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The Problem Areas in Diabetes scale: A follow-up study

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THE PROBLEM AREAS IN DIABETES SCALE:
A FOLLOW-UP STUDY

by

Roslyn M. Collins
Bachelor of Science,
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1994

A thesis submitted in partial fulfillment
of the requirements for the

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Department of Nursing
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ABSTRACT

The Problem Areas in Diabetes Scale: A Follow-Up Study

by

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Currently many support and educational services are available for persons with type 2 diabetes mellitus. Yet there are still numerous people with less than desirable long-term outcomes in terms of overall health status. The Problem Areas in Diabetes scale is a newly developed instrument designed to measure emotional distress associated with the diagnosis of diabetes mellitus. Results of its use have been previously published for three different population groups. The primary focus of this study was to describe the relationship between the scores on the Problem Areas in Diabetes scale and HbA1C laboratory test results for persons with type 2 diabetes mellitus. The relationship between the Problem Areas in Diabetes scale and other variables such as age, gender, race/ethnicity, length of time since diagnosis, and type of treatment for those same individuals have also been considered.
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CHAPTER 1

DIABETES MELLITUS

Introduction

This chapter will discuss some of the effects diabetes mellitus has on individuals and the economy. The differences in diabetes diagnoses and treatments will be explained. Nursing relevance will be addressed. The importance of two landmark studies, the “Diabetes Control and Complications Trial” and the “United Kingdom Prospective Diabetes Study” will be highlighted. The Problem Areas in Diabetes scale (PAID) will be discussed as an instrument used to assess diabetic patients’ abilities for self-care.

Statistics and Complications

In terms of health care dollars alone, $45 billion is spent annually to diagnose and treat patients with Type 1 and Type 2 diabetes, based on statistics published by Lehigh Valley Hospital and Health Network (1998). The Lehigh survey states that other related costs including absenteeism from work, disabilities, and mortality total $47 billion annually (1998). Diabetes has been the seventh leading cause of death in this country for several years during the previous decade of the 1990s, according to the
Center for Disease Control's National Center for Health Statistics (1998). Because diabetes impacts almost all of the organ systems in the body, there are many possible complications, including end-stage renal disease, blindness, cardiovascular disease, amputations, peripheral vascular disease, and neuropathy.

Current Strategies

Doctors, pharmacists, nurses and dietitians work one-on-one and in groups with both newly diagnosed and long-term diabetic patients. Educational opportunities are available to most patients with DM to learn new information and reinforce their existing knowledge. New medications are frequently introduced which offer increased potential for improved blood glucose control. Millions of DM information pamphlets are printed and distributed yearly by different profit and non-profit agencies. Public service announcements can be seen and heard via television and radio.

To assist individuals in monitoring their blood sugar, simple blood-glucose testing meters are readily available from a wide variety of competitive providers. These are available in pharmacies, chain stores, or through mail order companies. Recent changes in both state and federal laws have provided coverage for diabetes-related supplies for nearly all persons diagnosed with both Type 1 and Type 2 DM.

Type 1 and Type 2 Diabetes Mellitus

Persons with DM are usually divided into two different groups as determined by their insulin production. Type 1 patients (earlier known as Insulin Dependent Diabetes Mellitus or IDDM) require insulin injections because their pancreas does not produce any
insulin. In Type 2 DM (previously known as Non-Insulin Dependent Diabetes Mellitus or NIDDM), patients produce insulin, but it is either too little or resistance to the insulin has developed. The Type 2 patients can be treated with several regimens including diet and exercise alone, oral medications, insulin or combinations of these three. Persons with Type 1 DM will always require insulin. While these are extremely simplified definitions of Type 1 and Type 2 DM, many subtleties are involved and the distinction between diagnoses is evident.

Reducing Complications of Type 1 and Type 2 Diabetes Mellitus

Two landmark studies have been published which verify that the progression of diabetes related symptoms and consequences can be reduced, and sometimes almost completely eliminated. The Diabetes Control and Complications Trial (DCCT) (Diabetes Control and Complications Trial Research Group, 1993) established that tight blood glucose control greatly reduced diabetes-related symptoms in Type 1 patients. The United Kingdom Prospective Diabetes Study (1998) was published which demonstrated the same results for Type 2 patients independent of treatment regimen.

Klonoff and Schwartz (2000) conducted a literature review in order to stratify financial impact of those interventions that are most beneficial. These interventions included a yearly eye examination with dilation, pre-conception care for women with diabetes planning to become pregnant, and diabetic nephropathy screening and related interventions. In the area of preventing and/or treating diabetic retinopathy alone, the financial advantage (adjusted for inflation to 1998) was $2,613.00 per patient, per year.
This number took into account the cost of assessment and intervention for all diabetic patients studied. This was compared to the cost of rehabilitation and financial support for those that were not regularly evaluated or treated and where blindness was the consequence. For persons with Type 1 DM screened and treated for nephropathy, 2.15 years of life were gained per patient with direct savings per year of $17,371.00 (adjusted for inflation to 1998). The program for pre-conception care showed two benefits. The incidence of fetal malformations and spontaneous abortions was reduced and $10,637.00 (in 1998 dollars) was saved per live infant.

Significance to Nursing

Nurses have a formidable task to help patients improve their health status and therefore their overall quality of life. The Nevada State Board of Nursing: Nurse Practice Act (1996) defines the Practice of Professional Nursing as being paid for any action taken towards the caring, watching or teaching of others in the areas of health maintenance or prevention. Consequently, assisting patients with their treatment plans becomes an essential nursing obligation. It behooves nurses to work toward identifying factors that contribute to successful patient outcomes as this will help decrease both the humane and economic consequences of this chronic disease.

Failure to Adhere to Treatment Programs

The majority of diabetes-related studies have focused on the success or failure of different treatment regimens and identified factors that contribute to non-adherence to these programs. Even with all that has been learned and applied from these studies, many
patients still do not follow their physician’s advice. The outcome is frequently a significant reduction in quality of life due to both health problems and related financial status changes that follow complications of diabetes. If patients do not follow their health care providers’ prescribed plans, diabetes will continue to adversely impact their lives, the health care system in general, and the financial resources of this country. There is a need to identify those patients least likely to follow their diabetes treatment regimens in order to design interventions specifically for them in the hope of reducing the complications from uncontrolled diabetes.

The Problem Areas in Diabetes Scale

Three studies involving the PAID have found that it can determine which patients are experiencing the most diabetes-related distress (Polonsky et al, 1995; Welch, Jacobson and Polonsky, 1996; and Snoek, Pouwer, Welch and Polonsky, 2000). This scale has potential to predict which patients need more intense intervention from their health care providers in order to enhance glucose control. The authors have attempted to associate the PAID score with an objective measure of glycemic control, the HbA1C level.

According to Glasgow (1997), other instruments for health protection have been proposed, but few are currently used in the clinical environment because of various factors ranging from reliability to practicality. The succinctness of the PAID facilitates its use to highlight underlying problem areas faced by patients in regard to their DM.

Three studies have been published using this tool. The first, “Assessment of Diabetes Distress” (Polonsky et al) was published in 1995. Female patients with Type 1 and Type 2 DM participated. The second study, “The Problem Areas in Diabetes Scale”
(Welch, Jacobson and Polonsky, 1996) had a population group consisting of persons with Type 1 or Type 2 DM. Then the instrument was used again with American and Dutch patients with either Type 1 or Type 2 DM. The results of this study “Diabetes-Related Emotional Distress in Dutch and U.S. Diabetic Patients” (Snoek, Pouwer, Welch and Polonsky) were published in 2000. In all three of these studies, the authors suggested that further research be done using different population groups in order to further establish its validity and reliability.

No studies using the PAID Scale had been done where persons diagnosed with Type 2 DM were the sole focus. Consequently, this study concentrated on this group of patients alone.

Study Purpose

The purpose of this follow-up study was to determine if a relationship existed between blood glucose control, as measured by HbA1C levels, and scores on the PAID for a group of patients previously diagnosed with Type 2 diabetes. Other variables that could contribute to the PAID scores were investigated. These included age, gender, race/ethnicity, length of time since diagnosis with Type 2 diabetes mellitus, and treatment method.
CHAPTER 2

REVIEW OF RELATED LITERATURE

Introduction

Diabetes Mellitus is a condition that effects millions of people nationwide. While it is well known and well researched, there exists a definite differentiation between those diagnosed diabetic patients who are able to control their condition and those that are not. Thus, it becomes increasingly important from both humanistic and fiscal perspectives to isolate the details that separate the two groups. Researchers agree that The Problem Areas in Diabetes scale (PAID) was proposed for this reason.

The purpose of this chapter is to discuss factors relevant to medical treatment adherence and to review literature related to the development of the PAID. The instruments and tools used to establish its' validity are addressed. Discussion related to other variables such as age, gender, race/ethnicity, length of time since diagnosis, and type of treatment will be presented.

Compliance with Treatment Programs

Many items have been previously identified as important to successful self-care behaviors and how they affect adherence with treatment program regimens. These
include self-efficacy, educational level, cultural background, and financial status (Glasgow, Toobert, Hampson, and Wilson, 1995). In addition, social and family support have contributed to following the diabetes treatment program regimen and increased quality of life (Glasgow and Toobert, 1988; Littlefield, Rodin, Murray, and Crave, 1990; and Sherbourne, Hays, Ordway, DiMatteo, and Kravitz, 1992). Barriers to treatment compliance were identified and validated in earlier studies (Glasgow, McCaul, and Schafer 1984). Devine and Reifschneider (1994) conducted a meta-analysis of research done with hypertensive patients to determine the effects that patient education and support systems had on different factors including medication adherence. While the focus of their research was on hypertensive patients, their concluding recommendation was for ongoing patient education. This is appropriate for a wide variety of clients. Haynes (1979) showed that there is a direct relationship between knowledge of a medical condition and treatment compliance. Dunn, Smartt, Beeney, and Turtle (1986) concluded that there were so many factors involved in maintaining glycemic control that only complex analyses of different causal relationships would be meaningful. Many current research topics are focusing on these perplexing relationships in the hopes of identifying means by which patient care and patient self-efficacy can be enhanced.

Tools have been developed for measuring the various aspects involved in patient compliance. These have culminated in a general conclusion that increasing all aspects of patient knowledge of a chronic illness will increase acquiescence with the treatment program and therefore decrease resistance to compliance. But it has also been shown that understanding the disease process alone does not predict compliance (Pfister-
Pfister-Minogue (1993) advises nurses to conduct personalized assessments of all aspects of the patient’s life from dietary habits to activity levels and sleeping times. Kern, Penick, and Hamby (1996) also agree that strategies to increase adherence among patients should be individualized. Knowles (1984) advised questioning patients regarding their previous life experiences in order to design successful, individualized teaching programs. The recommendations in the nursing literature for determining patient needs regarding their illnesses would require extended time allocations making the feasibility unrealistic. A close patient-nurse relationship is ideal. However, the realities of economics and staffing shortages preclude that association in many cases.

Orem (Randell, 1992) recommended using technology to make nursing more practical. One way to do this would be to devise a tool that could quickly identify not only those patients in need of more intensive nursing interventions but where those interventions should be focused as well.

Glasgow (1997) specifically described factors that are important in any tool used to evaluate persons with diabetes. He concluded that such a tool must be relevant to both behavioral and psychosocial issues in order to obtain the best patient outcomes.

There were other facets that Glasgow (1997) found to be important in using a tool for the assessment of persons with diabetes. The first facet was utility which Glasgow (1997) defined as reliability and validity. He found that the developers of most tools for diabetic studies did not conduct longitudinal research to give their tools predictive validity. Another consideration with utility is that tools must be sensitive in such areas as cultural differences, age differences, and the literacy level of the reader.
The agency using the instrument must be able to easily determine if it is appropriate for the population group for which it is intended.

Practicality is the second concern. The cost of the use of the instrument includes the test purchase price and the amount of time involved to administer and score the test.

A third factor was whether a tool would assess general medical needs or those related specifically to a diabetes-related diagnosis. In addition, the form in which the test is given must be related to the needs and skills of the patient and the environment in which the test will be administered. For example, ideal measurement instruments can be completed on a computer, via the telephone, or in a person-to-person interview. Knowledge of factors associated with levels of glycemic control will allow all members of the health care team to appropriately match their efforts to the patients needing them the most (Nichols, Hillier, Javor, and Brown, 2000).

The Problem Areas in Diabetes Scale

The PAID was developed on the premise that there exists a relationship between emotional distress, specifically related to being diagnosed with diabetes, and adherence to the self-care behaviors that persons with diabetes need to accomplish, such as blood glucose testing, dietary control, and medication administration (Polonsky at al. 1995; Welch, Jacobson, and Polonsky, 1996). The results of the first use of the scale were published by its’ designers in 1995. The only information available on its use is derived from studies conducted by the instrument’s designers.
Development of the Problem

Areas in Diabetes Scale

The PAID instrument is a twenty-item scale with questions originally derived during meetings of health care providers at the Joslin Diabetes Treatment Center. Prior to the development of the instrument, a pilot study was undertaken using questionnaires administered to 25 insulin-using patients. Based on their responses, the original items were modified or eliminated and new questions were added. The questions the team retained represented different areas of diabetes-related distress.

General themes of the PAID included anger, interpersonal distress, and frustration associated with the diabetes diagnosis. Each item was answered using a six-point Likert scale. Study participants rated each item according to how much of a problem that area was for them. The scales ranged from one to six with the one being “no problem” and the six representing a “serious problem.” The total numbers representing the answers for each question were then tallied with a range of total scores from 24 to 144.

Establishing Validity and Reliability

The PAID was first used in a study at the Joslin Diabetes Center. Female patients (N=451) diagnosed with either Type 1 or Type 2 diabetes participated (Polonsky et al. 1995). Following completion of the PAID, this group of patients answered additional questions from previously established measures. These were chosen to correspond to the more specific questions included in the new instrument. These are detailed in the following section.
Brief Symptoms Inventory

The Brief Symptom Inventory is a multidimensional measure of psychological and physical distress developed by Derogatis in 1975. It uses a 53 item Likert scale to collect and describe symptoms for classification of psychological problems. The groups used to standardize test scores were psychiatric patients, ranging in age from adolescence to adult, including whites, non-whites, male and female inpatients and outpatients (NCS, 1999).

According to Benishek, Hayes, Bieschke, and Stoffelmayr (1998), a shorter version of the Brief Symptom Inventory was found to be inadequate in the assessment of psychological symptoms in the general population. This led to concerns about the Brief Symptom Inventory itself. The results of research conducted by Benishek, Hayes, Bieschke, and Stoffelmayr (1998) found that the “nine dimensions of the BSI were not supported via exploratory of confirmatory factor analyses” (p.110). However, it was used prior to 1998 by the PAID developers to correlate feelings of overall distress displayed by the participants. Internal reliability for the aspect of the scale was high, $\alpha = 0.97$, and its use appeared appropriate based on the information given.

Bulemia Test-Revised

The authors had evidence that many persons with diabetes acknowledge eating-related concerns, therefore one aspect of internal reliability, $\alpha = 0.95$, was established by use of the Bulimia Test-Revised. A dearth of journal articles explaining or documenting this test exists. The test has been used in additional research projects by the authors, although no added findings have resulted. The researchers stated that they used this measure because eating distress was identified as a problem during the
development of the PAID. It would appear, however, that eating distress for persons with diabetes is based on different factors than those of patients diagnosed with bulimia. According to Gelfand, Jensen, and Drew (1997), bulimia is seen most frequently in young, normal weight range females. Persons with diabetes represent both genders, all ages, and weight ranges, with the average age of 36.3 years (± 13.4) for the study participants.

Over sixty percent of persons with Type 2 diabetes in Western countries are obese according to Wing, Marcus, Epstein, and Jawad, (1991). Thompson, Cummings, Chalmers, Gould, and Newton (1996) reporting on patient reactions to the Diabetes Control and Complications Trial, found that many patients (no statistic given) were worried about the potential for weight gain if they followed intensive insulin therapy guidelines. While the basic reason for using this test is understood because the difficulties associated with menu choices for persons with diabetes causes distress, overall the use appears inappropriate for the reasons outlined.

Worry Subscale

A worry subscale from the Hypoglycemia Fear Survey was used to investigate the degree of worry about hypoglycemia and the avoidance behaviors used to ameliorate the concern. This was another factor that the authors of the PAID had identified as an area of concern for persons with diabetes that could affect their compliance behaviors. Again, this would seem appropriate because many patients are aware that severe hypoglycemia develops quickly and can be fatal. Indeed, Thompson et al (1996) state that “fear of hypoglycemia concerns all age-groups.” This conclusion was reached following the distribution of a leaflet describing the results of the Diabetes
Control and Complications Trial to 771 diabetic patients between fifteen and sixty years of age. Subjects were asked to complete a questionnaire describing their responses to the leaflet and their responses were evaluated. These results support the inclusion of the worry sub-scale.

Cox, Irvine, Gonder-Frederick, Nowacek, and Butterfield (1987) discussed several factors related to fear of hypoglycemia including patients associating negative moods with hypoglycemia. That perceived fear motivated patients to maintain higher glycemic levels than was considered optimum. Research conducted in Germany had subjects who were exposed to forced hypoglycemia via insulin infusion. Just one episode of experiencing the symptoms associated with hypoglycemia (weakness, blurred vision, headache, anxiety, dizziness and drowsiness) caused many of the same subjects to report these symptoms again, even while receiving a saline-only infusion. This research found that fear of hypoglycemia will influence psychophysiological processes with or without actual decreased blood sugar levels (Pohl, Frohnau, Kerner and, Fehm-Wolfsdorf, 1997).

Cox, Kieman, Schroeder, and Cowley (1998) concluded that loss of vision related to diabetes caused subjects to suffer from many more psychological and physiological symptoms related to hypoglycemia than a control group without vision deficits. The entire Hypoglycemia Fear Survey was used in this study. Internal reliability from this measure was $\alpha = 0.94$.

**Self-Care Inventory**

The Self-Care Inventory has been designed to appraise the behaviors patients use to follow their treatment regimens. It has questions specifically related to diabetes.
Polonsky et al (1995) found that internal reliability was acceptable, although it was significantly lower than the Brief Symptoms Inventory, the Bulemia Test-Revised, and the Worry Subscale. The subscale results listed consisted of blood glucose testing, $\alpha = 0.81$, using insulin correctly, $\alpha = 0.53$, use of food, $\alpha = 0.71$, and use of exercise, $\alpha = 0.65$.

Other clinical elements were also considered. Subjects were asked to state the blood glucose levels at which they personally would treat their own hypoglycemia (low blood glucose) and hyperglycemia (high blood glucose). While this would establish validity for the scale to be used with insulin-dependent diabetics, it would not apply to patients using oral agents or diet and exercise alone as they have no treatment mechanism. In addition, the extreme ramifications of high blood glucose levels are dependent on whether or not the patient is producing endogenous insulin. A Type 1 diabetic patient can quickly go into ketoacidosis, a potentially fatal condition while a Type 2 patient with some naturally produced insulin generally will not.

The levels at which patients would treat their blood sugars were collected to determine if higher numbers correlated with poor adherence to the treatment regimen. It would seem reasonable for the authors to recognize that the choice of these minimum/maximum numbers would be different depending on the treatments used by the patient group. For example, some patients use an insulin sliding scale to treat hyperglycemia starting at relatively low elevated blood glucose levels, while others are told to call their physician if their blood sugar is over 300. The authors did not acknowledge these dilemmas.
Hemoglobin Testing

Information regarding other clinical variables such as HbA1 (as representative of overall blood glucose control over the previous six to eight weeks) and the presence of neuropathy and retinopathy were also collected by the investigators. The HbA1 is a laboratory measurement used as a standard measurement of glycemic control. Lewis Morrow M.D., Endocrinologist for the University of Nevada School of Medicine, Reno, stated that this “was just an earlier and much simpler version of the HbA1C test” currently used in most institutions. According to the American Diabetes Association’s Standards of Care (2000), this type of test should be performed at regular two to three month intervals for all persons with diabetes. This is especially beneficial for newly diagnosed diabetics or when medication changes have been made. Laboratory normal range (non-diabetic persons) for the HbA1 is 5.0 – 7.5%, with a target level (for persons with diabetes) of less than 8.8%.

Data necessary for a longitudinal study, such as the presence of neuropathies and retinopathy were collected. The authors also recorded the HbA1 levels of these patients two years later in order to establish test-retest reliability.

Results of the First Use of the
Problem Areas in Diabetes Scale

Overall, when the resulting data were analyzed, it was to determine if the PAID scale had construct and predictive validity. This was done through correlating with other measures used and the PAID’s ability to forecast future and concurrent medical events for the study participants. Using Pearson correlations, analyses of variance, and
hierarchical multiple regressions, the authors drew the following conclusions from their study. First, the authors identified those items that caused diabetic patients to have the greatest levels of distress. The authors also looked specifically at the relationship between self-care behaviors, initial HbA1c and HbA1c results at follow-up. It was determined that scores of the PAID were closely associated with important adherence behaviors (blood glucose testing, insulin usage and meal planning) and harmful blood glucose levels. High levels of diabetes-related distress were also closely related to elevated blood glucose levels.

Polonsky et al (1995) concluded that this study with the PAID appeared promising because it supported the hypothesis that distress, specifically related to diabetes, and not general emotional distress contributes to poor adherence to a diabetes care program. The authors felt that the PAID was assessing those areas associated with the diabetes diagnosis that affect clinical outcomes. The PAID was determined to be positively correlated with HbA1c levels.

The authors clearly felt that the results did not necessarily indicate that the PAID could be used as a future predictor of program adherence. The baseline HbA1c level was felt to be more valuable as a predictor of diabetes control at the one year time frame than the PAID, unless there was a marked behavioral change caused by a major life event. Polonsky et al (1995) acknowledged that the results of their study could not be generalized because of the specific nature of the population. But the authors were still optimistic that use of the scale could identify those patients with high levels of diabetes-related distress (Polonsky et al, 1995).
In contrast to the conclusions reached with the PAID, a study conducted in Sweden determined that generalized positive and negative stressful life events could effect blood glucose levels (Stenstrom, Wikby, Hornquist, and Anderson, 1993). However, the authors found that men and women react differently. Women had lower HbA1C levels relative to the total overall number of stressful events while men had higher HbA1C levels. The HbA1C of the men also became higher as the number of negative stressful events increased. With women, a higher percentage of negative stressors did not appear to change the HbA1C score significantly in either direction.

A later study by Lloyd, Dyer, Lancashire, Harris, Daniels, and Barnett (1999) also investigated the responses of persons with diabetes to positive, negative and significant personal stress. The HbA1C level was again used as the measure of glycemic control. The results of this study differed from the one conducted by Stenstrom, Wikby, Hornquist, and Anderson (1993) in that no gender difference was recorded.

Second Use of the Problem Areas in Diabetes Scale

The PAID was next used in another study at the Joslin Diabetes Center, (Welch, Jacobson, and Polonsky, 1996). The population was men and women with either Type 1 or Type 2 diabetes (N=256). A comparison was done with outcomes of the PAID to determine if there were higher levels of distress in persons with Type 1 versus Type 2 diabetes. A second hypothesis considered three treatment groups of Type 2 patients consisting of those treated with diet and exercise alone; those using oral medications, and those on insulin. It was felt that PAID scores would be lowest for Type 2 patients.
treated with diet and exercise. In addition, the scores would be increased for the Type 2 patients using oral medications while those taking insulin would have the highest scores. Other aspects of the emotional functioning of persons with diabetes were investigated.

The PAID scoring was changed for this study to range of 20 – 100. In the first study the range was from 24-144. According to the authors, the range would make interpretation easier. Higher scores would show that the patients were experiencing more emotional distress related to diabetes. Other instruments were administered concurrently with the PAID in the continuing effort to establish validity.

**Coping Attitudes**

Several different scales were used to assess the relationship of coping attitudes to a diabetes diagnosis, the ATT39 and the three coping subscales of the Diabetes Coping Measure (DCM). The ATT39 is a measure of emotional adjustment in diabetic patients. It measures different factors including stress and guilt. Internal consistency was 0.86 and test-retest reliability varied from 0.70 to 0.87 over time (Dunn, Smartt, Beeney, and Turtle, 1986). The Diabetes Coping Measure (Welch, G. 1994) investigates the respondents’ thought process and behaviors specific to diabetes.

**Diabetes Support Scale**

The Diabetes Support Scale examines patient perception of social support for their diabetes from family members, friends and health care personnel. Reliability and validity are not claimed for these scales, instead, the authors state only that these scales were developed from earlier grounded theoretical research.
Health Belief Model

The Health Belief Model assesses the patient’s personal attitudes towards five different themes that address the ability of a patient to take appropriate action when confronted with medical symptoms (Janz and Becker, 1984). A general theme is motivation to learn related to the health concern being addressed. The patient must agree that there is susceptibility to the disease process. It had been previously determined that those persons with scores showing them to be well adjusted would have better blood glucose control and self-care behaviors than those who were not well adjusted.

Laboratory Findings

HbA1C values were collected both at baseline, which was defined as within one month after completion of the PAID, and one-year later. It should be noted that this laboratory blood test is a variation from the HbA1 test used in the earlier study. The reporting ranges of the results are distinctly different, but it also measures average glycemic control over the previous eight weeks. The HbA1C target range (ideal for persons with diabetes) is 7.0% with a laboratory normal range of 4.0 – 6.0%.

Results of the Second Use of the Problem Areas in Diabetes Scale

With the second study, the authors supported their first hypothesis that there is a difference between the PAID scores of Type 1 and Type 2 patients, with the Type 1 group demonstrating more diabetes-related distress. The second hypothesis was not supported. The differences in the scores of the insulin treated and the oral medication
treated groups of Type 2 patients were not significant. This result has been substantiated in other research studies (Nichols, Hillier, Javor, and Brown, 2000; and Glasgow and Toobert, 1988). The diet and exercise as treatment group was found to identify very few problems in emotional functioning as related to diabetes.

The authors determined that the PAID was short, simple to score and that it provided data on the emotional status of patients confronted with the reality of having a diabetes diagnosis. However, correlations attempted between the treatment groups and the HbA1C levels were statistically insignificant.

Third Use of the Problem Areas in Diabetes Scale

The PAID was next used in a group (n=1472) of Type 1 and Type 2 DM patients in Holland (Snoek, Welch, Pouwer, and Polonsky, 2000). The authors stated that these patients closely matched the U.S. samples in terms of all demographics but HbA1C values.

This study was conducted differently from the previous two. The PAID scale and the other measures detailed below were mailed to a limited number (3,000) of members of the Dutch Diabetes Association with written instructions on completion. In previous studies, the PAID was administered in person prior to clinic appointments. Additional data collected included the number of severe hypoglycemic events during the preceding six months and the number of diabetic ketoacidosis (DKA) episodes during the previous year. Patients also reported their own HbA1C values.

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Worry Subscale

The Dutch version of the Worry Subscale was used to assess fear of hypoglycemia. It was determined to have good internal consistency (Cronbach’s $\alpha=0.92$). This subscale was also used in the first two studies conducted in the United States with the PAID.

The (Bradley) Well-Being Questionnaire.

This test was used to measure emotional status. It was found to have “satisfactory” factorial and convergent validity. Internal consistency was acceptable at $\alpha=0.73$-$0.87$. Test-retest reliability was adequate at 0.66-$0.80$.

The Trait Anxiety Subscale of the State Trait Anxiety Inventory

This scale was used to assess patient status in general. The authors reported good internal consistency ($\alpha=0.90$) and test-retest reliability ($\alpha=0.85$).

Both the (Bradley) Well-Being Questionnaire and The Trait Anxiety Subscale of the State Trait Anxiety Inventory were new questionnaires introduced as a way to establish validity, internal consistency, and test-retest reliability. Both were used in their Dutch versions.

Results of the Third Use of the Problem Areas in Diabetes Scale

While no hypotheses were listed for this study, the authors determined that American and Dutch patients experience stress in similar problem areas associated with their DM diagnosis. However, the U.S. patients showed more distress with their diagnosis in general. There were several possible explanations presented as reasons for
this including the way in which the sample was obtained as compared to the U.S. patients. The Dutch patients were mailed the questionnaires whereas the U.S. patients completed their questionnaires in the clinic environment.

The authors noted that the lower mean HbA1c values (Dutch value 7.7%, American value 9.9%) that were recorded by the Dutch patients compared to the American patients could have been caused by false reporting or by differences in laboratory procedures.

**Overall Outcomes of Use of the Problem Areas in Diabetes Scale**

The results compiled show that the PAID scale has concurrent validity with other tests used. While the first use showed a relationship between the PAID and HbA1c levels, this was not upheld in the second and third studies where the correlations were statistically insignificant. An attempt by the authors to explain this continues to be unclear. However, a qualitative research study done with Type 2 patients by Handron and Leggett-Frazier (1994) may help with clarification. Handron and Leggett-Frazier (1994) found that when stress levels were high, denial techniques were often used, sometimes to the point of failure to follow a diabetes treatment regimen. These patients also had a tendency to deny the impact of diabetes as a serious illness. This is in keeping with the Health Belief Model. Consequently, patients may not always answer questions truthfully.
Welch, Jacobson, and Polonsky (1996) determined that the PAID had high internal reliability and could be confidently used as both an assessment and monitoring tool to screen the emotional status of persons with diabetes. It was also stated that individual PAID questions could be used to confirm specific problem areas for individual patients. The authors advised that using the questions in this way would not be as accurate as using the scale as a whole.

The authors established with the first study that the PAID correlated positively with blood glucose control as measured by the HBA1c but was not a predictor of future values. This study was done using female patients with Type 1 DM. The investigators felt that this result was due in part to the short-term nature of their project and also because of the different stages of disease process and treatment represented in their study sample. Consequently, longitudinal studies were recommended comparing blood glucose control and emotional status over an extended period of time.

A potentially significant short-term result was that the HBA1c levels of patients in the first two studies who refused to answer or did not complete the study questions was elevated above the norm as compared to the contributing patients. With these patients and the sample in general, further analysis of statistics did indicate that the PAID scale does recognize appropriate health-related attitudes for diabetic patients and has construct validity.

Important to note is that the PAID scale meets most of the criteria established by Glasgow (1997) for a useful assessment tool. It measures both behavioral and psychosocial issues. It would be practical in a clinical setting because it is a short, and therefore fast measure requiring only paper and pencil which could be administered at
several different times during an office visit. Scoring would also take minimal time as there are only twenty questions. There is no charge for the use of the scale. The questions are easy to understand and require no previously acquired skills or knowledge. It is geared towards issues related specifically to diabetes, however, personnel involved in the care of the patients would have access to other relevant medical records. While the PAID has not been proven to predict patient outcomes, data are currently being collected for further research to determine if the scale is valid.

This Use of the Problem Areas in Diabetes Scale

This section will address the reasons why data was collected on the variables outlined below. It is acknowledged that other variables (such as the presence of comorbidities) may have affected the outcome of the study, however these variables were not considered to be within this study design.

Type 2 Diabetes Mellitus

Health care providers for patients with Type 1 or Type 2 DM are confronted with basically the same assessment issues. They want to know if their patients are performing the deliberate actions necessary for self-care which includes controlling their blood glucose levels. They try to make sure that their patients understand the implications of poor blood glucose control.

Previous studies have shown that regardless of the similarities in assessment, responses to questions and feelings about the disease processes may be significantly different (Nelson, 1992; Rubin and Peyrot, 1992). This is explained by comparisons in
the course of onset and treatment of the two diseases. Type 1 DM is diagnosed dramatically, frequently during a hospitalization for an acute condition caused by the diabetes. The onset of Type 2 DM is slow and insidious, usually diagnosed during a routine medical care visit. Patients understand that Type 2 DM is not immediately life-threatening whereas Type 1 DM is. This increases the stress level association with Type 1 DM as compared to Type 2 DM. Many medical practitioners also downplay Type 2 diabetes by describing the onset as borderline diabetes or a touch of sugar (Nelson, 1992; Rubin and Peyrot, 1992).

Age

It has been established in the literature that the cost of medications and physician visits increases as a person ages (Meiner, 2001a). These are just two of the factors that may affect an individuals’ distress with the diagnosis DM. Functional status also changes as a person ages leading to inability to follow the prescribed treatment plan (Meiner, 2001a). Assessment tools are useful to assist in the recognition of whether a patient is unable to follow a treatment plan because of financial or other environmental concerns or because there is an inability to accomplish a specific task (such as visual deficits preventing correct administration of insulin). These determinations assist nursing staff in devising an appropriate treatment plan. Nelson (1992) determined that the stage of life in which a patient is diagnosed with DM contributes greatly to the ability to cope. He stated that persons in middle age may not want to take the appropriate actions to deal with the diagnoses because it does not yet interfere with their lives. In addition, there are many other changes in their lives at this time including the birth of grand children, retirement, and becoming aware of their own mortality. It is

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therefore appropriate that this study considered age as a possible factor contributing to emotional distress relating to the DM diagnosis.

**Gender**

Gender was considered as a variable because the studies on the effects of stress on male and female patients with diabetes differed in their results. Research conducted by Stenstrom, Wikby, Hornquist, and Anderson (1993) found that men and women react differently to stress which in turn affected their blood glucose control accordingly. Yet a study directed by Lloyd et al (1999) found that the amount of stress experienced by either gender caused an equivalent rise in blood glucose levels.

There are also several studies that have drawn different conclusions regarding the amount social support and spousal influence affect psychosocial adjustment to diabetes (Talbot, Nouwen, Gingras, Gosselin, and Audet, 1997). These factors may influence emotional distress associated with the diagnosis.

It has been recommended that research conducted with health problems that impact on both genders attempt to isolate the differences between the responses of men and women (Meiner, 2001b). This is in part to correct the inequities found in earlier research studies and also to acknowledge that there are differences in the way women and men view their health status.

**Race/Ethnicity**

Studies have found that culture is important in diabetes treatment as all facets of life may have to be changed including diet, eating patterns and activity levels (Anderson, Herman, Davis, Friedman, Funnell and Neighbors, 1991). There are also significant numbers of African-Americans and Hispanics who have been diagnosed
with Type 2 DM. Black men and women are diagnosed with diabetes at a rate at least
double that of whites (Anderson et al, 1991). According to statistics published by the
National Diabetes Information Clearinghouse (1998), Hispanics are almost twice as
likely to be diagnosed with DM as non-Hispanic whites at comparable ages.

Orem (McQueiston and Webb, 1995) has postulated that patients are never
isolated from their environment. By the time a nurse is seeking to establish a
relationship with an individual patient, environment has already affected how that
patient views disease, treatment, and medical care. Cultural issues and family
relationships are part of this synergy. Therefore it is important to ensure that the PAID
scores were evaluated in terms of race/ethnicity. If race/ethnicity were found to be
factors contributing to variability, nurses would need to address issues such as specific
cultural practices and differences in views of the medical provider relationship (Luggen
and Kish, 2001). This may require that nurses acquire additional training to recognize
and investigate such complex issues.

Length of Time Since Diagnosis

The data on length of time since diagnosis was also collected to see if it has an
effect on diabetes-related distress. Peyrot, McMurphy, and Kruger (1999) found that
circumstances that are stable, but different, in the lives of people with diabetes can
explain individual differences in diabetes control. Length of time since diagnosis was
considered to be a factor with this stability when viewed within the context of cohorts.
Other examples of items that contributed to stability are coping styles, education and
marital status (Peyrot, McMurphy, and Kruger, 1999).
From the interviews this investigator has had with individuals who have been diagnosed with DM, it would appear that those who have had the diagnosis the longest would tend to have levels of emotional distress at the two extremes of the scale. If their past blood glucose control has been less than adequate these patients can be very worried that complications related to DM are imminent. Yet, if they have been free of the signs and symptoms of complications and have had relatively good blood glucose control, there is little or no concern.

This current study evaluated whether a relationship existed between length of time since diagnosis and emotional distress associated with the diabetes diagnosis.

**Type of Treatment**

Fitzgerald et al (2000) found that the use of insulin as treatment for diabetes had a significant effect on the attitudes of Caucasian patients towards their diagnosis whereas it had almost no impact on the attitudes of African-Americans. It was also suggested that Caucasians view DM diagnosis and treatment differently than African-Americans, perhaps because African-Americans expect treatment with insulin whereas Caucasian patients count on being treated with oral medications.

There was a paucity of literature discussing differences between treatment groups for Type 2 DM. The authors of the original studies with the PAID did suggest that there was a difference in emotional distress related to the DM diagnosis when comparing treatment groups (Polonsky et al, 1995; Welch, Jacobson, and Polonsky, 1996; and Snoek, Welch, Pouwer, and Polonsky, 2000). The four different treatment groups that were considered in this study are insulin alone, oral medications alone, insulin and oral medications together, and diet and exercise.
In Summary

The results of the use of the PAID with persons diagnosed with Type 1 and Type 2 DM have already been published (Polonsky et al, 1995; Welch, Jacobsen, and Polonsky, 1996; Snoek, Pouwer, Welch, and Polonsky, 2000). However, varying results have been obtained. Validity and reliability have been established through concurrent administration with other measures that had previously been validated.

Because of recommendations for use with different population groups made in the first three studies (Polonsky et al, 1995; Welch, Jacobsen, and Polonsky, 1996; Snoek, Pouwer, Welch, and Polonsky, 2000) this study looked at patients with Type 2 DM. Data on other variables mentioned in the previous studies was also collected in order to determine if the results of statistical analysis for persons with Type 2 DM are significant.

The question of functional status with aging and a connection with following a treatment plan successfully was determined. Because of gender differences in research findings, this variable was studied. Recommendations from multiple studies indicated a need to consider race/ethnicity in research of healthcare related issues. Length of time since diagnosis of DM was identified as a factor to be considered. The dearth of information related to the effect of differences in treatment for Type 2 DM lead to the inclusion of this variable.

Emotional distress associated with the lifestyle alterations required of patients diagnosed with DM are in need of scholarly inquiry. This study addresses the multiple factors that are included in emotional distress as measured by the PAID and the five other variables that might impact the disease management.
CHAPTER 3

CONCEPTUAL FRAMEWORK

Introduction

This chapter will identify and discuss the nursing framework chosen and its' specific application to this study.

Identification of the Framework

There are many general theories of nursing. These try to encompass all areas of nursing including why and when nursing is needed, who needs nursing services and what results can be expected from nursing. The one chosen as the framework for this research was The Self-Care Deficit Nursing Theory by Dorothea E. Orem. This theory was developed by Orem over the course of more than forty years of practice, first as a nurse in various specialty areas, next as a consultant on nurse training and curricula, and finally as a nursing professor. Throughout her career, she received many honors for the work she did on this theory (Marriner-Tomey, 1994). This framework was appropriate for this study as Glasgow, who has written guidelines for determining the appropriateness of assessment tools (1997), has indicated that self-care activities are fundamental to positive outcomes for persons with diabetes mellitus (DM).

As early as 1959, Orem defined the need for nursing in general terms as “The
inabilities of people to care for themselves at times when they need assistance because of their state of personal health” (McQuiston and Webb, 1995, p.148). It is recognized that the needs of patients differ over time. The demands of daily living, or extended periods of stress, may cause changes in the ability of patients to cope with the many facets of their treatment regimen. When this happens, a self-care deficit has occurred (Orem, 1997). This is relevant to the Problem Areas in Diabetes scale (PAID) because the intent of the instrument is to predict when people are unable to care for themselves competently for reasons of emotional distress related to DM.

![Diagram](Figure 1 Diagram of current intervention pattern and results for people with DM.)

**Orem’s Concepts**

Orem has six concepts that are important to understanding her theory.

1. **Self-Care.** Self-care relates to the activities that people engage in to maintain their own health.
2. Self-Care Agency. The ability of people to learn what they need to know for effective self-care and to be able to apply their knowledge to their own care.

3. Therapeutic Self-Care Demand. Self-care falls into three categories. The first applies to all people and focuses on the activities that are necessary to sustain life. The second is to effectively cope with experiences that individuals are subjected to as part of their day-to-day life experience. The third, health-deviation, reflects the ability of people to identify situations where their health is threatened and to then take the necessary action to engage in activities that will enable them to care for themselves, even if it involves the help of others.

4. Self-Care Deficit. When the ability of a person to care for him or herself does not match the needs of that person a self-care deficit occurs. A patient must acknowledge this situation in order for true nursing to take place.

5. Nursing agency. The knowledge, skill and ability necessary to meet a patient’s needs when a self-care deficit has occurred and is acknowledged.

6. Nursing system. How the nurse and patient interact to meet patient needs and encourage self-care to the fullest extent possible.

Orem states that “Nurses must be knowledgeable about and skilled in investigating and calculating individuals’ therapeutic self-care demands, in determining the degrees of development and operability of self-care agency” (Orem, 1997, p.27). If patients do not know enough about their illnesses or disabilities to appropriately care for themselves, nurses have the perception necessary to recognize this and assist them in becoming self-sufficient. This may mean actually teaching about the disease process or
providing appropriate resources for the patients. Through their activities, nurses are instrumental in securing for their patients the highest level of functioning within the limitations of the illness.

Nurses teach their patients the skills necessary to control their diabetes, such as how to monitor blood sugar and administer insulin, and are therefore assisting patients in overcoming self-care deficits. Nurses can recognize appropriate available resources in order that patients have the materials necessary for self-care, including blood-glucose monitors and dietary counseling. Through interaction with their clients, nurses are able to recognize the factors that will make self-care difficult, for example poor eyesight, decreased manual dexterity, inability to read, and memory problems. However, most of these problems become evident when teaching a patient or counseling one regarding available resources. Self-care deficits that are the least obvious, such as emotional distress, can affect people most profoundly.

These items all relate to the purpose of the PAID. It is designed to identify those patients most in need of the assistance of nurses and other health care professionals because of the stress they may feel due to their medical diagnosis and the lifestyle changes they have to make in order to delay or prevent symptoms of diabetes complications. The goal would be to involve patients in programs where they learn skills necessary to cope effectively with diabetes in hope of enabling them to maintain their own self-care needs as independently as possible.

A tool with proven ability to identify those patients who are at risk for self-care deficits leading to non-adherence with treatment programs could be valuable if used appropriately in the overall care of patients with diabetes.
Thus the purpose of this study was to offer more clarification on the connection between emotional distress associated with the diabetes diagnosis (as measured by the PAID), the Type 2 diabetes condition (as measured by HbA1C levels), and the overall prospective offered by Orem’s model. The following hypothesis is offered: Scores on the Problem Areas in Diabetes scale are directly related to glycosylated hemoglobin levels (HbA1C). If patients are experiencing higher than normal distress, related to their diabetes diagnosis, which can be ascertained by their responses to the questions posed by PAID scale, then they are less likely to be able to care for themselves properly thus causing their condition to deteriorate.
CHAPTER 4

METHODOLOGY

Introduction

In this chapter issues related to methodology will be addressed. Topics to be covered include design, identification of the setting, description of the population and sample, clinical considerations and measurement methods.

Research Questions

There are several research questions this study has addressed for a group of patients with Type 2 Diabetes Mellitus (DM):

1. What is the relationship between the Problem Areas in Diabetes scale (PAID) score and HbA1c levels?
2. What is the relationship between PAID scores and age?
3. What is the relationship between PAID scores and gender?
4. What is the relationship between PAID scores and ethnicity?
5. What is the relationship between PAID scores and the length of time since the patient was diagnosed with DM?
6. What is the relationship between PAID scores and the treatment used for Type 2 DM?
Study Design

The design of the study is post hoc descriptive correlational. The study used a chart review in order to describe the relationship between blood sugar control, as measured by a one-time measure of \( \text{HbA}_{1\text{C}} \) levels, and total scores obtained from a single administration of the PAID for a group of Type 2 DM patients. The chart review also collected information on patient age, gender, race/ethnicity, length of time since diagnosis, and type of treatment used for the Type 2 diabetes. The format of the first two studies using the PAID was used as a guide for this study and was followed as closely as possible based on the information given. One notable difference was that the \( \text{HbA}_{1\text{C}} \) blood test was drawn within two-weeks of the PAID completion as opposed to the different time spans allowed in the original studies. This could potentially allow the scores on the PAID to have a closer correlation to the \( \text{HbA}_{1\text{C}} \) levels by reducing the overall effect of life-changing events that could impact the blood test results.

Setting

Patients participating in this study were drawn from a faculty practice for a medical school. All physicians in the group are Board-Certified, seven in Internal Medicine and two in Endocrinology. The clinic is located in the central part of the Las Vegas valley.

Ninety-five percent of the patients seen in the practice have private insurance, Medicaid or Medicare coverage. The rest of the patients either pay with cash or have made payment arrangements. The physicians do not see indigent patients in this facility. Male patients account for approximately forty-five percent of the regular clientele. The
majority of patients are adults, older than eighteen years of age. Less than five percent of the patients with DM treated by these physicians have Type 1 DM. Consequently there is a concentration of Type 2 DM patients. As the instrument designers have recommended using different population groups in future studies, (Polonsky et al, 1995; Welch, Jacobsen, and Polonsky, 1996; Snoek, Pouwer, Welch, and Polonsky, 2000) the patients with Type 2 DM were the focus of this study.

Individuals being treated for both Type 1 and Type 2 DM at the Patient Care Center have been completing the PAID as part of a routine office visit since October, 2000. If an individual’s score is above 70 or there are more than five 5’s circled, the patient is offered the opportunity for an appropriate form of diabetes education or an earlier than usual return appointment with the physician.

Description of the Population

The accessible population consisted of Type 2 DM patients age twenty-five or older who have been diagnosed with diabetes for more than one year. The diagnosis of diabetes must be based on a minimum of two fasting blood sugar levels of >126 mg/dl or a positive 2-hour glucose tolerance test.

The Sample

Because the participants in the study were obtained from only one institution it can be considered a convenience sample. Inclusion criteria for patients from whose charts data was collected are listed as follows:
Inclusion Criteria:

1. Diagnosis with Type 2 DM for a minimum of one year.
2. HbA$_{1C}$ levels checked within two weeks in either direction of the completion of the PAID.
3. Age twenty-five or older.

Procedure

The charts of patients with Type 2 DM were reviewed. The data was retrieved to be included for analysis if the patient met the inclusion criteria. Charts with uncompleted questionnaires were not included. This process continued until the charts of 150 patients that met the inclusion criteria were reviewed.

Assumptions

1. Patients have answered the PAID questions truthfully.
2. Patients have understood the PAID questions.
3. Patients' answers are their own and do not reflect the opinions of person accompanying them.

Demographics

Data collected on each respondent included age, gender, ethnicity, length of time since original diagnosis of DM, and treatment group (insulin, oral medications, combination oral medications and insulin, or no medications using diet and exercise alone).
The Problem Areas in Diabetes Scale

The PAID is a twenty-item scale that includes questions related to diabetes knowledge, dietary attitudes, worries associated with hypoglycemia, emotional distress, and treatment regimen adherence. All questions are answered using a 5-point Likert scale. Scores range from 1 ("no problem") to 5 ("serious problem"). Summing of the individual choices will result in total scores between 20 and 100.

The validity and reliability of the PAID scale has been previously established during its use with three different groups of diabetic patients (Polonsky et al, 1995; Welch, Jacobson, and Polonsky, 1996; and Snoek, Pouwer, Welch, and Polonsky, 2000). The authors correlated scores on the PAID with other instruments whose validity and reliability had already been confirmed. Cronbach’s $\alpha$ was 0.95, which indicates that internal consistency is appropriate. Test-retest reliability was established by re-administering the PAID two weeks to one month after original completion. While other studies are presently being conducted, the results are not available at this time.

Glycosylated Hemoglobin

All patients with DM followed by the physicians in this practice have their blood drawn by Associated Pathologist Laboratory personnel at two to six month intervals depending on medication regimens and the scheduling of follow-up appointments. Two of the values obtained, the fasting or random glucose level and the Glycosylated Hemoglobin (HbA$_{1C}$), are used to assess both the effectiveness of and the adherence to the prescribed treatment program regimens. There are established records of these...
laboratory result in the patient charts that allow for comparison and analysis of results that may seem inconsistent.

The HbA<sub>1C</sub> is simply a more current version of the HbA<sub>1</sub> blood test used in the original studies done with the PAID. When glucose attaches to hemoglobin, the electrical charge of the combined molecule (called glycosylated hemoglobin) is changed. Over time, more hemoglobin molecules in the blood stream become glycosylated. The net change in charge can easily identified by electrophoresis. Whereas the target level of glycosylated hemoglobin in the HbA<sub>1</sub> test is less than 8.8%, the HbA<sub>1C</sub> seeks a level below 7.0%. Thus, it is important to know which test is being used. Using the HbA<sub>1C</sub> in this particular study will allow for more consistency as it is the test that is most frequently done for diabetic patients in this area. The numbers achieved from the HbA<sub>1C</sub> tests are representative of the average blood glucose levels over the preceding six to eight weeks (Pagana and Pagana, 1990). ADA vice president, Dr. Gerald Bernstein, offers “HbA<sub>1C</sub> levels provide a kind of blood sugar batting average” (Diabetes Insight, 1998). Tests such as these are part of the Standards of Care for diabetic patients established by the American Diabetes Association (American Diabetes Association, 2000).

### Statistical Analyses

All collected data was entered into the Statistical Packages for the Social Sciences (SPSS). All calculations, as appropriate, were done for the entire sample and to variables such as gender, age, ethnicity/race and treatment regimen. Due to the types of variables that were collected, different statistical testing was used for each research question.
Measures of central tendency were performed first for applicable variables. The mode and mean values were valuable in providing a description of a typical research subject as well as demonstrating the normal distribution of the sample. The standard deviation was also calculated.

The data collected for this study met the assumptions for using the Pearson's Product-Moment Correlation Coefficient (r) for research questions 1, 2 and 5 as follows:

1. There was interval measurement of the variables.
2. There was a normal distribution of at least one variable.
3. The observational pairs were independent.
4. The data are evenly dispersed above and below the regression line.

The Pearson's Product-Moment Correlation analysis gives a numerical result (r value). The r value result is between —1 and +1. A score within this range indicates the degree of relationship (with scores closer to 0 showing a small correlation and those nearer to 1 or —1 demonstrating a large correlation).

For research question #3, Levine's Test of Equality of Variance was used in addition to a t-test. Levine's Test for Homogeneity and Analyses of Variances were used with research questions 4 and 6.
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CHAPTER 5

RESULTS

Introduction
The purpose of this chapter is to describe the patient sample, discuss the statistical testing methods used and the results obtained. All data were entered into the Statistical Package for the Social Sciences (SPSS) which performed the calculations. Results will be presented in order of the research questions.

Description of the Sample
The sample consisted of 150 persons with Type 2 diabetes mellitus (DM) who met the inclusion criteria listed below.

Inclusion Criteria:
1. Diagnosis with Type 2 DM for a minimum of one year.
2. HbA1c levels checked within two weeks in either direction of the completion of the PAID.
3. Age twenty-five or older.

There were 61 male subjects and 89 female subjects.
Figure 2 Bar graph showing the gender distribution of the sample.

The subjects ranged from 29 years to 80 years of age with a mean age of 58.42. The median age was 59.5. The standard deviation was 12.5.

Figure 3 Bar graph showing the age distribution of the sample.
The sample consisted of 115 Caucasian subjects, 7 of Hispanic descent, 9 Asian, and 19 African-Americans.

Figure 4 Bar graph illustrating the race/ethnicity of the sample

The range of the number of years since the patients were diagnosed with Type 2 DM was from 1 to 37 years, with an average of 10.6, a median of 8 years and a standard deviation of 7.82.

Figure 5 Bar graph demonstrating the analysis of the ages of the study participants.
The patients were divided into four treatment groups. In the insulin-only category there were 21 persons. Oral medications alone were used by 73 patients. Insulin and oral medications combined were used by 53 respondents. Diet and exercise were used by 3 people to control their Type 2 DM.

![Bar graph showing the distribution of treatment groups found within the sample.](image)

**The Problem Areas in Diabetes Scale**

The scores of the Problem Areas in Diabetes scale (PAID) questionnaires that were included in data analysis belonged to the patients with Type 2 DM who had answered all of the questions. PAID questionnaires were not used where more than one answer to an item was marked. Scores on the PAID ranged from 20 to 91. The mean score was 41.4, the median score was 37.5 and the standard deviation was 16.1.
Glycosylated Hemoglobin

The charts of patients included in this study indicated an HbA1c level drawn in either the two weeks prior to completing the questionnaire or in the two weeks after. The range of HbA1c levels was from 4.5 to 14.4 mg/dL. The mean HbA1c value was 8.9, the median was 7.8 and the standard deviation was 1.7.
Results

Research Question #1

What is the relationship between the Problem Areas in Diabetes scale (PAID) score and HbA1C levels?

A Pearson’s Product-Moment Correlation performed using the PAID scores and the HbA1C levels showed a weak positive relationship of .329. Although it is a weak correlation it is significant at any α level. The value for the 2-tailed significance is 0.000.

![PAID Scores Vs. HBA1C](image)

Figure 9 Scatter Plot with Regression Line.

<table>
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<th>PAID SCORE</th>
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<td>HEMOGLOBIN A1C Pearson Correlation</td>
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<tr>
<td>Sig. (2-tailed)</td>
<td>.000</td>
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</tbody>
</table>

Figure 10 Pearson’s Product-Moment Correlation between the PAID scores and HbA1C levels.

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Research Question #2

What is the relationship between PAID scores and age?

Pearsons’ correlation coefficient was -.127 which indicates that there is no relationship at the level of $\alpha=.05$.

<table>
<thead>
<tr>
<th>AGE</th>
<th>PAID SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Correlation</td>
<td>-.127</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td>.121</td>
</tr>
<tr>
<td>N</td>
<td>150</td>
</tr>
</tbody>
</table>

Figure 11 Pearson’s Product-Moment Correlation between the PAID scores and age.

Research Question #3

What is the relationship between PAID scores and gender?

The first statistical analysis performed was the Levene’s Test for Equality of Variance which leads to the conclusion that the variances in the relationship between gender and PAID scores are equal. Once it was established that an equality of variance did exist, the t-statistic was used to further clarify that there is no significant difference between the PAID scores achieved by either gender. Consequently, there is no relationship between an individual PAID score and that persons gender.
Figure 12 A box plot demonstrating the equality of the two genders.

Independent Samples Test

<table>
<thead>
<tr>
<th>Levines Test for Equality of Variances</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
</tr>
<tr>
<td>PAID SCORE</td>
</tr>
</tbody>
</table>

Figure 13 Levene's Test for Equality of Variance of the two genders.

Independent Samples Test

<table>
<thead>
<tr>
<th>Equal Variances Assumed</th>
</tr>
</thead>
<tbody>
<tr>
<td>t-test for Equality of Means</td>
</tr>
<tr>
<td>T</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>PAID SCORE</td>
</tr>
</tbody>
</table>

Figure 14 t-test for equality of means for the two genders.
Research Question #4

What is the relationship between PAID scores and ethnicity?

The Levene's Test of Homogeneity of Variance showed that homogeneity of variance did exist between the four ethnic/racial groups. The next step was to perform an Analysis of Variance (ANOVA). This showed that equality of means was not rejected. In conclusion, there is no relationship between PAID scores and race/ethnicity.

Test of Homogeneity of Variances

PAID SCORE

<table>
<thead>
<tr>
<th>Levene Statistic</th>
<th>df1</th>
<th>df2</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>.988</td>
<td>3</td>
<td>146</td>
<td>.400</td>
</tr>
</tbody>
</table>

Figure 15 Levene's Test of Homogeneity of Variances for race/ethnicity.

Anova

PAID SCORE

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>Df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>1297.85</td>
<td>3</td>
<td>432.618</td>
<td>1.689</td>
<td>.172</td>
</tr>
<tr>
<td>Within Groups</td>
<td>37388.518</td>
<td>146</td>
<td>256.086</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>38686.373</td>
<td>149</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 16 Analysis of Variance for the PAID scores and race/ethnicity.
Research Question #5

What is the relationship between PAID scores and the length of time since the patient was diagnosed with Type 2 DM?

The Pearson’s Product-Moment Correlation was an extremely weak to nonexistent correlation with no significance.

<table>
<thead>
<tr>
<th>YEARS SINCE DIAGNOSIS</th>
<th>Pearson Correlation</th>
<th>Sig. (2-tailed)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-.081</td>
<td>.327</td>
<td>150</td>
</tr>
</tbody>
</table>

Figure 17 Pearson’s Product-Moment Correlation for the PAID scores and years since diagnosis with Type 2 Diabetes Mellitus.

Research Question #6

What is the relationship between PAID scores and the four different treatment groups?

The Levene’s Test of Homogeneity of Variance demonstrated that there were no significant differences between the four treatment groups. The ANOVA reinforced this result. Consequently, there is no relationship between method of treatment for Type 2 DM and an individual’s PAID score.

Test of Homogeneity of Variances

<table>
<thead>
<tr>
<th>PAID SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levene Statistic</td>
</tr>
<tr>
<td>1.126</td>
</tr>
</tbody>
</table>

Figure 18 Levene’s Test of Homogeneity of Variances for the PAID scores and type of treatment.
Anova

PAID SCORE

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>300.870</td>
<td>3</td>
<td>100.290</td>
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<td>.767</td>
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<tr>
<td>Within Groups</td>
<td>38385.503</td>
<td>146</td>
<td>262.914</td>
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<td></td>
</tr>
<tr>
<td>Total</td>
<td>38686.373</td>
<td>149</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 19 Analysis of Variance for the PAID scores and type of treatment.

Summary of Results

Research Question #1:

What is the relationship between the PAID score and HbAIC levels? The Pearson’s Product-Moment Correlation between the PAID scores and the HbAIC levels showed a weak positive relationship of .329 which is significant at any $\alpha$ level. The value for the 2-tailed significance is 0.000.

Research Question #2:

What is the relationship between PAID scores and age? The Pearson’s correlation coefficient established that there is no relationship at the level of $\alpha=.05$.

Research Question #3:

What is the relationship between PAID scores and gender? The Levene’s Test for Equality of Variance and a subsequent t-test showed that gender does not play any role in predicting an individual PAID score.
Research Question #4

What is the relationship between PAID scores and ethnicity? The Levene’s Test of Homogeneity of Variance and the subsequent ANOVA showed that there is no relationship between race/ethnicity and the PAID score.

Research Question #5

What is the relationship between PAID scores and the length of time since the patient was diagnosed with Type 2 DM? The Pearson’s Product-Moment Correlation was an extremely weak to non-existent correlation with no significance.

Research Question #6

What is the relationship between PAID scores and the four different treatment groups? The Levene’s Test of Homogeneity of Variance and the ANOVA established that there is no relationship between method of treatment for Type 2 DM and the four different treatment groups.
CHAPTER 6

DISCUSSION

Introduction

This chapter includes a discussion of the previous studies using the Problem Areas in Diabetes Scale (PAID) as they relate to this study. Relevance to the chosen nursing framework for the study was considered. Comments regarding the actual results and limitations of this study are provided. A possible usage for nursing staff in the medical office environment is presented. Recommendations for future studies using the PAID will be made.

Discussion of the Previous Studies using The Problem Areas in Diabetes Scale

The results of this study included a weak positive correlation between emotional distress exhibited in response to a diabetes diagnosis as measured by the PAID and blood glucose control as measured by HbA1c levels. The PAID developers found the same results in previous uses.

While this study found no correlation between the PAID and any other variables analyzed, the initial study showed that persons managing their diabetes with diet and
exercise alone had very little emotional distress compared to the other treatment groups. These data were not isolated in the subsequent studies.

The mean PAID scores obtained through the four uses of the PAID are not consistent. The first use of the PAID that was reported (Polonsky et al, 1995) showed a mean of 54.5 with a standard deviation (SD) ± 23.1. However this study was scored differently than the subsequent three studies and is therefore not comparable. In the following study (Welch, Jacobson and Polonsky, 1996), the mean PAID for the patients with Type 2 DM was 25, SD ±20.9. The third study used Dutch and American patients (Snoek, Welch, Pouwer, and Polonsky, 2000). In this study the mean PAID for the American patients with Type 2 DM was 27.8, SD ±23.2 In this current study the PAID score mean is 41.4, SD ±16.11. While this may have contributed to the differences in the interpretation of the results of the four studies, it may also indicate that PAID scores are not stable across population groups. There may be factors that have yet to be identified contributing to emotional distress with the diabetes diagnosis.

The presupposition of the PAID scale is that those with high scores are more distressed about their diabetes diagnosis. Participants are therefore less able to deal with the changes DM demands including diet, medications, and exercise regimens (Polonsky et al, 1995; Welch, Jacobson, and Polonsky, 1996; Snoek, Welch, Pouwer, and Polonsky, 2000). If the participant has not realized the true impact and possible effects of his condition, then the level of distress is certain to be lessened. As a result, the PAID lose internal validity as the instrument was not designed to compensate for a patient’s lack of awareness of the DM diagnosis.

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This finding is in direct opposition of the conclusions reached by previous studies used with the PAID cited in this paper. The PAID was found to have significant internal reliability when correlated with other subjective measures of emotional functioning (Polonsky et al., 1995; Welch, Jacobsen, and Polonsky, 1996; Snoek, Pouwer, Welch, and Polonsky, 2000). Unfortunately, none of the previous studies were able to provide a significantly high correlation between the PAID scale and an objective measure of coping with the emotional distress associated with the diabetes diagnosis. Though they too compared PAID scores with a long-term measure of blood glucose control (HbA\textsubscript{1c} level), their results were near or less than the correlation value obtained in the current study. The study published in 1996 by Welch, Jacobsen, and Polonsky provided an interesting point. The authors argue that the HbA\textsubscript{1c} correlation is diminished due to “cross sectional analyses” (Welch, Jacobsen and Polonsky, 1996, p. 65).

Patients may be handling their diabetes exactly as required because they are in emotional distress whereas other patients have been lax in self-treatment because they do not feel any distress. In the first situation, the PAID score would undoubtedly be high but any objective measurement of the patient’s ability to deal with DM, such as HbA\textsubscript{1c} levels, would be low. In the second case, the PAID score would be low and the HbA\textsubscript{1c} would be high. Both scenarios imply a negative correlation between the two. The authors included this analysis in the conclusions of the study making it appear that they were trying to justify continuing with studies using the PAID even though their results did not support the use of the PAID as an independent measure of emotional distress with the diabetes diagnosis.
The comparison of various subjective measures to confer internal validity on the PAID does not depend on true self-awareness. If patients are distressed about their diabetes diagnosis, as measured by the PAID, then that distress will most likely be evident on other similar tests as well. In a theoretical examination of this a patient could be asked if he is concerned about the effect of diabetes on his future. If the person claims little to no worry, he will probably maintain that nonchalance on a subsequent related question. If a patient is distressed about the effect of his illness on any future endeavors then that concern will also be seen in answers to subsequent related questions. The patient may have little distress regarding his condition because he is unaware of the possible complications of his diagnosis. Or he may have accepted that complications could occur and be doing his best to control the situation. Determining the difference is an important concern. Unfortunately, the PAID does not provide an answer to this dilemma. Thus, though its reliability may be high in comparison to other subjective measures, it loses validity as a predictor of an individual’s ability to cope with a diabetes diagnosis.

Relevance to the Nursing Framework

The nursing framework chosen to integrate results from this use of the PAID into nursing practice was Dorothea Orem’s Self-Care Deficit Theory. Fundamental to Orem’s theory is deliberate activity, whether it is from patients or nurses (Hartwig, 1995; Orem, 1997). In this context, her six concepts can be linked to the results of this study using the PAID as follows.
I. Self-Care. Self-care relates to the activities that people engage in to maintain their own health.

There are many deliberate actions that persons diagnosed with Type 2 DM have to take in order to control their diabetes. They include checking blood glucose levels regularly and frequently, taking medications, following through on diagnostic procedures including laboratory blood draws, following a diabetic diet, and seeing a health care provider on a regular basis. While reviewing charts for this study, it became apparent that many patients are not taking these deliberate actions. There were very few charts where patients were having prescriptions for test strips written frequently enough to establish that their blood sugar was being checked regularly.

Further evidence indicated that medications were not refilled in a manner that would indicate that patients were taking them as directed. Patients were not getting their blood draws as requested by the health care providers. This last evidence of failure to take deliberate action may have skewed the results of the study since these patients were eliminated through failure to meet the inclusion criteria. The patients that did get their blood drawn for the HbA1c levels in a timely manner are the only ones whose PAID scores are included.

2. Self-Care Agency. The ability of people to learn what they need to know for effective self-care and to be able to apply their knowledge to their own care.

In this area deliberate action would include seeking out diabetes education. While all of the persons with Type 2 DM seen in the clinic in which chart review took place are
offered the opportunity for diabetes education, very few charts indicated that the education had actually been received. Nelson (1992) recommends that medical providers should be willing to negotiate with their patients in order to achieve the desired goals. This implies knowing the patient well enough to be able to enter into a mutual relationship where the need for education and the resources for obtaining it can be explored.

3. Therapeutic Self-Care Demand. Self-care falls into three categories. The first applies to all people and focuses on the activities that are necessary to sustain life. The second is to effectively cope with experiences that individuals are subjected to as part of their day-to-day life experience. The third, health-deviation, reflects the ability of people to identify situations where their health is threatened and to then take the necessary action to engage in activities that will enable them to care for themselves, even if it involves the help of others.

The patients whose charts were reviewed readily met the goals of the first category of this concept as it implies taking care of basic needs such as eating and sleeping. The requirements of the second category were fulfilled by the patients’ ability to recognize the need for medical care for acute conditions. However, from the HbA1C levels recorded for this study, many of these patients are either not recognizing that poor blood glucose control in Type 2 DM is a threat to their health or are not willing to engage in the activities that would enable self-care. This attitude may have been reflected in the absolute lack of correlation between so many of the HbA1C levels and PAID scores.
4. **Self-Care Deficit.** When the ability of a person to care for him or herself does not match the needs of that person a self-care deficit occurs. A patient must acknowledge this situation in order for true nursing to take place.

Very few of the patients whose charts were reviewed were disabled in any manner that would compromise self-care. Yet self-care deficits still existed, as the patients were not taking the deliberate actions necessary to control their chronic disease processes. Furthermore, the failure of the patients to acknowledge their deficits, according to Orem (Hartwig, 1995), means that truly effective nursing cannot take place. Answering the PAID questions honestly requires a patient to realize that the diabetes diagnosis does present a risk to their health and well-being and is aware of the actions that have to be taken to control that threat. It should be noted that Orem relates the patient environment to the ability to perform self-care (Orem, 1997). Several questions in the PAID focus on the patient environment. For example, Question 17 “Feeling alone with your diabetes?” addresses at a minimum the issues of resources and family dynamics.

5. **Nursing agency.** The knowledge, skill and ability necessary to meet a patient’s needs when a self-care deficit has occurred and is acknowledged.

Nurses generally possess the skills and abilities necessary to assist their patients when a self-care deficit has occurred. The lack of patient diabetes education noticed throughout the chart review and the corresponding HbA1c levels of the patients may indicate that either the patients do not realize how little they know or do not want to know more. According to Orem, teaching would not be welcomed in this situation.
6. Nursing system. How the nurse and patient interact to meet patient needs and encourage self-care to the fullest extent possible. Nursing outcomes are related to the reasons why the individual would need patient care.

Time constraints mean that nurses have only a few minutes during each office visit in which to establish a nurse-patient relationship. Not surprisingly, this does not provide an adequate time frame for a nurse to ask the questions that would indicate the patient’s true status and needs. Therefore, unless the patient actually asks for assistance from the nurse, the effectiveness of the initial and subsequent meetings are drastically reduced.

The PAID is designed to expose those patients who are in emotional distress because of their diabetes diagnosis. However it would seem that the questions in the PAID itself could be contributing to the weak correlation found. For example, question 5 asks the patient to rate “Feelings of deprivation regarding food and meals.” In a hypothetical situation a 50 year-old male answers this question by rating it a 5 (Serious Problem) as he follows the diet but feels deprived most of the time. Another person who does not follow the diabetic diet answers the question by rating it a 1 (Not a Problem). If the same logic is applied to the other diet-related questions, the person taking the deliberate actions to control his diabetes is going to be perceived as needing assistance from his health care providers. The second person is going to have a low overall score because he does not follow his treatment program and so there are no problems with those aspects of the scale. While the first individual does exhibit distress related to his diabetes diagnosis he is taking deliberate action to control his diabetes and is consequently not suffering from a self-care deficit at this level. The second person does
not exhibit emotional distress because of the diagnosis but is the one experiencing a self-care deficit and is most in need of nursing assistance. The PAID would not identify this patient under these circumstances.

As with any subjective test, the answers to the PAID questions would reflect the patients’ state of mind at the exact time the questionnaire was completed. There were five questionnaires from the sample that showed scores of 20. This establishes that for every question the choice “not a problem” was chosen. These patients either had no emotional distress associated with their diabetes diagnosis or are they in denial or there may be other possible explanations. It is difficult to believe that a patient that understands the implications of the DM diagnosis would have no emotional distress.

Results and Limitations

Several limitations of this study must be considered when interpreting the results that were obtained. The study used a convenience sample (n=150) obtained from the charts of patients with Type 2 DM alone. The other gender/ethnic groups surveyed had very limited numbers in their groups compared to the Caucasian population. None of the office staff speak Spanish which may explain the low number of Hispanic patients included in the study.

A limitation may also have been caused by the culture from which many of the study patients were extracted. Inexpensive all-you-can-eat buffets aimed at local residents may increase the level of deprivation felt by locals as compared to those living outside the Las Vegas, Nevada area and away from such temptation.
The HbA1C level that was used for this study was collected within fourteen days from the patient completing the PAID scale. The HbA1C is a two-month measure of average blood glucose control. Events may have occurred in a patient’s life prior to the laboratory test which were stressful at the time, and affected blood glucose control, but have since been resolved. This may have limited the potential for finding a relationship between the PAID and the HbA1C level.

Many of the persons with Type 2 DM who completed the PAID scale had other medical problems both related and unrelated to their diabetes diagnosis. It is therefore not possible to determine whether their answers were related to their distress with the diabetes diagnosis or the co-morbidities such as neuropathy, retinopathy and heart disease.

The first goal of this study was to demonstrate whether a correlation existed between the HbA1C level and PAID score for each of the 150 subjects monitored. With an r value of 0.329, this correlation was found to be moderately weak though significant. The percent of variance ($r^2 = .108$) implies that approximately 11% of the differences in scores is due to the linear relationship between them. Though this is not a high number, it does provide a starting level for prediction of HbA1C levels based on a PAID score or the PAID score based on a given HbA1C level.

**Recommendations for Use by Nursing Staff in Office Environments**

In order for Orem’s framework for nursing efficacy to be met, a patient has to be aware that they have a self-care deficit and the nurse has to possess the skills to assist the...
patient in overcoming that deficit. Based on chart review and HbA1c levels, it would seem that some of the participants in this study were not fully aware of the true consequences of their medical situation. Orem stresses that nurses must understand the patients’ biological and psychobiological features that are brought into the relationship (Orem, 1997).

The adequacy of using the PAID scale as the solid predictor of an individual’s ability to deal with their diabetes diagnosis (as represented by their HbA1c scores) was not supported in this study. Rather it seems that the PAID scale would have greater success if it was used more as discussion tool by nursing staff for gauging a patient’s distress rather than simply as a questionnaire.

The PAID could play an important role in patient care as addressed by Dorothea Orem. Because the scale is brief and can be completed in a few minutes, the overall recommendation would be that the patient complete the scale in the nurse’s presence. Because the nurse would have chart information available, patient reasoning behind answers to the questions that appear to be incongruous can be investigated at the time the scale is completed. Thus, a truer picture of the emotional status of the person with DM may emerge, leading to effective intervention, or nursing agency, to reduce the self-care deficit. In this manner, the outcomes of nursing are “contributory to the life, health, and well-being of individuals under the care of nurses” (Orem, 1997, p. 27).

Recommendations for Further Study

The other factors taken in to consideration regarding a patient’s overall efficacy in dealing with their diagnosis (as represented by their HbA1c level) were race/ethnicity,
gender, years since diagnosis, and type of treatment. None of these showed a significant correlation at the \( \alpha = 0.05 \) level.

At the present time, the PAID should not be used as an independent assessment tool. If the designers of the PAID are to continue research studies using the tool to measure emotional distress associated with the DM diagnosis, the patient focus should change.

A follow-up study should be done with patients that appear to be stable and adherent to their treatment program. This would isolate the PAID scores and HbA1c levels from the influences of some of the other factors that may contribute to the emotional distress. If the data from these patients shows a meaningful relationship, further investigation of the correlation with the PAID may assist it in becoming a useful tool in the future.
DATE: February 28, 2001

TO: Roslyn Collins
    Nursing
    M/S # 3018

FROM: Dr. Jack Young, Chair
      UNLV Biomedical Sciences Institutional Review Board

RE: Status of Human Subject Protocol Entitled:
    "The Problem Areas in Diabetes Scale: A Follow-Up Study"

OPRS #501s0201-258

This memorandum is official notification that the protocol for the project referenced above has been reviewed by the Office for the Protection of Research Subjects and has been determined as having met the criteria for exemption from full review by the UNLV Biomedical Sciences Institutional Review Board. In compliance with this determination of exemption from full review, this protocol is approved for a period of one year from the date of this notification and work on the project may proceed.

Should the use of human subjects described in this protocol continue beyond a year from the date of this notification, it will be necessary to request an extension.

If you have any questions or require assistance, please contact the Office for the Protection of Research Subjects at 895-2794.

cc: OPRS File

Office for the Protection of Research Subjects
4505 Maryland Parkway • Box 451046 • Las Vegas, Nevada 89154-1046
(702) 895-2794 • FAX (702) 895-4242
APPENDIX II

UNLV

PROTOCOL FORM APPROVAL SHEET
FOR RESEARCH INVOLVING HUMAN SUBJECTS

Log Number: 31 March 2001

Title of Project:
The problem areas in diabetes scale: a follow-up study

Investigator: Roslyn Collins & Sue Meiner

After reviewing this proposal, the members of the Department of Nursing, Human Subjects Rights Review Committee has indicated below their approval/disapproval of this proposal.

Signature of Committee Members  Approve  Disapprove

__________________________  

__________________________  

__________________________  

The above named project is hereby approved/disapproved (circle one).

Date: 31 March 2001

Committee Chairperson's Signature

Department of Nursing
4505 Maryland Parkway • Box 453018 • Las Vegas, Nevada 89154-3018
(702) 895-3360 • FAX (702) 895-4807
APPENDIX III

Permission to use the Problem Areas in Diabetes Scale

(Copy pulled from the Internet)

Dear Ms Collins,

Thanks for your interest in the PAID. I attach a few files (Word97) for your interest:
- a copy of the PAID questionnaire (you have permission to use it with the request that you keep us informed of any results obtained with it)
- a brief PAID reference list
- some info on scoring the PAID (using SAS). The raw score is converted to a 0-100 scale for ease of interpretation

There are a number of studies around the country that are currently using the PAID and we regularly help people with their related requests. At the Joslin Diabetes Center we have recently gathered PAID pilot data on an inner city minority diabetes patient group in Boston. The data we have so far from this and other studies suggests good internal reliability, concurrent validity and responsiveness. Also we have some normative data for a range of diabetes clinical groups.

We also have developed or use a range of other diabetes specific measures of psychological and social functioning. Their suitability would depend on the type of study you propose and the patient group. I hope this feedback is useful. Let me know how things develop and whether you need any other help

Sincerely

Garry Welch, PhD
Assistant Professor
Mental Health Unit
Joslin Diabetes Center
APPENDIX IV

February 26, 2001

Dr. Sue E. Meiner
Nursing Department
University of Nevada, Las Vegas

Dear Dr. Meiner,

Roslyn Collins has permission to do a chart review for her graduate thesis. It is understood that these records will be from the charts of patients with Type 2 Diabetes Mellitus who are over 25 years of age. These records will not be identifiable in any way. A code number will be assigned. Any written work will reflect summary information only.

Sincerely,

Ambika Rao, M.D.
Department of Internal Medicine
## APPENDIX V

### THE PROBLEM AREAS IN DIABETES SCALE

**INSTRUCTIONS:** From your own perspective, to what degree are the following diabetes-related issues currently a problem for you? Please circle the number that gives best answer for you for each question.

1. **Not having clear and concrete goals for your diabetes care?**
   - Not a problem
   - Minor problem
   - Moderate problem
   - Somewhat serious problem
   - Serious problem

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

2. **Feeling discouraged with your diabetes treatment plan?**
   - Not a problem
   - Minor problem
   - Moderate problem
   - Somewhat serious problem
   - Serious problem

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<tr>
<td>1</td>
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<td></td>
<td></td>
<td>4</td>
<td>5</td>
</tr>
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</table>

3. **Feeling scared when you think about living with diabetes?**
   - Not a problem
   - Minor problem
   - Moderate problem
   - Somewhat serious problem
   - Serious problem

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<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<td></td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
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4. **Uncomfortable social situations related to your diabetes care (e.g., people telling you what to eat)?**
   - Not a problem
   - Minor problem
   - Moderate problem
   - Somewhat serious problem
   - Serious problem

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<thead>
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<th>1</th>
<th>2</th>
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5. **Feelings of deprivation regarding food and meals?**
   - Not a problem
   - Minor problem
   - Moderate problem
   - Somewhat serious problem
   - Serious problem

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<th></th>
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<th>5</th>
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6. **Feeling depressed when you think about living with diabetes?**
   - Not a problem
   - Minor problem
   - Moderate problem
   - Somewhat serious problem
   - Serious problem

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<td>Question</td>
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<td>7. Not knowing if your mood or feelings are related to your diabetes?</td>
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<td>8. Feeling overwhelmed by your diabetes?</td>
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<td>9. Worrying about low blood sugar reactions?</td>
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<td>10. Feeling angry when you think about living with diabetes?</td>
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<td>11. Feeling constantly concerned about food and eating?</td>
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<td>12. Worrying about the future and the possibility of serious complications?</td>
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<td>13. Feelings of guilt or anxiety when you get off track with your diabetes management?</td>
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<td>14. Not &quot;accepting&quot; your diabetes?</td>
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<td>15. Feeling unsatisfied with your diabetes physician?</td>
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16. Feeling that diabetes is taking up too much of your mental and physical energy every day?

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17. Feeling alone with your diabetes?

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18. Feeling that your friends and family are not supportive of your diabetes management efforts?

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19. Coping with complications of diabetes?

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20. Feeling "burned out" by the constant effort needed to manage diabetes?

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REFERENCES


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Zeta Kappa Chapter

Thesis Title: The Problem Areas in Diabetes Scale: A Follow-Up Study

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Committee Member: Rosemary Witt, Ph. D.
Committee Member: Harvey Wallman, DPTSc