Patients' Perceptions of Living with a Diabetic Foot Ulcer

A dissertation submitted
by
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to
College of Saint Mary
in partial fulfillment of the requirement
for the degree of
DOCTOR of EDUCATION
with an emphasis on
Health Professions Education
This dissertation has been accepted for the faculty of
College of Saint Mary by:

We hereby certify that this dissertation, submitted by your name, conforms to acceptable standards and fully fulfills the dissertation requirements for the degree of Doctor in Education from College of Saint Mary

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Dedication

This Dissertation is dedicated to my husband Christopher: Always maintain your integrity and love your family .

Acknowledgement

This dissertation was made possible with the help and support of my Chair and Committee members. I would like to thank Dr. Lois Linden, Dr. Pat Morin, and Dr. Jeff Ehrlich for their guidance and continued support though this dissertation process. Their expertise has been invaluable. My committee has been ideal and I couldn’t have worked with a better group of scholars.

I would especially like to express my gratitude to the men and women who participated in this study for their courage and willingness to share their lived experiences and perceptions of living with a diabetic foot ulcer with me.

Over the last two years, I have been inspired by my husband Christopher. You are a tower of strength and without you I could not have completed this dissertation. Thank you for loving me and know that having you in my life is the best gift of all.

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Abstract

Introduction

The prevalence of patients living with diabetic foot ulcers is steadily increasing. Rural communities have limited access to diabetes educational programs which can exacerbate the detection of complications of the disease. The prevention or delay of a diabetic foot ulcer can improve the quality of life for this population. Exploring the lived experiences and how educational programs affect the perceptions of patients with diabetic foot ulcer in western Nebraska is important in developing effective diabetes educational and prevention programs.

Methods

In-home, clinic, and hospital qualitative semi-structured interviews were conducted with 6 white non-Hispanic and 4 Native American men and women from 1 hospital and 2 rural health clinics in Western Nebraska. Phenomenology study design was used to gain a deeper understanding of the participants lived experiences. NVivo 9 was used to analyze the verbatim transcripts.

Results

The participants' interviews indicated that there is significant need for diabetes educational programs in Western Nebraska. The participants believed that a diabetes educational program would provide self-management and support to patients with diabetes.

PATIENTS' PERCEPTIONS OF DIABETIC FOOT ULCERS

CHAPTER I: INTRODUCTION

Individualized diabetic educational programs are in high demand (Orstead, 2007). These programs contribute to a decrease in the incidence of diabetic foot ulcers (Orstead). The lack of availability of diabetes education has been associated with the development of foot ulcers and leg amputations. Diabetes education is vital in the prevention of foot ulcers and lower leg amputations. Educational programs need to consider how perceptions and lived experiences may influence the learning process for clients with diabetic foot ulcers (Gonzalez, 2008).

In this research study, the researcher sought to explore the ways that educational programs may influence the perception of disease, health, and well-being in patients diagnosed with diabetic foot ulcers. The purpose of this research study will be discussed. Previous diabetic foot ulcer research will be examined. A general overview of the research design will be described. Definitions of terms found in the research project will also be defined. The researcher’s assumptions about the participants will be discussed. Finally, the delimitations and limitations of this research will be considered.

Educational Programs

Many health care providers recognize that individualized educational programs enhance self-esteem and learning and promote self-care management (Skinner, 2007). Diabetic foot ulcer management refers to the mutual working relationship between medical providers and clients (Gonzalez, 2008). It is crucial to define how clients with diabetic foot ulcers (DFU) perceive and understand foot ulcerations. Many clients find that it difficult to live with a diabetic foot ulcer. Individualized educational programs assist educators in assessing how patients feel about their diabetic foot ulcer. The programs allow patients to describe any problems they may have with their diabetes care plan. If the clients verbalize any problems, educators may be able to help patients find ways to deal with these problems. Individualized diabetes educational programs are a growing need that promises short-lasting and long-lasting successes (Bastable, 2007).

Educators and health care professionals should utilize best practice guidelines to formulate policies and procedures that ensure high quality and safe patient care (Indian Health, 2009). Educational best practice guidelines are resources that are available to educators, providers, and clients. These recommendations are useful in the prevention of DFU and are available from the Centers for Disease Control (CDC) (Armstrong, 2005). Patient Education Best Practice guidelines stress that patients with DFU and their families need to understand the disease process and the resources available to manage the disease (Weems, 2008). This understanding will optimize the general health of the client.

Client education is an essential empowerment strategy for diabetic foot care management (Bastable, 2007). The client and the provider mutually agree upon short and long term goals (Rankin, 2005). This non-traditional teaching strategy, individualized teaching, aids in identifying and optimizing systemic, local, and extrinsic factors that can influence the healing of the foot ulcer (Armstrong S., 2005). The health care provider and client work together to modify any factors that may interfere with the healing process (Shultz, 2009). Scheduling follow-up visits provides for continuity of care and allows for the evaluation of the educational program (Byron, 2008).

Purpose of the study

The purpose of this descriptive phenomenological study was to investigate the patients' perceptions of living with a diabetic foot ulcer. The purpose of this study was to explore the lived experiences of clients with Type 1 or Type 2 diabetes (DM) and a diabetic foot ulcer. A secondary purpose of this study was to investigate how educational programs affected the perceptions of ten patients with diabetic foot ulcers (DFU) in Western Nebraska.

Prior research offers recommendations for quality improvement in diabetic teaching programs. These approaches are useful in assessing and improving the education of outpatients and inpatients with DFU (Rivera, 2009). Second, the review of literature provides knowledge on how to analyze the current level of diabetic education provided to clients. Third, the existing research emphasizes the use of the client's input as a tool to evaluate the success or failure of the educational program. The research encourages providers and educators to develop patient-centered teaching programs. These programs need to be re-evaluated every six months to judge their successes or failures (Donahue, 2010).

This qualitative study was undertaken in a rural hospital and two rural health clinics. In this study, interviews were conducted with 10 clients with diabetic foot ulcers. IRB approval was obtained for the interviews from the College of Saint Mary and the rural hospital. The American Diabetes Association (ADA) recommends educators use a client-centered setting (MMWR, 2003). The interviews in this study took place in a location of the client's preference.

Significance of the Study

National attention has been given to a staggering increase in diabetic foot ulcers over the last decade (Clinical Practice, 2008). The increase in DFU and lower extremity amputations (LEA) has been attributed to the relationship between the client's perceptions regarding the DFU, a lack of client education, and a lack of adherence to medical treatment (Assessment, 2005). National attention has begun to focus on the quality and outcomes of one to one teaching strategies (Bastable, 2007).

Education is essential as a self-empowerment strategy for self-management, prevention, and reduction of DFU (Dabney, 2008). The National Diabetes Education Program (NDAP) and the American Diabetes Association (ADA) encourage educators and health care providers to consider the patient's emotions when assessing adherence to medical treatment (MMWR, 2003). It is important to elicit the client's views of the pros and cons of making lifestyle changes. Individualized educational strategies can reinforce learning, prevent complications, and encourage lifestyle changes (Weems, 2008). One-to- one teaching techniques can identify the factors that contribute to noncompliance with medical treatment (Struthers, 2003).

The existing research has revealed some achievements in diabetes care through the improvement of diabetic education (Diabetes Prevention, 2009). These strategies allow for discussion and the setting of realistic short and long-term goals. The individual teaching strategies are designed to communicate the key components of an effective DFU prevention regimen to the clients (Dabney, 2008). The goals of the diabetes regimen programs are patient accountability and monitoring the effective preventive lifestyle interventions (Donahue, 2010).The success of these teaching programs can be determined by a decrease in the occurrences of diabetic foot ulcers.

Background

Diabetes is the sixth leading cause of death in the United States (Rivera, 2009). The CDC and Healthy People 2010 report that patient education programs and chronic disease track systems can help decrease the rate of DFU and LEA. How a person lives with foot ulcers and how they perceive diabetes affects their treatment (Armstrong, 1998).

Some clients with diabetes suffer some loss of sensation to pain, pressure, or temperature in their feet (Kasper, 2005). The cause of this problem is the prolonged elevation of blood sugars (Singh, 2005). The elevated blood sugars destroy the nerve endings in the feet. These endings are responsible for sensing and stimulating perspiration of the feet. Many of these clients develop hammer toes and a Charcot’s joint (Assessment, 2005). The literature on the client’s perceptions of diabetic foot ulcers is minimal. Much of the existing research focuses on the physical elements of the disease (Rivera, 2009). The elevated blood sugars also cause impairment of arterial circulation in the major arteries (Armstrong, 2005).

The Center for Disease Control and Prevention (CDC) has issued information that proposes a model that describes the influence of people’s behaviors on the increased risk of diabetic foot ulcers (MMWR, 2003). This model requires educators and health care providers change their approach to diabetic education (Armstrong S., 2005). In 2003, the CDC reported a LEA rate of about 5 per 1000 persons with diabetes (MMWR, 2003).The high incidence of diabetic complications forces providers to examine the relationship between perceptions, prevalence, and the cost of foot problems (Assessment, 2005).

Research Questions

- What are the lived experiences of patients with Type 1 or Type 2 diabetes mellitus diagnosed with a diabetic foot ulcer regarding their disease, health, and well-being?

- How did diabetic education influence the perceptions of disease, health, and well-being in patients diagnosed with a diabetic foot ulcer?

Overview Research Design and Methods

The researcher utilized a qualitative phenomenological method. The researcher obtained authorization from the institutional review board at the College of Saint Mary and the rural hospital. The client recruitment procedures included flyers posted at the medical clinics, hospital, and senior resource center in a rural community. A signed consent was obtained before data collection and a copy was given to each participant. In this study, a purposeful sample of men and women with foot ulcers were interviewed. The interviews were audio-recorded and later transcribed verbatim. Pen and paper for note taking were also used for field notes during the interviews. A professional transcriptionist was employed to transcribe the interviews. The researcher used the thematic analysis procedure described by Creswell (2007). The researcher used NVivo 9 to interpret and manage the data obtained from the interviews.

The inclusion criteria for the selection of the participants included: (a) English speaking; (b) a diagnosis of Type 1 or Type 2 diabetes mellitus; (c) 19 or older with a diagnosis with a diabetic foot ulcer between 6 weeks and

18 months earlier; (d) had the ability to articulate the experience. Exclusion criteria included the following: (a) did not meet one or more of the above inclusion criteria; (b) children; (c) those mentally incapable for this study.

Definition of Terms

- Adherence- Adherence to medical treatment is defined as the extent to which an individual decides to comply with their medical treatment under the supervision of a health care provider (Rivera, 2009).
- Best-Practice Guidelines- Best practice guidelines are documents that have been developed by professionals for the prevention, diagnosis, and management of chronic diseases. This information is published and it is accessible to the general public (Dorsey, 2009).
- Competence for valid informed consent- An individual who has the capacity to make decisions in every aspect of their life. The clients have been given information that is relevant to the research. The client makes an informed decision about their participation in the research. The client receives information regarding the nature, purpose, risks, and benefits of their participation in the research. The client has the ability to communicate a choice. The client understands the presented

information. The client verbalizes their understanding (Warsi, 2004).

- Diabetes education- Diabetes education is the teaching of a patient to self-manage their disease. Self-glucose monitoring, diet, exercise, and medication administration are key components of education (Assessment, 2005).
- DFU- Diabetic foot ulcers are complications of diabetes. In many occasions it can lead to lower extremity amputations. The ulcers are local excavations of the surface of tissue. Ulcers on the sole of the foot result from repeated injury because of a lack of sensation and impaired circulation caused by diabetes (Rivera, 2009).
- Diabetes mellitus (DM) - Diabetes is a chronic metabolic disorder marked by hyperglycemia. Type 1 DM results from a failure of the pancreas to produce insulin. Type 2 DM results from insulin resistance. In Type 2 DM, the insulin production by the pancreas is inadequate to sustain a normal metabolism. Diabetes mellitus damages blood vessels, nerves, kidneys, and retina (Kasper, 2005).

- Disease- Disease can be defined as any departure from health. Diabetes is a chronic and progressive disease. Diabetic foot ulcers are complications of diabetes.
- Health- Health is a subjective interpretation of physical, mental, and social functioning. The client's behaviors reflect their beliefs regarding health. Health education activities can alter health behavior (Kasper, 2005).
- Perceptions- The client's underlying thoughts or feelings. Perceptions influence the client's behaviors.
- Well-being- Well-being is defined as the client's evaluation of their happiness. It is the client's sense of purpose and fulfillment in life (Rakel, 2007).

Assumptions

In this study, the researcher assumed that all the participants answered questions honestly.

Delimitations

The study was delimited to a small sample of 10 clients. The study was carried out in a rural area of Western Nebraska.

Limitations

The information obtained in this research may not reflect the perceptions of others with the same diagnosis who live in other areas of the country. The ages of the participants ranged from 51 to 87 years. Limitations of this study included the lack of recruitment of participants with Type 1 diabetes. The interviews were conducted over a shorter amount of time than originally anticipated. The small convenience purposeful sample limited this study. There were no participants under the age of 50, so it may be difficult to generalize the results to younger people. None of the participants are currently working.

In summary, individualized programs for the prevention and maintenance of DFU appear to be useful in the prevention of foot ulceration (Skinner, 2007). Educational programs need to be planned to assess the client’s perceptions, needs, risk factors, and health status (Clark, 2000).

According to the American Diabetes Association (ADA), and Healthy People 2010, DFU is an emergent health concern (Dorsey, 2009). In this research study, exploring the patient’s perceptions of a diagnosis of diabetic foot ulcer and lived experiences can give indications of how well the patients implement self-care management strategies. Much of the diabetes foot ulcer management relies on the patients’ ability to self-manage the disease. Therefore, it is imperative to assess the patient’s knowledge and attitudes of their diabetic foot ulcer (Kasper, 2005).

CHAPTER II: LITERATURE REVIEW

Diabetic foot ulcers are complications of diabetes (Kasper, 2005). This chapter will discuss the review of literature of a number of subjects. First the impact of diabetes on the health care system will be addressed. The benefits of diabetes education will be discussed. The analytical process of DFU education will then be mentioned.

Impact of Diabetes

Diabetes is a growing problem (Kasper, 2005). There are about 10 million people in the United States today that suffer from diabetes. The incidence of diabetes has increased 48% in the last 10 years (Rakel, 2007). The incidence of diabetes is more prevalent in Blacks, Hispanics, Native Americans, and Asian Americans (Kasper).

The body uses insulin to metabolize and thereby derive energy from starches and sugars in the diet (Serlin, 2009). Diabetes is a disease in which the body doesn’t produce or properly use insulin. The disease takes two forms: insulin- dependent (Type 1) and non-insulin-dependent (Type 2). Type 1 diabetes is characterized by insulin insufficiency which is caused by the destruction of pancreatic beta cells. It is usually associated with islet cell antibodies (Kasper, 2005). In non-insulin-dependent diabetes (Type 2), the body does not respond to insulin or the pancreas does not produce enough insulin to maintain normal glucose levels.

Diabetes is a burden for the health care system. The cost for medical care has been estimated to be about 174 billion annually (Rivera, 2009). The cost can be reduced through diabetes education and lifestyle changes (Sunn, 2009). Clients should be taught to work with educators to develop health management plans to manage the disease and prevent complications (Skinner, 2007).

The Benefits of Diabetes Education

Weems (2008) feels that educational programs give the client knowledge to understand the causes, management, and treatment of diabetes. Educating clients is an enormous task (Dabney, 2008). The high percentage of emergency room visits and hospital admissions and readmissions can be decreased. It has been proven that patient management through individualized education benefits the clients and lowers the cost of health care (Butcher, 2007). Communication between educators and clients results in outcomes that are more positive.

General Patient Education

Rivera (2009) points out that clients need to be aware that the risk of diabetes increases with age and weight. This author also recommends that educators use simple terminology to explain the disease process. DiMatteo (2000) defines psychological factors as behaviors that influence adherence to medical treatment. This author states that many clients with diabetes and diabetic foot ulcers experience confusion and shock upon receiving the diagnosis. Some clients feel like giving up and feel that there is no hope. Many clients feel that this is the worst thing that has ever happened to them.

Serlin (2009) states that clients with DFU often express feelings of denial. As a result, the clients may seek multiple medical opinions. Many of these clients fear LEA. The clients feel a loss of control over their lives, fearful of having to depend on others for their activities of daily living (ADL's) (Serlin). Guilt is also common because some are not able to provide for their families. A subset of clients blame themselves for acquiring diabetes. Clients in denial about their disease may choose to make lifestyle changes that can negatively influence their health (Dabney). A few feel that diabetes and DFU is a punishment from God (Schneider, 2008). It takes a long time to adjust to the diagnosis of diabetes or DFU.

Many clients experience feelings of relief when they share their feelings with educators or providers (Bastable, 2007). The clients become more hopeful and are more willing to participate in their medical care. The clients learn that complications could be prevented by following a good glycemic control (Kasper, 2005). Complications are adverse consequences that occur after a person has had diabetes for a long time. In 2004, Lin conducted a quantitative study with 4463 clients and concluded that depression influences client's behaviors. It interferes with physical exercise, medication intake, and foot care. Communication between educators and clients results in outcomes that are more positive. Diabetic education defines health problem identification as the step during which the client identifies the problem (Lin, 2004). Diabetic self-management education is a fundamental component of diabetes care. The goal is to help clients acquire the knowledge for self-care practices, coping skills, and attitudes required to prevent DFU (Eckman, 2001).

Standards for Diabetic Foot Care

The new recommendation is that all clients with a diagnosis of DM need to learn the risks of diabetic foot ulcers (ADA, 2009). Rivera (2009) said that a major force behind this recommendation is the increase in DFU in the past decade. The clients need to be taught to avoid high blood sugar levels and to report any change of sensation and shape of their feet. The ADA recommends that every client should receive a complete foot exam at least once per year (Kasper, 2005). The comprehensive foot exam should include checking the feet for circulation, sensation, and the condition of the skin. Sensation can be checked with a monofilament. Providers need to visually inspect the feet at every visit (Kasper).

Clients need to understand as much as possible about the ulcer development and its sequelae (Armstrong, 2005). New standardized patient education best practice guidelines describe foot care guidelines for clients and providers (Clark). The guidelines include teaching health care providers the need to assess the feet for sensation, circulation, and the skin integrity. Special attention need to be given to calluses, corns, and ingrown toe nails. The health care providers can provide debridement of calluses, corns, and nails. The clients are taught to avoid walking barefoot, hydrate the skin, and inspect the feet daily. The clients need to wear shoes and socks at all times (Armstrong, 2005). This measure will protect the skin from the damage that hot and cold weather can do to the skin. Clients need to call their health care provider if there is any breaks in the skin, changes in the color, shape, or if they have a change in the feelings of the feet (Rivera, 2009).

Improvement of Diabetic Foot Care through Education

Many diabetic educational programs do not instruct clients regarding diabetic foot care. This problem is an urgent and important issue (Butcher, 2007). The client's noncompliance can cause providers to become overwhelmed and confused (Dabney, 2009). This does not mean that the clients are hopeless. Educators can have success utilizing new innovative teaching strategies (Butcher). The clients need to receive the support of family members and providers. This allows for the implementation of educational and behavioral strategies.

Shultz (2009) mentions that education is recommended as a core facet of diabetic foot care self-management. This author also points out that studies support the relationship between behaviors, prevention of DFU, HbA1c, and self-management. Individualized teaching sessions allow for the needs of the client to become fully addressed. The learning sessions are flexible. The individualized program also provides a safe and confidential environment (Diabetes Prevention, 2009). Current research has shown that educational programs help decrease the rate of diabetic complications (Mulvaney, 2009).

Holmboe (2002) conducted four case studies at two medical clinics. Holmboe determined that diabetic education, proper diet, and exercise lower the incidence of complications. The client's age varied from 40 to 50. The participants were two males and two females first diagnosed with diabetes within the last ten years. Patients were treated with diet, exercise, and oral medication. The client's hemoglobin A1C dropped from 8.55 to 6%. The client's data also demonstrated improvements in cholesterol levels and blood pressure. These clients did not develop visual or foot ulcer problems. The study concluded that the client's education improved the diabetic control.

Moss (2003) reports the results of a cohort study of 996 clients with diabetes. The clients had been diagnosed with diabetes prior to their 30th birthday. The clients were followed through four clinic visits over a 20 year period. The researcher stated that there was a 15.7% increase in the development LEA in those clients having retinal arteriolar disease versus those without narrowing retinal blood vessels. The researcher found that an increase in blood sugars is associated with visual problems. The results of this study imply that early screening, education, and early treatment decreases the rate of LEA development. Plantinga (2008) conducted a quantitative study of 2,992 clients that examined the independent association of the client's awareness of diabetes. The study was carried out over a six-year period. The study used a multivariate logistic regression. The study concluded that more innovative efforts should be used to increase the awareness of chronic diseases. The goals of diabetic management are to reduce LEA, reduce costs, and enhance the quality of life of clients. Many people with diabetic foot ulcers receive most of their care in the hospital. These clients are admitted more frequently than people without diabetes are. Education reduces frequent and longer hospital admissions.

Vale (2003) states that educational programs need to encourage clients to work with providers on how to achieve target levels for laboratory data and risk factors. Clinical settings remain the most appropriate setting for DFU education. This author also concluded that more than 50% of people with diabetes received limited or no DFU self-management education.

Warsi (2004) reviews 71 trials of self-management education programs in chronic diseases. This author concluded that individualized teaching only resulted in a small to moderate improvement in the health of clients with chronic illnesses. The author suggests that more research needs to be done in order to properly document the benefits of individualized teaching in chronic disease management.

Analytical Process of DFU Education

Critical thinking

Individualized education is underused (Assessment, 2005). Many experts have concluded that educators need to teach critical thinking. This strategy increases the positive outcomes of DFU (Davis, 2000). To develop curricula material, it is important to understand the concept of critical thinking. Analytical or critical thinking is the client’s ability to solve problems and make accurate decisions based on facts or gathered information (Billings, 2005). Clients interact and collaborate with the educator. The critical thinking process increases knowledge about problem solving (Bastable, 2007). It is an essential step in improving educational and learning practices.

Research data provides evidence indicating that critical thinking is influenced by psychological factors. Critical thinking requires motivation. Motivation is defined as the force that drives the subject (Bastable, 2007).

Motivation is required to create a change in behavior. Beliefs and values affect motivation (Weems, 2008). The clients learn new knowledge that helps them change their mind and their behavior.

The analytical process requires practice. The client needs to be motivated to activate the mind and apply the learned skills. Clients use their deductive reasoning to make logical choices. Deductive reasoning is defined as the process by which specific concepts are inferred from general principles (Moore, 2008). Deductive reasoning relies on the accuracy of the general knowledge to arrive at a valid conclusion. The client learns the facts of the disease process. Clients learn the steps necessary to avoid the complications of diabetes (Assessment, 2005).

Clients need to use their cognitive abilities to make reasonable choices. Cognitive abilities are the client's abilities to carry out a task (Bastable, 2007). Clients can move from a simple to a more complex task. The tasks are separated into the different cognitive skills needed to complete the task. These cognitive skills need to be used continually to achieve mastery (Rankin, 2005). If the clients do not use their cognitive skills, the skills will diminish over time. The clients need to make decisions based on evidence and upon considering other alternatives. The client uses a framework and process to reach quality decisions. The critical thinking process covers basic good decision-making and explores how it can be applied in a variety of situations. The client learns the basics of good decision-making (Moore, 2008).

The client needs to be able to analyze themselves (Daniel, 2000). The client aims to improve their health status. The educators assess the client's thinking process by observing the client's behavior and performance during the clinic visits (McCarthy, 1998). This strategy helps educators to analyze how clients process information and make decisions. Critical thinking needs to be evaluated in each teaching session. The clients learn critical thinking through the educational program. The clients become experts by practicing the learned skills (Bastable, 2007). The educator serves as a role model that can provide a logical thought process (Bastable, 2007).

The educator presents a hypothetical situation to the clients. The clients are asked what they would do in that specific situation. The client has the opportunity to verbalize the choices that they would make (Osman, 2006). A gap in knowledge or faulty information may lead clients to make wrong choices (Dabney, 2008). The clients validate information for reliability. The clients make their choices based on prior knowledge presented by research and experts. The critical or analytical process helps clients eliminate inaccurate information. Deductive reasoning is utilized to draw logical and accurate conclusions (Osman, 2006).

Individualized teaching programs are in more demand because they utilize the analytical process (Mulvaney, 2009). In real life situations, clients see the skills presented to them. The client practices the skill until they master it. More complex skills and knowledge are introduced in consecutive sessions. The analytical process facilitates formative evaluations, summative evaluations, goals, and objectives.

The analytical process is also defined as the ability to correctly understand information or a problem from different points of view (Liu, 2009). This gives clients the opportunity to make the best possible action. The critical thinking process allows clients to arrive at better decisions with confidence (Daniel, 2000).

In summary, the use of the analytical process emphasizes the nature of the learning process (Chaffee, 2004). The motivation and independent thinking processes of the client are crucial components for learning to occur. Changes in behavior are the goals and objectives of the educational program (Bastable, 2007).

Many educational programs utilize Bloom’s, Kolb’s, Gestalt’s, and Prochaska’s theories to create successful curricula (Bastable, 2007). Diabetic foot educational programs have been shown to reduce the incidence of ulcerations and the risks for LEA for these patients (Adams, 2007). The theories utilized by individualized educational programs emphasize the need for improving patient outcomes. The content of these programs includes principles that advocate for self-management. The success of the program requires the input of the client (Bastable, 2007). Dabney (2008) implies that the learning model can be applied to a client-centered teaching plan. The combination of several learning principles and frameworks ensure the success of basic teaching principles.

These frameworks provide the foundation for patient best practice guidelines. Clients have the opportunity to integrate new knowledge and expand previously learned cognitive, affective, and psychomotor skills (Rankin, 2005). Self-care is the single most important factor in preventing these complications. Family involvement is crucial especially for those clients that are not able to see their feet due to poor vision or obesity, or those with mobility problems (Dabney, 2008).

Diabetes educational process recognizes that patients have the responsibility to choose their own educational objectives and behavioral goals. Educational plans are based on the assessment of participants’ needs and their ability to engage in self-care. Educators help facilitate the patients' learning process by helping them build their self-confidence and self-efficacy. Educators provide feedback and coaching regarding progress and ability to master the skills being taught Educational planning and implementation should respect the client's learning styles. Educational programs need to be planned to assess the client's perceptions, needs, risk factors, and health status (Clark, 2000). The educational programs are evaluated through the accomplishment of short and long term objectives.

Assessment

Client's Learning Styles, Needs, and Barriers to Education

Assessing the clients' learning needs, styles, and barriers to education is beneficial. This approach allows educators and providers to organize learning materials for the client (Billings, 2005). There are several steps in the development of an educational program such as one that would prevent DFU. First, the educator assesses the learning needs and abilities of the client. The educator plans the goals and teaching strategies for the educational program. The educational interventions facilitate the learning process. Finally, the educator evaluates the learning outcomes (Bastable, 2007).

Assessing the needs of the client determines which content areas need to be delivered (Diabetes Prevention, 2009). An individualized assessment, development of an educational plan, and periodic assessments between client and educator direct the selection of appropriate educational materials and interventions. Each client living with a diabetic foot ulcer brings unique life experiences and preferences to an educational meeting (Armstrong, 2005). The client's preferences help to determine the educational interventions (Bastable, 2007). The assessment includes relevant medical history, health perceptions, cultural influences, prior knowledge of diabetes, self-management skills, readiness to learn, learning style, cognitive and psychomotor abilities, family support, and financial resources (FAQs- Diabetes Education, 2009).

The educators and the clients need to recognize that all individuals have learning strengths and weaknesses (Davis, 2000). The term learning style defines the way an individual learns best. Bastable (2007) defines learning style as the composite of characteristics of cognitive, affective, and psychomotor behaviors or domains. These views serve as a stable indicator of how the client perceives, interacts, and responds in the learning environment.

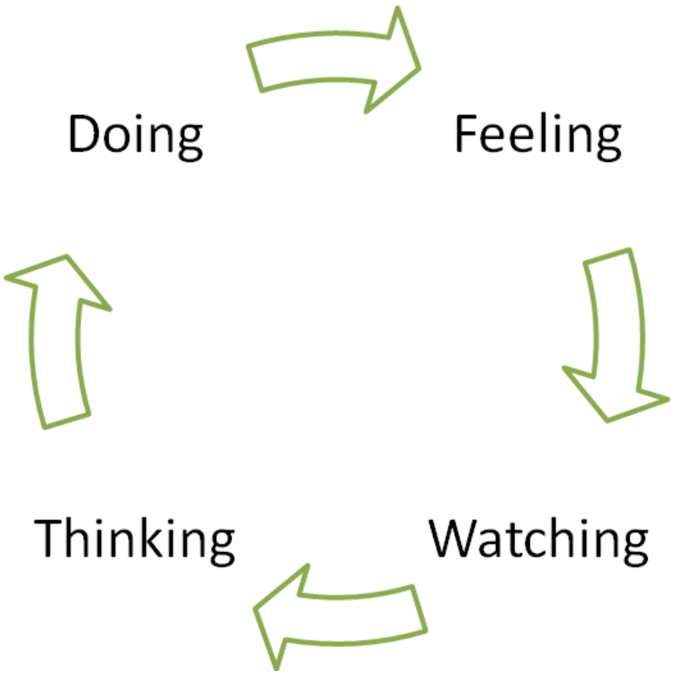
Experiential learning is the way pragmatic knowledge may be learned. The learner reflects on prior experiences to learn new information (Fromme, 2005). The experiential learning theory provides a way to understand and explain the learning process. This theory can be applied to all educational fields. Bastable (2007) describes that this is done in four steps. The client has an immediate experience, which provides for reflective observations. The client turns the reflections into abstract concepts. These abstract concepts can be actively tested (Butcher, 2007).

Models, published in 1983, present a combination of two preferred styles. Diverging learners use a combination of concrete experiences and reflective observations. These clients learn better by watching and feeling. They have a strong feelings and imagination (Kolb, 1983). They generate good ideas and see things from different perspectives. They have a strong interest in people from many cultures. They like to participate in groups and are open-minded. The coverger uses abstract conceptualization and active experimentation (Kolb, 1983). These individuals have a strong practical application of ideas. They use deductive reasoning to focus on specific problems. They do not use emotions when making decisions. Their interests in life are very narrow (Bastable, 2007). They like to solve problems. They are attracted to technical tasks and problems. The assimilator uses abstract conceptualization and reflective observation. They like ideas and concepts rather than people (Rankin, 2005). They are attracted to logic and its approaches. They like science, prefer reading to lectures, and like to explore analytical models. They have a strong ability to create theoretical models through inductive reasoning and abstract concepts.

The accommodator uses concrete experience and active experimentation in their learning process (Kolb, 1983). Their greatest strengths are in doing things. They like new challenges and are risk takers. They respond well in immediate circumstances and solve problems following their own intuition. They work well in-group to accomplish tasks (Armstrong E., 2005).

Much of diabetes management relies on the client's ability to self-manage the disease. Thus, education is a key part of diabetes treatment and management. Many issues can hinder a client's ability to absorb and retain the information provided by the educator. In order to provide the best learning environment, it is crucial for educators to understand some of the barriers that can stand in the way of the learning process (Rankin, 2005). Some of the factors that affect learning are the individual's literacy level, learning style, potential learning disabilities, potential behavioral disabilities, language, culture, religion, health, emotions, and socioeconomic factors. These factors also affect the way individuals perceive their functional ability. This research study sought to explore the possible relationship between the client's perceptions of diabetic foot ulcers and education (Rivera, 2009). Diabetes self-management programs require a certain amount of knowledge about the client. The Kolb's learning styles in figure one illustrate the individualized learning cycle.

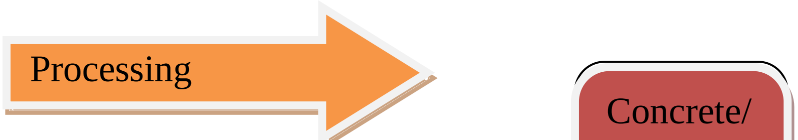
Figure 2.1
Kolb's Learning Cycle

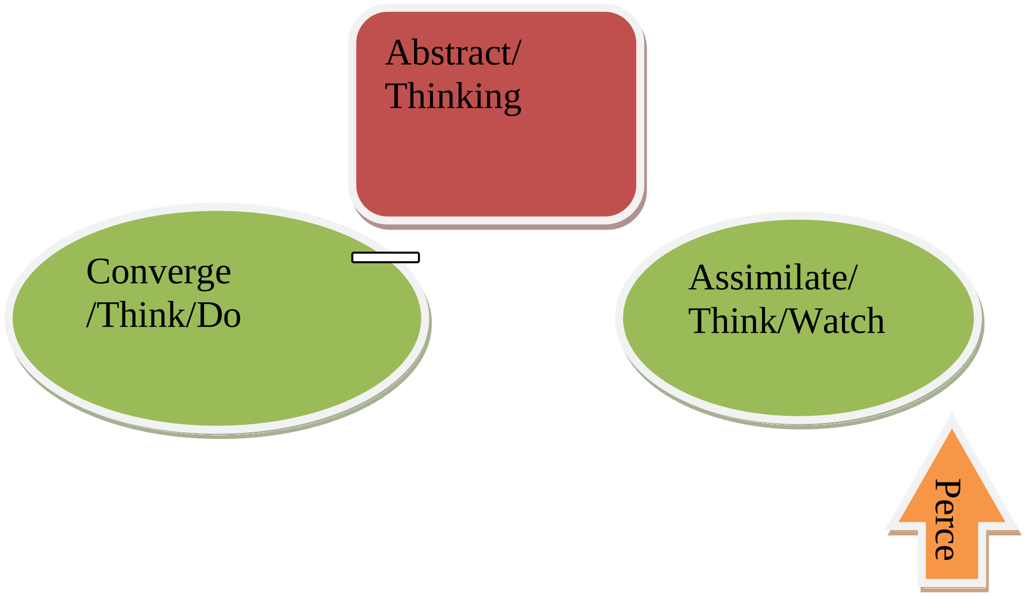


Note. Adapted from “Experiential Learning,” by Kolb, 1983.

Figures two describes the preferred approaches to learning.

Figure 2.2
Preferred Approaches to Learning





Note. Adapted from “Experiential Learning,” by Kolb, 1983.

The learner learns by processing information through watching and doing. These can be described as reflective and kinetic learning. In the perception or emotional response, the learner learns through thinking and feeling. Figure three clarifies Kolb’s types of learners. This figure illustrates the learning styles as it relates to adult learning and the individual’s learning preferences.

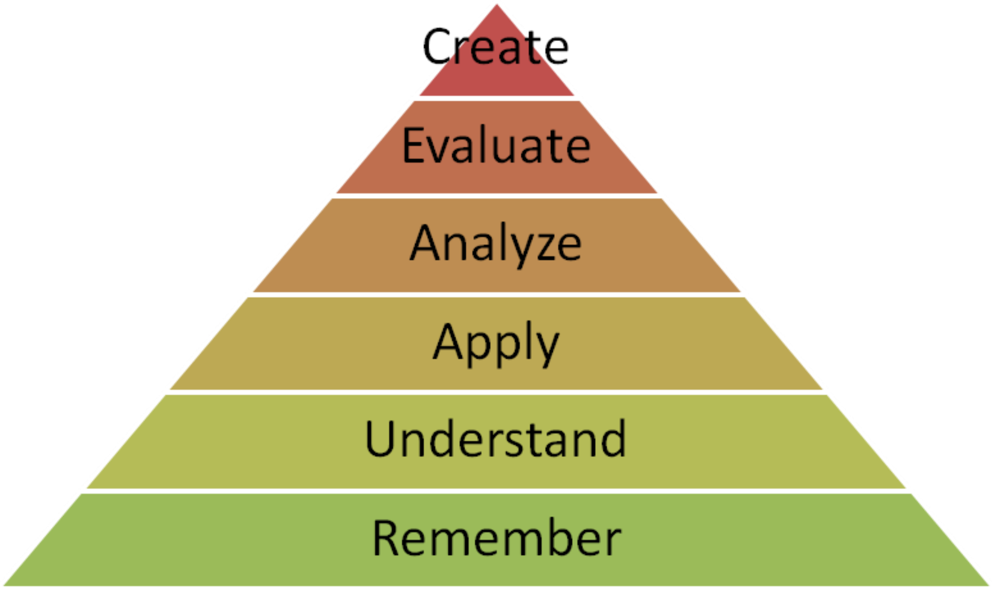
Figure 2.3
Kolb’s Types of Learners

	Doing (Active Experimentation - AE	Watching (Reflective Observation – RO)
Feeling (Concrete Experience)-CE)	Accommodating (CE/AE)	Diverging (CE/RO)
Thinking (Abstract Concrete Conceptualization- AC)	Converging (AC/AE)	Assimilating (AC/RO)

Note. Adapted from "Experiential Learning," by Kolb, 1983.

The Kolb's learning styles allow for assessment of prior knowledge and skills and the development of new learning goals and objectives. Figure four describes the learner's ability to recall information from prior experiences.

Figure 2.4
Bloom's Taxonomy Cognitive Domain



Note. Adapted from “Taxonomy for Learning, Teaching, and Assessing,” by Anderson, And Krathwohl, 2000, from “Changing for Good,” by Prochaska, 1995.

Clients may have different learning goals and needs. For example, a client may have a certain base of knowledge that just needs expanding on or the client may be ignorant of what diabetes is and how to treat it (Skinner, 2007). Research studies in the area of diabetes education need to assess what each client perceives are their needs in terms of self-management. The client’s attitude toward learning influences their self-management (Assessment, 2005). Bloom’s Taxonomy identifies three areas in which learning takes place- the cognitive, the psychomotor, and the affective (Bloom, 1956).

The learner is able to utilize prior knowledge to understand new concepts (Bloom). The learner then applies the new information. The learner is able to determine how each part of the educational program relates to each other. The clients then evaluate their learning progress (Bloom). After the goals and objectives are evaluated, the client is able to form a new educational program (Bastable, 2007). Figure five describes how learners can move from a lower thinking level to a higher level.

Figure 2.5

Bloom's Taxonomy

Cognitive	Affective	Psychomotor
Knowledge	Attitude	Skills
1.Recall data	**1Receive (awareness)**	**1.Imitation (copy)**
2.Understand	**2.Respond (react)**	**2. Manipulation (fallow instructions**
3.Apply	**3.ValueUnderstand/act**	**3.Develop precision**
4.Analyse (structure/elements)	**4.Organize personal value system**	**4.Articulation(combine, integrate related skills**
5.Synthesize (create/build	**5.Internalize value system (adopt behavior)**	**5.Naturalization (automate, become expert, masters the skills)**
6.Evaluate (Assess, judge)		

Note. Adapted from "Taxonomy for Learning, Teaching, and Assessing," by Anderson, And Krathwohl, 2000. Bastable, 2007, Billings, 2005.

For example, the learner moves from thinking about a task to creating a task (Bloom). In the cognitive domain, the clients recall or recognize knowledge. Individuals can move from a simple to a more complex level (Bastable). In this research project, the client's confidence and understanding of diabetes foot care will be assessed.

Learning Needs

While Kolb's theory allows the educator to assess the learning style of the client, Bloom's taxonomy is a useful tool for creating client-centered educational programs (Bastable, 2007). This gives educators a precise vocabulary for describing the intended goals, objectives, and outcomes (Davis, 2000).

According to Bloom's taxonomy, there are three types of learning. Cognitive learning deals with mental skills or knowledge (Bloom, 1956). The affective domain describes the client's attitudes, feeling, or emotional reaction toward the new or past task. The psychomotor learning domain describes the client's physical skills in performing the desired task (Bloom). In higher education, the word domain means categories. The three domains are cognitive, psychomotor, and affective (Bastable, 2007).

In clinic settings, the client's knowledge of the diabetic ulcer, the skills they have to perform care for the ulcer, and their perceptions about the care of their ulcer can be described with the use of Bloom's taxonomy (Ramani, 2003). The taxonomy is useful in developing goals and serves to evaluate the client's acquired new skill (Slemenda, 2000).

Within each level of knowledge, the client becomes aware of the foot ulcer problem. Knowledge, skills, and attitudes are listed from simple to complex (Billings, 2005). The concept of knowledge is used to elicit facts. The term comprehensive refers to understanding and interpreting facts. The application of Bloom's taxonomy is used to stimulate critical thinking in the clients. This strategy allows the clients to move to a higher level of thinking (Chaffee, 2004). Ranking (2005) describes the Bloom's taxonomy published in 1956.This taxonomy allows educators to help clients become involved in their own care and begin to ask questions about their care (Rankin).

Barriers to Learning

As clients become aware, they identify barriers to self-management, and participate in the elimination of these barriers (Butcher, 2007). The clients and their families need ongoing support and motivation to ensure the success of their educational program and eliminate barriers to communication. The learner has the undivided attention of the educator. This means more opportunity to engage in feedback and a better understanding of the client's needs (DiMatteo, 2000).

There are two ways that educators can address the motivation and compliance issues. One is to create scenarios for the client. Clients can develop problem-solving strategies. These strategies can provide short-term and long-term benefits. The second intervention is to use the reward approach for small behavioral changes (Cews, 2009). Client-centered interventions have great potential for affecting behavioral changes. The client needs to discuss the problem. The first and most important step in DFU prevention involves identifying the problem. The second step is to help clients identify the barriers to self-management or the reasons for noncompliance. This allows the client to express their feelings about the disease. Expressing feelings is part of the affective domain. For many clients, identifying these reasons is the most difficult step. The individualized approach allows educators to discuss these issues with the clients (Sunn, 2009). Clients are able to focus on specific problems and their solutions.

Educational Plan and Goals

A health plan encourages clients to take an active role in their health care. Therefore, noncompliance, patient dissatisfaction, and a loss of economic resources can be avoided (Rakel, 2007). Research demonstrates that these approaches have been proven successful in many educational fields. The educator or provider anticipates the client's needs and empowers the client to manage their own health care (Byron, 2008). The clients with DFU deserve to receive realistic information about their condition. The client deserves to know that they can change the outcome of their disease (Butcher, 2007). The program enables the client with solution-focused programs. Solution-focused programs are behavior modification approaches designed to support educational strategies (Byron). Solution focus tools help clients improve their ability to make meaningful decisions. These methods provide information that help clients to set short-term and long-term goals for their educational program.

Patient Education Best Practice

Numerous educational guidelines have been published to propagate evidence-based practice approaches to standardize the care of clients with DFU (Williams, 1998). Foot infection and LEA are major complications of diabetes leading to a high incidence of hospital admissions and morbidity. Clients with diabetes need to be assessed as to risk factors for peripheral neuropathy, peripheral arterial disease, poor glycemic control, foot deformities and decreased perceptions (Kasper, 2005). Self-monitoring of blood glucose supports a feeling of self-responsibility and willingness to work with health care providers. This strategy is the cornerstone of care for all individuals with diabetes who want to achieve successful health-related outcomes (Jokisalo, 2002).

The ADA has designed quality self-management educational programs that can be implemented in diverse settings (DiMatteo, 2000).These settings include outpatient clinics and hospitals. Quality self-management programs focus on the patients and their goals. The delivery of diabetes educational programs requires continuous quality improvement. This process is a daily operation. It requires the application of data analysis. The improvement occurs on a continuous incremental basis. The continuous quality improvement program (CQI) identifies problems and opportunities to make improvements. After data is collected and analyzed, the CQI offers alternatives, solutions, and recommendations. The CQI then implements the recommendations. Interventions are evaluated to see if any improvements need to be made to the program.

Curriculum Criteria

- Describe the process of diabetes and treatment options and integrate psychosocial adjustments to daily life
- Incorporate nutritional management
- Incorporate physical activity into lifestyle
- Monitor blood glucose to improve control

  Learn to utilize medications for therapeutic effectiveness
- Learn to prevent, detect, and treat acute and chronic foot ulcers and other complications
- Set goals to promote health and problem solving for daily living.

The prevention programs are not routinely used in daily clinical management of clients with DFU (FAQs- Diabetes, 2009). Diabetes is a progressive disease (Assessment, 2005). Therefore when preventive strategies are not used, the burden of this disease results in unnecessary illness, disability, death, and an increase in cost (Dorsey, 2009). Several factors account for the increase in DFUs, including behavioral elements like poor nutrition and decreased physical activity (Eddy, 2009). There is also a lack of the use of surveillance systems (Butcher, 2007). If the diabetes management services are available but the qualities of the services are inadequate, the prevention programs will not be as effective in reducing DFU (Dorsey).

Educational Strategies

Effective strategies require a global or holistic understanding (Donahue, 2003). Therefore, innovative educational strategies and client accountability are crucial for the success of the educational program (Kasper, 2005). Educators in the nursing and medical fields have endorsed teaching quality improvement projects (Butcher, 2007). The positive outcomes associated with these learning programs suggest that providing learners with access to preexisting data can improve outcomes (Gonzales, 2008). Innovative curricula encourage learners to collect their own performance data. The positive aspect of these programs is in providing clients with rich knowledge and self-management tools (Singh, 2005).

All individuals learn and process information in different ways. In the clinical setting, educators and providers encounter diverse populations from many cultures. Therefore, educators need to focus their instruction to target the different learning styles (Bastable, 2007). In developing a diabetic foot ulcer prevention program, a problem based learning curricula can be a successful approach. The one to one teaching strategy is a powerful educational form that can contribute to the decrease of LEA. This strategy involves an active, collaborative learning process that focuses on the challenges encountered by the clients (Byron, 2008). A variety of teaching strategies may be necessary to capture the attention of the client.

During planning and implementation, the client discovers steps needed to carry out the education or medical care. The client and educator mutually develop the plan of care. In the evaluation step, the success or failure of the program is analyzed. The program continues to be revised to increase the possibility for success (Donahue, 2003).

The assessment of learning strategies and learning needs provides an understanding of how education can affect the outcome of DFU (Clinical Practice guidelines, 2008). A critical problem with educational programs is that information is often presented in didactic settings (Rankin, 2005).

Clients who are concerned about their condition may not present information about their illness in group settings.

A better alternative is patient–centered learning in which the educator listens to the client's concerns (Billings, 2005). The clients feel that they are in a safe and private environment. The client becomes the focus of the program. Clinician visits need to focus on communication between the client and the educator (Byron, 2008). The sessions include open discussions about the client's feelings concerning their treatments. This allows for the development of cooperative decisions. The clients learn ways in which they can improve their health or prevent future illnesses. The educators become sensitive to what the client needs and wants (Butcher, 2007). The clinical setting provides for a patient–centered educational program. These programs produce compassionate, innovative, and prevention–oriented educators. Research that focuses on these areas needs to be sharply accelerated (Struthers, 2003).

Singh (2005) asserts that education is the most productive strategy. It produces clear problem solving skills removing barriers to self-management. Problem solving is an essential skill. Lack of self-care adherence indicates an interaction between psychological barriers, self-management, inadequate application of education, and coping skills. Educational strategies allow for the utilization of active problem solving approaches. These approaches focus on self-management and have been related to improving patient outcomes.

According to Cottrell (2005), group settings can be mentally exhausting if the client does not respond to the teaching strategies. Individual settings do not allow interaction, support, and group solving skills. Group setting participation is less costly than individualized education.

The literature covering individualized educational programs at clinics and hospitals suggests a two-prong initiative: while attempting to introduce a more holistic approach to education, these institutions feel the need to offer individual teaching, group sessions, and a curriculum that would make a positive outcome (Orstead, 2007).

Educational Recommendations

- The design reflects a continuity of care. The program should include a structured, comprehensive, and organized approach to prevention of DFU complications, and effective treatment protocols that promote healing as well as prevent recurrence (Assessment, 2005).
- The educational program should target the clients, educators, providers, and family members. The educator should present information at an appropriate level for the target audience in order to maximize retention

and facilitate a carry over into practice (Utilize Kolb's and Bloom's methods to ascertain success of the program) (Assessment, 2005).

- The active participation of the client and family member is necessary for the success of foot treatment and prevention strategies (Assessment).
- Other areas of education may include knowledge of exercise and nutrition (Assessment, 2005).

Theoretical Frameworks in Patient Education

A central concept of a diabetes educational program includes the combination of frameworks to help clients achieve the desired goals. Effective educational programs are based on an understanding of the theoretical bases of learning. Theories provide frameworks from which educators find tools that can adapt to each client (Bastable, 2007).

The Gestalt Social Field Analysis can be useful in exploring the client's participation in their diabetic foot care. The Gestalt theory explains the dynamics between a person's perceptions and the environment (Daniels, 2004). The clients will be asked if they have had any difficulties at home because of their diabetic foot ulcer. This model addresses a person's past and present life experiences (Figure 6).

Figure 2.6
Gestalt Fields Analysis

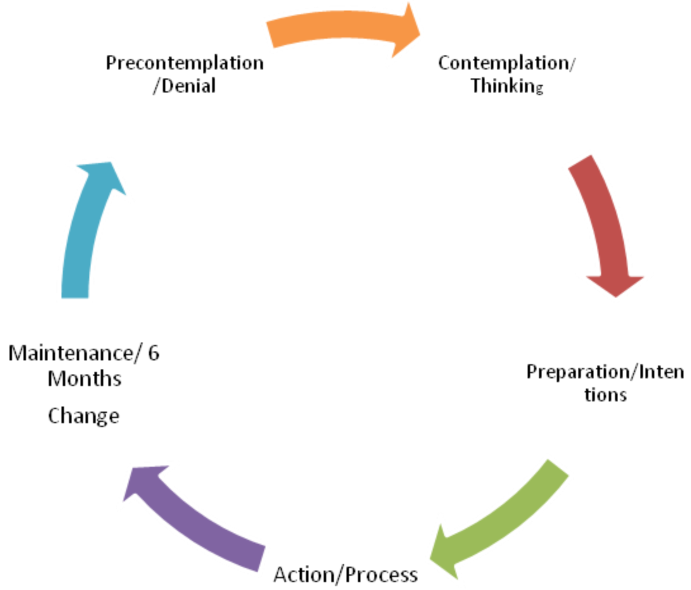
Note. Adapted from "*A gestalt therapy and field theory based model for social analysis and change*" by Daniels, 2004.

Figure six explains the Gestalt model. This model can be used to plan strategies that reduce resistance to change. In this study, the client's support systems need to be assessed. Family support is important in maintaining new behavioral changes. This allows the individual to make better health choices (Daniels).

The literature on the perceptions of diabetic foot ulcers is minimal. Self-care behaviors and family support can affect the patients' coping with the diabetic foot ulcer (Daniels, 2004). Improve coping skills and family support can lead to an improvement of blood glucose levels. Much of the existing research focuses on the physical elements of the disease (Daniels, 2004).

Prochaska's stages of change can be applied to the management of chronic diseases (Figure 2.7). This model is based on the belief that behavior change happens in multiples steps.

Figure 2.7
Prochaska's Stages of Change



Note. Adapted from "Changing for Good," by Prochaska, 1995.

According to Bandura, efficacy is based on the client's own beliefs and abilities (Bandura, 1985). The client decides when they have completed each step before moving to the next (Bastable, 2007). The decision to change is an internal process. The clients experience new challenges as they move from one stage to the next. The first stage of change is precontemplation. In this stage, the clients may experience denial. They do not acknowledge that there is a problem. They see no issue with their current condition (Davis, 2000).

The client is reluctant to make any changes. In the contemplation stage, the client acknowledges that there is a problem but they are not ready to make any behavioral changes (Davis). They recognize that the behavior may be dangerous and begin to consider making changes. Clients who are getting ready to make changes in their life are in the preparation stage. Clients that make changes in their behaviors are in the action stage. Clients in the maintenance stage require the support of the family and the educator (Rankin, 2005). Relapses are common and clients need to receive all the tools needed to handle these situations. Clients may return to older behaviors and abandon the new changes (Bastable, 2007).

Adult education is a complex process. Perceptions play a crucial role in the success or failure of the educational program. Figure eight describes the ultimate goal of the Bandura’s theory (Diabetes self-management, 2009).

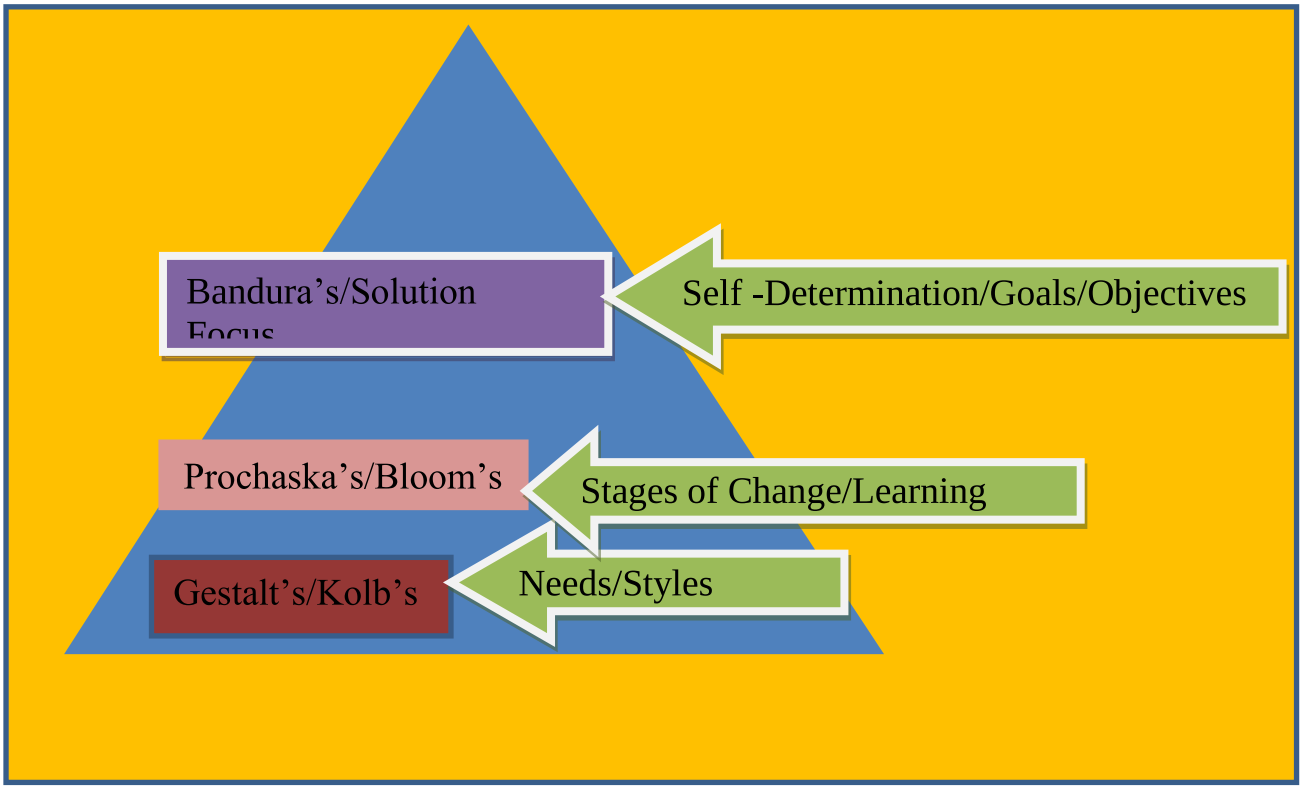
Figure 2.8
Self-Determination Theory

Note. Adapted from "*Diabetes self-management training (DSMT) program*," by DSMT, 2009.

The goal is to assist adults to become self-sufficient and learn to self-manage their health care (Bastable, 2007). Educators need to use preventive tools that can help clients achieve their educational goals (Rankin, 2005). Self-efficacy is based on self-confidence (Bandura, 1985). It requires the mastery of skills, the modeling of the educator, and social persuasion. This social support can help the client believe in himself or herself (Bastable, 2007). The environment also influences how the clients feel about accomplishing a task (Figure 8). The client is expected to master and model the learned skills successfully (Gonzales, 2008).

Figure 2.9

Patient Education



Note. Created by L. Costa , 2011.

Program Facilitator

Educators help facilitate the patients' learning process by helping them build their self-confidence and self-efficacy. Educators provide feedback. The educator becomes a guide or facilitator. The educator acts as a facilitator that helps clients to distinguish needs and set priorities (Bastable, 2007). The educator asks for input rather than offering advice. The client has control over the aims of the education program, the pace, and the materials used. The client uses the educator or the provider as a resource. The relationship between client and educator becomes productive.

Educational Program Evaluation

The goal of the educational program is to offer quality, comprehensive educational services to ensure the decrease of LEA rates (Sunn, 2009). The client learning outcome assessment cycle is a four- stage process (Figure 4):

- Identifying student learning outcome
- Design, implementation, and assessment plan
- Reflect on the results of the assessment and draw conclusions
- Share the results of the assessment with all other providers and client; invite review, comments, and recommend changes that may improve the health care of the clients.

The outcomes of the educational program are expressed at the various levels of Bloom's taxonomy (Bastable, 2007). The teaching strategies, instructional materials, plans, and interventions are developed based on the assessment provided by Kolb’s learning styles and Bloom’s taxonomy (Fromme, 2005).The short-term and long-term goals and objectives are evaluated for success or failure against this initial assessment. This plan of care is flexible and serves as a guide (Rankin, 2005).

In conclusion, effective communication is essential for an accurate assessment of the patient’s needs and learning styles. It gives crucial recognition to the connection between emotional factors, education, and self-management of health care. The educational program must be relevant, acceptable, and understandable to the intended learners (Bastable 2007). There must be an agreement of purpose between the educator and client. Diabetes educational programs that are not meaningful to their clients may risk failure in the prevention of DFU (Assessment, 2005).

CHAPTER III: METHODS AND PROCEDURES

The prevention of diabetic foot ulcers is a complex process (Rivera, 2009). Diabetic foot education requires continual reinforcement. This is especially true among high-risk patients. The researcher asked these questions:

- What are the lived experiences of patients with Type 1 or Type 2 diabetes mellitus diagnosed with a diabetic foot ulcer regarding their disease, health, and well-being?
- How does diabetic education influence the perceptions of disease, health, and well-being in patients diagnosed with a diabetic foot ulcer?

In this chapter, the study design utilized in this research project will be described. Ethical considerations will be identified. The sample and process used to recruit the participants will be considered. The data gathering and data analysis will be explained.

Research Design

This study provided a scheme of knowledge for health care providers that can be employed to improve existing best practice guidelines. Relevant research in this area can guide practitioners to develop personalized educational programs in the prevention of DFU (Eckman, 2001). The focus was to help health care practitioners make sound clinical decisions in the management of DFU. The purpose of this study was to explore the lived experiences of clients with Type 1 or Type 2 diabetes (DM) and a diabetic foot ulcer. A secondary purpose of this study was to investigate how educational programs affected the perceptions of ten patients with diabetic foot ulcers (DFU) in Western Nebraska.

Responsibilities of the Researcher

In planning the research project, the researcher sought the assistance of experts in the field of diabetes, pain control, and neurology. The researcher also contacted the chief executive officer of the rural hospital and medical clinics to obtain authorization for the research. The researcher ensured that the facility had an institutional IRB and a federal-wide assurance certification provided by the Office for Human Research Protection (OHRP). The researcher also obtained an IRB authorization from the College of Saint Mary.The researcher was aware of how emotional factors may affect education and the healing process of foot ulcers.

Ethical Considerations

The proposal and the request for an Institutional Review Board (IRB) were sent to the College of Saint Mary for approval. An IRB and a federal-wide assurance form were filed with the Department of Health and Humans Services and the Office of Human Research Protection. The participants in the study were notified that participation in the study was voluntary. No coercion was used in the recruitment process (Regulations and Ethical Guidelines, 1979).

The hospital protected the rights and welfare of the individuals that were recruited for the research. The hospital IRB was part of the national IRB that reviews and approves research involving humans. All research at the institution was guided by the Belmont Report. The researcher was familiar with pertinent Nebraska law for biomedical research and the current discussion at the Offices of Human Research Protections (Regulations and ethical guidelines, 1979).

Ethical Considerations

Informed Consent

A written informed consent was obtained prior to informant participation (Appendix A). Participants were assured that their participation, nonparticipation, or their refusal to answer questions would have no effect on services they receive from health or social service providers. The participant's decision to participate or not to participate in the research was not related to their medical benefits or treatment. At each stage of recruitment, potential participants were encouraged to ask questions. All subjects were advised that participation was completely voluntarily and they could leave the study at any time without penalty or effect on medical care. The potential subjects were offered information about the study in the first telephone session.

Risks to the Participants

Participants were informed that they may be at risk for fatigue and such negative emotions as anxiety and sadness during discussion and recollection of their experiences (Billings, 2005). They were told that if fatigue occurred, (or for any other reason) the participant may terminate the interview at any time to rest or reschedule it, or may choose to not continue in the study. The welfare of the participant was a major concern for the researcher. If the participant had a problem as a direct result of being in the study, the participant was told that they should immediately contact the person listed at end of the consent form.

The clients were informed that the potential risks in this study were outweighed by the potential benefits resulting from this study. The benefit of this study is that it may provide an understanding of the value of educational programs in changing perceptions regarding DFU and diabetes.

Protection of Confidentiality

To protect the confidentiality of the participants, the researcher coded all the information using numbers. All information was stored in a locked file cabinet or password-protected computer file at the Gordon Memorial Hospital. Only the researcher and her advisor had access to the data. All data will be kept a minimum of five years before being destroyed.

Population and Sample

The information for this study was gathered from individuals with a diagnosis of diabetic foot ulcer. The target number of participants was 8 to 10. The sample size was deliberately small to help focus on individual experiences (Creswell, 2007). Participants were recruited for interviews until the information was sufficient. Women and men were both studied.

This study was conducted in a rural hospital and 2 medical clinics in Western Nebraska. The three facilities were part of the Gordon Memorial Health Services (Appendix B). The interviews were conducted at a place of the subject’s preference. The rural hospital in this study serves a population of 5,264. The population in the county consists of 85.3% Caucasians, 0.1% African Americans, 2.5% Hispanics, 0.2% Asians, and 11.9% Native Americans – mostly Lakota (Krotz, 2010). The male population is 49.4%

and the female population is 50.6%. The county has an area of 2,470 square miles (Krotz).

The primary care facilities have five full time primary care providers. No fulltime specialists are available on site. Satellite specialty clinics are available from regional hospitals. The hospital has 25 acute care beds. The hospital provides services for two counties in Nebraska, and an area in southwestern South Dakota (Krotz). The study attempted to interview clients from diverse ethnic groups. Cultural sensitivity is critical in providing appropriate communication with diverse populations (Cottrell, 2005).

There were several inclusion criteria for participation in this study. Clients were English speaking. The clients were 19 or older with a diagnosis of Type 1 or Type 2 DM. They had to have been diagnosed with a diabetic foot ulcer between 6 weeks and 18 months earlier. The clients had the ability to articulate the experience. The exclusion criteria for the study included clients that did not meet one or more of the above inclusion criteria. The study excluded children and those mentally incapacitated.

This study used a purposeful and convenience sampling. The purposeful sampling allowed the researcher to examine the participants' perceptions (Creswell, 2007). The participants provided in-depth rich information that is unique only to the participant. The researcher gained insight about the client’s perceptions of living with DFU. The purposeful sampling was used to identify the 10 clients with DFU.

In this study, convenience sampling focused on the recruitment process. The participants were recruited from two medical clinics and a rural hospital. The participants lived across a large geographical area of Western Nebraska. This geographical area makes it difficult to do a random sampling (Fox, 1976).

Recruitment of Participants

The researcher employed flyers in the recruitment of participants. Flyers that introduced the study and asked for participation were posted at the medical clinics, hospital, and the senior center (Appendix C). Additional participants were gained through the snowball effect from those who already were a part of the research project (Creswell, 2007). Participants were asked to give a recruitment flyer to potentially interested acquaintance(s), should they know of any appropriate persons.

The flyers (see Appendix C) were posted at the medical clinics and the hospital. Prospective participants telephoned the researcher at the telephone number listed on the flyer. The researcher introduced the purpose of the study. The clients were given information about the informed consent and the need to ask demographic questions. The participants in the study were notified that participation in the study is voluntary. No coercion was used in the recruitment process (Regulations and ethical guidelines, 1979).

The researcher met with each participant at a mutually agreed upon location of the client's choice. The signed consent was obtained before data collection and a copy was given to each participant .The probing questions were clear, easy to understand, and inoffensive. The probing questions sought to clarify and explore any vague answers. The researcher avoided biased questions. Biased questions influence the client's responses (Denzin, 2008). The researcher asked general questions before specific questions (Appendix D).The researcher kept an open mind when reporting the results of the research. Therefore, the researcher avoided personal biases. The researcher was objective. The researcher did not blame the patient for the development of the DFU. The researcher did not ask questions such as 'what happened?' These types of questions may make the patient feel ashamed because they were not able to prevent the DFU. The researcher was prepared to follow up on vague or incomplete answers (Appendix D).

Data Collection

This phenomenological research required the researcher to respect individuals, listen to them, and believe them. Listening and empathy were required to obtain rapport (Creswell, 2007). The clients were the instruments that provided the information. The researcher was the instrument that gathered the information.

The researcher did not know ahead of time what would be encountered in the research (Huber, 2006). The researcher used perceptiveness and dedication to conduct a meaningful research (Creswell, 2007). The researcher used semi-structured interviews to collect information from the participants. These methods allowed for the description of rich human experiences (Bilklen, 2007). The researcher gained the trust of the participants by introducing herself. The clients were reassured that the information they providednwould be kept confidential. The clients were informed that no names would be used in the research. They were told that the information would be kept locked in the hospital for five years. They were advised that the information would only be available to the researcher or the researcher's advisor. The researcher talked to the participants on a personal level. The clients were notified that they may withdraw from the study at any time. The researcher was honest about the purpose of the study, the risks of the study, and the benefits of the study. The clients were given a sense of choice. The researcher did not make any empty promises.

The questions in the interview needed to be adapted to the individual client. The information was collected primarily through interviews and stories from clients who have experienced life with DFU (Armstrong, 2005). The questions that were posed by the researcher guided the recall and reflection of the clients with foot ulcers. .

The clients were notified that the interview might last from 60 to 90 minutes. The clients were informed that they may develop fatigue. They were told that if they develop fatigue, the interview can be stopped and continued on a later day. The researcher was empathetic about the client's emotions while utilizing probing questions. The clients were informed that their feedback would be valuable (Creswell, 2007).

The researcher identified the phenomenon the researcher is interested in. The researcher gathered the descriptive accounts of the phenomenon from the respondents regarding their life experience with the diabetic foot ulcer. These four steps revealed the client's descriptive accounts of living with DFU. The four steps allow the researcher to bracket their preconceptions (Creswell, 2007). The interview was interactive. The clients were asked to verbally describe their experiences of living with DFU (Indian health, 2009).

The reliability of phenomenological research requires appropriate interpretations (Bloomberg, 2008). Therefore, it was important for the researcher to seek a link between experience, language, and knowledge. Will there be empathy? Or can the reader feel the respondent's situation and meaning? Therefore, it was crucial that the researcher provided vividness, honesty, accuracy, and the respondents own words of the lived experiences (Bilklen, 2007). The descriptions of the event needed to be rich in depth and quality. This allowed the reader to use intellect to interpret the event (Denzin, 2008). In this research study, the researcher sought the corroboration of the participants to ensure the accuracy of the transcripts (Creswell, 2007).

Phenomenology assumes that people and the world are connected (Skinner, 2007).The interviews were carried out at a mutually agreed location of the client's choice. This provided a familiar, safe, quiet, and undisturbed environment for the client (Fox, 1976).

The researcher listened carefully and approached the participants with an open mind. The researcher remembered that people from different cultures have more in common than they have differences (Dorsey, 2009). The researcher based the entire research project on a holistic understanding of the participant's perceptions (Diehl, 2009). Cultural sensitivity minimizes the risk of obtaining inaccurate information (Appendix E).

The researcher became knowledgeable about the cultures being studied. In the Lakota culture, the researcher needed to develop a partnership agreement with the client to ensure informed consent (Afraid of Bear, 2009). The partnership agreement is a verbal understanding between the client, the researcher, and a possible third party of the purpose and methods of the study.

The clients were their own spokespersons. When interviewing an elderly Native American, it is the traditional custom that a son or daughter be present during the interview. The same belief applies when a women is interviewed (Pickering, 2000). The participants were interviewed without the presence of a family member when it was their wish.

Afraid of Bear (2009) adds that questions asked by the researcher might prove to be irrelevant, unclear, or even offensive. The researcher needed to ask questions within the context of the American and Lakota culture. The researcher needed to know that Lakota participants should not be addressed as clients or patients (Pickering, 2000). The participants were addressed as relatives (Afraid of Bear, 2009). The researcher learned to translate certain words, and identify spiritual and religious practices (Indian Health, 2009). This approach ensured that the researcher captured the client's perceptions. Honor and respect was given to the elders as per tribal tradition (Afraid of Bear, 2009).

The researcher did not use leading questions to obtain the answers the researcher was looking for. The researcher used the general questionnaire that had been prepared prior to the interview (See appendix D). The researcher asked the most important questions first. The use of open-ended questions facilitated the gathering of information (Creswell, 2007). The goal of the researcher was to obtain descriptions from the participants.

Recording of Information

A pilot study with one member of the Lakota culture was conducted in February 2011. The participant was selected from one of the clients at the rural health clinics. The participant received an informed consent. The interview was informal at a location of the participant’s preference. The questions on appendix B guided the interview. The interview lasted 40 minutes. The participant’s feedback was encouraged. This pilot study gave information about conducting a culturally-sensitive interview. The researcher utilized a series of questions about how educational programs have affected the participant’s disease and overall health. The participant gave favorable feedback that encouraged the use of the interview questionnaire. The participant verbalized that the questionnaire was appropriate for members of the Lakota culture.

The interviews were audio-recorded and later transcribed verbatim. A professional transcriptionist was employed to transcribe the interviews. A pledge of confidentiality was obtained (Appendix E) prior to transcription of the interviews. Pen and paper for note taking was also used for data collection during the interviews. The information was obtained from the demographic data form (see Appendix F) and the Interview Guide (see Appendix B for General Statements/Interview Guidelines).

Data Analysis

The horizonalization process was used to list all statements related to the perception of the clients (Carnevale, 2005). Each experience or perception was of equal value. The researcher utilized bracketing to avoid biases that may conflict with the collection and analysis of information (Fox, 1976). The researcher used the bracketing process to keep an open mind regarding the respondent and their answers (Creswell, 2007). The bracketing also allowed the researcher to focus on the client. Bracketing ensured a neutral approach to the research topic (Creswell). The researcher obtained the help of the clients when reviewing the transcripts for accuracy and clarity. These procedures avoided distortion of the results (Creswell).

The researcher constructed generalizations of statements through the horizonalization process (Creswell). The data was analyzed at the time of collection and after the identification of common themes. These themes were clustered into groups. Each statement received equal value. The horizonalization process was used to list all statements related to the perception of the clients (Carnevale, 2005). The researcher used existing research to support the purpose and findings of the study (Creswell, 2007).

Phenomenological research employs textural and structural descriptions. The researcher wrote a textural description to disclose what occurred. The structural description explained how the clients experience living with a foot ulcer (Denzin, 2008). The last step of the data analysis was to cluster or group statements into similar meanings. This procedure allowed for the elimination of repetitive and irrelevant information (Creswell).

This research study used the software program NVivo 9 to interpret and manage the data obtained from the participants. NVivo 9 has the ability to manage complex ideas as well as search and explore contexts (QSR, 2007). NVivo 9 removes many of the manual tasks associated with data analysis. The software classifies, sorts, and arranges information. This software will provide graphics that display the data and its connections (QSR, 2007). The information is assembled into themes or codes that make it easy for the researcher to interpret the data (Liverpool University, 2009).

Verification

Rigor was established by the triangulation of the information through the collection of data from multiple sources (Creswell, 2007). The researcher used epoche to become aware of her own beliefs or pre-conceived assumptions. The clients were given copies of the transcripts. The clients were asked to corroborate the accuracy of the information (Merrian, 2009). This step validated the descriptions allowing the researcher to make changes.

The data was analyzed at the time of collection and after the identification of common themes. The participants were given copies of the transcripts. The participants were asked to corroborate the accuracy of the information (Merrian, 2009). This step validated the descriptions. This allowed the researcher to make changes. The researcher used existing research to support the purpose and findings of the study (Creswell).

In summary, this research study utilized a phenomenological research design. Phenomenology was used to explore the ways that educational programs may influence the client's perceptions of their DFU. Phenomenogy describes experiences unique to the individual (Creswell). The participants interpreted their own lived experiences to the researcher. The researcher collected the information through interviews and field notes. The information was analyzed and common themes were identified (Creswell).

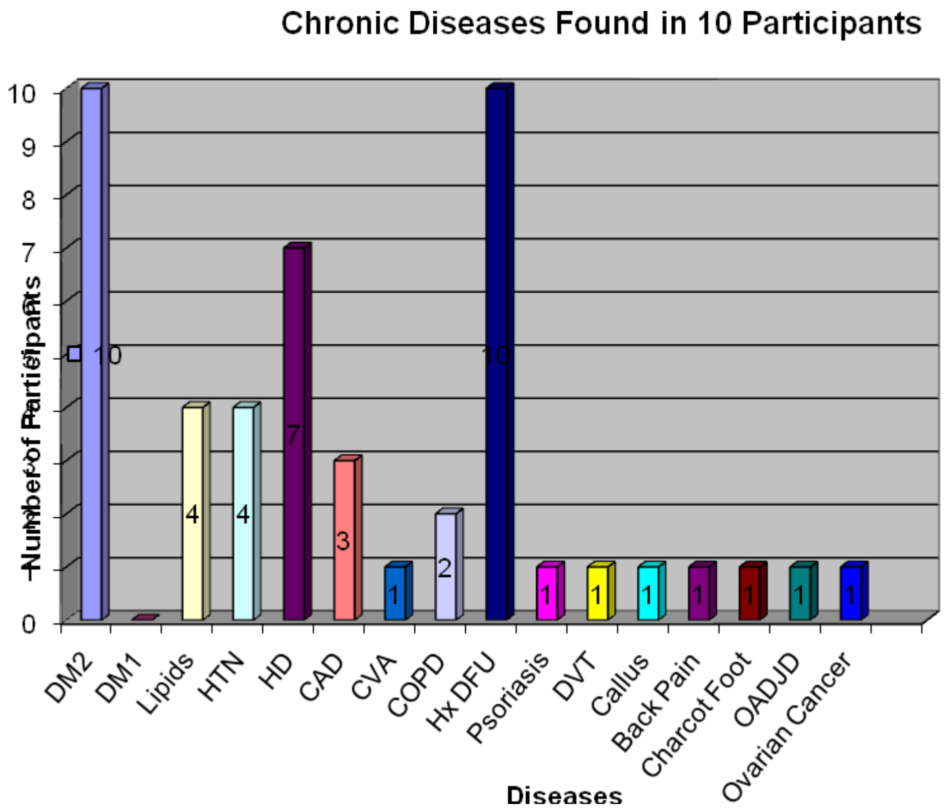
CHAPTER IV: RESULTS

Introduction

An analysis of the interviews revealed a number of constructs which can be discussed within the context of education. The first section of this chapter describes the demographic characteristics of the participants. The next section of this chapter addresses a collective summary of themes.

The sample consisted of 10 United States citizens (Appendix F). The sample was composed of 7 women and 3 men. Their ages ranged from 51 to 87 years. Sixty percent of the participants were Caucasian and 40% were Native American. Seventy percent were married, 20% were widowed, and 10% were divorced. Thirty percent of the participants had an annual income ranging from $15,000.00 to $38,160.00. Seventy percent did not know their annual income (Appendix F). All the participants reported that they did not work outside the home. One participant reported having only a kindergarten education but he was able to read and write. One individual reported having an elementary education, two participants had attended junior high school, two participants received a high school diploma, four reported having associate’s degrees, and one participant reported having a bachelor’s degree. The ages when the participants were first diagnosed with diabetes ranged from 30 to 72 years. The participants reported living with a diagnosis of diabetes from 1 to 45 years. They reported living with 0 to 13 members in their household. Sixteen chronic conditions were found among the 10 participants. Some of the participants had multiple chronic diseases. Figure 4.1 displays the number of participants in each disease category.

Figure 4.1
Chronic Diseases



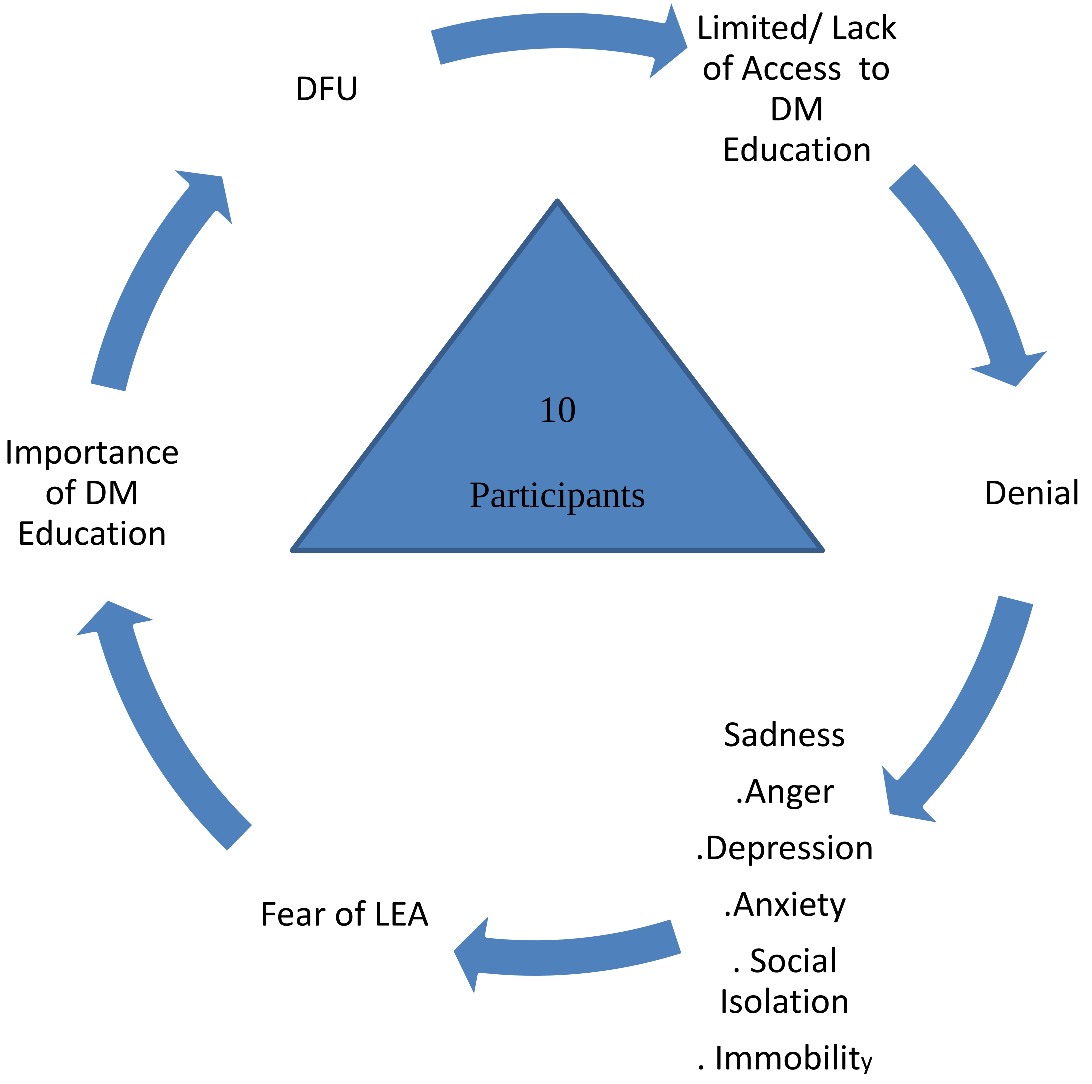
Note. Created by L. Costa, 2011.

An analysis of the interviews revealed a number of themes which were them analyzed by NVivo 9. The participants’ responses included a sense of being overwhelmed because of the inability to manage their diabetes and their foot ulcer. From 10 verbatim transcripts, 278 significant statements were extracted.

Six themes were identified in the answers obtained from the patient interviews. The findings in relation to each other are described diagram 4.2. Participants in rural areas often lack a diabetes education program in their communities. The ten participants in the study verbalized that they had limited knowledge about DM due to the lack of access to a diabetes educational program in their community. This lack of education contributed to their feelings of denial and sadness and fears of DFU. The 10 participants emphasized the importance of education in the prevention of DFU.

Figure 4.2

Diagnosis of DM



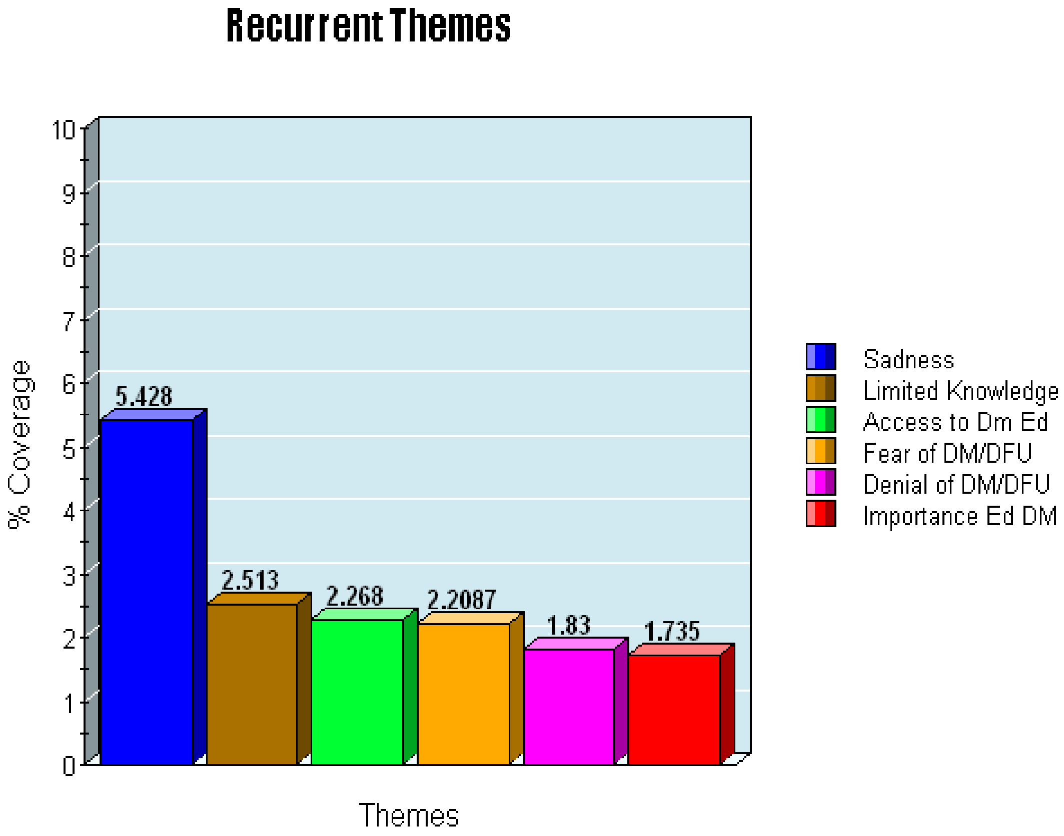
Note. Created by L. Costa, 2011.

The response values of each participant to each theme were added up and an average value was obtained. Responses were placed in a graph with response values ranging between 0 – 10 percent coverage. Sadness was the most common theme receiving 5.428 percent coverage. Limited knowledge about diabetes received 2.513 percent coverage. Lack of access to a diabetic educational program or diabetic educator was valued at 2.268. Fear of diabetic foot ulcers leading to an amputation or death was of great concern to the participants. It received a value of 2.087 percent coverage. Denial of the existence of the disease received a value of 1.830 percent coverage. The importance of diabetic educational programs received a value of 1.735. This information is found in Figure 4.3.

Figure 4.3

Recurrent Themes

DM - Diabetes Mellitus
DFU- Diabetic Foot Ulcer
Ed - Education



Note. Created by L.Costa, 2011.

Theme 1: Sadness**.** Sadness was the overriding emotion. Anger, depression, and anxiety seemed to relate to this. It was viewed by the participants as a long term result of DM and DFU. The most common verbalized comments concerning sadness also had elements of anger, depression, and anxiety.

Anger

Ten participants reported that diabetes and DFU had a major impact on their lives. Their responses regarding immobility related to DFU often revealed feelings of anger. “Very upset.” “I was sure it would never heal.” “Why did this happen to me?” “I did not like it”. Some are angry about the perceptions of others. “People do tell me that I am too old. I get real upset over that.” “They treat us just like children. I mean you can’t do this, you can’t do that and they just act like we have no common sense.” Some participants reported anger over the inability to take care of the foot ulcer. “Mentally, how do I feel about my diabetes? I feel it sucks. I am stressed out. It sucks because I think my life could have more things.”

Depression

All ten participants reported that they had feelings of hopelessness. “Emotionally, I think it is stressing again because I can’t feel it and I don’t understand the severity of it because I can’t feel it.” “It was disturbing and sad because it is hard to treat.” A sense of doom and defeat was expressed by a 51 year old Native American female diagnosed with diabetes type 2 at age 30. She cried during the interview. “It fouls up some things.” “Well, I almost felt like it was the end of the road.” “What am I going to do now?” “Emotionally it was a drag because they would not heal.” “A lot of them don’t understand what I am going through.” Participants verbalized the difficulty of social interaction. “He puts up with me.” Many participants reported that they had loss of interest in their social life. “I don’t really do anything recreational per se.”

Participants described a sense of emptiness. “When I stay home by myself, I am lonesome and was sad.” “I felt isolated. Not really satisfied.” Six participants reported that they were treated with antidepressants. “They have got me on, what is it, Zoloft? I was very depressed you know really, really depressed when I ended up in the hospital over Christmas.” “Of course I am taking it every night. I think I better keep taking it as long as I am having problems here.” Relationships with family and friends were gradually eroded as the participants felt they were becoming a burden. “My oldest daughter is the only one that seems to really care.” “I feel very guilty you know having to depend on people at all times for rides and everything.” Diabetes was described as devastating disease. “I was really feeling bad and crying,” “I do not want to be like that.” “I was feeling bad and don’t like it” Some participants verbalized that their life seemed senseless. They did not feel they had meaning in their life. “I don’t think I have a purpose in life.” ”I don’t have any sense of fulfillment.”

Sadness was often related to limitations in physical or social activity. “It limits my mobility a little bit.” “I stay home.” A sense of distress was evident in some descriptions. “I can’t do some stuff. I can’t play softball and I can’t run anymore.” “There are a lot of activities that I don’t do.” “Well, I just feel like my life is over because I can’t go unless I take insulin with me.” “It is not like it used to be.” “I just like to stay in my room.” “I don’t really have a social life.” One person longed for a better past marital relationship with their spouse. “I can’t have nothing to do with him anymore.”

Anxiety

The participants described feelings of apprehension and powerlessness. “I feel like I am a wreck.” “At first I was confused.” “I feel like the walls are closing in on me.” “I just want to scream help me, help me, help me.” “I feel like I am just going to explode.” Sometimes they described general anxiety. “I have discovered here lately, I have been suffering with anxiety attacks. I get real anxious.” “I could not pray.” ‘I could not do nothing.”

Some participants reported that the feeling of doom was too much to bear. “I really try hard, but I don’t want to be losing my mind. I don’t want to go downand I don’t want to be dying you know.” “I was really scared that it was going to get worse.”

Theme 2: Limited Knowledge about DM. In this cluster, participants described the management of diabetes as a challenge. Participants spoke of self-directed learning. “Most of the education came from the books I bought.” “I really have not learned anything.”

One participant was unable to describe his foot care. The participant had been diagnosed with Type 2 DM since 2003. The client was wearing tennis shoes that seemed to be tight around his toes. His foot ulcer was draining a thick fluid. ”I have not learned to do anything; they just showed a couple videos.” “I really did not get a whole lot of education about the diabetes itself or footwear.” Others described their education. “I think it could be more specific or more intense probably.” “If I could learn a little bit more about it.” “I have got diabetic books all over the place.” “I think I just learned that I had to do that.” The participants described the quality of diabetes education they had received. “Am I satisfied with the way I got my information? No.” “They just come over and check me out and leave.” “I don’t feel like I have enough education.” “I think I am smarter than I give myself credit.” “I am going to have to say I don’t feel that I know everything that I should.”

Some participants believed that there should be more dietary education. “I like to snack on sugars and my sugars are out of control.” “I am not exactly sure how diet is related.” “I wish I had more education about it.” “I think there is probably a lot out there that I don’t know.” “I am not sure about it. I got septic and then I landed in the hospital. I did not realize it and boy am I watching it close now.”

Theme 3: Lack of Access to Medical Education. Many participants believed that there is lack of access to diabetic education. “I did not have the education.” “I have learned a lot of that on my own researching it. “Maybe once or twice a month; I don’t like to go to Pine Ridge.” “On the reservation, it is a terrible education.”

Ten out of ten (100%) of the participants stated they had some access to medical care. This medical care included access to medications but not always access to a medical doctor. “The only one I have seen is the podiatrist.” Some participants stated that they had had minimal or no diabetes education. Six of ten (60%) participants verbalized that they had no access to a diabetes educator or educational program. ”I am very upset about it. Well, not so much diabetic teaching.” Participants complained about the lack of diabetic education in this area. “Because once we moved here there really was no diabetic education here.” “I don’t have a whole lot of education about it but R.L. gives me some diabetic education." "I am not really in an educational program." "I did not have the education."

One participant received education after the development a diabetic ulcer from home health. "Well, the home health nurse was here for about a month or two months and she educated me on a lot of things on the foot ulcers." The same participant stated "A little education especially on the foot ulcer care from the home health nurse. I was very satisfied."

Theme 4: Fear of DFU. Eight of the participants (80%) described worrying about the complications of DFU. "I was afraid if I did not take care of it that it would lead to worse complication." Many participants expressed fears of lower extremity amputations. "So I don't lose my foot." "Not lose my leg."

The participants were afraid of numbness and the development of foot ulcers. "That was disturbing only because I could not feel everything that was going on and it was hard for me see how bad the problem was." "I feel that I don't want to be cutting my leg." Many participants fear that walking will cause a foot ulcer. "I can't walk and it affects me because I can't always feel if something there is hot or cold." Many participants described fear of the pain of a DFU. "I had pain. I panic" "It was kind of weird and stressful" "I was afraid of it." "I don't want to be lying around and sick and have my feet hurt." "It hurts so bad that I can't wear by shoes and it is painful."

Some participants verbalized fears of falling due to the DFU. “I am afraid I will fall.” “Fall, yes and I am afraid for the diabetes to get worse.” “Mobility and safety because 3 months ago I fell and got a crack.” “I don’t want to land in the hospital again. You know, because boy that will be bad.”

Theme 5: Denial of DM and DFU. Many participants described denial. “I was in denial for about three years until I had that stroke and then I realized I had to exercise and diet.” “I don’t think my ulcer is from diabetes is from the Staph infection you know.” Initial denial is seen as a normal part of coping with the diagnosis. “I just isolated myself like a depressed person or something and I had to teach myself to study and learn to come out to it.” “I think it was not real.”

Some participants denied the seriousness of diabetes. “You know sometimes they are sweaty when you are diabetic and you have had too much sugar.” ”Not so much, because it is just another symptom of the disease.” Some participants denied even having diabetes. “It is not diabetes having to take the pills and things.” “First, I was borderline and my kidneys are bad, BUN and creatinine are up. I feel fine now. I am just hoping I don’t have to go on dialysis.”

A 79 year old Native American, diagnosed with diabetes at age 30, believed that diabetes can be cured. “I have to go to get cure.” One form of denial is forgetfulness. “I forgot about diabetes, I forget about my feet when I visit people.”

Theme 6: Importance of Diabetes Education. Participants variously described the importance of education. A 52 year old Native American female diagnosed with diabetes since 1991 stated she could use diabetes education to teach her skills to manage her diabetes. “I did not have the education.” She goes on further to discuss her understanding of diabetes education. “I don’t understand the severity of it because I can’t feel it. If I understood it better I think that probably I would feel better about it.” The importance of diabetes education was illustrated in this statement. “I think it will influence more when I learn more about it. I am going to have to say I don’t feel that I know everything that I should know.”

Summary of Findings

- Participants outlined the impact of diabetes on emotional health characterized by the participants’ feelings of sadness, social isolation, anger, and depression.
- Participants expressed concerns about their limited knowledge of diabetes. Many participants voiced that they self-taught diabetes: one participant reported a single episode where education was delivered via a visual aid. Others received no education.

- Participants reported that this rural community did not have a diabetic education program and had poor access to a diabetes educator.
- Participants volunteered information about the fears of foot ulcers leading to amputation and death.
- Although some of the clients were receiving medications for type 2 diabetes, they denied having diabetes.
- The importance of diabetic education was emphasized by the participants.

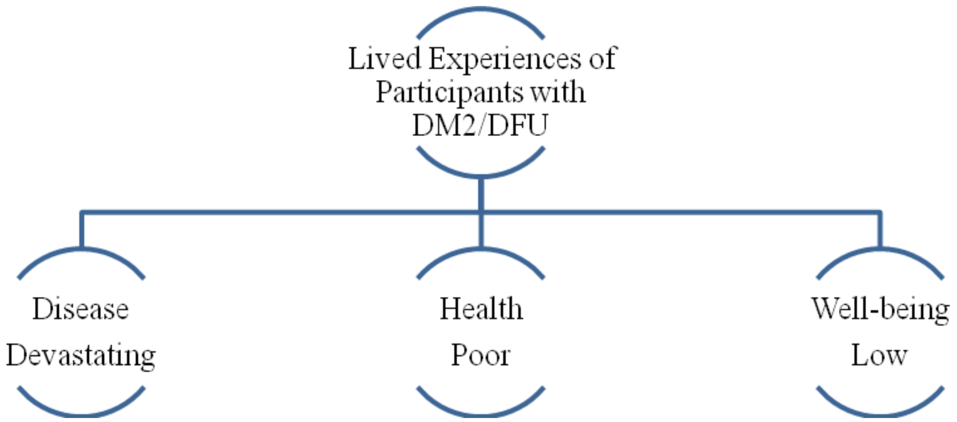
Figure 4.4 summarizes the answers to the first research question

Research Questions

- What are the lived experiences of patients with Type 1 or Type 2 diabetes mellitus diagnosed with a diabetic foot ulcer regarding their disease, health, and well-being?

  The 10 participants felt that diabetes was a devastating disease. They also felt that their health was poor and their well-being was low.

Figure 4.4
Lived of Experiences



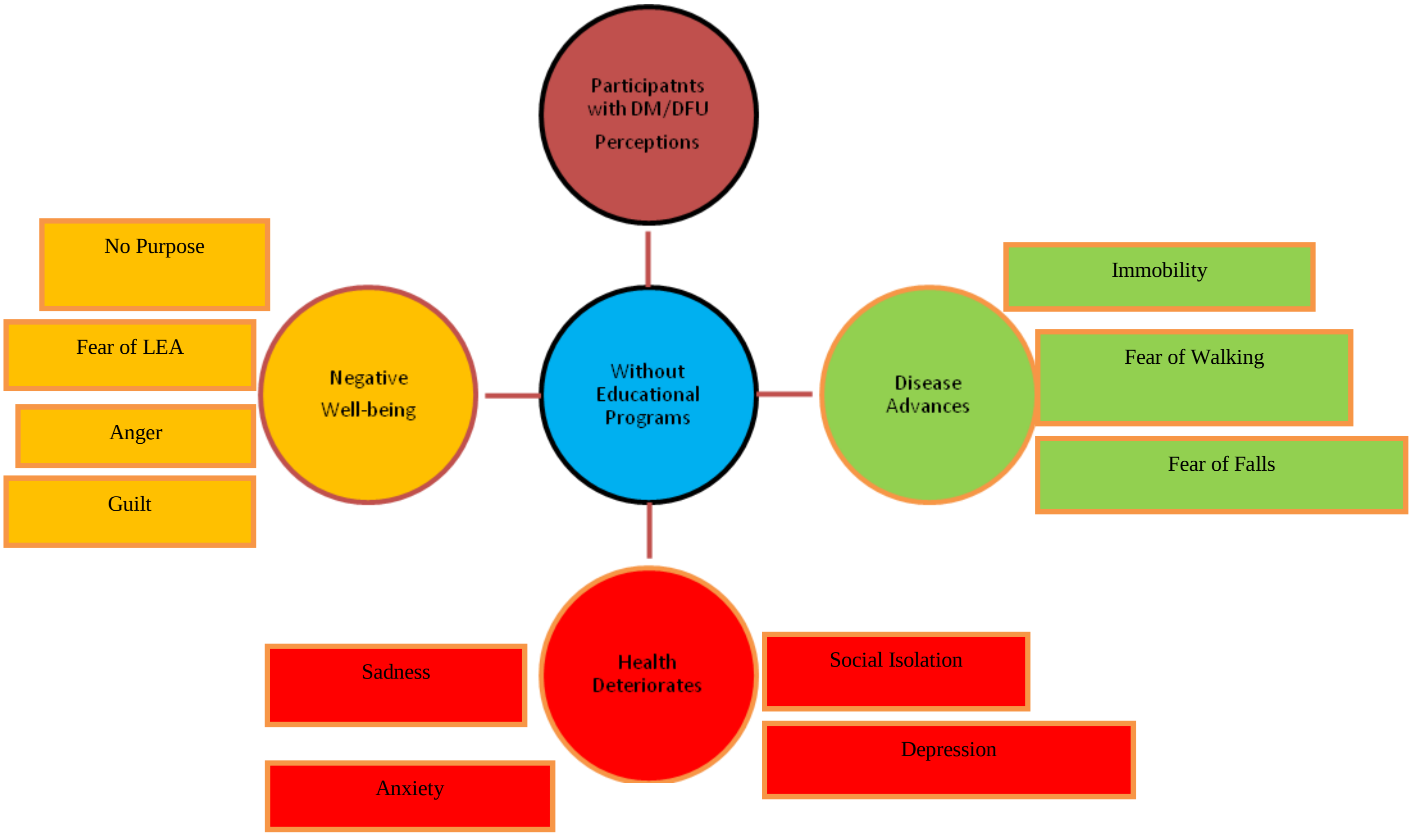
Note. Created by L. Costa , 2011.

- How did diabetic education influence the perceptions of disease, health, and well-being in patients diagnosed with a diabetic foot ulcer?

The 10 participants felt that their diabetes had advanced in part due to their lack of education. This lack of education thus negatively affected their perceptions of health and well-being.

Figure 4.5

Perceptions of Educational Programs Related to Diabetic Foot Ulcer



Note. Created by L. Costa , 2011.

CHAPTER V: RESULTS

Discussion

This chapter includes a discussion of the results from the data analysis, general implications for clinical practice, limitations of the study, and identification of future research needed.

In this study, participants with diabetes focused on feelings of stress caused by the daily management of diabetes. For these participants, diabetes was mentally, emotionally, and physically challenging. At first, the participants ignored the disease, though they were eventually overwhelmed with its complexity and management. Others reported being frustrated with the uncertainty of the disease and the loss of control. Some participants focused on the social isolation. Many participants reported suffering from stress, depression, and anxiety. In an effort to control the stress and negative emotions, participants looked for medical treatment. Some participants took anti-depressants.

Diabetes is a demanding disease (Dabney, 2008). Conducting a comprehensive psychological assessment is the first step in helping participants make informed choices concerning their diabetes. The assessment allows educators to identify the individual’s strengths and vulnerabilities with regard to diabetes education and self-care. This assessment should include perceptions, attitudes, and beliefs about the disease. The participant’s beliefs and attitudes about their physical and emotional status influenced their learning process (Dabney). The completion of the psychological assessment will give information on the psychological status of the participants (Gonzales, 2008).

Sadness was expressed by feeling of emptiness, depression, and anxiety. Diabetes intruded into their life (Lin, 2004). Sadness hampered the management of the disease. Feelings of helplessness and hopelessness contributed to poor self-care. These emotions interfered with learning. The participant’s degree of alertness and ability to concentrate on educational issues was also affected. Emotions affected interest in learning about diabetes (Davis, 2000).

The implications to clinical practice include the use of evidenced base guidelines (Assessment, 2005). These guidelines call for educational programs that are based on the uniqueness of the individual participant. Educators and clinicians need to remember that the participant’s emotions affect not only their overall health but also their approach to day to day management. The assessment of the participant’s beliefs, emotions, and attitudes about disease give information about their readiness to change

(Prochaska, 1995). Kolb’s learning theory can be applied to a diabetes educational program (Davis, 2000). A participant that is sad or fatigued requires motivational strategies that enhance their learning experience. Therefore, participants will be more likely to participate in their plan of care (Assessment).

The educational plan should include engaging the participant in self-management. The participant’s knowledge of the disease should be assessed (Sunn, 2009). The use of Banduras self-efficacy theory can help patients build self-confidence in their abilities to self-manage their disease. Educators and health care providers need to provide opportunities for clients to verbalize concerns regarding their disease (Sunn). These guidelines encourage the active participation of the participants in the management of their diabetes and prevention of DFU.

These educational strategies allow educators to assess for participants knowledge and needs. Participants have the opportunity to practice skills that have a high opportunity for success. Educators provide feedback and coaching regarding progress and improvements. Educators teach participants the importance of applying the new learned skills to enhance their learning process (Bastable, 2007).

Some participants taught themselves diabetes through books. Some clients did not receive diabetes education until after they developed foot ulcers. All the participants reported having access to some medical care and medication. On the other hand, there was limited access to diabetes education in the area.

Plantinga (2008) carried out a quantitative study with 2992 participants with diabetes. The study surmises that more creative efforts should be used to increase the awareness of chronic diseases. This study also concluded that patients with diabetic foot ulcers receive most of their care in the hospital. Moss (2003) concluded that early screening, education, and treatment decreases the rate of LEA.

Participants expressed concerns about their limited knowledge of diabetes and desired lifestyle changes that could prevent or delay the onset of the complications of diabetes (Skinner, 2007). Some participants had some knowledge of diabetes but some gaps were apparent. Some participants voiced that they self-taught diabetes. Other participants reported a single episode where education was delivered via a visual aid. Others received no education. The limited knowledge of diabetes was also found in participants with long-standing related complications and comorbidities (DiMatteo, 2000).

The management of diabetes is a major concern (Byron, 2008). Opportunities for education are missed. Outpatient settings present opportunities to address patient educational needs. Outpatient clinic visits can serve as opportunities for educational intervention (Byron). In many outpatient settings this is not a priority. Butcher (2007) supports the notion that education is related to the prevention of the complications of diabetes. Comprehensive patient education provides an opportunity for one to one teaching (Butcher). In evaluating diabetes education, the Gestalt model is used to encourage patients to become aware of their immediate educational needs, meet them, and learn to self-manage the disease (Daniels, 2004).

One to one teaching allows the client to practice the new learned skills and return demonstrations of concepts. Information needs to be provided through discussions, videotapes, and booklets (Bastable, 2007).

Teaching clients survival skills can prevent disease complications (Clinical Practice guidelines, 2008).

This research study gave insights into the participants general lack understanding of the disease and its treatments. Participants need to be able to take medications and injections accurately. Clients need to recognize the importance of following nutrition, exercising, and performing daily foot exams (Kasper, 2005). This requires assessment of psychomotor skills and the affective domain. Clients need to learn the importance of follow-up education (Kasper).

Evidence based practice guidelines have now been expanded to incorporate comorbidity and complication prevention strategies (Clark, 2000). Diabetes self-management education is essential because it is unique to the participant. Diabetic educators are equipped to address complex issues (Clark).

Diabetes self-management programs are the cornerstone of diabetes care (Orstead, 2007). In rural communities it is difficult to provide clinical evidence based management interventions. Diabetes educators and recognized programs are not readily available (DiMatteo, 2000). This poses a disadvantage for participants living in these communities. Factors that aggravate the management of diabetes include the distance to a diabetic educator and the lack of trained health care providers (DiMatteo). Participants in rural communities rely on health care providers for their diabetes education (Vale, 2003). In this research study, participants reported that this rural community did not have a diabetes educational program or a diabetic educator.

From the findings of this study, it is recommended that small hospitals and clinics should participate in telemedicine programs and web-based efforts, or develop their own diabetes educational program (DiMatteo). Diabetes self-management projects can be started by any health care provider or nursing staff interested in alleviating the burden caused by diabetes. Diabetes self-management programs have been useful in improving knowledge, self-efficacy, and self-care practices (Jokisalo, 2002).

To increase access to diabetes education, educators from large institutions need to engage in telemedicine, satellite, and mentoring programs (Assessment, 2005). This strategy will allow skilled personnel to deliver quality diabetes education to rural areas. The program needs to develop educational materials that will empower participants and promote the self-management of the disease (Assessment)

Future research is needed to delineate strategies to alleviate the ‘rural’ problem. More efforts are needed to investigate the feasibility of distance learning educational programs. The problems faced in this area include access and lack of transportation. Therefore, research is also needed for strategies to recruit and retain diabetic educators.

A foot exam is a powerful way to teach the importance of foot care (Clinical Practice, 2008). Participants need to know that a thorough exam should be performed once per year. Clinicians need to question participants about foot problems at every clinic visit (Clinical). In this research study, participants volunteered information about the fears of foot ulcers leading to amputation and death.

Educational interventions should follow the principles of adult learning. Education should be interactive and evidence based (Bastable, 2007). Addressing the fears, experiences, and needs of the pa participants should form the basis of the educational program (Butcher, 2007). Fears of foot ulceration and amputations can be alleviated by implementing prevention strategies. For example, participants need to learn that it is important to maintain good glycemic control, daily inspection of the feet, wear good fitted shoes, moisturize dry skin but not in between the toes, cut toe nails straight across, avoid self-treatment of calluses, and treat fungal infection promptly (Butcher).

Findings from this study support that appropriate diabetes education and preventive care can reduce the fears of foot ulcers and amputations. Rivera (2009) reported that meticulous foot care and proper patient education has been reported to reduce the amputation rate associated with diabetes by 50%.

Because present knowledge regarding the prevention of foot ulcers and amputations is not widely applied in practice, rates of foot ulcers and amputations remain high in the United States (Clinical Practice, 2008). More research needs to be done on how to encourage health care providers and participants to engage in foot exams.

Denial of diabetes has been associated with poor glycemic control, perceived stress, and lack of knowledge (Dabney, 2008). Although some of the participants were receiving medications for Type 2 diabetes, they denied having diabetes. Denial is considered a normal process of coping with the diagnosis. On the other hand, the continuation of denial is a barrier to education and can cause serious complications (Dabney). In this research study, some of the participants considered themselves to be only ‘borderline’. Sometimes denial was seen as way of coping with the bad news of having diabetes. Denial can reoccur because it is easier for the participants than dealing with diabetes (Dabney). Participants do not want to make lifestyle changes (Dabney). Participants who do not believe that diabetes is a serious disease will avoid self-care. Participants believed that denial shields them from the fact that diabetes is chronic disease that can lead to complications.

This study advocates that reminding educators that denial is part of the coping mechanism is important (Armstrong. 2005). Educators and clinicians need to allow participants to express their concerns at the beginning of each visit. Reflective listening techniques are useful in these cases. Educators can encourage participants to write down their diabetes care plan and health care goals (Armstrong). Participants need to be embolded to understand their learning objectives and to accept that it will take time to reach good glycemic control (Bastable, 2007). Educators need to encourage participants to ask for help if they encounter difficulty with their plan of care (Bastable, 2007).

Future research needs to be undertaken to investigate strategies to solve the problem of denial in patients with diabetes. If denial is long standing it will interfere with the process of acceptance and severe complications will become imminent (Singh, 2005). The participants emphasized the importance of diabetic education. Diabetic education requires a holistic approach. With the collaboration of the participant, educators can provide a comprehensive evaluation. Without diabetes education, participants are less prepared to make informed decisions, make behavioral changes, and utilize coping mechanisms (Butcher, 2007). Poor management can result in the development of complications and poor health outcomes. Diabetes education makes the participants become more aware of the disease, what it takes to treat it, and gives the participants the power to control it (DiMatteo, 2000).

The findings of this study affirm study that diabetic education was seen as important by the participants. Thus, participants would willingly be educated if given the opportunity. The diabetes educator is critically important to the health care team. The educator assists the participants to make informed choices based on evidence based practice. Health care professionals need to be trained to be responsible for diabetes education (Diabetes Prevention, 2009). Health care providers must be active participants in facilitating diabetes self-management education (Diabetes Prevention).

Educators and clinicians need to be aware that diabetic education is an ongoing process that should be repeated every one to two years. This allows clinicians and educators to keep up to date with new research (Diabetes Prevention). Future research concerning the importance of diabetes education in rural communities needs to be undertaken. Limitations of this study included the lack of recruitment of participants with Type 1 diabetes. The interviews were conducted over a shorter amount of time than originally anticipated. The small convenience purposeful sample limited this study. There were no participants under the age of 50, so it may be difficult to generalize the results to younger people. None of the participants are currently working.

General Application to Clinical Practice

The American Diabetes Association (2009) identifies education, diet and exercise as the foundations for diabetes self-management programs. Diabetes education benefits the patient. The patient benefits by living a healthy life. Patient education provides the participants with tools that help control the disease (Orstead, 2007). For example, patients learn coping mechanisms to manage denial, depression, anxiety, and anger. Patients can lose weight by following an exercise program and a healthy meal plan. Foot ulcers and amputations can be prevented through foot care education (Rivera, 2009).

This study suggests that many negative emotions are common in patients with diabetes. In order to make these perceptions and lived experiences more positive, education is essential. Therefore, access to education needs to improve in rural areas (Butcher, 2007). Educators need to consider a holistic approach to patient education. Participants felt that education was important and necessary, but they have not been instructed well enough.

In this study, the researcher examined the interrelationship of several educational models. These theories work together to explain the learner's retention and engagement (Bastable, 2007). The control of diabetes requires numerous changes. Gestalt (2004) and the Prochaska's (1995) theories explain the client's hesitancy in acknowledging their health problem and changing their lifestyle.

The assessment of the learning needs and styles guide the development of goals and objectives. This is evident with the use of the Bloom's and Kolb's theories. The learning strategies are developed to empower individuals to self-manage the DFU. The Bandura's self-efficacy describes how the patient's confidence affects self-care behavior. When the client expresses readiness to change, the introduction of educational materials is more effective. Clients who have a high degree of self-efficacy have better emotional well-being and glycemic control than people with low degree of self-efficacy. The ability to make the necessary adjustments will depend on the individual's ability to change unwanted behaviors. The fundamental assumption is that behaviors can be changed through education (Rankin, 2005). Learning to have healthy thoughts improves a person's feelings, self-concept, and behavior. Bandura's Self-efficacy Theory provides the basis for programs that establish short-term and long-term objectives and goals (Skinner, 2007). Prochaska's theory and Bloom's Taxonomy focus on how the individual's thought patterns, attitudes, and actions influence the learning process. Gestalt Social Field Analysis and Kolb's theory describe the process of interaction between the client's needs and their learning style (Shultz, 2009). The theories focus on past and present learning experiences. Positive experiences motivate clients to self-manage and build a positive sense of wellbeing (Rivera, 2009).

General Recommendations for Future Research

Nursing research about diabetes education must continue to move toward study designs in which interventional programs can be easily created and implemented (Byron, 2008). These approaches could encourage the availability of educational programs for rural communities. An existing issue that needs to be addressed is the identification and selection process of data collection instruments. On that note, emotional factors are important areas that need to be considered and appropriately addressed before instrument selection and utilization (Byron).

In conclusion, six major themes were identified in 10 participants with DM and DFU in Western Nebraska. The lived experiences of the participants regarding their disease, health, and well-being included experiences involving sadness, fear, and denial. Although patients felt that educational programs were worthwhile and necessary, many did not receive adequate education. For those who were educated, diabetes education made a difference in their life. Many participants felt that there was a limited access to diabetes education.

Summary

In summary, although diabetes educational programs did seem to influence the perceptions of disease, health, and well-being in patients diagnosed with diabetes and a diabetic foot ulcer, patients in this study generally lacked proper education. The lived experiences of these patients are often negative and need to be addressed with education (Cews, 2009).

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APPENDIX A

ADULT Consent Form – PAGE ONE

COLLEGE OF SAINT MARY

IRB#:11-04 **Approval Date:** 2/14/2011

Expiration Date: 2/14/2012

Title of this Research Study: PATIENTS' PERCEPTIONS OF LIVING WITH A DIABETIC FOOT ULCER

Invitation: You are invited to take part in this research study. The information in this form is meant to help you decide whether or not take part. If you have any questions, please ask.

Why are you being asked to be in this research study? You are being to participate in this study because you are 19 years of age or older with a diagnosis of Type 1 or Type 2 diabetes mellitus (DM) and have been diagnosed with a diabetic foot ulcer between 6 weeks and 18 months ago, and are able to articulate the experience.

What is the reason for doing this research study? The purpose of this descriptive phenomenological study will be to investigate the perceptions of patients diagnosed with a diabetic foot ulcer. The study will concentrate on how educational programs affect the perceptions of eight to ten patients with diabetic foot ulcers (DFU) in western Nebraska. A secondary purpose of this study will be to explore the lived experiences with clients with Type 1 or Type 2 diabetes mellitus (DM) and a diabetic foot ulcer.

What will be done during this research study? The research study will involve an interview with study participants. The interview will be approximately 60 to 90 minutes in length and will include some questions about you, [such as your age, income, and education.] The interview will take place at a time and a location convenient for you. With your permission, the researcher may contact you once by telephone in a few weeks after the interview to clarify some of your responses.

Participation is this study is entirely voluntary and you can refuse to answer any question and/or stop participating in the interview at any time. Should you choose to stop, no one will be upset with you and your information will be destroyed right away. Your health care and other social services you might receive will not be affected at all if you decide to stop participating in the interview.

Your interview will be audio-recorded, then written down by someone listening to the tapes. It will be analyzed, and studied by the researcher in a way that protects your identity. This means that a number will be used instead of your real name.

Participant Initial_____

A transcriptionist (a person who types your words while listening to your audio recordings) will sign a pledge of confidentiality before doing this work.

ADULT Consent Form – PAGE TWO

IRB#: 11-04 **Approval Date:** 2/14/2011
Expiration Date: 2/14/2012

Any information provided and/or identifying records will remain confidential and safeguarded in a locked fireproof safe/file at the Gordon Memorial Hospital Medical Records Department for a period of five years. The results of the research project may be made public and information quoted in professional journals or meetings, but your real name will never be used. Deciding not to participate or answer some of the questions will have no effect on your health care or any other services you might receive from doctors, nurses, or social services. There may be a risk that talking about the experience during the interview may bring up sad memories, make you feel tired, or make you anxious. Remember, you can stop the interview at any time that you feel tired or for any other reason. The benefit of this study is that it may provide an understanding of the value of educational programs in changing perceptions of disease and overall health.

What are the possible risks of being in this research study? You may be at risk for fatigue, anxiety, or sadness during discussion and recollection of your experiences (Billings, 2005). If fatigue occurs, (or for any other reason) you may terminate the interview at any time to rest or reschedule it, or may choose to not continue in the study. Your welfare is a major concern for the researcher. If you have a problem as a direct result of being in the study, you should immediately contact the person listed at end of the consent form.

What are the possible benefits to you? You may not get any direct benefit from being in this research study.

What are the possible benefits to other people? The benefit of this study is that it may provide an understanding of the value of educational programs in changing perceptions of disease and overall health.

What are the alternatives to being in this research study? Instead of being of this research study you can choose not to participate.

What will being in this research study cost you? There is no cost to you to be in this study.

Will you be paid for being in this research study? You will not be paid or compensated for being in this research study.

Participant Initial_____

What should you do if you have a problem during this research study?
Your wellbeing is the major concern of every member of the research team. If you have a concern as a direct result of being in this study, you should immediately contact the person listed at the end of this concern form.

ADULT Consent Form – PAGE THREE

IRB#: 11-04 **Approval Date:** 2/14/2011
Expiration Date: 2/14/2012

Note: *College of Saint Mary will not approve studies that have greater than minimal risk to participants*

How will information about you be protected? Reasonable steps will be taken to protect your privacy and confidentiality of your data. Your interview will be audio-recorded, then written down by someone listening to the tapes. It will be analyzed, and studied by the researcher in a way that protects your identity. This means that a number will be used instead of your real name. A transcriptionist (a person who types your words while listening to your audio recordings) will sign a pledge of confidentiality before doing this work.

Any information provided and/or identifying records will remain confidential and safeguarded in a locked fireproof safe/file at the Gordon Memorial Hospital Medical Records for a period of five years. The only persons who will have access to your records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study may be published in specific journals or presented at scientific meetings but your identity will be kept strictly confidential

What are your rights as a research participant? You have rights as a research participant. These rights have been explained in this consent form and in *The Rights of*

Research Participants that you have been given. If you have any questions concerning your rights, talk to the investigator or call the Institutional Review Board (IRB), telephone (402)-399-2400.

What will happen if you decide not to be in this research study or decide to stop participating once you start? You can decide not to be in this research study, or you can stop being in this research study ("withdraw") at any time before, during, or after the research begins. Deciding not to be in this research study or deciding to withdraw will not affect the relationship with the investigator, the College of Saint Mary, or with the Gordon Memorial Health Services. You will not lose any benefits to which you are entitled. If the research team gets any new information during this research study that may affect whether you want to continue being in the study, you will be informed promptly.

Participant Initial_____

ADULT Consent Form – PAGE FOUR

IRB#: 11-04 **Approval Date:** 2/14/2011
Expiration Date: 2/14/2012

Documentation of informed consent:

You are freely making a decision whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study.

If you have any questions during, you should talk to the investigator listed below. You will be given a copy of this consent form to keep.

If you are 19 years or older and agree with the above, please sign below.

Signature of Participant: _________________________Date: ______Time: _______

Investigator certification:

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntary and knowingly giving informed consent to participate.

Signature of Investigator:

APPENDIX B

Gordon Memorial Hospital Health Services
Institutional Review Board (IRB)

All researchers are required to be familiar with:
1) The Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm), 2) *45 CFR 46* of the code of federal regulations (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)
3) Research Integrity (http://www.hhs.gov/ohrp/irb/irb_chapter4.htm)
Biomedical Researchers only must be familiar with:
Pertinent Nebraska Law for biomedical research, current discussion at the *Offices of Human Research Protections*
To be completed for all *research*, defined in *45 CFR 46.102(d)* involving *human subjects*, defined in *45 CFR 46.102(f)* and conducted at the Gordon Memorial Hospital, Gordon Medical Clinic, and the Rushville Medical Clinic, by or under the direction of any employee, agent or student of this institution, including research conducted at or in cooperation with another entity.

1. **Title of Research**: *Patients' Perceptions of Living with a Diabetic Foot Ulcers.*
2a. Principal Investigator (PI): *Lety Costa, PA-C/ NP-C, MSN.*
2b. Additional Investigators/ Supervising Physicians: Christopher Costa, MD. Anthony VanBang, MD.

2c. Faculty Advisor (if PI is a CSM student, College of Saint Mary): *Dr. Martha Brown, College of Saint Mary.*
2d. GMH, Gordon Memorial Hospital, Sponsor:
3. Review Category
_____ Exempt (Complete Section A) by category _____
_____ Expedited (Complete Section B) by category __*6*__
___X__ Full (Complete Section C)

4. Anticipated Date on which Data Collection will begin: *When approved.*
5. If this is a funded project, please name funding source(s). N/A

6. If this proposed research has been, or will be reviewed by an IRB elsewhere please name the IRB(s). If applicable, attach a copy of each IRB's recommendations and findings, and dated approval. *N/A*

You must submit this form, all supporting documents and a description of the proposed research, as specified in Section B (for FULL Review) or in Section C (for Full Review) in paper format. Prior to submission to HHS - OHRP OFFICE, all proposals require all signatures below as necessary. Proposals that are incomplete or lacking signatures will be returned to the Principal Investigator.

_________________________________ ____________________________
Researcher (signature) Department/School and Date
Lety Costa PAC/NPC________________________ (308) 282-1444, e-mail: lcosta@gmh.org
Researcher (printed) Phone and email (both required)
_________________________________ **_____(308) 282-0401**
Jim LeBrun. CEO Sponsor (signature) Phone
_________________________________ ____________________________
Supervising Physician. Christopher Costa MD. (Signature) Date
_________________________________ ____________________________
Supervising Physician. Anthony VanBang, MD. (Signature) Date
_________________________________ ____________________________
Kathy King, BSN, IRB/ Education Department (Signature) Date

Timothy Costa M.D. Not Affiliated/Scientist (Signature) Date

The project described above has been approved by the GMH Institutional Review Board.

_________________________________ ____________________________
Chair or Administrator to IRB (signature) Date

APPENDIX C

If you are a client who has been diagnosed with a diabetic foot ulcer within the last 18 months

- **You are invited to share your personal experiences.**
- **Sharing your personal experiences of what it is like for you will assist providers to learn how to better help clients who live with diabetic foot ulcers.**
- **Your participation will include a 60 to 90 minute audio-recorded interview**

A doctoral student researcher from College of Saint Mary is looking for 10 men or women to age 19 or older to participate in this research study.

If you are interested and want to discuss the study
Please contact
Lety Costa, MS, PA-C/NP-C
(308) 282-1442 or email: lety00@msn.com

APPENDIX D

General Statements/Interview Guide

Disease

- Please describe the diabetic education you have received.
- Please tell me about how diabetes is related to a foot ulcer.
- How did you feel when you were first diagnosed with diabetes?
- How has diabetic education influenced your feelings about diabetes?
- What were your feelings when you were first diagnosed with a diabetic foot ulcer?
- Has diabetic education influence your beliefs about DFU? If yes, how?
- Please describe the methods you have learned for preventing foot ulcers.
- How often did you receive this education?
- Tell me how or if the educational program taught you to perform daily foot exams.
- Did you receive any follow up foot care education? If yes, what type of follow up and from whom?

- How did the education you have received influence your ability to manage your diabetes?
- How did the education you have received influence your ability to care for your foot ulcer?
- How satisfied are you with the quantity and quality of the education you have received?

Health

Physical Functioning

- Describe for me your physical condition.
- How satisfied are you with your physical condition?
- How does your foot ulcer affect your physical health?
- Describe for me things that you do differently because of your diabetic foot ulcer.
- Tell me about any physical activities you have learned to do in the educational program.
- How did diabetic education influence your health?

Mental Functioning

- Can you describe your mental health?
- What stresses you out?
- What are you doing to cope with the stress?
- How does your foot ulcer affect your feelings or emotions?

- How did diabetic education influence your ability to cope?

Social Functioning

- Please describe your interaction with friends and family.
- How does your foot ulcer affect your social life?
- What are the recreational activities you are engaged in?
- How did your diabetes education affect your social functioning?

Wellbeing

- How happy are you with your personal life?
- What do you believe is your purpose in life?
- How has your DFU impacted your purpose in life?
- How has diabetic education influenced this?
- Describe any change in your sense of fulfillment since having a DFU.
- How has diabetic education influence this?
- What motivates you to take care of your foot ulcer?
- How satisfied are you with the condition of your foot?
- How satisfied are you with the skills you learned in your educational program?

- Overall, what has been the biggest impact of diabetic education on your well-being?
- What was most helpful regarding your diabetic education?
- What has been the least helpful?
- How satisfied are you with your general health?

APPENDIX E

Transcriber's Pledge of Confidentiality

I will be participating in the dissertation research project entitled:

PATIENTS' PERCEPTIONS OF LIVING WITH A DIABETIC FOOT ULCER

I will be transcribing audio-recorded interviews into text. I will not know the names of the informants, but if I should recognize information that enables me to identify any of the participants I agree to maintain their confidentiality. By signing this agreement I pledge to keep all information strictly confidential. I will not discuss the information I transcribe with any person for any reason. I understand that to violate this agreement would constitute a serious and unethical infringement on the informant's right to privacy.

______________________________ ___________

Signature of Transcriptionist Date

_________________________________ __________

Signature of Principle Investigator Date

APPENDIX F

Research Participants with a Diabetic Foot Ulcer - Demographic

Client number: _______________ Today's date: ________________
Address: ____
City, state, zip: ____________________________________
Telephone: home (   )___- ____Date of birth: ____________
Sex: ☐ Female ☐ Male

Background

- Ethnic origin:

☐ White not Hispanic ☐ Black not Hispanic ☐ American Indian or Alaska Native
☐ Hispanic ☐ Filipino ☐ Asian Indian ☐ Chinese ☐ Japanese ☐ Korean
☐ Vietnamese ☐ Native Hawaiian ☐ Guamanian or Chamorro ☐ Samoan
☐ Other Asian – Print race, for example, Hmong, Laotian, Thai, Pakistani, Cambodian and so on. ________________
☐ Other Pacific Islander – Print race, for example, Fijian, Tongan, and so on. ___________________

- Please circle the **highest level** of education completed:

Level 0: Pre-primary education
Level 1: Primary education
Level 2: Lower secondary education
Level 3: Upper secondary education
Level 4: Post-secondary education
Level 5: First stage of tertiary education
Level 6: Second stage of tertiary education

- Are you currently?

☐ Married ☐ Separated ☐Widowed
☐ Single ☐ Divorced
Other_________________________

- Please, indicate below which chronic condition(s) you have:

☐ Diabetes type 2 ☐ Diabetes type 1 ☐ High cholesterol ☐ High blood pressure
☐ Heart disease. Type of heart disease:
☐ Lung disease. Type of lung disease:
☐ Other chronic condition Specify: ___________________________

- Number of people living in the household_______

- Do you work outside the home? (Y) (N). Annual Household Income_______

- What type of diabetes do you have?

- When were you first diagnosed with diabetes?

- How old were you then?

- Did you have access to a doctor?

- Did you have access to medications?

- Did you have access to diabetes education?

APPENDIX G
DEMOGRAPHIC TABLE

# of People House	Acc. to Diabetic Edu	Acc to MD	Acc to Med	Age when DX with DM	Annual Income	Other Chronic Diseases	Ethnic Origen	Level of Edu	Marital Status	Sex
6	Y	Y	Y	44	Unknown	Y	Native American	4	Divorced	Male
2	Y	Y	Y	48	35,000.00	Y	White	4	Married	Male
2	N	Y	Y	30	Unknown	Y	Native American	2	Married	Female
2	Y	Y	Y	30	Unknown	Y	Native American	0	Married	Female
13	N	Y	Y	39	Unknown	Y	White	1	Widowed	Female
2	Y	Y	Y	30	38,160.00	Y	White	4	Widowed	Female
2	N	Y	Y	64	Unknown	Y	White	3	Married	Female
2	N	Y	Y	71	Unknown	Y	White	4	Married	Male
2	N	Y	Y	55	Unknown	Y	White	3	Married	Female
11	N	Y	Y	35	15,000.00	Y	Native American	5	Married	Female

APPENDIX H

NATIONAL INSTITUTES OF HEALTH

Regulations and Ethical Guidelines

The Belmont Report

Ethical Principles and Guidelines for the protection of human subjects of research

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Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes(1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

Part A: Boundaries Between Practice & Research

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergoreview for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called ”experimental” when the terms ”experimental” and ”research” are not carefully defined.

For the most part, the term ”practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. (2) By contrast, the term ”research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is ”experimental,” in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project. (3)

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Part B: Basic Ethical Principles

B. Basic Ethical Principles

The expression ”basic ethical principles” refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to ”volunteer” or to ”protect” them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term ”beneficence” is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim ”do no harm” has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients ”according to their best judgment.” Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of ”fairness in distribution” or ”what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Part C: Applications

C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent. -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of ”the reasonable volunteer” should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that **(1)** incomplete disclosure is truly necessary to accomplish the goals of the research, **(2)** there are no undisclosed risks to subjects that are more than minimal, and **(3)** there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

2. Assessment of Risks and Benefits. -- The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term ”risk” refers to a possibility that harm may occur. However, when expressions such as ”small risk” or ”high risk” are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term ”benefit” is used in the research context to refer to something of positive value related to health or welfare. Unlike, ”risk,” ”benefit” is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be ”balanced” and shown to be ”in a favorable ratio.” The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: **(i)** Brutal or inhumane treatment of human subjects is never morally justified. **(ii)** Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. **(iii)** When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation). **(iv)** When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. **(v)** Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects. -- Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only ”undesirable” persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

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(1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

(2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

(3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

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