will be able to send you the results of both the quality of life and the glycosylated hemoglobin A1c tests.

For those of you willing to participate, please find the informed consent form paperclipped to your questionnaire packet. Please read this form and sign it at this time and return it in the envelope with your completed questionnaires. Also, please note the enclosed letter from me, containing my work and home phone numbers. If you have any questions or concerns regarding filling out the questionnaires please call me. To properly assess quality of life with these questionnaires it is important that all items be filled out. Thus, it is very important for you to get in touch with me to clear up any problems you may have with any of the questions. You are welcome to leave a message at either of those numbers and I will get back to you as soon as possible.

Lastly, if you have any questions or comments regarding this study or your participation in it, please feel free to ask. Otherwise, I would like to begin taking finger sticks for the glycosylated hemoglobin assessment.

APPENDIX B

Cover letter and informed consent

APPENDIX C

Instruments used

Demographic Survey

This four page demographic survey developed by the author for use in the present study, and includes items pertaining to: age, gender, duration of diabetes, marital status, education, body weight perception, income, and dietary restrictions. Information gathered on this form is useful as both covariates and predictor variables, depending on the specific research question.

Nutrition Hassles Questionnaire (NHQ)

This 37-item, 7 point Likert response option scale has been previously tested in both pilot work and the large multi-center trial referred to above. This instrument was developed by Dr. Daniel C. Hatton and Ann A. Ward with consultation from physicians, nurses, dietitians, and patients on restricted diets. Pilot testing of this questionnaire included samples of people with "normal" eating patterns as well as people on restricted diets. Pilot study analyses have included item-analyses, and exploratory factor analyses for item reduction and subscale configuration. Confirmatory factor analyses have been done in subsequent studies and subscale loadings are consistent, indicating subscale reliability among different populations. These factor analyses identified seven nutrition hassle subscales: 1) Nutritional Complexities, 2) Control, 3) Dysphoria, 4) Monitoring, 5) Planning and Preparation, 6) Social Hassles, and 7) Vigilance (Ward & Hatton, 1995).

Internal reliability of this instrument was tested in the present study by use of Cronbach's alpha coefficient; high reliability was found (α = .9307) (Cronbach, 1951). This instrument was used in the present study to test the convergent validity the NHQ and determine if a relationship existed between the NHQ, HRQOL, and glycosylated hemoglobin A1c.

The Diabetes Quality of Life Scale (DQOL)

This 39-item, 5 point Likert response option scale was developed by the Diabetes Control and Complication Trial Research Group for the assessment of diabetes-related quality of life among people with Type I Diabetes Mellitus (DCCT, 1986, 1987, 1988). The original use of this instrument among Type I subjects has recently been expanded to Type II Diabetes Mellitus patients (Jacobson, De Groot, Samson, 1994). This scale is comprised of four subscales as found by item reduction techniques: 1) Satisfaction, 2) Impact, 3) Diabetes Worry, and 4) Social Vocational Worry. Reliability and validity testing of this questionnaire has shown it to be both reliable and valid among type I and type II patients.

Internal reliability of this instrument was tested in the present study by use of Cronbach's alpha coefficient; moderate reliability was found (α = .7651). This instrument was chosen for the present study as it is the only well-tested diabetes-specific health-related quality of life instrument presently available.

The Diabetes Daily Hassles Scale (DDHS)

This 37-item 6 point Likert response option scale was developed by A.W. Meisler and M.P. Carey (1991) with consultation from diabetologists and people with Type II Diabetes Mellitus. The purpose for developing this scale was to assess stressors associated with diabetes. Pilot work has been completed on this questionnaire, showing it to have high internal reliability, good concurrent validity, and reasonable factor structures. Subscales comprising this scale include: 1) Physical Disability, 2) Medical and Social Concerns, 3) Weight, and 4) Insulin.

In the present study, high internal reliability was found by use of Cronbach's alpha ($\alpha = .8545$). This instrument was chosen for the present study as it measures diabetes-related hassles that are not addressed in the DQOL.

Medical Outcomes Study Short-Form 36 (SF-36)

This 36-item dichotomous and Likert response options scale was developed by J.E. Ware, and C.D. Sherbourne (1992) to measure eight health concepts. These health concepts (comprising subscales) are: 1) Physical Functioning, 2) Role Functioning due to Physical Problems, 3) Bodily Pain, 4) General Health Perceptions, 5) Vitality, 6) Social Functioning, 7) Role Functioning due to Emotional Problems, and 8) Mental Health. This instrument was developed to be a more reliable and valid short-form of the full length version of the MOS Health Profile than was the MOS SF-20 (Stewart, Hays, & Ware, 1988). Accordingly, numerous reliability and validity studies have been done on this instrument, all showing it to be a reliable and valid instrument.

Cronbach's alpha for the present study was high, indicating this instrument had good internal reliability (α = .8692). This instrument was chosen for the present study as it is considered a gold standard for the measurement of health-related quality of life.

Quality of Well-Being Scale (QWB)

The original version of this 64-item multiple response option, interviewer administered instrument was developed by Kaplan, Bush, and Berry (1976). This instrument was developed with the goal of ascertaining patient perceived health status. This instrument has undergone extensive validity and reliability testing among several disease-populations (Kaplan, 1990; Kaplan et al., 1989; Kaplan et al., 1995; Kaplan, Bush & Berry, 1976; Kaplan, Hartwell, Wilson, & Wallace, 1987; Orenstein & Kaplan, 1991). An intricate weighting system is used in the scoring of this instrument. Weights were derived from sampling the general population and identifying the perception of the severity of numerous physical states. The total score that can be obtained from this instrument is an outcome of general well-being discussed in terms of quality of well-years (Kaplan, 1990; Kaplan, Bush, & Berry, 1976, 1979). However, the self-administered version used in the present study has not been psychometrically tested according to this weighting scale. Thus, in the present study, this questionnaire is scored as an unweighted health index, with no symptoms or functional difficulties represented by low scores, the opposite represented by high scores. Support for using an unweighted scoring approach for QOL instruments can be found in Cox et al. (1992). However, the results obtained by this scoring method should be viewed with

caution. A more reliable scoring system for this instrument is to be available in February 1997 (Dr. William Siebert, personal communication December 18, 1996).

The original QWB is comprised of four health status dimension, one symptoms list and three function scales: 1) Mobility, 2) Physical Activity, and 3) Social Activity. These three subscales have undergone rigorous item reduction analyses over the past 20 years. The item structures for these subscales remains consistent in the self-administered version employed in the present study.

Although this present version of this instrument has not undergone extensive reliability and validity testing, Cronbach's alpha for the present study was moderate, therefore, this instrument is considered moderately internally reliable ($\alpha = .6929$) among the present sample. This instrument was chosen for the present study as the original version is considered a gold standard for the measurement of health-related quality of life. This instrument measures symptoms and functional aspects of living with chronic illness in more detail than does the SF-36, and was thought to be useful for the purposes of this study.

The Diabetes Care Profile (DCP)

This instrument was developed and tested by researchers at the Michigan Diabetes Research and Training Center (Davis, Hiss, Van Harrison, & Hess, 1987; Hess, Davis, & Van Harrison, 1986) to assess psychological and educational needs of people with diabetes. This instrument consists of several regimen adherence questions as well as beliefs about the efficacy of treatment approaches. Only a small proportion

of data from this instrument was necessary for the present study to assess convergent validity of the NHQ. Because this instrument was not used in its fullest capacity in the present study, no internal reliability estimates were made. This instrument has been psychometrically tested among both Type I and Type II diabetics (Davis, Hiss, Van Harrison, & Hess, 1987).

The Life Orientation Test (LOT)

This 10 item Likert response option test was designed to assess optimism versus pessimism (Scheier, Carver, & Bridges, 1994). A common use for this instrument is in health outcome and health-related quality of life research settings. This instrument is often used, as in this study, to assess the confounding influences of pessimism or optimism on health outcomes and/or QOL outcomes.

Cronbach's alpha for the present study was high, thus internal reliability of this instrument within the context of this study is was high (α = .7923).

DEMOGRAPHIC FORM

Identification Number _____

Today's Date _____ Age _____ (years)
(Month, Day, Year)

Sex ☐ Male ☐ Female

What year were you first told you had diabetes? _____

What is your marital status?

- ☐ Never married
- ☐ Married
- ☐ Separated/Divorced
- ☐ Widowed

What is your ethnic origin/race?

- ☐ White
- ☐ Black
- ☐ Hispanic
- ☐ Native American
- ☐ Asian or Pacific Islander
- ☐ Arabic
- ☐ Other

Where do you live most of the year?

- ☐ Your home, apartment or condo
- ☐ Senior citizen apartment or condo
- ☐ Retirement home
- ☐ Adult foster care
- ☐ Nursing home
- ☐ Other _____

How many people live with you? _____

How much schooling have you had?

(Years of formal schooling completed)

- ☐ 8 or less
- ☐ 9 - 11
- ☐ 12
- ☐ 13 - 15
- ☐ 16 or more

What is your usual activity?

Employed:

- ☐ Outside home
- ☐ At home
- ☐ Looking for work

Not Employed:

- ☐ Student
- ☐ Homemaker
- ☐ Retired
- ☐ Retired for health
- ☐ Other_____

How many hours per week are you involved in school and/or work?

- ☐ Less than 10 hrs/week
- ☐ 11-20 hrs/week
- ☐ 21-30 hrs/week
- ☐ 31-40 hrs/week
- ☐ More than 40 hrs/week
- ☐ Not applicable

Do you feel you are ☐At ☐Above **or** ☐Below your ideal body weight?

Nutrition Information

Are you on a special diet? ☐Yes ☐No

If **YES**, please answer the following questions:
If **NO**, please go on to "Meal Preparation"

Do you have a medical condition that requires you to be on a special diet? ☐Yes ☐No

If **YES**, what is that condition? _____

How long have you had that condition? _____ (months)

How long have you been on a special diet? _____ (months)

Did a medical professional advise you as to the types of foods you should be eating? ☐Yes ☐No

If **YES**, who was that person? A:

- ☐ Doctor
- ☐ Nurse
- ☐ Nutritional Consultant
- ☐ Dietitian
- ☐ Diabetes Educator
- ☐ Other _____

What items are restricted according to your diet plan?
(Check all that apply)

- ☐ Salt
- ☐ Fat
- ☐ Calories
- ☐ Potassium
- ☐ Magnesium
- ☐ Cholesterol
- ☐ Sugar
- ☐ Protein
- ☐ Phosphorus
- ☐ Other _____

Meal Preparation

Which meals do you prepare on a regular basis?

- ☐ Breakfast
- ☐ Lunch
- ☐ Dinner
- ☐ None

Income Information

What was your total household income for the past year, before taxes?

- ☐ None
- ☐ $1 to $24,999
- ☐ $25,000 to $74,999
- ☐ $75,000 to $99,000
- ☐ $100,000 or over

Support Group Information

Have you ever been or are you currently in a Diabetes Support Group?

- ☐ Yes
- ☐ No

IF YES, how is this group funded?

- ☐ Free
- ☐ Donations
- ☐ Registration Fee
- ☐ Unknown

NUTRITION HASSLES QUESTIONNAIRE

INSTRUCTIONS: Hassles are irritants that can range from minor annoyances to fairly major pressures, problems, or difficulties. They can occur few or many times. Listed on the following pages are a number of ways in which a person can feel hassled about nutrition and diet.

Please rate the following items according to <u>irritability</u> of those hassles experienced **during the past month** as:

	NOT IRRITATING	SOMEWHAT IRRITATING	SLIGHTLY IRRITATING	MODERATELY IRRITATING	QUITE IRRITATING	VERY IRRITATING	EXTREMELY IRRITATING
1. Concerns about eating the right foods	0	1	2	3	4	5	6
2. Cravings for foods not on your diet	0	1	2	3	4	5	6
3. Finding the right foods	0	1	2	3	4	5	6
4. Avoiding favorite foods	0	1	2	3	4	5	6
5. Figuring out which foods to buy	0	1	2	3	4	5	6
6. Preparing food	0	1	2	3	4	5	6
7. Time spent preparing food	0	1	2	3	4	5	6
8. Keeping track of sugar	0	1	2	3	4	5	6
9. Embarrassment about diet	0	1	2	3	4	5	6
10. Taste of food on diet	0	1	2	3	4	5	6
11. Foods not satisfying	0	1	2	3	4	5	6

	NOT IRRITATING	SOMEWHAT IRRITATING	SLIGHTLY IRRITATING	MODERATELY IRRITATING	QUITE IRRITATING	VERY IRRITATING	EXTREMELY IRRITATING
12. Time required to shop for food	0	1	2	3	4	5	6
13. Going out to dinner	0	1	2	3	4	5	6
14. Eating right when not at home	0	1	2	3	4	5	6
15. Family problems over food	0	1	2	3	4	5	6
16. Lack of control over diet	0	1	2	3	4	5	6
17. Learning new recipes	0	1	2	3	4	5	6
18. Don't like what you eat	0	1	2	3	4	5	6
19. Planning menus	0	1	2	3	4	5	6
20. Feeling hungry	0	1	2	3	4	5	6
21. Keeping track of cholesterol	0	1	2	3	4	5	6
22. Keeping track of salt	0	1	2	3	4	5	6
23. Keeping track of minerals	0	1	2	3	4	5	6
24. Keeping track of fat content	0	1	2	3	4	5	6
25. Keeping track of calories	0	1	2	3	4	5	6
26. Eating junk food	0	1	2	3	4	5	6
27. Reading nutrition labels	0	1	2	3	4	5	6

	NOT IRRITATING	SOMEWHAT IRRITATING	SLIGHTLY IRRITATING	MODERATELY IRRITATING	QUITE IRRITATING	VERY IRRITATING	EXTREMELY IRRITATING
28. Eating too much	0	1	2	3	4	5	6
29. Finding time to eat	0	1	2	3	4	5	6
30. Food portions	0	1	2	3	4	5	6
31. Remembering what to eat	0	1	2	3	4	5	6
32. Remembering when to eat	0	1	2	3	4	5	6
33. Refusing food that is offered ...	0	1	2	3	4	5	6
34. Telling others about diet	0	1	2	3	4	5	6
35. Holidays and special occasions ..	0	1	2	3	4	5	6
36. Not enjoying food	0	1	2	3	4	5	6
37. Keeping track of vitamins	0	1	2	3	4	5	6

MEDICAL OUTCOMES STUDY SHORT-FORM 36

INSTRUCTIONS: This survey asks for your views about your health **during the past 4 weeks.** This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by **circling the appropriate number OR checking the appropriate box.** If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)

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

2. Compared to one year ago, how would you rate your health in general **now**? (Circle one number)

   1. Much better now than 1 year ago
   2. Somewhat better now than 1 year ago
   3. About the same
   4. Somewhat worse now than 1 year ago
   5. Much worse now than 1 year ago

3. During the **past 4 weeks,** to what extent **has your physical health or emotional problems** interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)

   1. Not at all
   2. Slightly
   3. Moderately
   4. Quite a bit
   5. Extremely

4. How much **bodily** pain have you had during the **past 4 weeks**? (Circle one number)

   1. None
   2. Very Mild
   3. Mild
   4. Moderate
   5. Severe
   6. Very Severe

5. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)? (Circle one number)
   1. Not at all
   2. Slightly
   3. Moderately
   4. Quite a bit
   5. Extremely

6. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number)

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

7. The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? (Check one box for each line).

		Yes, Limited A Lot	**Somewhat Limited**	**No, Not at all**
a)	Vigorous activities, such as running, lifting heavy objects participating in strenuous sports	☐	☐	☐
b)	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c)	Lifting or carrying groceries	☐	☐	☐
d)	Climbing several flights of stairs	☐	☐	☐
e)	Climbing one flight of stairs	☐	☐	☐
f)	Bending, kneeling, or stooping	☐	☐	☐
g)	Walking more than a mile	☐	☐	☐
h)	Walking several blocks	☐	☐	☐
i)	Walking one block	☐	☐	☐
j)	Bathing or dressing yourself	☐	☐	☐

8. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? (Check one box for each line)

		Yes	**No**
a)	Cut down the amount of time you spent on work or other activities	☐	☐
b)	Accomplished less than you would like	☐	☐
c)	Were limited in the kind of work or other activities	☐	☐
d)	Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐

9. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? (Check one box for each line)

		Yes	No
a)	Cut down the amount of time you spent on work or other activities	☐	☐
b)	Accomplished less than you would like	☐	☐
c)	Didn't do work or other activities as carefully as usual	☐	☐

10. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks:....**(Check one box for each line)

		All of the time	Most of the time	A Good Bit of the time	Some of the time	A Little time	None of the time
a)	Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b)	Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c)	Have you felt so down in the dumps nothing cheer you up?	☐	☐	☐	☐	☐	☐
d)	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e)	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f)	Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐
g)	Did you feel worn out?	☐	☐	☐	☐	☐	☐
h)	Have you been a happy person	☐	☐	☐	☐	☐	☐
i)	Did you feel tired?	☐	☐	☐	☐	☐	☐

11. Please choose the answer that best describes how **true or false** each of the following statements is for you. (Check one box for each line)

		Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
a)	I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b)	I am as healthy as anybody I know	☐	☐	☐	☐	☐
c)	I expect my health to get worse	☐	☐	☐	☐	☐
d)	My health is excellent	☐	☐	☐	☐	☐

QUALITY OF WELL-BEING SCALE

INSTRUCTIONS: This survey asks about health problems that you have experienced in the last three days, not including today. Please make sure to answer all questions. Thank you for your patience and time in carefully completing this survey.

1. Please indicate whether you currently experience any of the following health symptoms or problems.

Do you have.....	Please Check: YES	NO
A. Blindness, or severely impaired vision in both eyes?	1	2
B. Speech problems such as stuttering, or being unable to speak clearly?	1	2
C. Missing or paralyzed hands, feet, arms or legs?	1	2
D. Any deformity of the face, fingers, hand or arm, foot or leg, or back (e.g. severe scoliosis)	1	2
E. General tiredness or weakness?	1	2
F. A problem with unwanted weight gain or weight loss?	1	2
G. A problem with being under or over weight?	1	2
H. Problems chewing your food adequately?	1	2
I. Any hearing loss or deafness?	1	2
J. Any noticeable skin problems, such as bad acne or large burns or scars on face, body, arms, or legs?	1	2
K. Excema or burning/itching rash?	1	2

Which of the following health aides do you use/have?

Please Check:	YES	NO
dentures	1	2
oxygen tank	1	2
prosthesis	1	2
eye glasses or contact lenses	1	2
hearing aide	1	2
magnifying glass	1	2
neck, back, or leg brace	1	2

2. For the following list of problems indicate which days (if any) over the past three (3) days, not including today, you had the problem. If you have not had the symptom in the past 3 days, **do not just leave the question blank**, please circle "1" for :NO DAYS". If you have experienced the symptom in the past 3 days, please check which of the days you had it; if you experienced it on more than one of the days, please check all days that apply.

For example, if you had a headache yesterday and the day before that, the following should be circled:

	NO DAYS	YESTERDAY	2 DAYS AGO	3 DAYS AGO
A) Headache	1	(2)	(3)	4

Did you have...(Please Circle All Days That Apply)	NO DAYS	YESTERDAY	2 DAYS AGO	3 DAYS AGO
A. Any problems with your vision not corrected with glasses or contact lenses (such as double vision, distorted vision, flashes, or floaters)?	1	2	3	4
B. Any eye pain, irritation, discharge, or excessive sensitivity to light?	1	2	3	4
C. A headache?				
D. Dizziness, earache, or ringing in your ears?	1	2	3	4
E. Difficulty hearing or discharge or bleeding from an ear?	1	2	3	4
F. Stuffy or runny nose or bleeding from the nose?	1	2	3	4
G. A sore throat, difficulty swallowing, or hoarse voice?	1	2	3	4
H. A tooth ache or jaw pain?	1	2	3	4
I. Sore or bleeding lips, tongue, or gums?	1	2	3	4
J. Coughing or wheezing?	1	2	3	4

		NO DAYS	YESTERDAY	2 DAYS AGO	3 DAYS AGO
K.	Shortness of breath or difficulty breathing?	1	2	3	4
L.	Chest pain, pressure, palpitations, fast of skipped heart beat or other discomfort in the chest?	1	2	3	4
M.	An upset stomach, abdominal pain, nausea, heart burn or vomiting?	1	2	3	4
N.	Difficulty with bowel movements, diarrhea, constipation, rectal bleeding, black tar-like stools, or any pain or discomfort in the rectal area?	1	2	3	4
O.	Pain, burning, or blood in urine?	1	2	3	4
P.	Loss of bladder control, frequent night-time urination or difficulty with urination?	1	2	3	4
Q.	Genital pain, itching, burning, or abnormal discharge, or pelvic cramping or abnormal bleeding? (does not include normal menstruation).	1	2	3	4
R.	A broken arm, wrist, foot, leg, or any bone (other than in back)?	1	2	3	4
S.	Pain, stiffness, cramps, weakness or numbness:				
	a) in the neck or back?	1	2	3	4
	b) in the hips, sides, knees, or back?	1	2	3	4
	c) in any of the joints or muscles of the hands, feet or legs?	1	2	3	4
T.	Swelling of ankles, hands, feet, or abdomen?	1	2	3	4
U.	Fever, chills, or sweats?	1	2	3	4
V.	Loss of consciousness, fainting, or seizures?	1	2	3	4
W.	Difficulty with your balance, standng, or walking?	1	2	3	4

3. The following symptoms are about your feelings, thoughts and behaviors. Please check which days (if any) over the past three (3) days, not including today, have you had...

		NO DAYS	YESTERDAY	2 DAYS AGO	3 DAYS AGO
A.	Trouble falling asleep or staying asleep?	1	2	3	4
B.	Spells of feeling nervous or shaky?	1	2	3	4
C.	Spells of feeling upset, downhearted, or blue?	1	2	3	4
D.	Excessive worry or anxiety?	1	2	3	4
E.	Feeling of little or no control over events in your life?	1	2	3	4
F.	Feeling lonely or isolated?	1	2	3	4
G.	Feelings of frustration, irritation or close to losing your temper?	1	2	3	4
H.	A hangover?	1	2	3	4
I.	Any decrease of sexual interest or performance?	1	2	3	4
J.	Difficulty understanding the written or spoken word, or significant memory loss?	1	2	3	4
K.	Thoughts or images you could not get out of your mind?	1	2	3	4
L.	To take <u>any</u> medication including over-the-counter remedies (aspirin/tylenol, allergy medications, insulin, hormones, estrogen, thyroid, prednisone)?	1	2	3	4
M.	To stay on a medically prescribed diet for health reasons?	1	2	3	4
N.	A loss of appetite or over-eating?	1	2	3	4

4. In the past three (3) days did you have any symptoms, health complaints, or pains that have not been mentioned? (Please Circle:)

1. YES
2. NO

If YES, what were the symptoms and on which days did you have them?

A.		1	2	3	4
B.		1	2	3	4

	NO DAYS	YESTERDAY	2 DAYS AGO	3 DAYS AGO
5. Over the last three (3) days....				
A. Did you spend any part of the day or night as a patient in a hospital, nursing home, or rehabilitation center?	1	2	3	4
B. Because of any impairment or health problem, did you need help with your personal care needs, such as eating, dressing, bathing, or getting around your home?	1	2	3	4
6. Over the last three (3) days...				
A. Which days did you drive a motor vehicle?	1	2	3	4
B. Which days did you use public transportation such as a bus, subway, Medi-van, train, or airplane?	1	2	3	4
C. Which days did you either not drive a motor vehicle or not use public transportation because of your health or need of help from another person?	1	2	3	4
7. Over the past three (3) days did you...				
A. Have trouble climbing stairs or inclines or walking off the curb?	1	2	3	4
B. Avoid walking, have trouble walking, or walk more slowly than other people your age?	1	2	3	4
C. Limp or use a cain, crutches or walker?	1	2	3	4
D. Avoid or have trouble bending over, stooping or kneeling?	1	2	3	4
E. Have any trouble lifting or carrying everday objects such as books, a briefcase or groceries?	1	2	3	4
F. Have any other limitations in physical movements?	1	2	3	4
G. Spend all or most of the day in bedm chair or couch because of health reasons?	1	2	3	4
H. Spend all or most of the day in a wheelchair?	1	2	3	4
If so, on which days did someone else control its movement?	1	2	3	4

8. Over the last three (3) days...	NO DAYS	YESTERDAY	2 DAYS AGO	3 DAYS AGO
A. Because of any physical or emotional health reasons, on which days did you avoid, need help with, or were limited in doing some of your usual activities, such as work, school, or houspekeeping?	1	2	3	4
B. Because of physical or emotional health reasons, on which days did you avoid or feel limited in doing some of your usual activities, such as visiting family/friends, hobbies, shopping, recreational, or religious activities?	1	2	3	4
C. On which days did you have to change any of your plans or activities because of your health that you did not report on the previous two questions?	1	2	3	4

Please Describe:

Would you say that your health is (Please Check One):

☐ Excellent ☐Very Good ☐Good ☐Fair ☐Poor

Compared to a year ago, how would you rate your health in general now? **(Please Circle One):**

(1) Much better now than a year ago
(2) Somewhat better now than one year ago
(3) About the same as a year ago
(4) Somewhat worse than a year ago
(5) Much worse than a year ago

Think about a scale of 0 to 100, with zero being the least desirable state of health that you could imagine and 100 being perfect health. What number, from 0 to 100 would you give to the state of your health, on average, over the past 3 days? **(Please Circle One)**

0 5 10 15 20 25 30 35 40 45 50 55

60 65 70 75 80 85 90 95 100

DIABETES QUALITY OF LIFE SCALE

INSTRUCTIONS: For each item **circle one answer** that best describes your level of satisfaction **during the past 4 weeks.**

	VERY SATISFIED	SOMEWHAT SATISFIED	SATISFIED	SOMEWHAT DISSATISFIED	VERY DISSATISFIED
1. How satisfied are you with the amount of time it takes to manage your diabetes?	1	2	3	4	5
2. How satisfied are you with the time it takes to determine you sugar level?	1	2	3	4	5
3. How satisfied are you with the flexibility you have in your diet?	1	2	3	4	5
4. How satisfied are you with the burden your diabetes is placing on your family?	1	2	3	4	5
5. How satisfied are you with your daily activities?	1	2	3	4	5
6. How satisfied are you with your sleep?	1	2	3	4	5
7. How satisfied are you with your sex life?	1	2	3	4	5
8. How satisfied are you with the time you spend exercising?	1	2	3	4	5
9. How satisfied are you with your life in general?	1	2	3	4	5
10. How satisfied are you with the amount of time you spend getting checkups?	1	2	3	4	5
11. How satisfied are you with your current treatment?	1	2	3	4	5

	VERY SATISFIED	SOMEWHAT SATISFIED	SATISFIED	SOMEWHAT DISSATISFIED	VERY DISSATISFIED
12. How satisfied are you with your knowledge about your diabetes?	1	2	3	4	5
13. How satisfied are you with your social relationships and friendships?	1	2	3	4	5
14. How satisfied are you with the appearance of your body?	1	2	3	4	5
15. How satisfied are you with your leisure time?	1	2	3	4	5

INSTRUCTIONS: For each item **circle one answer** that best describes **how often during the past 4 weeks** you have experienced the following.

	VERY OFTEN	OFTEN	SOMETIMES	NOT VERY OFTEN	NEVER
16. How often do you find that you eat something you shouldn't rather than tell someone that you have diabetes?	1	2	3	4	5
17. How often do you feel that because of your diabetes you go to the bathroom more than others?	1	2	3	4	5
18. How often do you worry about whether you will be denied insurance?	1	2	3	4	5
19. How often do you worry about whether you will miss work?	1	2	3	4	5
20. How often do you worry about whether you will pass out?	1	2	3	4	5
21. How often do you worry that your body looks different because you have diabetes?	1	2	3	4	5
22. How often do you worry that you will get complications from your diabetes?	1	2	3	4	5
23. How often do you have low blood sugar?	1	2	3	4	5
24. How often does your diabetes interfere with your family life?	1	2	3	4	5
25. How often do you worry about whether you will be able to take a vacation or a trip?	1	2	3	4	5
26. How often do you feel good about yourself?	1	2	3	4	5
27. How often does your diabetes keep you from driving a car or using a machine (e.g., computer)?	1	2	3	4	5

	VERY OFTEN	OFTEN	SOMETIMES	NOT VERY OFTEN	NEVER
28. How often do you find yourself explaining what it means to have diabetes?	1	2	3	4	5
29. How often are you teased because you have diabetes?	1	2	3	4	5
30. How often do you feel pain associated with the treatment for your diabetes?	1	2	3	4	5
31. How often are you embarrassed by having to deal with your diabetes in public?	1	2	3	4	5
32. How often do you feel physically ill?	1	2	3	4	5
33. How often do you find your diabetes limiting your social relationships and friendships?	1	2	3	4	5
34. How often do you feel restricted by your diet?	1	2	3	4	5
35. How often does your diabetes interfere with your sex life?	1	2	3	4	5
36. How often does your diabetes interfere with your exercising?	1	2	3	4	5
37. How often do you miss work, school, or household duties because of your diabetes?	1	2	3	4	5
38. How often do you find that your diabetes interrupts your leisure-time activities?	1	2	3	4	5
39. How often do you have a bad night's sleep?	1	2	3	4	5

DIABETES DAILY HASSLES SCALE

INSTRUCTIONS: Below are a number of hassles related to having diabetes that may have happened to you in the **last month**. If a hassle did not happen to you in the last month, circle 0. If the hassle did happen to you in the last month, please indicate how severe of a hassle you believed it to be by circling one number between 1 and 5.

	DID NOT HAPPEN	NOT SEVERE AT ALL	SOMEWHAT SEVERE	MODERATELY SEVERE	VERY SEVERE	EXTREMELY SEVERE
1. Taking injections	0	1	2	3	4	5
2. Remembering to take insulin or pills	0	1	2	3	4	5
3. Being offered food you shouldn't eat	0	1	2	3	4	5
4. Blood sugar testing	0	1	2	3	4	5
5. Troubling thoughts about your health	0	1	2	3	4	5
6. Thoughts about death	0	1	2	3	4	5
7. Low blood sugar	0	1	2	3	4	5
8. High blood sugar or diabetic coma	0	1	2	3	4	5
9. Medical bills	0	1	2	3	4	5
10. Getting adequate medical insurance	0	1	2	3	4	5
11. Getting adequate life insurance	0	1	2	3	4	5
12. Scheduling doctors' appointments	0	1	2	3	4	5
13. Eating when your supposed to	0	1	2	3	4	5
14. Concerns about getting food in case of low blood sugar	0	1	2	3	4	5
15. Difficulty finding food you can eat when out	0	1	2	3	4	5
16. Difficulty adhering to diet	0	1	2	3	4	5
17. Fear of going to the doctor	0	1	2	3	4	5

	DID NOT HAPPEN	NOT SEVERE AT ALL	SOMEWHAT SEVERE	MODERATELY SEVERE	VERY SEVERE	EXTREMELY SEVERE
18. Getting enough exercise	0	1	2	3	4	5
19. Coordinating food and exercise	0	1	2	3	4	5
20. Coordinating insulin and exercise	0	1	2	3	4	5
21. Pain or numbness	0	1	2	3	4	5
22. Trouble with vision	0	1	2	3	4	5
23. Trouble with sexual functioning	0	1	2	3	4	5
24. Time spent in hospital	0	1	2	3	4	5
25. Planning meals and/or snacks	0	1	2	3	4	5
26. Trouble losing weight	0	1	2	3	4	5
27. Concerns about family members dealing with your diabetes	0	1	2	3	4	5
28. Concerns about your children getting diabetes	0	1	2	3	4	5
29. Feeling tired or run down	0	1	2	3	4	5
30. Embarrassment due to diabetes	0	1	2	3	4	5
31. Limitations on your recreational activities	0	1	2	3	4	5
32. Limitations on your work activities	0	1	2	3	4	5
33. Feeling thirsty all the time	0	1	2	3	4	5
34. Having to urinate frequently	0	1	2	3	4	5
35. Skin irritation or deformity due to injections	0	1	2	3	4	5
36. Self-doubt or low self-esteem	0	1	2	3	4	5
37. Concerns about the future	0	1	2	3	4	5

Have We Missed any of Your Diabetic Hassles?

If So, PLEASE Write Them in On The Following Page.

	DID NOT HAPPEN	NOT SEVERE AT ALL	SOMEWHAT SEVERE	MODERATELY SEVERE	VERY SEVERE	EXTREMELY SEVERE
38. _____	0	1	2	3	4	5
39. _____	0	1	2	3	4	5
40. _____	0	1	2	3	4	5
41. _____	0	1	2	3	4	5
42. _____	0	1	2	3	4	5

DIABETES CARE PROFILE

INSTRUCTIONS: Please answer each of the following questions by filling in the blanks with the correct answer or by choosing the single best answer for you. **Circle one answer for each question.**

. a) Were you admitted to the hospital for your diabetes when you were **first diagnosed**? 1 YES 2 NO

b) How many times in the **past year** have you been in the hospital for diabetes or its complications? _____Number of times

	POOR	NOT GOOD	GOOD	GREAT	EXCELLENT
. Overall, how would you rate your health?	1	2	3	4	5
. Compared to people your age, how would you rate your overall health?	1	2	3	4	5

	0	1-3	4-6	7-12	12+
. How many times in the **last month** have you had a **low blood sugar** (glucose) reaction with symptoms such as sweating, weakness anxiety, trembling, hunger or headache?	1	2	3	4	5
. How many times in the **last year** have you had **severe low blood sugar** reactions such as passing out or needing help to treat the reaction?	1	2	3	4	5
. How many **days** in the **last month** have you had **high blood sugar** with symptoms such as thirst, dry mouth and skin, increased sugar in the urine, less appetite, nausea, or fatigue?	1	2	3	4	5
. How many **days** in the **last month** have you had **ketones** in your urine?	1	2	3	4	5

☐ DON'T TEST FOR KETONES

☐ DON'T KNOW WHAT KETONES ARE

	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS	DO NOT KNOW
. During the **past year**, how often have you had changes in your blood sugar (<u>too high</u>) because:						
a) you were upset or angry?	1	2	3	4	5	6
b) you took the wrong amount of medicine?	1	2	3	4	5	6
c) you ate the wrong types of food?	1	2	3	4	5	6
d) you ate too much food?	1	2	3	4	5	6
e) you had less physical activity than usual?	1	2	3	4	5	6
f) you were feeling stressed?	1	2	3	4	5	6
. During the **past year**, how often have you had changes in your blood sugar (<u>too low</u>) because:						
a) you were sick or had an infection?	1	2	3	4	5	6
b) you were upset or angry?	1	2	3	4	5	6
c) you took the wrong amount of medicine?	1	2	3	4	5	6
d) you ate the wrong types of food?	1	2	3	4	5	6
e) you ate too little food?	1	2	3	4	5	6
f) you had more physical activity than usual?	1	2	3	4	5	6
g) you waited too long to eat or skipped a meal?	1	2	3	4	5	6
h) you were feeling stressed?	1	2	3	4	5	6
0. How often has your diabetes kept you from doing your normal daily activities during the past year (e.g. couldn't: go to work, work around the house, go to school, visit friends)?	1	2	3	4	5	6

	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
1. My diabetes and its treatment keep me from:					
a) having enough money	1	2	3	4	5
b) meeting school, work, household, and other responsibilities	1	2	3	4	5
c) going out or traveling as much as I want	1	2	3	4	5
d) being as active as I want	1	2	3	4	5
e) eating foods that I like	1	2	3	4	5
f) eating as much as I want	1	2	3	4	5
g) having good relationships with people	1	2	3	4	5
h) keeping a schedule I like (e.g. eating or sleeping late)	1	2	3	4	5
i) spending time with my friends	1	2	3	4	5
j) having enough time alone	1	2	3	4	5
2. Paying for my diabetes treatment and supplies is a problem	1	2	3	4	5
3. Having diabetes makes my life difficult	1	2	3	4	5
4. I am afraid of my diabetes	1	2	3	4	5
5. I find it hard to believe that I really have diabetes	1	2	3	4	5
6. I feel unhappy and depressed because of my diabetes	1	2	3	4	5
7. I feel satisfied with my life	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
8. I feel I'm not as good as others because of my diabetes	1	2	3	4	5
9. I can do just about anything I set out to do	1	2	3	4	5
0. I find it hard to do all the things I have to do for my diabetes	1	2	3	4	5
1. Diabetes doesn't affect my life at all	1	2	3	4	5
2. I am pretty well off, all things considered	1	2	3	4	5
3. Things are going very well for me right now	1	2	3	4	5
4. I am **able** to:					
a) keep my blood sugar in good control	1	2	3	4	5
b) keep my weight under control	1	2	3	4	5
c) do the things I need to do for my diabetes (diet, medicine, exercise, etc.)	1	2	3	4	5
d) handle my feelings (fear, worry, anger) about my diabetes	1	2	3	4	5
5. I think it is **important** for me to:					
a) keep my blood sugar in good control	1	2	3	4	5
b) keep my weight under control	1	2	3	4	5
c) do the things I need to do for my diabetes (diet, medicine, exercise, etc.)	1	2	3	4	5
d) handle my feelings (fear, worry, anger) about my diabetes	1	2	3	4	5

	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
6. I keep my blood sugar in good control	1	2	3	4	5
7. I keep my weight under control	1	2	3	4	5
8. I do the things I need to do for my diabetes (diet, medicine, exercise, etc.)	1	2	3	4	5
9. I feel dissatisfied with my life because of my diabetes	1	2	3	4	5
0. I handle the feelings (fear, worry, anger) about my diabetes fairly well	1	2	3	4	5

1. How tall are you? _____(feet) _____(inches)

2. How much do you weigh? _____(pounds)

3. How has your weight changed over the last year?

1 Stayed same
2 Lost
3 Gained

If **loss or gain**, how much _____(pounds)

4. What would you like to weigh? _____(pounds)

	YES	NO	NOT SURE
5. Has any doctor or nurse told you to follow a meal plan or diet?	1	2	3
If **YES**, was the purpose of the diet to:			
a) control your diabetes?	1	2	3
b) lose weight?	1	2	3
c) gain weight?	1	2	3
d) eat a healthy diet?	1	2	3

	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
6. How often do you follow a meal plan or diet?	1	2	3	4	5
7. How often do you follow the schedule for your meals and snacks?	1	2	3	4	5
8. How often do you weigh or measure your food?	1	2	3	4	5
9. How often do you (or the person who cooks your food) use the exchange lists or food group lists to plan your meals?	1	2	3	4	5

	YES	NO	
0. Have you been told to follow a schedule for your meals and snacks?	1	2	
1. Have you been told to weigh or measure your food?	1	2	
2. Have you been told to use exchange lists or food group lists to plan your meals?	1	2	
3. Do you depend on someone else to cook or shop for your food?	1	2	
If **YES**, do your meals fit your diet plan?	1	2	3 (N/A)
4. **If** you drink non-diet beverages do you count them in your meal plan?	1	2	
a) Soft drinks or tea or coffee containing sugar?	1	2	3 (N/A)
b) Alcoholic beverages?	1	2	3 (N/A)

5. How many calories a day in your diet? _____(Calories)

1 (Not Sure)

6. About how many calories a day do you usually eat? _____(Calories)

1 (Not Sure)

	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
7. Following my meal plan (eating the right foods at the right times) helps me control my diabetes	1	2	3	4	5
8. I can stray from my meal plan and still control my diabetes	1	2	3	4	5
9. Following a diet interferes with my other activities	1	2	3	4	5

0. Which of the following have you ever used to treat your diabetes? (CIRCLE all that apply)

1 Diet

2 Pills

3 Insulin

1. Do you take pills **now** to treat your diabetes (to lower blood sugar)?
If **NO**, go to Question No. 55

1 YES

2 NO

2. How many pills have you been told to take **each day**? _____(pills)

3. How many pills do you take **each day**? _____ (pills)

4. How many times a **day** do you take pills? _____ (times)

5. Do you use insulin?
   1 YES
   2 NO

   If you answered **NO** and you are taking pills, go on to Question No. 65
   If **NO** AND you **are not** taking diabetes pills, go on to Question No. 66

6. Do you keep a source of sugar with you to treat an insulin reaction?
   1 YES
   2 NO

7. How do you take your insulin?
   1 Syringe
   2 Infusion pump

   If **infusion pump**, go to Question No. 62

8. How many times during the day have you been told to take your insulin?
   _____ (times)

9. How many times during the day do you usually take your insulin?
   _____ (times)

0. How many different types of insulin do you take (e.g. Regular, 70/30, NPH, Lente)
   1 ONE
   2 TWO
   3 THREE

1. Do you inject your own insulin?
   1 YES
   2 NO

2. How long have you taken insulin? _____ (Years)

3. Have you taken insulin for as long as you have had diabetes?
   1 YES
   2 NO

	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
4. How often have you changed the timing and/or dose of your insulin because:					
a) you wanted to lose weight?	1	2	3	4	5
b) you wanted to gain weight?	1	2	3	4	5
5. People with diabetes sometimes change how much medicine they take. How often do you change the timing and/or dose of your insulin or diabetes pills because:					
a) you missed an earlier dose?	1	2	3	4	5
b) you wanted to experiment?	1	2	3	4	5
c) you thought the dose was wrong?	1	2	3	4	5
d) you were upset about something?	1	2	3	4	5
e) you ate more food than usual?	1	2	3	4	5
f) your blood sugar level was too high or too low?	1	2	3	4	5

6. Have you been told by your doctor or nurse to take special care of your feet?

1 YES
2 NO
3 NOT SURE

7. If foot care was advised, how often are you you supposed to check your feet for signs of problems?

1 NOT AT ALL
2 MONTHLY
3 WEEKLY
4 DAILY
5..N/A

8. How often do you check your feet for signs of problems?

1 NOT AT ALL
2 MONTHLY
3 WEEKLY
4 DAILY

9. Have you ever received advice about exercise from your doctor or nurse?

1 YES

2 NO

0. If you received advice about exercise, how often are you supposed to exercise?

1 Never told to exercise

2 No schedule was advised

3 Told to avoid exercise

4 1-2 times weekly

5 3 or more times weekly

1. What is your current level of exercise or physical activity?

1 None

2 Light (walking)

3 Moderate (e.g. bike riding)

4 Strenuous (e.g. running, organized sports)

2. How often do you exercise?

1 Less than once a week

2 Once a week

3 2-3 times a week

4 4-6 times a week

5 Daily

3. How often do you have trouble getting enough exercise because:

	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
a) you are too busy?	1	2	3	4	5
b) it takes too much effort?	1	2	3	4	5
c) you don't believe it is useful?	1	2	3	4	5
d) you don't like to do it?	1	2	3	4	5
e) the weather is bad?	1	2	3	4	5
f) you have a health problem?	1	2	3	4	5
g) it makes your diabetes more difficult to control?	1	2	3	4	5

4. How many **days a week** have you been told to test your:

a) urine sugar? _____(days per week) 1 (Not told to test)

b) blood sugar? _____(days per week) 1 (Not told to test)

If **you do not** test for sugar, go on to Question No. 84

5. How many days a week do you test your:

a) urine sugar? _____(days per week) 1 (Not told to test)

b) blood sugar? _____(days per week) 1 (Not told to test)

6. On days that you test, how many times do you test?

a) urine sugar? _____(times per day) 1 (Not told to test)

b) blood sugar? _____(times per day) 1 (Not told to test)

	0	1-3	4-6	7-12	12+
7. How often in the **last month** have you had blood sugar readings below 70 without any symptoms?	1	2	3	4	5
8. How many times in the **last month** have you had blood sugar readings above 240 without any symptoms?	1	2	3	4	5

9. When you **don't** test for **sugar** as often as you have been told to, how often is it because:	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
a) you forgot?					
b) you don't believe it is useful?	1	2	3	4	5
c) the time or place wasn't right?	1	2	3	4	5
d) you don't like to do it?	1	2	3	4	5
e) you ran out of test materials?	1	2	3	4	5
f) it costs too much?	1	2	3	4	5
g) it's too much trouble?	1	2	3	4	5
h) it's hard to read the test results?	1	2	3	4	5
i) you can't do it by yourself?	1	2	3	4	5
j) your levels don't change very often?	1	2	3	4	5
k) it hurts to prick your finger?	1	2	3	4	5

	NOT IMPORTANT	SLIGHTLY IMPORTANT	SOMEWHAT IMPORTANT	QUITE IMPORTANT	VERY IMPORTANT
0. How important is it that you follow your **sugar test** schedule exactly?	1	2	3	4	5
1. How important is sugar testing in helping you control your diabetes?	1	2	3	4	5

	YES	NO
2. Do you own a meter to test your **blood sugar**?	1	2
3. Do you use a meter to test you **blood sugar** level?	1	2

4. At what times have you been told by your health care provider to test your **urine for ketones**? (CIRCLE all that apply)

1 Have not been told to test for ketones (**Go to** Question no. 87)
2 When you are sick
3 When sugar levels are high
4 When on a weight loss diet
5 Fixed schedule (e.g. weekly)

5. When do you test for urine **ketones**? (CIRCLE all that apply)

1 When you are sick
2 When sugar levels are high
3 When on a weight loss diet
4 Fixed schedule (e.g. weekly)

	NOT IMPORTANT	SLIGHTLY IMPORTANT	SOMEWHAT IMPORTANT	QUITE IMPORTANT	VERY IMPORTANT
6. How important do you think it is that you test for ketones at the times you were told?	1	2	3	4	5

	YES	NO	ONLY ODD VALUES
7. Have you been told to keep a record of sugar or ketone test results?	1	2	3
8. Do you keep a record of test results?	1	2	3

	YES	NO	N/A
9. Do you change your insulin or pill dose on the basis of your sugar or ketone tests?	1	2	3
0. Do you change your diet on the basis of your tests?	1	2	3
1. Do you change your exercise on the basis of your tests?	1	2	3
2. Has your doctor told you to change your insulin dose on the basis of your tests?	1	2	3
3. Have you ever received diabetes education? If NO, go to Question No. 97	1	2	3

	YES	NO
94. What topics were included in your education program? (CIRCLE all that apply)		
a) diet	1	2
b) weight management	1	2
c) exercise	1	2
d) use of insulin/pills	1	2
e) foot care	1	2
f) complications of diabetes	1	2
g) eye care	1	2
h) combining diabetes medication with other medications	1	2
i) alcohol use and diabetes	1	2
j) blood sugar control	1	2
k) symptoms of low blood sugar	1	2
l) symptoms of high blood sugar	1	2
95. Did you receive enough education to understand your diabetes?	1	2
96. Would you like more diabetes education?	1	2

97. How do you rate your understanding of:	POOR	NOT GOOD	GOOD	VERY GOOD	EXCELLENT
a) diet and blood sugar control	1	2	3	4	5
b) weight management	1	2	3	4	5
c) exercise	1	2	3	4	5
d) use of insulin/pills	1	2	3	4	5
e) foot care					
f) complications of diabetes	1	2	3	4	5
g) eye care	1	2	3	4	5
h) combining diabetes medication with other medications	1	2	3	4	5
i) alcohol use and diabetes	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
8. Taking the best possible care of diabetes will delay or prevent:					
a) eye problems	1	2	3	4	5
b) kidney problems	1	2	3	4	5
c) foot problems	1	2	3	4	5
d) hardening of the arteries	1	2	3	4	5
e) heart disease	1	2	3	4	5

	NONE	FEW	SOME	MOST	ALL
9. About how many members of your family know that you have diabetes?	1	2	3	4	5
00. About how many of your friends know that you have diabetes?	1	2	3	4	5

	FAMILY	FRIENDS
01. How many people do you feel close to?	_____ (number)	_____ (number)
02. Of the people you feel close to how many help and support you with your diabetes?	_____ (number)	_____ (number)

	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
03. I **want** a lot of help and support from my family and friends in:					
a) following my meal plan	1	2	3	4	5
b) taking my medicine	1	2	3	4	5
c) taking care of my feet	1	2	3	4	5
d) getting enough physical activity	1	2	3	4	5
e) testing my sugar	1	2	3	4	5
f) handling my feelings about diabetes	1	2	3	4	5
04. My family and friends help and support me a lot to:					
a) follow my meal plan	1	2	3	4	5
b) take my medicine	1	2	3	4	5
c) take care of my feet	1	2	3	4	5
d) get enough physical activity	1	2	3	4	5
e) test my sugar	1	2	3	4	5
f) handle my feelings about diabetes	1	2	3	4	5

05. Have you ever had an eye exam on account of your diabetes?

1 YES

2 NO

F YES how Often?

1 Never

2 Once

3 Yearly

	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
106. My family and friends:					
a) accept me and my diabetes	1	2	3	4	5
b) feel uncomfortable about me because of my diabetes	1	2	3	4	5
c) encourage or reassure me about my diabetes	1	2	3	4	5
d) discourage or upset me about my diabetes	1	2	3	4	5
e) listen to me when I want to talk about my diabetes	1	2	3	4	5
f) nag me about diabetes	1	2	3	4	5

107. Who helps you the most in caring for your diabetes?
(CIRCLE the **one** best answer)

1 Spouse
2 Other family members
3 Friends
4 Paid Helper
5 Doctor
6 Nurse
7 No one

108. Have your feet been checked by your doctor or nurse?

1 YES
2 NO
3 NOT SURE

LIFE ORIENTATION TEST

INSTRUCTIONS: Indicate the extent of your agreement with each of the following items. There are no right or wrong answers. Please be as accurate as possible and try not to let your answer to one question influence the way you answer other questions.

	STRONGLY DISAGREE	DISAGREE	NEUTRAL	AGREE	STRONGLY AGREE
1. In uncertain times, I usually expect the best	1	2	3	4	5
2. It's easy for me to relax.	1	2	3	4	5
3. If something can go wrong for me, it will.	1	2	3	4	5
4. I'm always optimistic about my future.	1	2	3	4	5
5. I enjoy my friends a lot.	1	2	3	4	5
6. It's important for me to keep busy.	1	2	3	4	5
7. I hardly ever expect things to go my way.	1	2	3	4	5
8. I don't get upset too easily.	1	2	3	4	5
9. I rarely count on good things happening to me.	1	2	3	4	5
10. Overall, I expect more good things to happen to me than bad.	1	2	3	4	5

REFERENCES

Aaronson, N.K. (1989). Quality of life assessment in clinical trials: Methodologic Issues. Controlled Clinical Trials, 10, 195S-208S.

American Diabetes Association. (1995). American diabetes association: Clinical practice recommendations [Special issue]. Diabetes Care, 18(Suppl. 1).

Anderson, J.W., & Gustafson, N.J. (1989). Adherence to high-carbohydrate high-fiber diets. The Diabetes Educator, 15(5), 429-434.

Anson, O., Paran, E., Neumann, L., & Chernichovsky, D. (1993). Gender differences in health perceptions and their predictors. Social Science and Medicine, 36, 419-427.

Ary, D.V., Toobert, D., Wilson, W., & Glasgow, R.E. (1986). Patient perspective on factors contributing to nonadherence to diabetes regimen. Diabetes Care, 9(2), 168-172.

Bech, P. (1987). Quality of life in psychosomatic research. Psychopathology, 20, 169-179.

Bergner, M., Bobbitt, R.A., Carter, W.B., & Gilson, B.S. (1981). The sickness impact profile: Development and final revisions of a health status measure. Medical Care, 19, 787-805.

Brunetti, A., Brunetti, L., Foti, D., Accili, D., & Goldfine, I.D. (1996). Human diabetes associated with defects in nuclear regulatory proteins for the insulin receptor gene. Journal of Clinical Investigation, 97, 258-262.

Burkhardt, C.S., Woods, S.L., Schultz, A.A., Ziebarth, D.M. (1989). Quality of life of adults with chronic illness: A psychometric study. Research in Nursing and Health, 12, 347-354.

Burroughs, T.E., Pontious, S.L., & Santiago, J.V. (1993). The relationship among six psychosocial domains, age, health care adherence, and metabolic control in adolescents with IDDM. The Diabetes Educator, 19(5), 396-402.

Casselith, B.R., Lusk, E.J., Strouse, T.B., Miller, D.S., Brown, L.L., Cross, P.A., & Tenaglia, A.N. (1984). Psychological status in chronic illness: A comparative analysis of six diagnostic groups. The New England Journal of Medicine, 311, 506-511.

Cox, D.R., Fitzpatrick, R., Gore, S.M., Spiegelhalter, D.J., Fletcher, A.E., & Jones, D.R. (1992). Quality-of-life assessment: Can we keep it simple? Journal of the Royal Statistical Society, 155(3), 353-393.

Cronbach, L.J. (1951). Coefficient alpha and the internal structure of tests. Psychometrika, 16, 297-333.

Davis, W.K., Hess, G.E., Van Harrison, R., & Hiss, R.G. (1987). Psychosocial adjustment to and control of diabetes mellitus: Differences by disease type and treatment. Health Psychology, 6(1), 1-14.

de Boer, A.G.E.M., Wijker, W., Speelman, de Haes, J.C.J.M. (1996). Quality of life in patients with Parkinson's disease: Development of a questionnaire. Journal of Neurology, Neurosurgery, and Psychiatry, 61, 70-74.

De Conno, R., Caraceni, Augusto, Gamba, A., Mariani, L., Abbattista, A., Brunelli, C., La Mura, A., & Ventafridda, V. (1994). Pain measurement in cancer patients: A comparison of six methods. Pain, 57, 161-166.

Diabetes Control and Complications Trial Research Group. (1986). The diabetes control and complications trial (DCCT): Design and methodologic considerations for the feasibility phase. Diabetes, 35, 530-545.

Diabetes Control and Complications Trial Research Group. (1987). Diabetes control and complications trial (DCCT): Results of feasibility study. Diabetes Care, 10(1), 1-19.

Diabetes Control and Complications Trial Research Group. (1988). Reliability and validity of a diabetes quality-of-life measure for the diabetes control and complications trial. Diabetes Care, 11(9), 725-732.

Dimsdale & A. Baum (1995). (Eds.), Quality of Life in Behavioral Medicine Research. Hillsdale, NJ: Lawrence Erlbaum Associates.

Drossman, D.A., Patrick, D.L., Mitchell, C.M., Zagami, E.A., & Appelbaum, M.I. (1989). Health-related quality of life in inflammatory bowel disease: Functional status and patient worries and concerns. Digestive Diseases and Sciences, 34, 1379-1386.

Dunn, G. (1989). Design and analysis of reliability studies. New York, NY: Oxford University Press.

Durkin, M.S., Wang, W., Shrout, P.E., Zaman, S.S., Hasan, Z.M., Desai, P., & Davidson, L.L. (1995). Evaluating a ten questions screen for childhood disability: Reliabity and internal structure in different cultures. Journal of Clinical Epidemiology, 48, 657-666.

Epstein, A.M., Hall, J.A., Tognetti, J., Son, L.H., & Conant, L., Jr. (1989). Using proxies to evaluate quality of life: Can they provide valid information about patients' health status and satisfaction with medical care? Medical Care, 27 (Suppl. 3), S91-S98.

Erikson, K.F., & Lindgarde, F. (1991). Prevetion of type 2 (non-insulin-dependent) diabetes mellitus by diet and physical exercise. Diabetologia, 34, 891-898.

Expert Committee of the Canadian Diabetes Advisory Board. (1992). Clinical practice guidelines for treatment of diabetes mellitus. Canadian Medical Association Journal, 147(5), 697-711.

Fertig, B.J., Simmons, D.A., & Martin, D.B. (1995). Therapy for diabetes. In M.I. Harris, C.C. Cowie, M.P. Stern, Boyko, E.J., G.E. Reiber, & P.H. Bennett (Eds.), Diabetes in American (2nd ed.), (pp. 1-14). Bethesda, MD: National Institute of Health.

Fitz, J.D., Sperling, E.M., & Fein, H.G. (1983). A hypocaloric high-protein diet as primary therapy for adults with obesity-related diabetes: Effective long-term use in a community hospital. Diabetes Care, 6, 328-333.

Flanagan, J.C. (1982). Measurement of quality of life: Current state of the art. Archives of Physical Medicine and Rehabilitation, 63, 56-59.

Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., & Gallop, P.M. (1977). Glycosylated hemoglobins and long-term blood glucose control in diabetes mellitus. Journal of Clinical Endocrinology and Metabolism, 44, 859-864.

Garg, A., Grundy, S.M., & Koffler, M. (1992). Effect of high carbohydrate intake on hyperglycemia, islet function, and plasma lipoproteins in NIDDM. Diabetes Care, 15, 1572-1580.

Geiss, L.S., Herman, W.H., Goldschmid, M.G., DeStefano, R., Eberhardt, M.S., Ford, E.S., German, R.R., Newman, J.M., Olson, D.R., Sepe, S.J., Stevenson, J.M., Vinicor, R., Wetterhall, S.F., & Will, J.C. (1993). Surveillance for Diabetes Mellitus - Unites States, 1980-1989. Morbitiy and Mortality Weekly Report, 2 (SS-2), 1-20.

Ghosh, S., & Schork, N.J. (1996). Genetic analysis of NIDDM: The study of quantitative traits. Diabetes, 45, 1-14.

Gilden, J.L., Hendryx, M.S., Clar, S., Casia, C., & Singh, S.P. (1992). Diabetes support groups improve health care of older diabetic patients. Journal of the American Geriatrics Society, 40, 147-150.

Given, C.W., Given, B.A., Gallin, R.S., & Condon, J.W. (1983). Development of scales to measure beliefs of diabetic patients. Research in Nursing and Health, 6, 127-141.

Guyatt, G.H., Berman, L.B., Townsend, M., Pugsley, S.O., & Chambers, L.W. (1987). A measure of quality of life for clinical trials in chronic luncg disease. Thorax, 42, 773-778.

Guyatt, G., Bombardier, C., & Tugwell, P.X. (1986). Measuring disease-specific quality of life n clinical trials. Canadian Medical Association Journal, 134, 889-895.

Guyatt, G., Feeny, D., & Patrick, D. (1991). Issues in quality-of-life measurement in clinical trials. Controlled Clinical Trials, 12 (Suppl.) 81S-90S.

Guyatt, G.H., Feeny, D.H., & Patrick, D.L. (1993). Measuring health-related quality of life. Annals of Internal Medicine, 118, 622-629.

Guyatt, G.H. & Jaeschke, R. (1990). Measurements in clinical trials: Choosing the appropriate approach. In B. Spilker (Ed.), Quality of Life Assessments in Clinical Trials (pp. 131-149). New York, NY: Raven Press.

Guyatt, G.H., Kirshner, B., & Jaeschke, R. (1992). Measuring health status: What are the necessary measurement properties? Journal of Clinical Epidemiology, 45, 1341-1345.

Guyatt, G.H., Veldhuyzen Van Zanten, S.J.O., Feeny, D.H., & Patrick, D.L. (1989). Measuring quality of life in clinical trials: a taxonomy and review. Canadian Medical Association Journal, 140, 1441-1448.

Hadden, D.R., Blair, A.L.T., Wilson, E.A., Boyle, D.McC., Atkinson, A.B., Kennedy, A.L., Buchanan, K.D., Merrett, J.D., Montgomery, D.A.D., & Weaver, J.A. (1986). Natural history of diabetes presenting age 40-60 years: A prospective study of the influence of intensive dietary therapy. Quarterly Journal of Medicine, 59, 579-598.

Hampson, S.E., Glasgow, R.E., & Toobert, D.J. (1990). Personal models of diabetes and their relations to self-care activities. Health Psychology, 9(5), 632-646.

Harman, H.H. (1970). Modern factor analysis (Rev. ed.), (pp. 11-28, 113-134). Chicago, Il: The University of Chicago Press.

Harris, M.I. (1995). Summary. In M.I. Harris, C.C. Cowie, M.P. Stern, Boyko, E.J., G.E. Reiber, & P.H. Bennett (Eds.), Diabetes in American (2nd ed.), (pp. 1-14). Bethesda, MD: National Institute of Health.

Harris, M.I., Hadden, W.C., Knowler, W.C., & Bennett, P.H. (1987). Prevalence of diabetes and impaired glucose tolerance and plasma glucose levels in U.S. populations aged 20-74 years. Diabetes, 36, 523-534.

Hatton, D.C., Haynes, R.B., Oparil, S., Kris-Etherton, P., Pi-Sunyer, F.X., Resnick, L.W., Stern, J.S., Clark, S., McMahon, M., Morris, C., Metz, J., Ward, A., Holcomb, S., & McCarron, D.A. (1996). Improved quality of life in patients with generalized cardiovascular metabolic disease on prepared diets. American Journal of Clinical Nutrition, 64, 935-943.

Hays, W.L. (1988). Statistics (4th ed.), pp. 653-655. Orlando, FL: Holt, Rineholt, & Winston, Inc.

Helmrich, S.P., Ragland, D.R., Leung, R.W., & Paffenbarger, R.S., Jr. (1991). Physical activity and reduced occurrence of non-insulin-dependent-diabetes mellitus. The New England Journal of Medicine, 324, 147-152.

Henry, R.R., Wallace, P., & Olefsky, J.M. (1986). Effects of weight loss on mechanisms of hyperglycemia in obese non-insulin-dependent diabetes mellitus. Diabetes, 35, 990-998.

Hess, G.E., Davis, W.K., & Van Harrison, R. (1986). A diabetes psychosocial profile. The Diabetes Educator, 12(2), 135-140.

Hunt, S., McKenna, S.P., McEwen, J., Backett, E.M., Williams, J., & Papp, E. (1980). A quantitative approach to perceived health status: a validation study. Journal of Epidemiology and Community Health, 34, 281-286.

Hussain, M.A., Schmitz, O., Mengel, A., Keller, A., Christiansen, J.S.m Zapf, J., & Froesch, E.R. (1993). Insulin-like growth factor 1 stimulates lipid oxidation, reduces protein oxidation, and enhances insulin sensitivity in humans. Journal of Clinical Investigaion, 92, 2249-2256.

Iwasaki, N., Kawamura, M., Yamagata, K., Cox, N.J., Karibe, S., Ohgawara, H., Inagaki, N., Seino, S., Bell, G.I., & Omori, Y. (1996). Identification of microsatellite markers near the human genes encoding the beta-cell ATP-sensitive K+ channel and linkage studies with NIDDM in Japanese. Diabetes, 45, 267-269.

Jacobson, A.M., de Groot, M., & Samson, J.A. (1994). The evaluation of two measures of qualtiy of life in patients with type I and type II diabetes. Diabetes Care, 17(4), 267-273.

Jacobson, A.M., de Groot, M., & Samson. J. (1995). Quality of life research in patients with diabetes mellitus. In J.E. Dimsdale, & A. Baum (Eds.), Quality of Life in Behavioral Medicine Research (pp. 241-262). Hilldale, NJ: Erlbaum.

Jaeschke, R. & Guyatt, G.H. (1990). How to develop and validate a new quality of life instrument. In B. Spilker (Ed.), Quality of Life Assessments in Clinical Trials (pp. 131-149). New York, NY: Raven Press.

Kahn, R.C. (1994). Insulin action, diabetogenes, and the cause of Type II Diabetes. Diabetes, 43, 1066-1084.

Kaplan, R.M. (1990). Behavior as the central outcome in health care. American Psychologist, 45, 1211-1220.

Kaplan, R.M., Anderson, J.P., Patterson, T.L., McCutchan, J.A., Weinrich, J.D., Heaton, R.K., Atkinson, J.H., Thal, L., Chandler, J., Grant, I., & the HNRC Group. (1995). Validity of the quality of well-being scale for persons with human immunodeficiency virus infection. Psychosomatic Medicine, 57, 138-147.

Kaplan, R.M., Anderson, J.P., Wu, A.W., Mathews. W.C., Kozin, F., & Orenstein, D. (1989). The quality of well-being scale: Applications in AIDS, cystic fibrosis, and arthritis. Medical Care, 27 (Suppl. 3), S27-S43.

Kaplan, R,M., & Bush, J.W. (1982). Health-related quality of life measurement for evaluation research and policy analysis. Health Psychology, 1, 61-80.

Kaplan, R,M., Bush, J.W., & Berry, C.C. (1976). Health status: Types of validity and the index of well-being. Health Services Research, 11 , 478-507.

Kaplan, R.M., Bush, J.W., & Berry, C.C. (1979). Health status index: Category rating versus magnitude estimation for measuring levels of well-being. Medical Care, 17, 501-525.

Kaplan, R.M., & Hartwell, S.L. (1987). Differntial effects of social support and social network on physiological and social outcomes in men and women with type II diabetes mellitus. Health Pscyhology, 6, 387-398.

Kaplan, R.M., Hartwell, S.L., Wilson, E.K., & Wallace, J.P. (1987). Effects of diet and exercise interventions on control and quality of life in non-insulin-dependent Diabetes Mellitus. Journal of General Internal Medicine, 2, 220-227.

Kavanagh, D.J., Gooley, S., & Wilson, P.H. (1993). Prediction of adherence and control in diabetes. Journal of Behavioral Medicine, 16(5), 509-522.

Kim J.O., & Mueller, C.W. (1978). Factor analysis: Statistical methods and practical issues. In (Eds.), (pp. 7-45, 61-79). Beverly Hills, CA: Sage.

King, H., & Kriska, A.M. (1992). Pevention of type II diabetes by physical training. Diabetes Care, 15 (Suppl. 4), 1794-1799.

Kolaczynski, J.W. & Caro, J.F. (1994). Insulin-like growth factor-1 therapy in diabetes: Physiologic basis, clinical benefits, and risks. Annals of Internal Medicine, 120, 47-55.

Kravitz, R.L., Hays, R.D., Sherbourne, C.D., DiMatteo, M.R., Rogers, W.H., Ordway, L., & Greenfield, S. (1993). Recall of recommendations and adherence to advice among patients with chronic medical conditions. Archives of Internal Medicine, 153, 1869-1878.

Kressin, N., Spiro, A., Bosse, R., Garcia, R., & Kazis, L. (1996). Assessing oral health-related quality of life: Findings from the normative aging study. Medical Care, 34, 416-427.

Kurtz, S.M.S. (1989). Adherence to diabetes regimens: Empirical status and clinical applications. The Diabetes Educator, 16(1), 50-56.

Laupacis, A., Wong, C., Churchill,D., & the Canadian Erythropoietin Study Group. (1991). The use of generic and specific quality of life measures in hemodialysis patients treated with erythropoietin. Controlled Clinical Trials, 12 (Suppl.) 168-179.

Licht, M.H. (1995). Multiple regression and correlation. In L.G. Grimm, & P.R. Yarnold (Eds.), Reading And Understanding Multivariate Statistics (pp. 19-64). Washington, DC: American Psychological Association.

Lord, F.M., & Novick, M.R. (1968). Statistical Theories of Mental Test Scores (pp. 261-283). Reading, MA: Addison-Wesley Publishing Company.

Lydick, E., & Epstein, R.S. (1993). Interpretation of quality of life changes. Quality of Life Research, 2, 221-226,

Macintyre, S., Hunt, K., & Sweeting, H. (1996). Gender differences in health: Are things really as simple as they seem? Social Science and Medicine, 42, 617-624.

Mayou, R., Bryant, B., & Turner, R. (1990). Quality of life in non-insulin dependent diabetes and a comparison with insulin-dependent diabetes. Journal of Psychosomatic Medicine, 34, 1-11.

McHorney, C.A., Ware, J.E., Jr., Lu, J.F.R., & Sherbourne, C.D. (1994). The MOS 36-Item short-form health survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Medical Care, 32(1), 40-66.

McHorney, C.A., Ware, J.E., Jr., & Raczek, A.E. (1993). The MOS 36-Item short-form health survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Medical Care, 31, 247-263.

Meisler, A.W., & Carey, M.P. (1991, March). The diabetic daily hassles scale: Preliminary psychometric. Poster session presented at the annual meeting of the Society of Behavioral Medicine, Washington, DC.

Nathan, D.M., Singer, D.E., Hurxthal, K., & Goodson, J.D. (1984). The clinical information value of the glycosylated hemoglobin assay. New England Journal of Medicine, 310, 341-346.

National Diabetes Data Group. (1979). Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. Diabetes, 28, 1039-1057.

National Diabetes Data Group. (1995). Diabetes in America. In M.I. Harris, C.C. Cowie, M.P. Stern, Boyko, E.J., G.E. Reiber, & P.H. Bennett (Eds.), Diabetes in American (2nd ed.), (pp. 179-220). Bethesda, MD: National Institute of Health.

Nerenz, D.R., Repasky, D.P., Whitehouse, F.W., Kahkonen, D.M. (1992). Medical Care, 30 (Suppl. 5), 112-124).

Orenstein, D.M., & Kaplan, R.M. (1991). Measuring the quality of well-being in cystic fibrosis and lung transplantation: The importance of the area under the curve. Chest, 100, 1016-1018.

Patrick, D.L. & Deyo, R.A. (1989). Generic and disease-specific measures in assessing health status and qualtiy of life. Medical Care, 27 (Suppl. 3), S217-S232.

Pearlman, R.A., & Uhlmann, R.F. (1988). Quality of life in chronic diseases: Perceptions of elderly patients. Journal of Gerontology, 43 (2), M25-M30.

Pedhazur, E.J. (1982). Multiple regression in behavioral research (2nd ed., pp. 233-247). Orlando, FL: Harcourt Brace College Publishers.

Polly, R.K. (1992). Diabetes health beliefs, self-care behaviors, and glycemic control among older adults with non-insulin-dependent diabetes mellitus. The Diabetes Educator, 18(4), 321-327.

Polonsky, K.S., Sturis, J., & Bell, G.I. (1996). Non-insulin-dependent diabetes mellitus- a genetically programmed failure of the beta cell to compensate for insulin resistance. New England Journal of Medicine, 334, 777-783.

Powell, K.E., & Blair, S.N. (1994). The public health burdens of sedentary living habits: theoretical but realistic estimates. Medicine and Science in Sports and Exercise, 26 851-856.

Revicki, D.A. (1990). Quality of life and non-insulin-dependent diabetes mellitus. Diabetes Spectrum, 3(4), 260-266.

Rewers, M., & Hamman, R.F. (1995). Risk factors for non-insulin-dependent diabetes. In M.I. Harris, C.C. Cowie, M.P. Stern, Boyko, E.J., G.E. Reiber, & P.H. Bennett (Eds.), Diabetes in American (2nd ed.), (pp. 179-220). Bethesda, MD: National Institute of Health.

Riddle, M.C. (1993). Strategies for non-insulin-dependent diabetes mellitus. Hospital Practice, April, 14-20.

Rodger, W. (1991). Non-insulin-dependent (type II) diabetes mellitus. Canadian Medical Association Journal, 145(12), 1571-1581.

Rubin, R.R., & Peyrot, M. (1992). Psychosocial problems and interventions in diabetes. Diabetes Care, 15(11), 1640-1657.

Schafer, L.C., Glasgow, R.E., McCaul, K.D., & Dreher, M. (1983). Adherence to IDDM regimens: Relationship to psychosocial variables and metabolic control. Diabetes Care, 6(5), 493-498.

Schafer, L.C., McCaul, K.D., & Glasgow, R.E. (1986). Supportive and nonsupportive family behaviors: Relationships to adherence and metabolic control in persons with type I diabetes. Diabetes Care, 9(2), 179-185.

Scheier, M.F., Carver, C.S., & Bridges, M.W. (1994). Distinguishing optimism from neuroticism (and trait anxiety, self-master, and self-esteem): A reevaluation of the life orientation test. Journal of Personality and Social Psychology, 67, 1063-1078.

Schipper, H., Clinch, J.J., & Olweny, C.L.M. (1996). Quality of life studies. In B. Spilker (Ed.), Quality of life and pharmacoeconomics in clinical trials (pp. 11-23). Philadelphia, PA: Lippincott-Raven Publishers.

Schipper, H., Clinch, J., & Powell, V. (1990). Definitions and conceptual issues. In B. Spilker (Ed.), Quality of Life Assessments in Clinical Trials (pp. 11-24). New York, NY: Raven Press.

Shenkel, R.J., Rogers, J.P., Perfetto, G., & Levin, R.A. (1985). Importance of "significant others" in predicting cooperation with diabetic regimen. International Journal of Psychiatry in Medicine, 15(2), 149-155.

Sowers, J.R., & Epstein, M. (1995). Diabetes mellitus and associated hypertension, vascular disease, and nephropathy: An update. Hypertension, 26, 869-879.

Spilker, B. (1990). Introduction. In B. Spilker (Ed.), Quality of Life Assessments in Clinical Trials (pp. 3-9). New York, NY: Raven Press.

Sprangers, M.A.G., & Aaronson, N.K. (1992). The role of health care providers and significant others in evaluating the quality of life of patients with chronic disease: A review. Journal of Clinical Epidemiology, 45, 743-760.

Stewart, A.L., Greenfield, S., Hays, R.D., Wells, K., Rogers, W.H., Berry, S.D., McGlynn, E., & Ware, J.E., Jr. (1989). Functional status and well-being of patients with chronic conditions: Results from the medical outcomes study. Journal of the American Medical Association, 262, 907-913.

Stewart, A.L., Hays, R.D., & Ware, J.E., Jr. (1988). The MOS short-form general health survey: Reliability and validity in a patient population. Medical Care, 26(7), 724-735.

Tabachnick, B.G., & Fidell, L.S. (1989). Using multivariate statistics (2nd ed., pp. 58-122). New York, NY: Harper Collins Publishers, Inc.

Taylor, R., Fostr, B., Kyne-Grzebalski, K., & Vanderpump, M. (1994). Insulin regimens for the non-insulin-dependent: Impact on diurnal metabolic state and quality of life. Diabetic Medicine, 11, 551-557.

Taylor, S.I. (1992). Lessons from patients with mutations in the insulin-receptor gene. Diabetes, 41, 1473-1490.

Taylor, S.I., Accili, D., & Imai, Y. (1994). Insulin resistance or insulin deficiency: Which is the primary cause of NIDDM? Diabetes, 43, 735-739.

Testa, M.A. (1987). Interpreting quality-of-life clinical trial data for use in the clinical practice of antihypertensive therapy. Journal of Hypertension, 5(Suppl. 1), S9-S13.

Toobert, D.J. & Glasgow, R.E. (1991). Problem solving and diabetes self-care. Journal of Behavioral Medicine, 14(1), 71-85.

UKPDS. (1983). UK prospective study of therapies of maturity-onset diabetes: I. Effect of diet, sulphonylurea, insulin or biguanide therapy on fasty plasma glucose and body weight over one year. Diabetologia, 24, 404-411.

U.K. Prospective Diabetes Study Group. (1991). UK prospective diabetes study (UKPDS) VIII. study design, progress and performance. Diabetologia, 34, 877-890.

U.K. Prospective Diabetes Study Group. (1995). U.K. prospecitve diabetes study 16: Overview of 6 years' therapy of type II diabetes: A progressive disease. Diabetes, 44, 1249-1258.

Uusitupa, M.I.J., Niskanen, L.K., Siitonen, O., Voutilainen, E., & Pyorala, K. (1993). Ten-year cardiovascular motrtality in relation to risk factors and abnormalities in lipoprotein composition in type 2 (non-insulin dependent) diabetic and non-diabetic subjects. Diabetologia, 36, 1175-84.

Vickrey, B.G., Hays, R.D., Rausch, R., Sutherling, W.W., Engel, J., Jr., & Brook, R.H. (1994). Quality of life of epilepsy surgery patients as compared with outpatients with hypertension, diabetes, heart disease, and/or depressive symptoms. Epilepsia, 35, 597-607.

Ward, A.A., & Hatton D.C. (1995, March). Nutrition Hassles: Testing a new questionnaire. Poster session presented at the annual meeting of the Society of Behavioral Medicine, San Diego, CA.

Ware, J.E., Jr., Sherbourne, C.D. (1992). The MOS 36-Item short-form health survey (SF-36): I. Conceptual framework and item selection. Medical Care, 30(6), 473-483.

Weinberger, M., Kirkman, M.S., Samsa, G.P., Cowper, P.A., Shortliffe, E.A., Simel, D.L., & Feussner, J.R. (1994). The relationship between glycemic control and health-related quality of life in patients with non-insulin-dependent diabetes mellitus. Medical Care, 32, 1173-1181.

Wilson, W., Ary, D.V., Biglan, A., Glasgow, R.E., Toobert, D.J., & Campbell, D.R. (1986). Psychosocial predictors of self-care behaviors (compliance) and glycemic control in non-insulin-dependent diabetes mellitus. Diabetes Care, 9(6), 614-622.

Wing, R.R., Epstein, L.H., Nowalk, M.P., Koeske, R., & Hagg, S. (1985). Behavior change, weight loss, and physiological improvements in type II diabetic patients. Journal of Consulting and Clinical Psychology, 53, 111-122.

Wolffenbuttel, B.H.R., & van Haeften, T.W. (1995). Prevention of compications in non-isulin-dependent diabetes mellitus (NIDDM). Drugs, 50, 263-288.

Wool, C.A. & Barsky, A.J. (1994). Do women somatize more than men? Gender differences in somatization. Psychosomatics, 35, 445-452.

Wooldridge, K.L., Wallston, K.A., Graber, A.L., Brown, A.W., & Davidson, P. (1992). The relationship between health beliefs, adherence, and metabolic control of diabetes. The Diabetes Educator, 18(6), 494-500.

World Health Organization. (1947). Development and constitution of the W.H.O. Chronicle of the World Health Organization, 1, 29.

Zenobi, P.D., Jaeggi-Groisman, S.E., Riesen, W.F., & Froesch, E.R. (1992). Journal of Clinical Ivestigation, 90, 2234-2241

Zimmerman, B.R., & Service, F.J. (1988). Management of noninsulin-dependent diabetes mellitus. Medical Clinics of North America, 72(6), 1355-1364.