The Power of Words in Diabetes Care

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Abstract

Words/language have the power to instill hope, comfort, and engagement or create the opposite effect of fear and doubt. Language plays a key part in the way relationships develop. The language movement in diabetes care is a campaign intended to change attitudes about diabetes and raise awareness of the impact of language on persons managing the disease (Dickinson et al., 2017). This scholarly project adds to the language movement in diabetes care with the creation of a communication guide for health care providers. The guide increases awareness of language used and provides education on this important aspect of patient care. The Donabedian quality improvement framework of *Structure*, *Process* and *Outcome* guided the project along with the middle range *Theory of Self-Efficacy* by Barbara Resnick. The framework guided the assessment of required care, the patient-provider relationship and socioeconomic and environmental conditions. The theory provided a basis for understanding behavior and guided the development of interventions presented in the communication guide to change behavior and improve health outcomes for persons living with diabetes. The project also included a questionnaire inquiring about how a person feels when certain words/phrases are used in a health care encounter. The questionnaire data collected added to the science surrounding the language movement within diabetes care by supporting the premise that the words/language used by healthcare providers and others does impact the patient-provider relationship. The results showed that people with diabetes are affected positively by positive communication and negatively by negative communication techniques.

Keywords: language movement, diabetes care, self-efficacy, patient-provider relationship

Acknowledgements

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The Power of Words in Diabetes Care

Chapter One

The words/language used in health care can impact the patient and provider relationship and may unintentionally have a negative impact on patient outcomes. Words have the power to instill hope, comfort, and engagement or create the opposite effect of fear and doubt (Dickinson, 2017). Words used in health care interactions can affect self-confidence and motivation, and can influence health outcomes (Speight, Conn, Dunning, & Skinner, 2011). Creating a therapeutic relationship with a healthcare provider can influence a person's willingness to actively engage in self-management of their diabetes (Dickinson, 2017). How does word choice by health care professionals impact the care of people with diabetes? Studies looking at the use of words/language in diabetes care are limited. However, the literature that is available supports the premise that improving health outcomes requires health care professionals to use language that promotes active engagement in health maintenance activities and supports self-care and self-management for people with diabetes.

This scholarly project intends to uncover how patients with diabetes feel when certain words or phrases are used in a health care encounter. This information along with evidence found in research on this topic will direct the development of a "*How To*" guide on positive communication for healthcare providers. The communication guide will be useful to a wide range of health care providers in many types of locations from diabetes education settings to primary care clinics.

Background and Significance

Diabetes mellitus is a complex chronic disease requiring continuous medical care and on-going self-management. Living with diabetes presents many behavioral, emotional and psychosocial challenges. Currently, 34.2 million people or 10.5% of the population have diabetes

in the United States and the number continues to rise (Centers for Disease Control and Prevention [CDC] 2020). The most common types of diabetes include type 1 and type 2. Type 1 diabetes is characterized by a lack of insulin production whereas type 2 is identified by insulin resistance as well as a gradual decrease in insulin production (American Diabetes Association [ADA] 2020). Type 1 diabetes accounts for 5 to 10% of all diagnosed cases and develops rapidly. Type 2 is present in 90 to 95% of people with diabetes, is slow to develop, and is chronic in nature (CDC, 2020).

The cost of diabetes is also on the rise. In 2017, the total cost of diabetes care in the U.S. was $327 billion dollars. Direct costs went from $188 billion in 2012 to $237 billion in 2017. Indirect costs rose from $73 billion to $90 billion in the same period (ADA, 2018). Indirect costs include things such as managing a disability, work loss and premature death (ADA, 2018). Between 2012 and 2017 additional medical costs associated with diabetes increased from $8,417 to $9,601 per person (ADA, 2018). After adjusting for age group and sex, average medical expenditures among people with diagnosed diabetes are more than twice the expenditures for people without diabetes (CDC, 2020). In addition, people with diabetes are at much higher risk of serious health complications such as blindness, kidney failure, heart disease and stroke (CDC, 2020). The impact of this chronic disease is widespread and has major implications in the overall health of our communities which makes it a complex public health challenge.

Words, Language and Relationships

Mark Twain (1999, p. 11) once said, "The difference between the right word and the almost right word is the difference between lightning and the lightning bug." How often do we think about the words we use when talking to or about our patients? Words reflect one's attitudes, thoughts, intentions and actions. Negative word choices used to address or reference a

person seeking assistance are identified as stigmatizing. Stigmatizing words can cause shame, dishonor, disgrace, and discrimination, and are based on stereotypes and misconceptions (Burda, 2020). More significantly, these negative words begin to define the person not their current behavior or situation. Researchers have looked at the effect of words on other health states. Wang et al. (2008) found that negative words induced anxiety and worry in postoperative patients. People who heard negative words had higher pain scores and secreted higher levels of the stress hormone cortisol. In a study of the effect of negative words on pain during venous blood draws, participants reported significantly more pain after hearing negative words such as *sting* or *beware* (Ott et al., 2012).

There are multiple definitions of *language*. The human language is unique and understanding its use can be complex. Language can be spoken, written, or electronic and conveyed by gestures or signs (Dunning, Speight, & Bennett, 2017). Language influences the way people perceive, experience and remember events as well as make decisions and it affects self-esteem (Speight, Conn, Dunning, & Skinner, 2011). Words have power and help create feelings that can affect physical and mental well-being (Pennebaker, Mehl & Niderhoffer, 2003). Language, and the attitudes it reflects, can affect self-confidence and motivation, and influence health and well-being directly or in-directly (Speight, Conn, Dunning, & Skinner, 2011).

Language plays a key part in the way relationships develop. It is through language, both verbal and non-verbal, that people interpret and apply context to an experience. Health care providers need to be aware that developing a trusting therapeutic relationship is key to promoting positive health outcomes (Leahy, 2008). Very often for persons with diabetes the language used has a negative undertone which limits the ability to develop a positive relationship and can contribute to an already stressful illness experience (Dickinson, 2017). Creating a strong

therapeutic relationship can influence a person's ability and willingness to actively take part in self-management of their diabetes (Dickinson, 2017).

Physical and Emotional Effects

Research has shown that negative words can trigger a stress response, which is activated by the hypothalamic-pituitary-adrenal (HPA) axis. The HPA axis releases corticosteroids, which are hormones that can lead to elevated blood glucose levels (Flier & Underhill, 1995). Stress hormones also have inflammatory and immune-suppressive properties, which can contribute to other co-morbid conditions such as heart disease. Stress can lead to high blood glucose levels, which in turn contribute to inflammation, increased risk of infection and decreased wound healing (ADA, 2020). Using negative language can contribute to stress in persons with diabetes potentially exacerbating an already unhealthy situation.

According to Sue et al. (2007), there may be a parallel connection between the unconscious use of hurtful language and racial microaggressions in clinical practice. Sue et al. (2007) define microaggressions as, "brief and commonplace daily verbal, behavioral, or environmental indignities, whether intentional or unintentional, that communicate hostile, derogatory, or negative racial slights and insults toward people of color." They emphasize the importance of teaching clinicians early in their education about this phenomenon, so they can identify and change their practice. This same understanding can be applied to the care of people with diabetes because all forms of microaggressions have harmful consequences (Sue et al., 2007). Over time, the negative language used with people who have diabetes begins to define the individual rather than describe their condition (Dickinson, 2018). Eventually this leads to how people with diabetes define themselves and their feelings about diabetes. This negative definition

of themselves can develop into apathy in self-management of their disease and ultimately may affect health outcomes in a negative way (Dunning, Speight, & Bennett, 2017).

The Language Movement in Diabetes Care

People with diabetes are exposed to the language used by health care providers and for many it is a foreign language. Many people struggle to understand and process basic health information because the words used are strange or uncommon.   Dunning, Speight and Bennett (2017) refer to the language of diabetes as a dialect. A dialect is defined as the way a group of people use the language, type of speech and the way relationships are established within a social context (Dunning, Speight, & Bennett, 2017). The dialect may not be deliberately negative or abusive. However many health care providers do not understand the effect their words have on patients. Very often, the patient is not in tune with the health care providers' use of the diabetes dialect leading to miscommunication which is a barrier to developing a therapeutic relationship.

Adding to the difficulty in communication is the covert message being conveyed through common words used in health care that emphasize control, surveillance and compliance. These messages may lead to feelings of powerlessness and decrease a person's self-efficacy. Research has shown that an individual's level of self-efficacy plays a key role in their ability to self-manage chronic disease (Resnick, 2014). Certain words and phrases used commonly in health care can be de-motivating, inaccurate or even harmful. Words such as *non-compliant, non-adherent,* and *uncontrolled* are examples that do not provide an assessment of the disease but instead provide a judgement about the person (Dickinson, 2017; Speight et al., 2011). A negative interaction with a health care provider can elicit negative emotions and can potentially decrease a person's level of self-efficacy (Resnick, 2014).

How can this negative approach be changed? A paradigm shift is needed to move from the traditional hierarchical approach of the health care provider being in charge to one of collaboration centered on the person with diabetes. The language movement within diabetes care is the start of this paradigm shift. A task force consisting of representatives from the Association of Diabetes Care and Education Specialists (ADCES) and the American Diabetes Association (ADA) convened to create a position statement on effective ways of communicating about diabetes (Dickinson et al., 2017). The statement provides recommendations for language to be used by health care professionals and others when discussing diabetes verbally or in writing. The authors present 5 recommendations. To use language that is (Dickinson et al., 2017):

1. Neutral, nonjudgmental, and based on facts, actions or physiology/biology

2. Free from stigma

3. Strengths based, respectful, inclusive and imparts hope

4. Fosters collaboration between patients and providers

5. Person-centered

Language cannot be separated from thought or experience. When empowering language is used it can motivate and engage people with diabetes to participate in healthy behaviors. The opposite is true when language is filled with judgment and blame. The language movement in diabetes care is a campaign intended to change attitudes about diabetes and raise awareness of the impact of language on persons managing the disease (Dickinson et al., 2017).

Organizational Assessment

Organizational readiness

The target organization is the largest non-profit health system in Wisconsin consisting of 23 hospitals and 110 physician clinics as reported on the organization website

(https://ascension.org/Our-Work/Healthcare/Ascension-Wisconsin/). As a Catholic health

ministry the organization is dedicated to spiritually centered, holistic care which sustains and

improves the health of individuals and communities. The state-wide diabetes program is focused

on providing safe, comprehensive and coordinated care to all persons with diabetes. The mission

of the diabetes education program is to foster effective diabetes management by providing

participants with tools, supports and encouragement for understanding and controlling their

diabetes (C. Kristbaum, personal communication, July 10, 2020). The organization has 18 sites

throughout the state for diabetes education. Type 2 diabetes management was named a fiscal

year 2020 (FY20) priority for the state with specific goals focused on education, quality and

community outreach to high risk and vulnerable populations (C. Kristbaum, personal

communication, July 10, 2020).

Organizational strengths

The hospitals located in the southern region of the state have a long-standing diabetes

education program that is accredited by both the American Diabetes Association (ADA) and the

Association of Diabetes Care and Education Specialists (ADCES). It follows a well-known

researched based curriculum provided by the International Diabetes Center (IDC). The educators

in the southern locations are all experienced nurses or dieticians and all are Certified Diabetes

Educators (CDE). The diabetes program has one state-wide director with regional managers in

charge of various locations. The program goals for FY20 included maintaining blood pressure

control of 130/70 in 75% of participants and a target A1c reduction for at least 24.9% of

participants with an A1c greater than 9%. Both goals were achieved in FY20 with 76% of

participants achieving blood pressure control and 26.79% achieving an A1c reduction (C.

Kristbaum, personal communication, July 10, 2020).

Organizational weaknesses

The program functions differently in the north part of the state as compared to the south. All diabetes education completed in the northern locations is through primary care clinics and not specific diabetes education clinics. All of the sites are dependent on referrals from physicians and the process is inconsistent across sites. Some of the sites experience high no-show rates. Also the non-accredited sites in the north do not have the benefit of a structured education curriculum such as that provided in the south by the IDC. In addition, not all sites in the south region are meeting A1c goals and the quality metrics for clinics serving mainly an African American population are below target (C. Kristbaum, personal communication, July 10, 2020).

Organizational opportunities

This project is fully supported by the diabetes program leadership (C. Kristbaum, personal communication, July 10, 2020). The information gained from patients who participate in this project will benefit both structured education clinics and diabetes educators and physicians working in primary care clinics without a structured education program. The project implementation will focus on one specific clinic in an urban location, with a high percentage of underinsured and uninsured African American patients living in an economically challenged community. In calendar year 2019 the clinic's average A1c was 9.8 with a range of 5.0 to 20.0. (A. Prout, personal communication, August 19, 2020). Per the ADA (2020) an A1c under 7.0 is recommended. This data represents an area of opportunity to improve patient outcomes.

Organizational threats

The clinic identified for improvement has a high patient census so time to participate in the project may be limited. The results of the project have the potential to uncover areas for improvement which may be difficult for the clinic to address. How providers communicate with

patients may be difficult to change and may not be a priority in the current health care climate. Patient threats include time and willingness to participate in the project.

Stakeholders

Project stakeholders include patients with diabetes, diabetes educators, nurses, medical assistants, physicians, clinic leaders and the diabetes program leaders within the organization. The end product of this scholarly project also has the potential to benefit office staff including schedulers, lab personnel, and other support services.

Purpose

The purpose of this Doctor of Nursing Practice (DNP) Scholarly Project will be to support and expand on the language movement in diabetes care and education. The words used in health care can impact the patient and provider relationship and may unintentionally have a negative impact on a patient's self-efficacy leading to poor health outcomes. This quality improvement project intends to uncover how patients feel when certain words or phrases are used in a health care encounter. This information along with evidence found in research on this topic will direct the development of a "*How to*" guide on positive communication for healthcare providers. The communication guide will be useful to a wide range of health care providers in many types of locations from diabetes education settings to primary care clinics

Summary

The words/language used in health care can impact the patient and provider relationship and may unintentionally have a negative impact on patient outcomes. Words used in health care interactions can affect self-confidence and motivation, and can influence health outcomes (Speight, Conn, Dunning, & Skinner, 2011). Certain words and phrases used commonly in health care can be de-motivating, inaccurate or even harmful. The language movement within diabetes

care is focused on changing and improving communication. When empowering language is used

it can motivate and engage people with diabetes to participate in healthy behaviors. This project

will support and expand on the language movement in diabetes care by developing a

communication guide for health care providers to increase awareness and educate on this

important aspect of patient care.

Chapter Two

Review of Literature

An extensive literature search was completed using the search engines Google Scholar, ProQuest, CINAHL and PubMed. Search terms included *diabetes, diabetes management, diabetes self-management, language, words, health outcomes, therapeutic relationship, compliance, and adherence.* The search yielded 1,322 results. Inclusion and exclusion criteria were used to narrow the results. The inclusion criteria included studies from 1990 to the present, full text, written in English, from academic journals with a focus on adults. The "search forward" feature in Google scholar's citation index was used to find other articles that cited research of interest. The reference list of various articles was used to find additional research. A standardized evidence level scale was used (Melnyk & Fineout-Overholt, 2005) and study types identified included randomized controlled trials (RCT), meta-analysis, cohort studies, descriptive studies, qualitative studies, position statements and expert opinion. A total of 30 studies was evaluated in this literature review. See evidence table (Appendix A). Three themes emerged from the literature search: *Negative words and other communication in health care*; *importance of words/language used in diabetes care;* and *self-management/self-efficacy-its effect on health outcomes*.

Negative and other communication in health care

Several studies have looked at the use of negative words and their effect on patient perception of care. In a RTC Ott et al. (2012) found that words associated with pain, *sting* and *beware,* increased the perception of pain during venous blood sampling. These results matched other studies demonstrating that words have an impact on individual's evaluation of external stimuli (Lang et al., 2005; Krosnick et al., 1992). A RCT study by Wang et al. (2008) found that

negative words used by nurses on surgical wards negatively influenced postoperative pain

management within the first postoperative day after abdominal surgery. The increase in post-

operative pain was associated with activation of the hypothalamic-pituitary-adrenal (HPA) axis

in which the body releases corticosteroid into the circulation as a stress response (Wang et al.,

2008). If the patient was prepared with negative words used by the nurse to describe what pain

or discomfort the patient might experience, it resulted in greater levels of reported pain and

anxiety than if the nurse said nothing about what might be experienced (Wang et al., 2008).

A meta-analysis of the psychological aspects of language and word use found that the

words people use in their daily lives can provide important insight into a person's social and

emotional world (Pennebaker, Mehl, & Niederhoffer, 2003). Words are a central feature of

social, clinical, personality and cognitive psychology. The words a person uses have a clear

impact on the listener, both positive and negative, and very often are processed at a nonconscious

level (Pennebaker, Mehl, & Niederhoffer, 2003).

In contrast to negative communication the cancer care community has long recognized

the importance of patient-centered communication. Common elements exist in communication

with cancer patients and in other areas of health care. Patient-centered communication requires

an understanding and validation of the patient's perspective, understanding of the patient within

their own psychological and social context, a shared understanding of the patient's problem and

needed treatment and requires that the patient share power with the clinician including

meaningful involvement in decision making (Epstein & Street, 2007). In a meta-analysis Street

et al (2009) found that patient-centered communication assists in building a therapeutic

relationship characterized by mutual respect, trust and commitment.

In the clinical area of substance abuse treatment, the use of stigmatizing words can cause shame, dishonor and discrimination (Burda, 2020). Research has shown that individuals diagnosed with substance use disorders (SUD's) report a higher number of stigmatizing experiences that any other social group (Room et al., 2001). In a ranking of stigmatizing experiences in 18 social groups, SUD's ranked number 1 and alcohol use disorder ranked number 4 (Room et al., 2001). Negative word choices used to address or reference a person can lead to the development of a negative stereotype which then promotes biased judgement of individuals (Room et al., 2001).

A racial microaggression is another form of negative interaction. It has been described as a "subtle insult" such as a dismissive look, or a negative tone or word that can be found in everyday conversation and interaction (Sue et al., 2007). These racial microaggressions can impair the ability of health care providers to develop a therapeutic relationship with their clients because they set up feelings of distrust (Sue et al., 2007; Leahy, 2008).

Words/language in diabetes care

Language has the power to persuade, change or reinforce beliefs and stereotypes. Language is the principal vehicle for sharing knowledge and understanding. Words are quickly shaped into meanings that can affect how a person views themselves. Position statements on the use of language in the care of people with diabetes have been developed by Australia, the United States and the United Kingdom (Speight et al., 2011; Dickinson et al., 2017; Cooper et al., 2018). Language and words used in the care of people with diabetes have the power to reinforce negative stereotypes but also to promote positive ones. The experts agree that health care professionals need to use language that promotes active engagement, supports the self-care efforts people make and acknowledge the frustrations, anxieties, guilt and distress that many

people with diabetes experience (Speight et al., 2011; Dickinson et al., 2017; Cooper et al.,

2018).

In the world of diabetes care a specific dialect has emerged. The diabetes dialect contains

many metric and target words such as *compliant, diabetic*, *control*, *test* and *lifestyle disease* but

very few positive or encouraging words (Dunning, Speight & Bennett, 2017; Glasgow et al.,

1999). The dialect used by health care professionals may contribute to an already stressful

illness experience and may contribute to a harmful stress response (Dickinson, 2017). In a

systematic review by Lloyd et al. (2005), research indicated a connection between stress and the

onset of diabetes, poor glycemic control and decreased lifestyle management. In addition, the

evidence strongly suggested that interventions promoting stress reduction, improved coping and

positive quality of life activities improved glycemic control. A qualitative study by Dickinson

(2018) used focus groups to study how adults with diabetes experience the words used in their

care. The facilitator transcribed the group's individual responses and developed a research

summary of themes. The themes that emerged included judgement, fear and anxiety, labels,

reminders, assumptions, oversimplification and directives, misunderstanding, misinformation,

disconnection, body language and tone (Dickinson, 2018). The study participants reported

experiencing negative diabetes-related words from the general public, with their health care

providers and in the media (Dickinson, 2018). The participants expressed a desire to increase

awareness of the effect of negative diabetes-related words and a need for better communication

with their health care providers in order to improve their diabetes management (Dickinson,

2018).

Self-management/self-efficacy

Barbara Resnick as well as others have used the Theory of Self-Efficacy extensively in research. The majority of studies address self-efficacy expectations versus the concept of outcome expectations. Cross-sectional studies use self-efficacy expectations to describe the relationship between demographic measures and self-efficacy, psychosocial factors, and performance of behaviors. Additionally, in longitudinal research self-efficacy expectations are used to predict behavior and to guide intervention development to change behavior (Resnick, 2014). Common topics studied include exercise, physical activity, activities of daily living (ADL's), parenting, nursing skills, health promotion behaviors and chronic disease management such as diabetes and congestive heart failure (Lorig et al., 2010; Resnick, Luisi & Vogel, 2008). Resnick (2014) highlights the most important point to consider when using the theory in research is that the researcher maintains the behavioral specificity by developing a specific fit between the identified behavior, the efficacy of completing that behavior and/or the outcome expectations.

Gortner and colleagues studied self-efficacy interventions focused on cardiovascular disease (Gortner& Jenkins, 1990; Gortner, Rankin, & Wolfe, 1988). Additional work with a chronic disease focus looked at self-efficacy and symptom management in those suffering with chronic pain (Bennett et al., 2011; Gustavsson, Denison, & von Koch, 2011). A RCT by Rosal (2011) addressed diabetes self-management by testing a series of culturally sensitive educational sessions for Latinos. The intervention improved self-efficacy expectations, improved knowledge, and increased adherence to monitoring of blood sugar along with other outcome expectations. The theory of self-efficacy can also be used to direct nursing care. Some examples include motivating individuals to participate in health-promoting activities including regular exercise, smoking cessation, weight loss and following through with preventative health screenings for cancer (Galik et al., 2014; Resnick et al., 2009).

Because self-efficacy theory is situation specific, it is difficult to generalize study results. An individual might have high self-efficacy concerning healthy eating but low self-efficacy with completing an exercise program. Therefore, more research is needed focusing on the generalizability of specific self-efficacy behaviors. Another area needing additional research is on outcome expectations. In some instances, outcome expectations are noted to be better predictors of behavior than self-efficacy expectations (Resnick, 2014).

Summary of Evidence

Studies looking at the use of language/words in diabetes care are limited. In reviewing the search results three themes emerged: *Negative and other communication in health care*; *Importance of words/language used in diabetes care;* and *self-management/self-efficacy-its effect on health outcomes*. The levels of evidence were varied ranging from Level 1 Systematic review and randomized controlled trials to Level 7 expert opinion (Melnyk & Fineout-Overholt, 2015).

The concept of negative words effecting health outcomes is well supported in research outside of diabetes care. Research looking at pain management after surgery and pain with blood draws identified a clear connection. In looking at patients with substance use disorder (SUD) the research showed the connection between stigmatizing language, stereotypes and biased judgment (Burda, 2020). Street and Epstein (2009) presented a pathway linking clinician-patient communication to health outcomes; positive language promoting positive outcomes and negative communication leading to less optimal outcomes.

Looking specifically at research focused on words/language used in diabetes care the results are limited. A strong connection between language and diabetes care was identified in position statements by national diabetes organizations in Australia, the United States and the United Kingdom. Diabetes experts concluded that language should promote active engagement,

support self-care and acknowledge frustration and anxiety (Speight et al., 2011; Dickinson et al., 2017; Cooper et al., 2018). The patients' voice was also represented in a qualitative study by Dickinson (2018) calling for an increase in awareness of the effect of negative diabetes-related words and a need for better communication with health care providers.

Lastly, the concept of self-efficacy is central to the care of people with diabetes. Positive, empowering, and encouraging language is shown in research to improve a person's level of self-efficacy (Resnick, 2014; Rosal, 2011). Patients who have a high level of engagement in the management of their diabetes and who have a positive therapeutic relationship with their health care provider have improved health outcomes (Street et al., 2009).   ``

Quality Improvement Framework
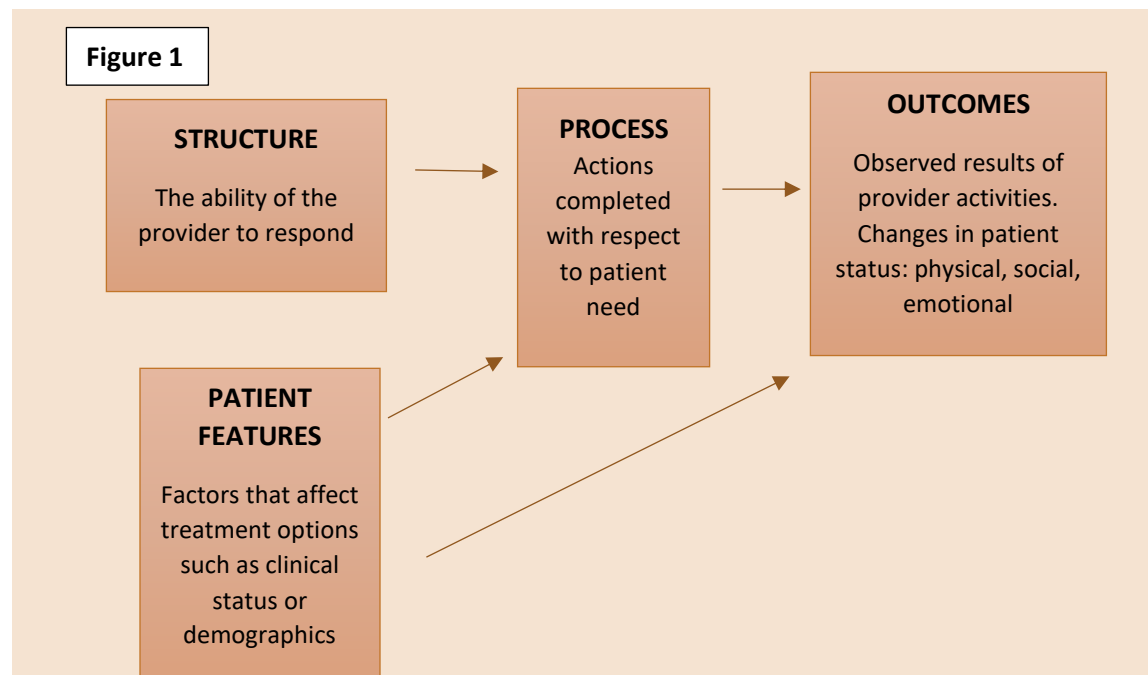
Note: Adapted from Donabedian's Structure, Process, Outcome Model Definitions, (Shaughnessy & Kurowski, 1982).

This quality improvement project follows the Donabedian quality improvement framework of *Structure*, *Process* and *Outcome*. Avedis Donabedian, a physician and health

services researcher at the University of Michigan, developed the original model in 1966

(Donabedian, 1985).

Figure 1 shows the connection among concepts in the Donabedian framework. This

framework is widely recognized and applied in many health care related fields, but its original

purpose was to assess quality of care in clinical practice (Donabedian, 1966). In today's health

care environment the Donabedian framework can have a broader application to the measurement

of quality extending beyond the clinical, technical or data aspects. The framework applies to

assessment of preventative care, rehabilitation, care coordination, the patient-provider

relationship and socioeconomic and environmental conditions (Ayanian & Markel, 2016).

Donabedian (1966) defined *Structure* as the setting, qualification of providers, and the

system where care takes place. For this project, the structure is the current state of care for

patients with diabetes and the common vernacular used in patient-provider encounters. The

structure is not specific to any one care setting but applies any time a provider is communicating

with a client. The qualification of providers refers to their level of education or understanding on

the topic of person-centered communication and the language movement within diabetes care.

When viewing the structure as the capacity of the provider to respond to patient needs, the

current state of communication within our current healthcare system is problematic. *Process* is

defined as the components that make up the care delivered (Donabedian, 1966). Process for this

project includes the activities performed with respect to patient needs consisting of the use of

positive, empowering communication techniques. Messages that empower people with diabetes

can lead to increased trust and the development of a positive therapeutic alliance with providers.

Outcome is the result of actions, the recovery or the restoration of function (Donabedian, 1966).

Observed outcomes include changes physically and emotionally. For this project that includes

increased patient self-efficacy, an improved patient-provider relationship and potentially a

clinically improved hemoglobin A1C measure. An additional area being examined for this

project includes *Patient Features* (Shaughnessy and Kurowski 1982). It is important to

understand the unique aspects of individuals with diabetes and how they impact both process and

outcome. Examples include ethnicity, primarily African American patients in this project, as well

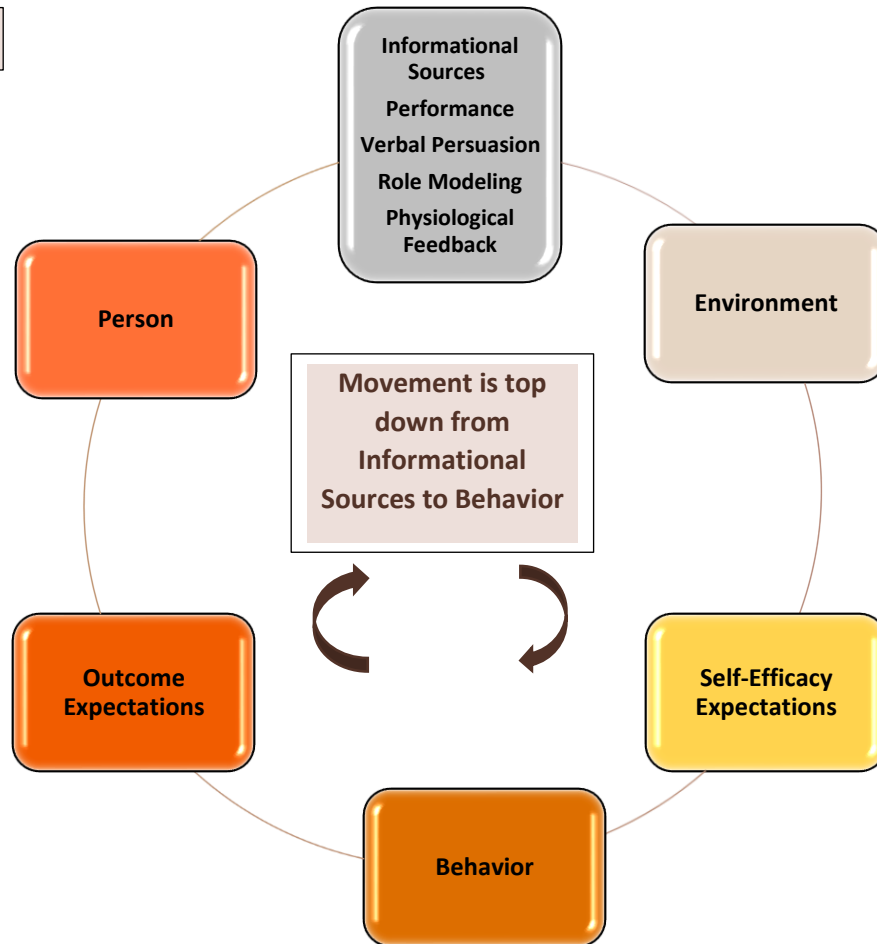as unique co-morbidities for each person.

Theoretical Framework

Self-efficacy is a concept often used to explain the issues surrounding management of

chronic disease. Many studies have been done examining self-efficacy interventions associated

with diabetes management (Lorig et al., 2010; Ober et al., 2011). The middle range *Theory of*

Self-Efficacy by Barbara Resnick has all the needed components to guide a project examining the

use of words and language on the health outcomes of persons living with diabetes.

The definition of self-efficacy found in Taber's Cyclopedic Medical Dictionary is "An

aspect of self-perception…that pertains to one's belief in his or her ability to perform a task or

behavior" (Venes, 2009, p2096). According to Resnick (2014) self-efficacy is the internal

conviction that one has the ability to take action to affect one's health. If persons believe they

have the ability to effectively act to achieve the desired outcome then they are more likely to

engage in the behavior (Resnick, 2014).

Important in choosing this theory was the use of an individual's experience that includes

their environment which aids in guiding action toward self-management. By looking closely at

the words and language used by health care providers as part of the patients' experience and

environment, interventions can be developed and implemented that will improve both self-

efficacy and health outcomes.

Figure 2

Informational Sources
Performance
Verbal Persuasion
Role Modeling
Physiological Feedback

Environment

Person

Movement is top down from Informational Sources to Behavior

Outcome Expectations

Self-Efficacy Expectations

Behavior

Note: This model shows self-efficacy and outcome expectations interact with the individual and the environment and are influenced by behavior. Adapted from Resnick, B. (2014). Theory of self-efficacy. In M. J. Smith & P. R. Liehr (Eds.)

Concepts and Relationships of Theory of Self-Efficacy

The *Theory of Self-Efficacy* is based on social cognitive theory and conceptualizes person-behavior-environment interaction as triadic reciprocality, the foundation for reciprocal determinism (Bandura, 1977, 1986). Triadic reciprocality is the interrelationship among person, behavior, and environment. Reciprocal determinism is the belief that behavior, cognitive thought, and other personal factors including environmental influences operate interactively as determinants of each other (Resnick, 2014). These factors are not necessarily equal in proportion to each other but instead vary over time and in strength. Cognitive thought is a critical dimension

of the person-behavior-environment interaction. Bandura (1977, 1986) proposed that individuals'

thoughts are developed and verified through four different processes: 1) direct experience of an

effect produced by the person's actions, 2) vicarious experience, 3) verbal judgements by others,

and 4) derived knowledge by using rules of inference. These ideas are incorporated by Resnick

into theory of self-efficacy.

Two major components of the theory include self-efficacy expectations and outcome

expectations. Self-efficacy expectations are personal judgements about one's own ability to

complete a given task. Outcome expectations are judgements about what will happen if a given

task is successfully completed. These components are differentiated because an individual may

believe a certain behavior will result in an expected outcome however, they may not believe they

are capable of performing the required behavior (Resnick, 2014). A diabetes management

example is a person reporting that daily exercise will lower their blood sugar, but they have

peripheral neuropathy and report pain when they attempt exercise therefore they are not

physically capable of daily exercise.

This theory also includes four sources of self-efficacy judgement used by individuals: 1)

performance or enactive attainment which is "doing" the behavior, 2) verbal persuasion, 3) role

modeling or vicarious experience which is watching someone else "doing" the behavior and 4)

physiological feedback occurring during a behavior such as pain or shortness of breath. The

cognitive appraisal of these factors results in a perceived level of confidence or self-efficacy that

reinforces performance expectations (Bandura, 1995).

As shown in Figure 2 all of the concepts are interrelated and move toward the enactment

of a specific behavior. Although not specifically represented in the model by Resnick (2014)

there is most likely a reciprocal relationship between performance and self-efficacy expectations.

This theory helps to understand behavior and guide the development of interventions to change behavior.

Summary

This scholarly project intends to uncover how patients feel when certain words or phrases are used in a health care encounter. Studies looking at the use of language/words in diabetes care is limited. However, the review of literature provided evidence to support the premise that health care professionals need to use language that promotes active engagement in health maintenance activities and supports self-care and self-management for people with diabetes. Negative words and language are shown to cause frustration, anxiety, guilt and distress among people with diabetes. The language movement within diabetes care is focused on removing the negative words and replacing them with empowering language thereby improving communication and health outcomes.

The Donabedian quality improvement framework of *Structure*, *Process* and *Outcome* is the guide for this scholarly project. The framework guides the assessment of preventative care, rehabilitation, care coordination, the patient-provider relationship and socioeconomic and environmental conditions. The theoretical foundation for the project is the middle range *Theory of Self-Efficacy* by Barbara Resnick. This theory provides a basis for understanding behavior and guides the development of interventions to change behavior and improve health outcomes for persons living with diabetes.

Chapter Three

Project Design

This scholarly project supports the language movement in diabetes care with the creation of a communication guide for health care providers. It also will uncover how patients feel when certain words or phrases are used in a health care encounter. The goal is to raise awareness on this important topic and to educate health care works on the use of positive language to improve patient self-efficacy and outcomes.

Project Outcomes

Project outcomes include the development of a communication guide for health care personnel that will serve to increase awareness and provide education on how to use positive language when working with patients with diabetes. A second outcome is to increase patient self-efficacy leading to improved diabetes self-management.   Data obtained from a patient questionnaire will add value to the information being presented by including the patient's perspective on what they think and feel related to words and phrases used in their care. Ultimately, improved self-management of diabetes will lead to improved health outcomes for patients and concurrently serve as a cost-saving measure for healthcare organizations.

Methodology

The setting for this quality improvement project was a primary care clinic within the largest Catholic healthcare organization in Wisconsin. The clinic is located in the north central part of the largest city in Wisconsin. Within the clinic is an outpatient diabetes education office. Patients from the primary care clinic who require education on diabetes self-management are referred to the diabetes educator at this site. The educator can also receive referrals from other primary care clinics within the larger organization.

This project consisted of two parts. The first part was the development and dissemination of a patient questionnaire to uncover how certain words or phrases used by healthcare workers are perceived by persons with diabetes. The second part of the project was the development of a communication guide for healthcare personnel on appropriate and positive communication techniques to use with persons with diabetes.

The target population for the questionnaire included any adult 18 years or older with a diagnosis of Type 1, Type 2 or Gestational diabetes. Patients who were scheduled for a diabetes education appointment within the primary care clinic were offered the opportunity to complete the questionnaire by the certified diabetes educator (CDE). Involvement was strictly voluntary, and the results were kept confidential with access only by the project lead and the CDE of the clinic. Patients who agreed to participate completed a consent form prior to filling out the questionnaire. The process occurred either before or after the patient's scheduled appointment. The CDE collected all completed forms and secured them in a locked box located in the diabetes education office for pick up by the project lead.

The target population for receiving the communication guide and additional education included the clinic physicians, nurses, medical assistants, diabetes educators and any other office personnel interested in this topic.

Project Intervention

The questionnaire was developed by the project lead using evidence from the literature on this topic. Three position statements developed by the United States, United Kingdom and Australia served as the template for question development (Speight et al., 2011; Dickinson et al., 2017; Cooper et al., 2018). Fifteen questions were created, 5 of them with a positive tone and 10 with a negative tone. The positive and negative questions were mixed throughout the

questionnaire. The participants were asked to rate how the questions *made them feel* or *think* when certain words, either positive or negative, were used in the phrases provided. A Likert scale from 1 to 5 was used to rate the question:

1= Very negative, sad, mad, hopeless or doubtful

2= Somewhat negative, sad, mad, hopeless or doubtful

3= Neutral – neither positive or negative – no strong feelings

4= Somewhat positive, happy, upbeat, hopeful or confident

5= Very positive, happy, upbeat, hopeful or confident

The questionnaire also included 2 open-ended questions for the participants to add any additional words or phrases that were either positive or negative.

The communication guide was developed during the same time as questionnaire collection. The project lead worked closely with a graphic designer to create both a booklet that included a downloadable and printable positive communication poster that could be displayed in any area within the primary care clinic such as workstations, breakrooms or patient waiting areas. In addition, an electronic version of the communication guide was created to facilitate on-line access to the document and to adapt easily to any web-based education platform. The communication guide provides education on the principals of appropriate communication with persons with diabetes, information on the language movement within the diabetes world, and guidelines on how to use strengths-based language. It also contains results from the patient questionnaire giving the reader insight into the patients' perspective.

Procedure

Human Subject Protection

Human subject protection approval was obtained through Alverno College IRB General

Request for Exemption Determination study ID number IRB-081M-20. The intended healthcare

organization's IRB deemed the project to be quality improvement and/or program evaluation

therefore not fitting the federal definition of research and not requiring IRB approval.

Timeline

The questionnaire was developed in May 2020. Dissemination of the questionnaire took

place from August through October 2020. The target goal for completed questionnaires was 30

however only 23 were obtained. A major barrier to patient participation in completion of the

questionnaire was the COVID 19 pandemic that began in March 2020. The original plan was to

start data collection in May or June of 2020 however the primary care clinic was closed due to

COVID 19 and all diabetes education appointments were cancelled while the state observed the

Governor's Stay at Home Order. The clinic did not re-open until July and so dissemination of

the questionnaires began in August. However, even though the clinic was open, many patients

were not returning for their appointments due to concerns of virus transmission. In addition

many appointments were being completed virtually which did not allow for participation as the

questionnaire was only available in hard copy. This unforeseen barrier contributed greatly to the

low number of completed questionnaires.

Development of the communication guide took place from July through November 2020.

Expert reviewers provided feedback on the final draft in October of 2020. The feedback was

used to finalize the document and prepare for dissemination within the healthcare organization in

December 2020.

Budget

The project lead's time was voluntary as a Diabetes Clinical Nurse Specialist within the designated project healthcare organization. The time of the Certified Diabetes Educator who assisted with distributing and collecting the patient questionnaires was included in her regular duties as an educator within the primary care clinic and so was not an extra expense. Supplies incurred to create the questionnaire and communication guide such as paper, printer ink and other miscellaneous items totaled $50. A small healthy snack was offered to those participants completing the questionnaire. The cost for the snacks totaled $67. The main project expense was the services of the graphic designer whose fee was $450. All costs were paid out of pocket by the project lead. No costs were incurred by the participating organization. The cost effectiveness of this project is difficult to measure up front. The improvement in communication between patients and healthcare workers will ultimately improve patient satisfaction which is measured by all healthcare organizations. Additional patient outcomes that could be assessed include changes in hemoglobin A1c levels, decreased disease complications such as kidney failure or wound development and increased quality of life measured by patient report. Lastly, this type of project and intervention has the potential to be cost saving to an organization by increasing positive patient outcomes creating a healthier population and decreasing the need for costly treatment of diabetes complications.

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Chapter Four

Project Analysis

Questionnaire Results

Data Overview

Twenty-three questionnaires were collected. Demographic data collected included

gender, type of diabetes, diagnosis length of time, type of medication used, A1c level and zip

code. Two of the demographic questions were not completed by all participants. Ethnicity was

not asked as part of the demographic data due to oversight of the project lead. See Figure 3 for

the demographic data breakdown.

Figure 3

Gender n=23	26% Male n=6 74% Female n= 17
Type of Diabetes n=23	0 Type 1; 60% Type 2 n=14; 18% Gestational n=4 22% Pre-diabetes n=5
Diagnosis length of time n=21	62% 0-2yrs n=13; 10% 3-5yrs n=2; 4% 6-10yrs n= 1; 14% 11-15yrs n= 3; 10% >15yrs n= 2
Type of Medication n=23	35% No medication n=8; 13% Insulin n=3; 30% Oral agents n=7; 22% Both Insulin and Oral n=5
A1c n=22	18% Under 6.0 n= 4; 32% 6.0-6.9 n=7; 4% 7.0-7.9 n=1; 10% 8.0-9.9 n=4; 36% 10.0-18.0 n=5
Zip Codes n=23	9% 53210 n=2; 9% 53206 n=2; 4% 53208 n=1; 13% 53216 n= 3; 65% Others n=15

The questionnaire consisted of 15 Likert type questions and 2 open ended questions. Five

of the questions had a positive tone and 10 had a negative tone. The question type was

intermixed so as not to create a flow in either the positive or negative direction. Figure 4

provides the overall results. Figure 5 are the results for the positively worded questions and

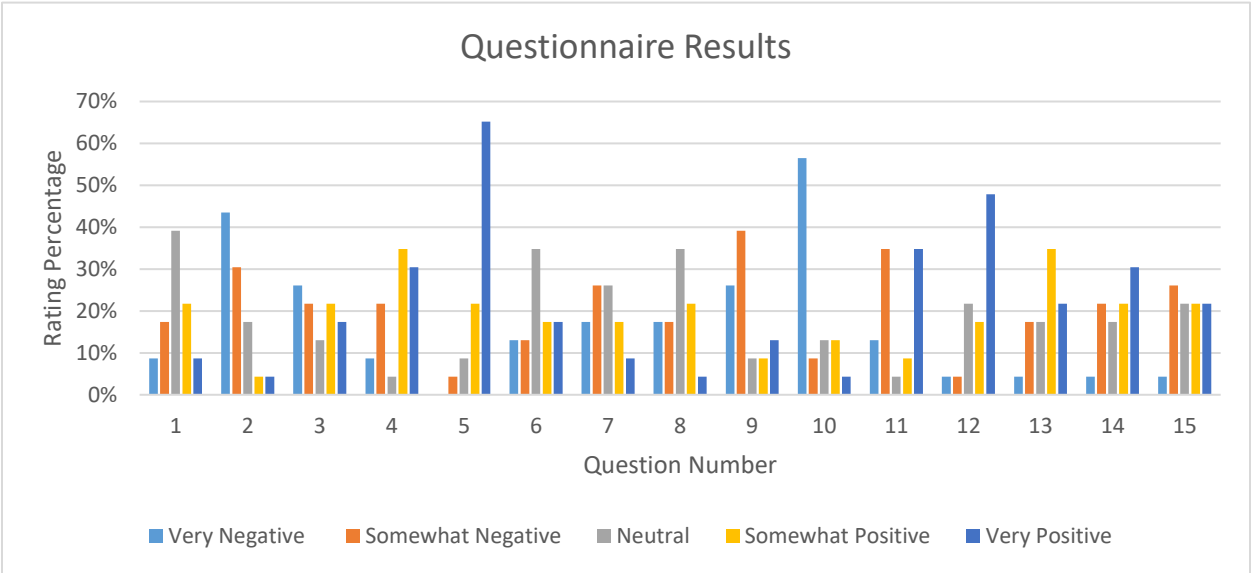Figure 6 displays the negatively worded question results.

Figure 4

Questionnaire Results

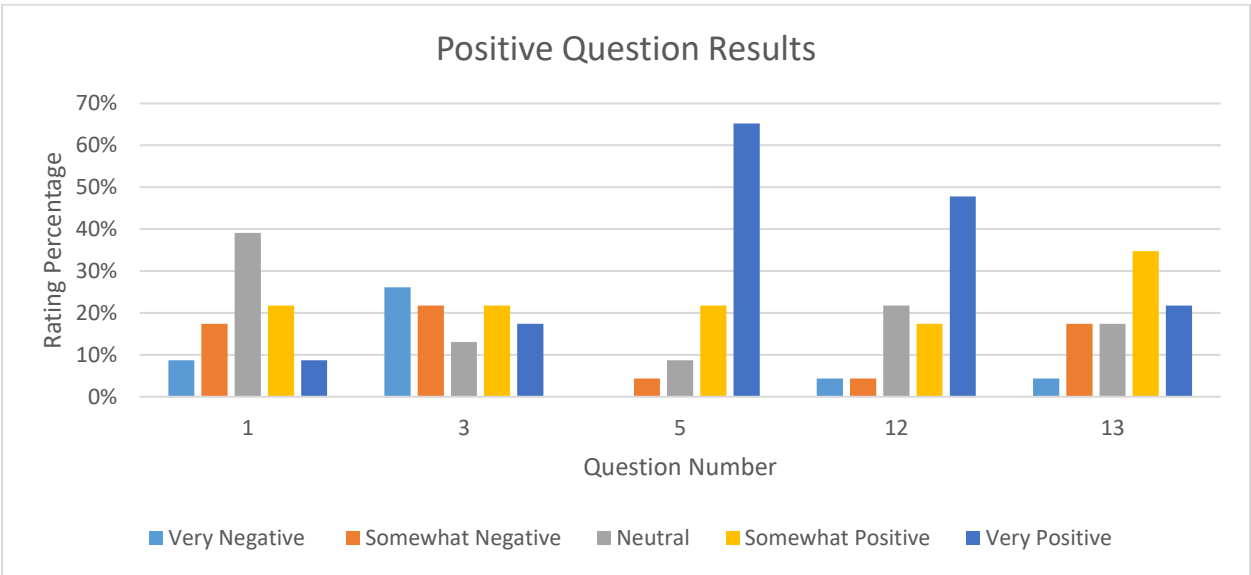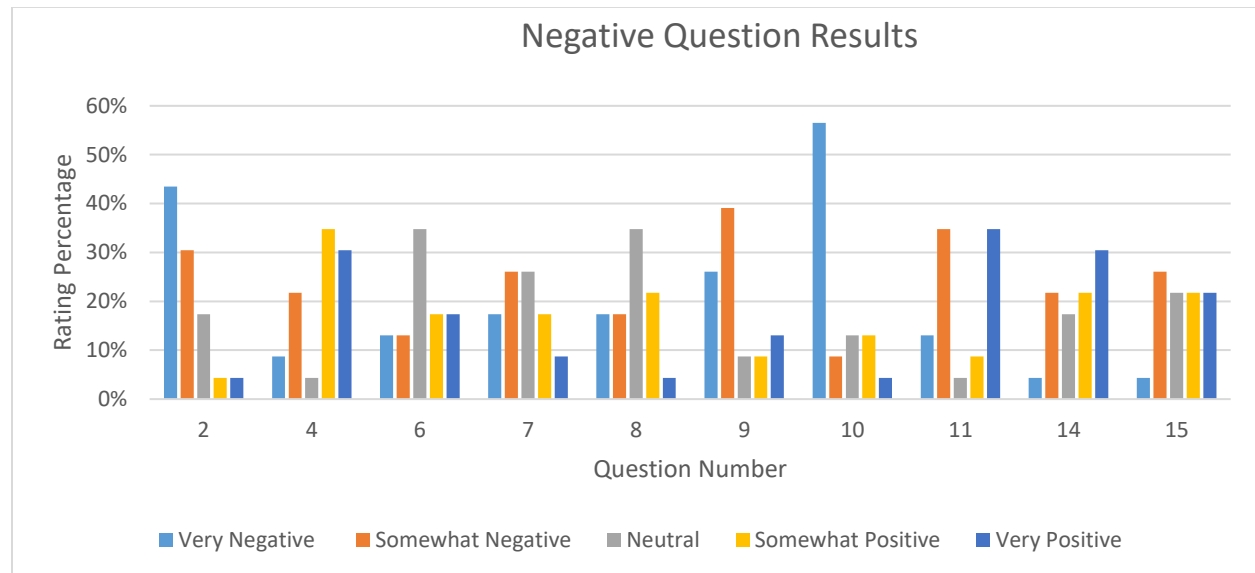**Figure 5**

Positive Question Results

Figure 6

The open-ended questions asked the participant to list any positive or negative words or phrases that were not found or addressed in the other 15 questions. Three participants completed these questions. One participant said "Your blood sugar level is fine, keep following your diet" as a positive comment they would like to hear. Another identified the comment "I see improvement" as positive and remarked that they would like their providers to talk about "doing things right" before going into "potentially bad news". The third participant completing the positive focused open-ended question commented that "it helps when providers are giving tips and are more helpful offering different solutions to questions." In addition, 2 of the participants added information regarding negative language. The first stated "when doctors say *you need to do something* it makes me not feel well or when doctors say *I don't know.*" The second participant stated that it bothers her "when providers come in and don't look at me and start asking questions without no introduction."
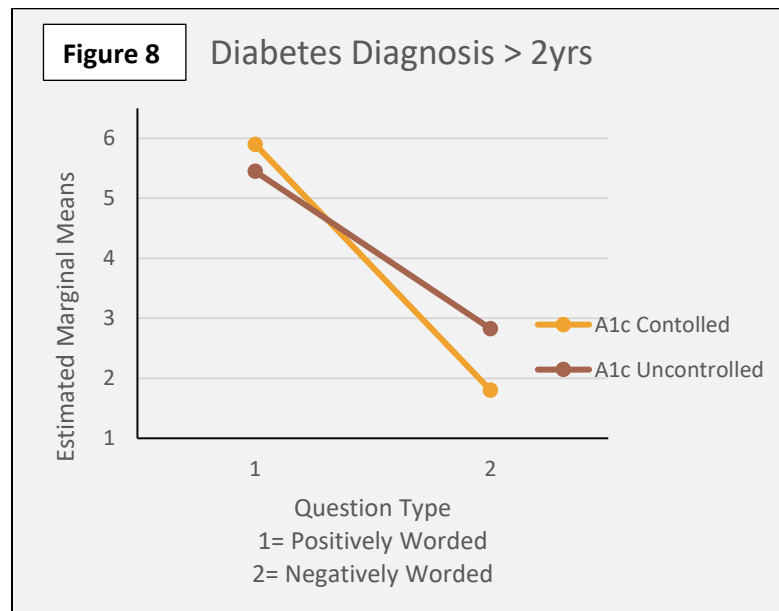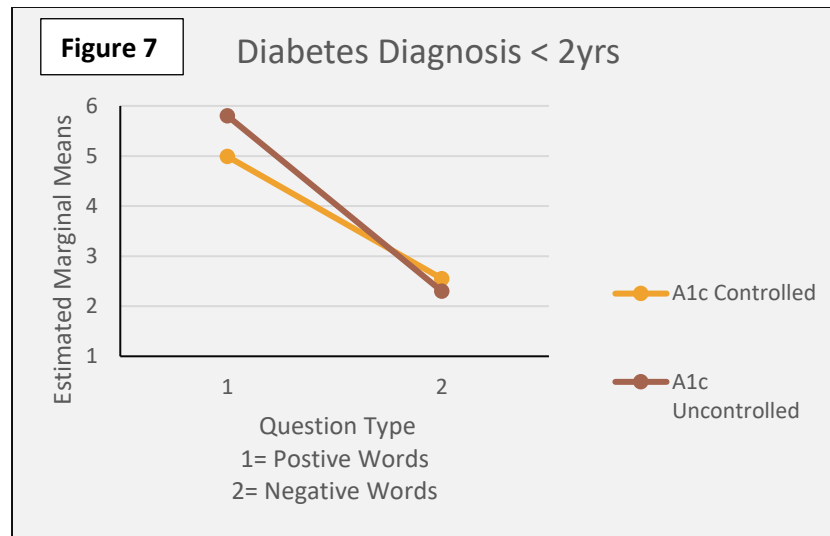
Statistical Analysis

Statistical analyses on the questionnaire results were completed using SPSS. The positive

and negative questions were first analyzed separately creating an average score for the positive

items and an average score for the negative items. A t test was run to see whether people, on

average, responded with more positivity to the positive items than to the negative items. This

resulted in a p < .001, indicating that the two scores were statistically different on average. The

number sentence is $t(22) = 18.58$, $p < .001$.

Next a general linear model was run to see whether any of the demographic variables

affected the amount of positivity or negativity people reported and looked for a significant

interaction between the question type and the demographic variable. In this analysis only the

question type had a significant effect, $F(1, 16) = 26.24$, $p < .001$. This correlated with the finding

from the t test. Participants felt more positive about the positive items. The three potential

interactions, with time having diabetes, A1c, and zip code are all nonsignificant. The partial Eta

squared (η^2) is the effect size, with the rule of thumb for ANOVA that .01 is a small effect, .06

is medium, and > .14 is large. The data showed that the question type had a large effect with $\eta^2 =$

.62. The zip code interaction with question type was nonsignificant, but the effect size was

medium (.10). A1c and length of time with disease were below the threshold for even small

effects.

Because the number of participants in this project was small n=23 and because many

different categories of demographic data were collected it resulted in very small numbers in each

category (see Figure 3). This became problematic when completing statistical analysis. Some of

the data categories were combined and an additional ANOVA test was run. The groups

consisted of *on insulin* or *not on insulin*, length of time having diabetes into *new* (<2years) and

old (>2years) categories, A1c into *controlled* (< or = to 7.9) and *uncontrolled* (> 7.9) and zip

codes were organized into 2 groups. The zip codes 53210 and 53206 made up one group (*high*

poverty) because they are the lowest income locations in the city and all other zip codes as the

second group (*not high poverty*). The ANOVA test was run with question type (positive or

negative) within subjects, and A1c (controlled or not), insulin (on insulin or not), zip code (high

poverty or not) and time since diagnosis (new or not) between subjects.

The ANOVA tested the hypothesis that the factors identified previously influenced the

degree to which people have positive or negative reactions to words/language used by the

provider. It is important to look at interactions with the variable *question type.* An interaction

there would mean that a person's positive and negative emotional reactions to the two types of

questions depend in part on their classification by other variables. Two significant interactions

were found. The main effect for question type was the same effect found in the previous tests:

people feel more positive with the positive questions than they do with the negative questions,

$F(1, 10) = 436.24$, $p < .001$. The 2-way interaction between question type and ZIP code, $F(1, 10)$

$= 5.97$, $p = .035$. The interaction was driven by the more neutral reactions to negative questions

among the less-poverty group. The 3-way interaction (See Figures 7 and 8) between question

type, time since diagnosis, and A1c, $F (1, 10) = 14.51$, $p = .003$.

Figure 7

Diabetes Diagnosis < 2yrs

Question Type
1= Postive Words
2= Negative Words

Figure 8

Diabetes Diagnosis > 2yrs

Question Type
1= Positively Worded
2= Negatively Worded

There are a variety of ways to try to explain this pattern. One possibility is that the interaction between controlled vs. uncontrolled A1c and the type of question on emotional response depends on the length of time since diagnosis. Among those with newer diagnoses, there are greater differences in the reactions of the controlled vs. uncontrolled group in how they react to the positive wording, but their responses to the negative wording are relatively similar. Among those with older diagnoses, the reaction to positive wording was relatively similar, but those in the controlled A1c group had more negative reactions to negative wording than those in

the uncontrolled A1c group did. Refer to Table 1 for the SPSS results. It is important to note that

due to the small sample size the results have a low power and therefore generalizing the results

have the possibility of leading to type 1 (false positive) error.

Table 1

2. length of time having diabetes, coded binary * A1c coded as binary * question_type

Measure: MEASURE_1

length of time having diabetes, coded binary	A1c coded as binary	question_type	Mean	Std. Error	95% Confidence Interval	
					Lower Bound	Upper Bound
new	controlled	1	4.990[a]	.247	4.440	5.541
		2	2.552[a]	.276	1.937	3.168
	uncontrolled	1	5.800[a]	.409	4.889	6.711
		2	2.300[a]	.457	1.281	3.319
old	controlled	1	5.900[a]	.409	4.989	6.811
		2	1.800[a]	.457	.781	2.819
	uncontrolled	1	5.483[a]	.289	4.839	6.128
		2	2.825[a]	.323	2.104	3.546

a. Based on modified population marginal mean.

Summary

The intent of this project was to improve the quality of care provided to people with

diabetes regarding the type of communication used by healthcare personnel. The design of the

project was not research based and therefore the data collected does not have the rigor required

of most statistical analyses. The results are not generalizable to other primary care clinics or

settings and speak only to the thoughts and feelings of those who participated in the project by

completing the questionnaire. However, that does not negate the value of the findings. The data

collected adds to the science surrounding the language movement within diabetes care by

supporting the premise that the words/language used by healthcare providers and others does

impact the patient-provider relationship. The results show that people with diabetes are affected

positively by positive communication and negatively by negative communication techniques.

Chapter Five

Project Implications

Patient Outcomes

This quality improvement project focused on supporting and expanding the language movement in diabetes care. People with diabetes are exposed to the language used by health care providers which can be strange and unfamiliar. This language has been referred to as a dialect by researchers Dunning, Speight and Bennett (2017). The dialect may not be deliberately negative or abusive but often contains words that emphasize control, surveillance and compliance (Dickinson, 2017). This project obtained data from persons with diabetes who voluntarily completed a questionnaire given to them while attending a diabetes education appointment. The questionnaire gave participants the opportunity to express how words and language make them personally think and feel about their diabetes. The data showed that people with diabetes are affected positively by positive communication and negatively by negative communication techniques. This is important information to understand and to gain awareness about for healthcare providers and others who work with people with diabetes. If healthcare workers intentionally move towards using strength-based and person-first language in order to improve the relationship they have with the patient, it will positively impact the patients' self-esteem, self-efficacy and potentially improve their overall health outcomes.

Healthcare Provider Outcomes

This project involved the development of a document titled *The Power of Words: A Guide for Positive Communication when Caring for People with Diabetes*. This "how to" manual is intended as education for healthcare personnel. It provides evidence-based information on the principals of positive communication as well as insight into the patients' perspective. The *Guide*

includes a printable poster with the do's and don'ts of communication. It is available in hardcopy

and electronically. Once implemented at the target healthcare organization the pre- and post-

knowledge level of those completing the education can be measured.

System and Nursing Implications

This type of quality improvement project has the potential to impact care across the entire

healthcare continuum. It is applicable to hospital in-patient care, out-patient clinic-based care,

and care provided within diabetes education programs. Communicating clearly, positively and

with empathy is important for all people working with those dealing with diabetes. The

communication guide can be used in education sessions for nurses, physicians, diabetes

educators, pharmacists, therapists, medical assistants, nurses' aides and anyone else who assists

with the care of people with diabetes. To support sustainability to the project the education could

be provided to all new hires, be added to the Nurse Residency education program and be added

to yearly clinical skills fairs. The communication poster can be displayed in many locations so

that it is visible to the healthcare staff as a reference and reminder how to skillfully implement

positive communication techniques. The organization will ultimately benefit from having

positive communication being used as a standard of care as evidenced by high patient

satisfaction scores.

Future Scholarship

The language movement within diabetes care is in its infancy. More rigorous research

specific to diabetes is needed both qualitatively and quantitatively to add to the science

surrounding this problem. In addition, education specific to proper communication techniques

including being person-first, strengths-based and empowering should be required in all medical

school and nursing school curricula. At a system level work still needs to be done to remove

from healthcare charting systems the negative language that emphasizes compliance and labels

our patients with their disease. Overall, the intention of this quality improvement project has

been to raise awareness and understanding regarding the power of words in diabetes care.

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Appendix A

Evidence Table

	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Bennett, M., Bagnall, A.M., Raine, G., Closs, S.J., Blenkinsopp, A., Dickman, A., & Ellershaw, J. (2011). Educational interventions by pharmacists to patients with chronic pain: Systematic review and meta-analysis. *Clinical Journal of Pain,* *27*(7), 623-630.	N/A	Systematic Review and meta-analysis Level 1. Searched electronic databases and published literature for randomized studies that examined an educational intervention in relation to the management of chronic pain that was delivered by a pharmacist to an adult patient. Four studies were included that randomized 400 patients with chronic pain and that followed up patients between 1 and 16 weeks	Defined an educational intervention as information, behavioral instructions, or advice in relation to the management of chronic pain (pain of any etiology persisting for more than 3months or associated with progressive disease) and delivered by a pharmacist to an adult patient	Trials were included that met the following criteria: randomized controlled trial, where the control group received usual care or attention only; included adults with chronic pain of any etiology, used a patient-based educational intervention, and assessed pain and related outcomes. No language or geographical restrictions were applied. Two reviewers independently selected the studies for inclusion in the review using titles and abstracts for articles after piloting the study selection criteria on a sample of the literature	N/A	The findings of each study were plotted for each outcome in RevMan 5 as point estimates with corresponding 95% confidence intervals. Continuous data were displayed as weighted mean differences or standardized mean differences (SMDs) where appropriate. Statistical pooling was limited to clinically homogeneous studies for which the study designs, populations, interventions, and outcome measurements were considered to be similar by the reviewers. The w2 and I2 tests were used to measure statistical heterogeneity,	Patients receiving these interventions experienced statistically significant benefits in the following outcomes compared with controls: a reduction in average pain intensity of 0.5 on a 0 to 10 rating scale, a reduction in adverse effects by more than 50%, and an improvement in satisfaction with treatment equivalent to approximately 1 point on a 0 to 10 rating scale. The interventions neither had effect on reducing interference from pain on daily life, nor on improving self-efficacy.	Small sample size is a limitation. Out of 67 potential studies only 4 met the inclusion criteria. 1 of these studies contributed a large number of patients and the other 3 studies included relatively small numbers of patients. 2 studies were from the US and the other 2 UK and Bulgaria. The role and practice of pharmacists in these different countries and settings is likely to vary and so we cannot quantify the influence of this variance on our findings. Although the studies were studies for methodologic quality, the small number of included studies, small sample sizes, and the dominance of 1 study mean that our interpretation of the data should be regarded with caution because of the risk of bias. Selection bias (of study participants) may be present in the data

				search results. Disagreements were resolved by consensus, and if consensus could not be reached, a full copy of the article was ordered, and a third reviewer was consulted if necessary.		with a w2P value of greater than 0.1 and an I2 value of less than 50% indicating relative homogeneity. If the studies were clinically and statistically homogeneous (and appropriate data were provided), a meta-analysis was conducted using the fixed effects model. If studies were clinically homogeneous but statistically heterogeneous, the random effects model was used		because of inadequate allocation concealment, although methods of randomization were reported as adequate. The patients recruited to the 4 studies included in this analysis may not represent all patients with chronic pain, only those who were willing and able to attend educational sessions and to be followed-up over several months.

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Burda, C. (2020). Substance use disorders: Semantics and stigma. *The Nurse Practitioner, 45*(1). 14-17.	N/A	Level 7- Expert Opinion	N/A	N/A	N/A	N/A	Nursing's power is in our ability to engage clients in therapeutic relationships. All nurses ae implored to use inclusive, person-first language that convey positive attitudes and respect. An informed nursing workforce is the solution to reducing stigmatizing language	N/A

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Cooper, A., Kanumilli, N., Hill, J., Holt, R. I. G., Howarth, D., Lloyd C. E., Kar P., Nagi, D., Naik, S., Nash, H., Nelson, H., Owen, K., Swindell, B., Walker, R., Whicher, C., & Wilmot, E., (2018). Language matters. Addressing the use of language in the care of people with diabetes: Position statement of the English Advisory Group. *Diabetic Medicine, 35,* 1630-1634.	N/A	Position Statement Level 5- Systematic Review of descriptive or qualitative studies.	United Kingdom	N/A	N/A	N/A	The language used by healthcare professionals can have a profound impact on how people living with diabetes experience their condition and feel about living with it day to day. This position statement combines the current evidence on this topic into a document providing practical examples of language that will encourage positive interactions and positive outcomes.	N/A

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Dickinson, J. K. (2017). The effect of words on health and diabetes. *Diabetes Spectrum, 30*(1). 11-16	N/A	Level 7- Expert Opinion	N/A	N/A	N/A	N/A	Summary of research that is available on the effect of words on health states. Focus on language as context and changing words and attitudes. A call to action.	N/A

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations	s
Dickinson, J. K. (2018). The experience of diabetes-related language in diabetes care. *Diabetes Spectrum, 31*(1). 58-64.	Critical Theory	Qualitative Study. Use of Focus groups. Level 6	In-person focus groups took place in Northwest Colorado The 2 virtual focus groups came from the Diabetes Online Community (DOC) Total number of participants= 68	Purpose of the study was to illuminate the experience of adults living with any type of diabetes.	N/A	Individual responses were considered the unit of analysis. The constant comparison method was used to analyze the data.	In question 1 and 2 six themes emerged. *Judgment *Fear and anxiety *Labels, reminders, and assumptions *Oversimplification and directives *Misunderstanding, misinformation, or disconnection *body language or tone In question 3 three themes emerged *General Public *Health care providers *Media Question 4 and 5 had three themes *Stop judging *Stop labeling	Findings cannot be generalized to all people with diabetes. Diabetes type was not identified.	

						*Stop discussion complication Question 6 had three themes *Suggestions for HCPs *Word replacement *If HCP's stopped using these words.	

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Dickinson, J. K., Guzman, S. J., Maryniuk, M. D., O'Brian, C. A., Kadohiro, J. K., Jackson, R. A., D'Hondt, N., Montgomery, B., Close, K. L., & Funnell, M. M. (2017). The use of language in diabetes care and education. *Diabetes Care, 40*, 1790-1799.	N/A	Expert opinion Level 7	N/A	N/A	N/A	N/A	Task force developed 4 guiding principles and 5 recommendations: Use language that is: *Neutral, on judgmental *Free from stigma *Strengths based *Fosters collaboration *Person-centered.	N/A

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Dunning, T., Speight, J., & Bennett, C. (2017). Language, the "diabetes restricted code/dialect" and what it means for people with diabetes and clinicians. *The Diabetes Educator, 43*(1). 18-26.	N/A	Literature review. Patient survey and information gained from clinical encounters. Level 5 to 7 including expert opinion	Information gathered from authors' clinical encounters, diabetes advisory groups and email sent to one author's diabetes network in various countries.	N/A	N/A	N/A	Themes developed including diabetes as a restricted language, Subliminal messages, language, and stress. Clinicians need to critically examine the words and dialect they use when communicating with and about people with diabetes.	N/A

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Epstein, R.M., & Street, R. L., Jr. (2007). *Patient-centered communication in cancer care: Promoting healing and reducing suffering.* Presented at the National Cancer Institute	None	Monograph commissioned by NCI Various levels of evidence within this monograph. Most at Level 5 but some reviewed within at Level 1,2, 3 and 4.	N/A	N/A	N/A	N/A	This monograph is a first step in the NCI's plans to facilitate more research around patient centered communication and health outcomes. This document is geared toward cancer patients, but the content and ideas have potential to extrapolate to chronic disease, specifically diabetes	**Strengths-** Literature synthesis, clinical experience of authors, summary of international experts at the NCI symposium **Limitations-** Potential bias from 2 main authors. Focus on cancer patients so content may not be transferable to diabetes patients.

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Flier, J.S., & Underhill, L.H. (1995). The hypothalamic-pituitary-adrenal axis and immune-mediated inflammation. *Seminars in Medicine of the Beth Israel Hospital, 332*, 121-127.	None	Seminar in Medicine – Review of the science article

Multiple levels cited. Most are Level 2-individual RCT's | N/A | N/A | N/A | N/A | This review outlines the influences that the HPA axis and immune-mediated inflammation reactions exert on each other and discusses the implications of these interactions for human disease. | **Strengths-** This article provides the physiological connection of a stress response to health outcomes for certain diseases. **Limitations-** The review does not look specifically at types of stress so it is not looking at how language can induce a stress response |

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Galik, E., Resnick, B., Hammersla, M., & Brightwater J. (2014). Optimizing function and physical activity among nursing home (NH) residents with dementia: Testing the impact of function-focused care. *The Gerontologist, 54*(6), 930-943.	Social Ecological Model and Function Focused Care for the Cognitively Impaired (FFC-CI) Self-efficacy	The purpose of the study was to test the effectiveness of FFC-CI intervention on moderate to severely impaired NH residents using a randomized controlled trial. Level 2	103 cognitively impaired residents and 77 nursing assistants from 4 nursing homes owned and operated by the same for-profit company in an urban setting.	**Independent variable**- FFC-CI intervention **Dependent Variable-** attention controlled Function Focused Care - Education (FFC-ED)	For residents the main outcome measures included function, physical activity, mood, behavior and adverse events. For the NA's the main outcome measures included knowledge, beliefs, and performance of function focused care.	Descriptive analysis and general estimating equations were used with outcome measures as the dependent variable. Covariate and chi-square	Significant improvement in the amount and intensity of physical activity and physical function in the treatment group. Significant decrease in the number of residents with adverse events.	Small sample from only 4 NH's. Recruitment bias. Study supports the use of FFC-CI to change care behaviors among NA's and suggests FFC-CI may help to prevent persistent decline and sedentary behavior.

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Glasgow, R. E., & Anderson, R. M. (1999). In diabetes care, moving from compliance to adherence is not enough. *Diabetes Care*, *22*(12), 2090**.**	N/A	Expert opinion Level 7	N/A	N/A	N/A	N/A	The words used to describe patient-provider relationships and diabetes self-management are important. They either facilitate or inhibit patient empowerment, autonomy, decision-making, sense of responsibility, and quality of life.	N/A

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Gortner, S., & Jenkins, L. (1990). Self-efficacy and activity level following cardiac surgery. *Journal of Advanced Nursing, 15*, 1132-1138.	Bandura's self-efficacy theory. The purpose of the study was to determine whether the combined in-patient and out-patient teaching and monitoring programs might enhance efficacy expectations for recovery at 12 and 24 weeks after surgery.	Randomized controlled trial Level 2	156 patients and family were randomized to control or experiment status following surgery. 125 males, 31 females. CABG or re-do CABG procedures and valve replacements. 81 in control group, 75 in experimental group. 95% retention rate through the 24 weeks. Mean age male 59.2 years and 57.0 female. Northern California surgical centers.	**Dependent variables-** efficacy with walking, climbing, lifting and general activities assessed before surgery, just prior to discharge after surgery and phone call to reassess at 4,8,12 and 24 weeks. Standard education sessions. **Independent variables-** Additional education on family coping and conflict resolution and a brief counselling session. A follow up phone call weekly for 4 weeks to monitor, coach and reassure patient and family. From week 4 to 8 the phone calls were biweekly	Self-efficacy scale developed by Jenkins was used to assess based on a 0 to 10 scale. A corresponding activity checklist was administered. Th Profile of Mood States (POMS) was used to evaluate mood.	t-tests were used to describe differences in treatment groups at each testing period. Repeated measures mixed effects analysis of covariance used for missing observations and differing amounts of data over time. All p values were for two-tailed tests.	Significant differences were found for experimental patients in self-efficacy expectations for walking between 4 and 8 weeks and between 8 and 24 weeks after surgery. Experimental patients reported higher levels of general activity at 4 and 8 weeks and more walking and lifting at 8 weeks. By 12 weeks treatment differences were not significant for continued higher general activity levels. Self-efficacy expectations were a significant predictor of self-reported activity	These findings suggest that efficacy expectations in the recovering cardiac surgery patient can be influenced by in-patient education and follow up out-patient coaching.

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Gortner, S., Rankin, S., & Wolfe, M. (1988). Elders' recovery from cardiac surgery. *Progress in Cardiovascular Nursing, 3*(2), 54-61.	Bandura's self-efficacy theory.	Randomized controlled trial Level 2	11 patients 70 to 77 years of age. 10 men and 1 woman.	**Dependent variable-** Usual care **Independent variable-** special in-patient teaching and telephone follow up designed to monitor and enhance recovery, reinforce teaching and provide support. 4 patients were assigned to this group.	The Family APGAR questionnaire for appraisal of family functioning A project derived questionnaire checklist to record actual risk factor management of diet, medication, exercise and smoking cessation. Profile of Mood Status (POMS)	Not specifically named Some qualitative data collected from phone calls.	No statistically significant differences between the two elder groups on measure of family functioning, self-efficacy, and value preferences.	Small sample size. Findings not generalizable

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Gustavsson, C., Denison, E., & von Koch, L. (2011). Self-management of persistent neck pain: Two-year follow-up of a randomized controlled trial of a multicomponent group intervention in primary health care. *Spine, 36*(25), 2105-2115.	Social cognitive theory	Follow-up self-assessment questionnaires were mailed to the participants at: 10 weeks, 20 weeks, 1 year, and 2 years after inclusion. Short-term effects, at 10 weeks and 20 weeks, and detailed description of design, methods, content of the interventions, and sample characteristics have previously been reported. This article reports long-term effects 1 year and 2 years posttreatment. Level 2	156 participants (139 women and 17 men) aged 19 to 65 years were randomly assigned; 77 to pain and stress self-management (PASS) and 79 to individually administered physical therapy (IAPT). Fifteen participants withdrew without completing the assigned treatment, referring to decreased neck pain or lack of time. Thirty-nine participants completed treatment but did not return all follow-up questionnaires. Compared with the 102 participants who completed all follow-ups, the withdrawals/non-responders were younger (P = 0.002).	**Independent Variable**= type of intervention either PASS or IAPT **Dependent variable**= level of pain control, self-efficacy, disability, and catastrophizing.	A self-assessment questionnaire was used to collect background information and data on outcome variables by instruments frequently used in studies concerning pain conditions, including: *Pain intensity by numerical rating scales (0 = "no pain", 10 = "worst possible pain").* *Consumption of analgesics due to neck pain.* *Pain control by using the two questions from the Coping Strategies Questionnaire (CSQ) (0 = "no control/cannot decrease", 6 = "complete control/can decrease completely").* *Self-efficacy was assessed by the Self-Efficacy Scale (SES). The participants rated*	Linear mixed models for repeated measures analysis were performed to evaluate differences between groups in the primary outcome measures. Pair-wise comparisons of simple main effects were conducted for variables with significant interaction Bonferroni corrections were made in the analyses of simple main effects to guard against Type 1 errors due to multiple comparisons.	Linear mixed models for repeated measures analyses showed significant time-by-group interaction effects in favor of PASS regarding the primary outcomes: ability to control pain (P < 0.001) and self-efficacy for performing activities in spite of pain (P = 0.002). There was also a significant time-by-group interaction effect regarding levels of catastrophic thinking according to CSQ Catastrophizing subscale (P < 0.001) in favor of PASS. Estimated marginal means for CSQ	The initial treatment effects of a multicomponent pain and stress self-management group intervention were largely maintained over a 2-year follow-up period and with a tendency to have superior long-term effects as compared to individually administered physical therapy, for patients with persistent tension-type neck pain with regard to the primary outcomes: ability to control pain and self-efficacy for performing activities in spite of pain, and the secondary outcome: levels of catastrophic thinking. Although statistically significant differences, the magnitude of the observed effect sizes and differences between groups, were in some cases small, which limits conclusions concerning clinically meaningful changes.

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					*how confident they felt about performing 20 everyday activities in spite of pain (0 = "not at all confident," 10 = "very confident"). *Disability. Perceived interference with daily activities due to neck pain was assessed using the Neck Disability Index (NDI) expressed as an index of 0 to 100. *Catastrophizing. The propensity to engage in negative thinking and worry in response to pain, was assessed by the Catastrophizing subscale (CSQ-CAT) of the CSQ (0 = "never," 6 = "always"). *Depression and anxiety were measured by the Hospital Anxiety and Depression Scale (HADS) consisting of two*	The χ^2 test was applied for analyses of between-group differences in: "Analgesics," "Satisfaction with care/treatment," and "Use of acquired skills in everyday life." A P-value $\leq$ 0.01 was accepted as statistically significant. Analyses were conducted using SPSS 18.0	pain control, SES, and CSQ. After adjusting for the baseline differences in NDI, there was no longer a time–by-group interaction effect regarding disability due to neck pain as measured by NDI. Both groups showed decreased pain intensity regarding pain scores at follow-ups, but there was no time-by-group interaction effect. There were no longer differences between groups in consumption of analgesics at 1 or 2 years. At 1 year (P = 0.001) and 2 years (P = 0.001), the PASS-group reported a higher satisfaction	The intervention entailed a limited number of sessions and one posttreatment booster session. It is suggested that the treatment procedure in this study was enough to sustain behavioral change. However, it is possible that additional sessions with check-ups of adherence to training could have produced even more exhaustive treatment gains. In this study, despite changes in self-efficacy and pain control, no outcome differences between groups in disability, as previously observed in the short-term evaluation, could be ascertained. Plausibly due to the withdrawals limiting the statistical power to detect differences between groups in NDI and due to the decision to include baseline values of NDI as covariate in the analyses to adjust for baseline differences between groups.

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					subscales, reflecting depression and anxiety, respectively. Also at the follow-ups Satisfaction with care (allocated treatment), by the question: "How satisfied are you with the care that you received during the intervention period?" Use of skills acquired during treatment to cope with pain, by the question: "Can you use/apply things you learned during treatment in everyday life situations to cope with pain?		with treatment received during the intervention, than the IAPT-group. At the 1-year follow-up the PASS-group reported that during treatment they had learned useful skills, which they could apply in everyday life to cope with pain, to a significantly higher degree than the IAPT-group ($P < 0.002$), and with a trend toward a difference at 2 years ($P = 0.030$).	Persons with signs of depression were excluded from the study, which limits the generalizability of the results A non-standardized procedure delivered by several therapists could have been a limitation, but was more likely a strength, as it ensured similarity to genuine treatment conditions and controlled for nonspecific treatment effects. Caution should be exercised in interpreting the results as 54 participants (35%), withdrew from treatment or failed to return all follow-up questionnaires. Completers/responders from both groups reported high satisfaction with care, but it may have been the least satisfied participants that withdrew.

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Krosnick, J. A., Bertz, A. L., & Jussim, L. J., (1992). Subliminal conditioning of attitudes. *Person Social and Psychological Bulletin, 18.* 152-153.	Not specified	Randomized controlled experiment Level 2 2 separate studies	**Study 1** 34 Ohio State undergraduates. Lab setting, viewing photographs. **Study 2** 128 Ohio State undergraduates. Lab setting, viewing photographs.	**Study 1** *Dependent variables-* questionnaire rating the target person on a series of 7-point scales assessing attitudes, personality beliefs and attractiveness. *Independent variables-* showing either positive-affect-arousing photos or negative-affect-arousing photos. Subliminally 13millisecond exposures. **Study 2** Same procedure at study 1 with 3 exceptions. First, affect arousing slides were exposed for 9millisecond. Second 3 experimenters were used instead of only	**Study 1** Attitude index and bipolar questions. **Study 2** Basic dependent measures were identical to study 1 and the same attitude, personality beliefs and attractiveness beliefs indexes were computed. Four additional questions were asked to assess whether the affect-arousing photos had altered the subject's mood.	**Study 1** t-tests, MANOVA **Study 2** Same as study 1	**Study 1** Subjects in the positive affect condition rated the target person significantly more favorable than subjects in the negative affect condition. The positive affect subjects also rated the target person more attractive but not statistically significant result. **Study 2** The positive affect group rated the target person more positively than the negative affect group. The affect-arousing slides did not create a general mood that influenced all ratings the subjects made.	**Study 1** Results support the expectation that pairing presentations of affect arousing stimuli with presentations of an object can condition attitudes towards that object. Limitations include the experimenter not being blinded to the subjects and no evidence that the affect arousing photos were actually subliminal **Study 2** Taken together the two studies show that attitudes toward an object can be generated through

				one and all were blind to the experimental condition. Third, a number of additional measures were collected to determine whether the observed effect was due to mood rather than attitude conditioning.				process other than deduction from beliefs about the attributes of the object. These studies demonstrate that it is possible to like or dislike a person without knowing the correct reason for the attitude.

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Lang, E.V., Hatsiopoulou, O., & Koch, T., (2005). Can words hurt? Patient-provider interactions during invasive procedures. *Pain, 11*. 303-309.	None specified	3-arm prospective randomized trial Level 2 This portion of the study is a retrospective review.	The primary trial tested the effect of a nonpharmacologic analgesia adjunct (self-hypnotic relaxation) during interventional radiological procedures. All interactions of patients with their health care providers were videotaped-159 patients The 159 videos from the two control arms of the trial were reviewed and transcribed by an independent researcher for this study. This took place at the University of Iowa Hospital and Clinics.	**Independent Variable-** Negatively loaded suggestions based on McGill Pain Questionnaire categories. Grouped either as a "warning" 2 minutes prior to event or "sympathizing" after the event. Treatment condition, type of procedure and whether or not the patient received a warning as **independent variables.** **Dependent-** pain and anxiety ratings and medication use in the interval after the painful event.	Spielberger State Anxiety Inventory	Multivariate analysis of variance for warning or sympathy statements.	Warning the patient of a potentially painful event with a negatively loaded wording was associated with subsequent greater reported pain and greater reported anxiety. Sympathizing wording was not associated with increased pain but was associated with increased anxiety.	A limitation could have been that everyone present during the procedures were asked not to initiate hypnosis or imagery with patients and because of this some providers may have felt artificially limited in how they could help patients cope which could have affected the suggestions they made to patients .

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Leahy, R. (2008). The therapeutic relationship in cognitive behavioral therapy. *Behavioral Cognitive Psychotherapy, 36*(6). 769-777.	Cognitive-behavioral	Expert Opinion Level 7	N/A	N/A	N/A	N/A	This article outlines dimensions of resistance, impasses, conflicts and confusions in building a therapeutic relationship and how to overcome these barriers.	N/A

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Lloyd, C., Smith, J., & Weinger, K. (2005). Stress and diabetes: A review of the links. *Diabetes Spectrum*, *18(2)*, 121-127.	N/A	Literature Review and Expert Opinion Level 7	N/A	N/A	N/A	N/A	Research has indicated that stressful experiences have an impact on diabetes. Stress may play a role in the onset of diabetes and can have a deleterious effect on glycemic control. Interventions provided to help individual prevent or cope with stress to improve glycemic control and quality of life.	N/A

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Lorig, K., Ritter, P. L., Laurent, D. D., Plant, K., Green, M., Jernigan, V. B., & Case, S. (2010). Online diabetes self-management program: A randomized study. *Diabetes Care, 33*(6), 1275-1281**.**	Self-efficacy theory	A randomized, controlled trial of an Internet-based diabetes self-management program (IDSMP) including American Indians and Alaskan Natives.

Level 2 | A total of 761 participants were randomized to *1*) the program, *2*) the program with e-mail reinforcement, or *3*) were usual-care control subjects (no treatment). This sample included 110 American Indians/Alaska Natives (AI/ANs). Participants were randomized using a random-numbers table. Roughly two-thirds became treatment subjects and one-third continued with usual care (no program or other treatment offered). Treatment subjects were further randomized one for one to receive follow-up reinforcement (membership in a list-serve discussion group) or no reinforcement. Usual care consisted of whatever care participants had been previously receiving and ranged from community clinics to | **Independent Variable**= The online diabetes self-management program IDSMP. Or the program with email reinforcement (a list-serve). **Dependent Variable**= 1) A1C 2) symptoms, *3*) exercise, and *4*) have self-efficacy and patient activation. In addition, participants randomized to list-serve reinforcement would have better 18-month outcomes than participants receiving no reinforcement. | The primary outcome measure was A1C, measured using capillary blood obtained with self-administered BIOSAFE kits.

Health-related distress was measured by the health distress scale, adapted from the Medical Outcome Study.

The activity limitations scale, which measures the impact of disease on role activities such as recreation and chores, was developed for an earlier study. Depression was measured by the Patient Health Questionnaire (PHQ)-9. A physical activities scale | Analyses of covariance models were used at the 6- and 18-month follow-up to compare groups.

T tests were used to compare baseline IDSMP participants with usual-care participants and to compare baseline reinforced with unreinforced IDSMP participants.

T tests were also used to compare the baseline variables for those who failed to complete the 6-month questionnaires with those who had completed questionnaires.

ANCOVA models were used to compare | Treatment participants, when compared with usual-care control subjects, had significantly lower A1C ($P < 0.05$) as well as improvements in patient activation (PAM) and self-efficacy (0.021 and <0.001, respectively). Health behavior and utilization changes were not significantly different for treatment compared with control group participants. When intent-to-treat analyses were used, PAM and self-efficacy remained significant, while the *P* value for A1C | The lack of a detailed analysis of effects of program utilization, as well as analyses of possible mediating effects of secondary and tertiary variables, is an important limitation but was beyond the scope of this study.

A further limitation of the study was the relatively low mean A1C at baseline. A large portion of the participants were in control and more likely to get worse rather than better due to both a floor effect and regression to the mean. When they |

			specialist care. Usual-care participants were not restricted from seeking additional care or programs. All participants received a $10 Amazon.com certificate after completing each questionnaire and returning their A1C sample. A total of 1,463 people visited the Web site to apply to participate. Of these, 1,019 completed enrollment screening and proceeded to the baseline questionnaire. A further 48 were disqualified, 22 subsequently declined, 74 failed to complete consent or baseline questionnaires, and 104 failed to complete A1C testing. The remaining 761 participants completed baseline assessments and were randomized to one of the three groups.		measured total minutes per week of aerobic exercise. Tertiary measures included the 13-item short-form Patient Activation Measure (PAM) and diabetes self-efficacy. PAM measures patient self-reported knowledge, skill, and confidence for managing their chronic condition. The diabetes self-efficacy scale was developed for a small-group diabetes program and based on earlier chronic-disease self-efficacy scales.	reinforced with unreinforced program participants. Least-square means (computed as part of the ANCOVA procedure and adjusted for covariates) were used to determine if there were significant differences between the treatment groups randomized to reinforcement and no reinforcement.	increased to 0.060. When only participants with baseline A1C $\geq$7.0% are included at 6 months, the difference between treatment and control for A1C was 0.614 (P = 0.010, effect size 0.499). Self-efficacy was also statistically significant (P = 0.040), although the effect size was small. At 6 months, results were mixed. The changes in the primary outcome variable (A1C) had a small (effect size = 0.111) but statistically significant difference between treatment and usual-care control groups when only looking at	looked at the subgroups of those with baseline A1C >7.0% at baseline, the differences in improvements in A1C increased from a very modest effect size of 0.11 for the entire randomized sample to a clinically significant effect size of 0.50. This suggests that the program may prove more successful if targeted to patients with higher A1C. Although results were both encouraging and discouraging, they suggest that the program can be beneficial to people with diabetes and that further study is warranted. A trial with

| | | | | | | | actual cases (P = 0.039) Secondary outcomes did not improve. None of the three health indicators showed significant differences, nor were the amount of exercise or number of physician visits significantly changed. The attempt at reinforcement was not effective. | broader recruitment, limited to only those with A1C >7.0%, and allowing randomized control subjects to participate in the program after a 6-month trial would prove more definitive. |

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Oberg, E. B., Bradley, R., Allen, J., & McCrory, M. A. (2011). CAM: Naturopathic dietary interventions for patients with Type 2 diabetes. *Complementary Therapies in Clinical Practice, 17*(3), 157-161.	N/A	Prospective observational pilot study evaluating the change in clinical and patient-centered outcome measures following a 12week individualized and group dietary education program delivered in naturopathic primary care. Level 3	Twelve participants completed the program and were included in the final analysis. One hundred and thirty-five participants were recruited, and phone screened, 29 were eligible for medical screening, 17 were eligible and signed consent forms, 15 began the intervention, and 3 withdrew prior to completing week 12. All three participants who withdrew stated it was due to being too busy to continue. Reported results are per- protocol analyses on the 12 participants who completed the trial.	**Independent Variable=** The program included a total of 10 hours of active intervention over twelve weeks chosen intentionally to match the "dose" of nutrition and dietician services covered by Medicare. The nutrition program was delivered as a combination of one-on-one naturopathic physician-delivered dietary counseling and bi-weekly educational sessions for the entire cohort conducted following potluck-style dinners. **Dependent variables=** Outcomes included biomarkers and patient-reported outcomes obtained at baseline and week 12. Biomarkers	Patient-reported outcomes included four validated surveys. *The Summary of Diabetes Self-Care Activities (SDSCA) questionnaire includes 5 sub-domains of self-care: general diet and specific diet, exercise, medication taking, blood glucose taking and foot care. *The Problem Areas in Diabetes (PAID) scale measures emotional functioning and resiliency including health attitudes, coping strategies, and social functioning on a 5-point Likert scale.	Analysis compared pre- and post-measures using paired t-tests for continuous outcome measures and descriptive statistics were calculated. Mean and SD or SEM are reported, except where noted. A p-value of 0.05 or less was accepted as significant.	HbA1c improved in all participants (n=12); mean -0.4% +/− .49% SD, (p=0.02). Adherence to healthful eating increased from 3.5 d/wk to 5.3 d/wk (p=0.05). Specific nutritional behavior modification included: days/week consuming ≥5 servings of fruit/vegetables (p=0.01), attention to fat intake (p=0.05), and −11.3% carbohydrate reduction. Measures of physical activity, self-efficacy and self-management also improved significantly.	The significant changes in eating behaviors suggest that, by addressing the underlying causes of overeating poor-quality foods, participants' new dietary behaviors may reflect lifestyle changes rather than simply adherence to a formulaic approach to diabetes eating. However, the lack of long-term follow-up is a limitation that should be addressed in future larger trials. While the program focused on nutritional dimensions of diabetes self-care, it is notable that participants also spontaneously increased their physical activity from 1.5 to 5 days a week. This study is of limited statistical power to adjust for multiple statistical comparisons. While nutrition was selected because of a priori opinions that nutritional management was the most potent component of the naturopathic approach to T2DM, results may

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
				included HbA1c (the primary outcome) and serum lipid profile. Anthropometric measures included blood pressure, height, weight, and calculated BMI. Patients completed 3-day diet diaries from which macronutrient intake was calculated.	*The Perceptions about Nutritional Counseling questionnaire measures self-efficacy in making dietary choices and satisfaction with treatment using a 5-point Likert scale. *The Seven Eating Styles Questionnaire assesses seven eating patterns on a 6-point Likert scale that are independently linked to overeating.			represent a fraction of the benefit that can be expected when a whole practice approach is used. Future studies should investigate whole practice naturopathy.

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Ott, J., Aust, S., Nouri, K., & Promberger, R. (2012). An everyday phrase may harm your patients: The influence of negative words on pain during venous blood sampling. *Clinical Journal of Pain, 28*, 324-328.	None specified	Prospective Randomized controlled trial Level 2 Purpose of the study to evaluate the influence of a pain-associated work on pain perception in a non-prestressed study population to test whether the lack of pain-related phrases would reduce perception of pain in the general population.	Conducted in Vienna Austria Sample- 100 healthy participants 50 males and 50 females.	**Independent variable**- using the word 'sting' prior to blood draw. Control group /**dependent variable** had the word 'beware' used before blood draw.	An independent investigator evaluated systolic and diastolic BP and HR before blood draw and immediately after. Patients were asked to rate their pain on a 0 to 10 scale with 0= no pain and 10= worst pain.	t-tests on independent and dependent variables and general linear model for repeated measures.	Participants experienced significantly more pain after having been warned with the word sting compared with beware. No statistical differences in BP or HR between groups.	Limitations- emotional reactivity might skew results. Also only young healthy people were studied. The investigator drawing the blood was not blinded . A strength is that blood draws are one of the most common diagnostic procedures and using healthy individuals might be representative of the general population.

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Pennebaker, J., Mehl, M., & Niderhoffer, K. (2003). Psychological aspects of natural language use: Our words, ourselves. *Annual Review of Psychology, 54*, 547-577.	None	Annual Review Level 5	N/A	N/A	N/A	N/A	This article explored the methods and recent findings on word use. It discussed how word use is a meaningful measure of social, natural and personal processes.	**Strengths**- Comprehensive presentation on the state of the science of language **Limitations-** For my purposes it didn't present a link to health and health outcomes.

Full citation	Conceptual Framework/ Theoretical basis for study	Design/ Method	Sample/ Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/ Analysis	Statistical findings, qualitative findings	Strengths Limitations
Resnick, B., Gruber-Baldini, A., Galik, E., Pretzer-Aboff, I., Russ, K., Hebel, J., & Zimmerman, S. (2009). Changing the philosophy of care in long-term care: Testing of the restorative care intervention. *The Gerontologist, 49*(2), 175-184	Bandura's Theory of Self-Efficacy	Randomized controlled trial using a repeated measure design with treatment sites randomized to either treatment (Res Care) or placebo control (education only). Level 2	Nursing assistants (NA) were recruited from 12 nursing homes (NH) in the greater Baltimore area. 556 NAs participated, 283 in treatment sites and 273 in control sites.	**Independent variable**- Res Care, treatment effect, time, and treatment by time interactions. **Dependent variable-** Outcome measures	NA Self-Efficacy for Restorative Care Activities (NASERCA). NA Outcome Expectations for Restorative Care Activities. Restorative Care Behavior Checklist NA Knowledge of Res Care Theory Job Satisfaction	Descriptive analyses were used to describe the sample, and differences between treatment and control groups were tested with t-tests and chi-square tests.	There was a statistically significant increase in the treatment group participants' outcome expectations related to Res Care activities and performance of Res Care at 4 months and an increase in knowledge of Res Care and job satisfaction at 12 months. No statistical difference between groups regarding self-efficacy.	Limited by the subjective reporting of most of the study outcomes and the attrition that occurred over the course of the study. Also the study design did not allow testing of the two different tiers of the intervention. Provided an important step in understanding the implementation of Res Care and the effect on NAs.

Full citation	Conceptual Framework/ Theoretical basis for study	Design /Method	Sample/ Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/ Analysis	Statistical findings, qualitative findings	Strengths Limitations
Resnick, B., Luisi, D., & Vogel, A. (2008). Testing the Senior Exercise Self-Efficacy Pilot Project (SESEP) for use with urban dwelling minority older adults. *Public Health Nursing, 25*(3), 221-234.	Bandura's Theory of Self-Efficacy	A feasibility study using a randomized control trial.\n\nLevel 2	166 participants 100 in the intervention group and 66 in the control group.\n\nBrooklyn, South Bronx, Upper Manhattan	Independent variable- SESEP	Primary Outcome- self-efficacy, outcome expectations, exercise and overall physical activity. Secondary outcomes- mental and physical health related quality of life, depressive symptoms, pain, fear of falling, mobility, and chair rise time.\n\n*Self-efficacy for Exercise (SEE) scale\n*Outcome expectations for Exercise (OEE) scale\n*Yale Physical Activity Survey (YPAS)\n*Health Related Quality of Life\n*Geriatric Depression Scale\n*Tinetti Scale	Analysis of Variance and chi-square MANOVA	Statistically significant improvements in outcome expectations, time spent in exercise and depressive symptoms.\n\nHypothesis 1 partially supported. Hypothesis 2 minimally supported.	Although good participation in the SESEP among minority older adults the primary outcomes were only minimally supported and there was even less support for the secondary outcomes.\n\nSelective sample Outcomes based on self-report Significant loss to follow up.

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Rosal, M. C., Ockene, I. S., Restrepo, A., White, M. J., Borg, A., Olendzki, B., … Reed, G. (2011). Randomized trial of a literacy-sensitive, culturally tailored diabetes self-management intervention for low-income latinos: Latinos en control. *Diabetes Care, 34*(4), 838-844.	Social Cognitive Theory It targeted previously identified needs in this population related to key SCT constructs: diabetes knowledge, attitudes (i.e., self-efficacy or confidence in making changes), and self-management behaviors.	Randomized control trial. Compared the efficacy of the Latinos en Control intervention to that of an enhanced usual-care condition. The intervention was guided by a detailed protocol and delivered by a trained team of two leaders and an assistant (either a nutritionist or health educator and trained lay individuals or three lay individuals supervised by two investigators.	A total of 252 patients recruited from community health centers were randomized to the Latinos en Control intervention or to usual care. Recruited participants from five community health centers. Eligibility criteria were as follows: Latino ethnicity, age 18 years, documented diagnosis of type 2 diabetes; last HbA1c (previous 7 months) 7.5%; ability to walk; no type1 diabetes or history of ketoacidosis; no medical contraindications to participation; no use of glucocorticoid therapy within the prior 3 months; not currently participating in a cardiac rehabilitation or formal weight loss program; no plans to move out of the area within the 12-month study period; access to a telephone; ability and willingness to provide informed consent (English or Spanish); and physician approval to participate. Participants in the usual care condition received no intervention.	**Independent variable=** The primarily group-based intervention consisted of 12 weekly and 8 monthly sessions and targeted knowledge, attitudes, and self-management behaviors. **Dependent variable=** The primary outcome was HbA1c. Secondary outcomes included diet, physical activity, blood glucose self-monitoring, diabetes knowledge and self-efficacy, and other physiological factors (e.g., lipids, blood pressure, and weight). Measures were collected at baseline and	Fasting blood samples were collected for determination of HbA1c and lipid panel. A measure of glucose variability, the Average Daily Risk Range (16), was obtained for participants in the intervention condition using data downloaded from glucose meters at each intervention session. Blood pressure was determined using the mean of two measures taken with a Dynamap XL automated BP monitor. Height and weight and waist circumference were determined using the mean of two measures obtained using	Baseline characteristics between randomized groups were tested using t tests for continuous variables and Fisher exact tests for categorical variables. Attendance trends were tested using a mixed-effect logistic regression model with the individual as a random effect. Outcomes over time were compared using mixed effects regression models with the individual as the random effect. Linear regression was used for means of continuous outcomes and logistic regression for proportions of binary outcomes.	A significant difference in HbA1c change between the groups was observed at 4 months (intervention 20.88 [21.15 to 20.60] versus control 20.35 [20.62 to 0.07], P , 0.01), although this difference decreased and lost statistical significance at 12 months (intervention 20.46 [20.77to 20.13]versus control 20.20[20.53 to 0.13], P = 0.293). The intervention resulted in significant change differences in diabetes knowledge at 12 months (P = 0.001), self-efficacy (P = 0.001), blood	This theory-based intervention targeting patients' diabetes knowledge, self-efficacy, and self-management behaviors was successful in producing significant improvements in all three targets areas. A limitation of this study was the self-reported nature of the behavioral data (diet and blood glucose self-monitoring). In addition, the study was unable to objectively measure physician prescription patterns and patient medication adherence or estimate the

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
				at 4- and 12-month follow-up.	standard methods. A trained registered dietitian made unannounced telephone calls to obtain 24-hour recalls of dietary intake (17), physical activity (18,19), and blood glucose self-monitoring. Diabetes knowledge was measured using a subset of items from the Audit of Diabetes Knowledge. The research team developed a 17-item tool to assess self-efficacy for dietary and physical activity change, which showed adequate psychometric properties (Cronbach's a = 0.85).		glucose self-monitoring (P= 0.02) and diet, including dietary quality (P=0.01) Kilocalorie consumed (P= 0.001). These changes were significantly associated with HgA1c changes at 12 months.	mediating effect of medications on physiological outcomes. Future studies will need to examine innovative ways to enhance diabetes self-management, especially long-term glycemic control, and the cost-effectiveness of these interventions.

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/ Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/ Analysis	Statistical findings, qualitative findings	Strengths Limitations
Speight, J., Conn, J., Dunning, T., & Skinner, T. (2012). Diabetes Australia position statement. A new language for diabetes: Improving communications with and about people with diabetes. *Diabetes Research and Clinical Practice, 97*, 425-431.	N/A	Position Statement Expert Opinion Level 7	N/A	N/A	N/A	N/A	Diabetes Australia believes optimal communication increases the motivation, health and well-being of people with diabetes, and that careless or negative language can be de-motivating, is often inaccurate, and can be harmful. This position statement was developed to encourage greater awareness of the language surrounding diabetes and provide recommendations for more careful and positive language use.	N/A

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Street, R. L., Makoul, G., Arora, N. K., & Epstein, R. M. (2009). How does communication heal? Pathways linking clinician–patient communication to health outcomes. *Patient Education and Counseling*, 74(3), 295-301	Communication pathway	Review of the literature

Provided a review of Level 1, 4 and 5 studies. | N/A | N/A | N/A | N/A | This article provided a critique of current approaches to the study of communication and health outcomes. It also used the theoretical model of direct and indirect pathways from communication to health outcomes. | **Strengths-** Written by experts in the field of communication. Clearly critiqued studies that have been done and provided a detailed research agenda of what needs to be done. Provides a theoretical approach to communication with a model to guide research. **Limitations-** Looks at outcomes from a broad perspective not specifically diabetes related. |

Full citation	Conceptual Framework/ Theoretical basis for study	Design/Method	Sample/Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/Analysis	Statistical findings, qualitative findings	Strengths Limitations
Sue, D.W., Capodilupo, C. M., Torino, G. C., Bucceri, J. M., Holder, A. M. B., Nadal, K. L., & Esquilin, M., (2007). Racial microaggressions in everyday life: Implications for clinical practice. *American Psychology, 62*, 271-286.	None but the authors make note that a conceptual or theoretical model on racial microaggressions has not been developed as of yet.	Review of the literature Level 5	N/A	N/A	N/A	N/A	This article using the literature describes and analyzes racist microaggressions that effect the therapeutic relationship. The authors propose a taxonomy of racial microaggressions highlighting the implications for practice, education, training and research.	**Strengths-** Clear identification of the problem/area of concern. Development of a useful taxonomy for practitioners. Connection made by authors to other areas of concern with microaggressions in addition to race. **Limitations**- Research provided is not specific to patients with diabetes. The connection to chronic disease is only proposed.

Full citation	Conceptual Framework/ Theoretical basis for study	Design/ Method	Sample/ Setting	Major Variables Independent Dependent	Measurement Of Outcome Variables	Data/ Analysis	Statistical findings, qualitative findings	Strengths Limitations
Wang, F., Shen, X., . . . Xu, S. (2008). Negative words on surgical wards result in therapeutic failure of patient-controlled analgesia and further release of cortisol after abdominal surgeries. *Minerva Anesthesiology 74*, 353-365	None	Randomized controlled trial. The study aim was to investigate the effect of different words (positive and negative) used by nurses on patient's pain. This was done in China with women undergoing elective abdominal hysterectomy. Level 2- One well designed RCT.	1500 women recruited; 771 enrolled and randomized to 4 groups. No Words (N=35) Positive Words (N=248), Partially Negative (N=241) and Totally Negative (N=246). Sixty-three were lost to follow up, forty left the study and twenty-two were unable to verbalize pain rating after surgery. Total that completed the entire study = 614.	**Independent variable-** the words used by nurses. **Dependent variable-** *Primary* – pain rating based on a 0 to 10 subjective intensity rating using the linear Visual Analog Scoring VAS. *Secondary-* 1) Subjective sedation rating 2) subjective satisfaction rating 3) morphine consumption 4) plasma cortisol concentration 5) overall conditions 6)incidence of side effects.	Pain rated with VAS- currently best practice on how to rate pain. Plasma cortisol measured with radioimmunoassay. Sedation and satisfaction use a modified version of VAS.	Statistical analysis performed using GraphPad Prism version 5.0. The two-way ANOVA was used to analyze the effects of words on patients VAS pain score, sedation score, satisfaction score and cortisol concentration. Chi squared t-test was performed to compare side effects among groups. Statistical significance was measured at the level of p=0.05.	Negative words on surgical wards are strongly associated with increased pain- statistically significant. Totally negative words produced more significant effect than partially negative words and this influence was earlier in the post-op period. Negative words significantly increased the total amount of morphine consumed and amount of side effects. Positive words had not significant effect compared to no words used. Plasma cortisol levels were significantly elevated in the negative word groups- approximately three-fold higher than baseline.	**Strengths-** The intervention is simple and easily incorporated into practice. It is a safe intervention. The study was well designed and explained in detail, so it could be replicated. Low attrition and relatively even loss of participants in each group. **Limitations-** The biggest is that the researchers did not reveal the actual words they used. They did not tell us the negative and positive words. So, we don't know if certain words are better or worse than others. The study was on elective abdominal hysterectomy patients, so it is not generalizable to men and/or all surgical patients. It was completed in China and so may not be generalizable to the US because

						In summary, this study asserts that negative environmental influences (words) should be avoided during the earlier period after lower abdominal surgery in women.	they may have different healthcare practices for this patient population.

Appendix B

The Power of Words in Diabetes Care

Patient Survey

<u>General Information</u>

Gender: Male _____   Female_____   Age: _____

Type of Diabetes: Please circle   Type 1   Type 2   Gestational   Pre-Diabetes

How long have you had diabetes? _____

Medication: Please circle   Insulin   Pills   Both Insulin and Pills

A1c: _____   Date of result_____   Obtained from health record

Zip Code: _____

These questions are asking **how you feel** or **what you think** when certain words or phrases are used by the doctor, nurse or other medical person such as an educator or therapist. This could be during office visits; emergency room visits or hospitalizations. Think about any contact you have had with a medical person helping you with your diabetes care.

<u>Please rate the following phrases using the scale:</u>

1= Very negative, sad, mad, hopeless or doubtful

2= Somewhat negative, sad, mad, hopeless or doubtful

3= Neutral- neither positive or negative – no strong feelings

4= Somewhat positive, happy, upbeat, hopeful or confident

5= Very positive, happy, upbeat, hopeful or confident

Please rate the following phrases using the scale:

1= Very negative, sad, mad, hopeless or doubtful

2= Somewhat negative, sad, mad, hopeless or doubtful

3= Neutral- neither positive or negative – no strong feelings

4= Somewhat positive, happy, upbeat, hopeful or confident

5= Very positive, happy, upbeat, hopeful or confident

How would ***you feel or what would you think*** if this was said to you by a medical person?

Use the scale above and circle your answer:

#1- "How long have you had diabetes? Tell me about any trouble you have had dealing with your diabetes."

1   2   3   4   5

#2- "I am looking at your blood sugar numbers, and you are completely out of control. The numbers should be 80 to 150 and all of yours are above 250. "

1   2   3   4   5

#3- "Ms. Jones I understand that you are worried about starting insulin. Please tell me what is bothering you?"

1   2   3   4   5

#4- "I want you to start to exercise for at least 30minutes every day."

1   2   3   4   5

#5- "It's important to set goals for staying healthy with diabetes. May we make a plan for you? "

1   2   3   4   5

#6- "I understand that suffering from diabetes is a really hard burden to carry."

1   2   3   4   5

#7- "Please tell me why you don't want to start insulin? It is the best thing for you and I really want you to start now."

1   2   3   4   5

#8- "I am looking at your blood sugar numbers, please tell me what you did on Saturday that made the number shoot through the roof?"

1   *2*   *3*   *4*   *5*

#9- "Mary is very non-compliant. She doesn't take her medication the way I told her to at her appointment."

1   *2*   *3*   *4*   *5*

#10- "We have talked about the complications of diabetes and if you continue to not follow my directions you are going to end up losing your foot or going on dialysis."

1   *2*   *3*   *4*   *5*

#11- "You must quit smoking. It is not helping you get healthy."

1   *2*   *3*   *4*   *5*

#12- "I would like you to check your blood sugar 3 times per day. Together we will use those numbers to help adjust your medication doses."

1   *2*   *3*   *4*   *5*

#13- "Mary takes her insulin whenever she can afford it and tries to eat fruit or vegetables a few times per week."

1   *2*   *3*   *4*   *5*

#14- "People who are diabetic need to follow a diabetic diet at all times."

 1   *2*   *3*   *4*   *5*

#15- "How often are you testing your blood sugar?" When you see bad numbers, what do you do?"

1   *2*   *3*   *4*   *5*

Did we miss any **Negative words or phrases** that bother you? List any not found above.

_____

_____

Did we miss any **Positive words or phrases** that help you? List any not found above.

_____

_____

Appendix C

The Power of Words in Diabetes Care

Quality Improvement Project Consent Form

August 1, 2020

You are invited to participate in a quality improvement survey about the use of words/language by medical or healthcare professionals and its effect on patient outcomes. This project is being conducted by Joanne Archer MSN, RN, CNS, BC-ADM a doctoral student at Alverno College in Milwaukee Wisconsin. The objective of the quality improvement project is to uncover how patients feel when certain words or phrases are used in a healthcare encounter. This survey is being offered to all patients with a diabetes education appointment at the Ascension Medical Group clinic- St. Joseph professional office building location.

There are no known risks if you decide to participate in this quality improvement project and no costs for participating. The information you provide will help improve communication between healthcare providers and patients. The information collected may not benefit you directly but will provide general benefits to patients and to doctors, nurses and other healthcare providers throughout Ascension.

Your participation in this study is voluntary and your answers on the survey will be kept confidential. Only the project lead and diabetes educator will have access to your answers. Nothing you say on the survey will in any way directly influence the care you receive.

By signing this consent form you are agreeing to allow the project lead and the diabetes educator at the St. Joseph medical clinic to access your A1c lab result and record it on your survey.

If you have any questions or concerns about completing the survey or participating in this project you may contact Joanne.Archer@alverno.edu (project lead), Judeen.Schulte@alverno.edu (faculty chair) or Paul.Smith@alverno.edu (IRB chair).

The Ascension and Alverno College Institutional Review Boards have reviewed my request to conduct this project.

Thank you

Joanne Archer MSN, RN, CNS, BC-ADM

Patient Name: (print) _____

Patient Signature: _____

Appendix D

Institutional
IRB
Review Board

Alverno College

	Paul Smith
8/11/2020	IRB Chair

To: Joanne Archer

   I have read over your revised research proposal ("The Power of Words in Diabetic Care"), and this is your formal approval letter to begin data collection. The identification number for this study will be IRB-081M-20. Please reference that number in any communications about this project. Also I approve the waiver of documentation of consent.

   You may begin data collection immediately. Please remember that as researcher you have an obligation to promptly report to me any breaches in the protections of the privacy of participants, and any other potentially harmful incidents that occur in your research. Also please notify me when you have completed your data collection so we can close out the study.

Best of luck with your project.

_____

Paul Smith
IRB Chair
Alverno College
3400 S. 43rd St.
P.O. Box 343922
Milwaukee, WI, 53234-3922
(414) 382-6363

Appendix E

Ascension Wisconsin IRB QI Self-Certification Tool

Confidential Participant

ID 47

Projects that do not meet the federal definition of research do not require IRB review. This tool was developed to assist the Ascension Wisconsin community in determining when a project falls outside of the IRB's purview because it does not constitute research but does qualify as a Quality Improvement (QI) or Program Evaluation project.

NOTE: This tool is not designed to determine all cases when a project falls outside of the IRB's purview. This tool is only for determining if a project is QI/Program Evaluation. The Ascension Wisconsin IRB Office has additional resources that can help determine the need for IRB review and guidance on types of review and IRB submissions.

FOR RESIDENTS and STUDENTS: If you are a Resident at Ascension Wisconsin, check with your Resident Program Director before using this tool. Many programs require submission directly to the IRB as a training exercise. Additionally, colleges or universities may have additional requirements for students, check with your school to ensure you meet all applicable requirements.

Instructions:

Complete the requested project information in the questions below. Select the appropriate answers to each question in the order they appear. Additional questions may appear based on your answers .If you receive a STOP HERE message, the project will not qualify for the Self- Certification, follow the provided direction to contact the AW IRB for additional information and guidance. If you do not receive a STOP HERE message, the completed questionnaire may be printed as certification that the project is "not research", and does not require IRB review. The AW IRB Office will not review your responses as part of the self-certification process. Responses are, however, maintained for quality assurance/improvement purposes.

Project Details	
Name of project lead/investigator	Joanne Archer
Project title	The Power of Words in Diabetes Care
Brief description of project/goals	This is a quality improvement/ scholarly project for my DNP (Doctorate in Nursing Practice) degree. The words/language used in health care can impact the patient and provider relationship and may unintentionally have a negative impact on patient outcomes. This quality improvement

	project intends to uncover how patients feel when certain words or phrases are used in a healthcare encounter by administering a survey to complete prior to attending an outpatient education appointment. The survey is voluntary. This information along with evidence found in research on this topic will guide the development of a "How To" guide on Positive Communication for healthcare providers. The communication guide will be useful to a wide range of health care providers in many types of locations from diabetes education settings to primary care clinics .
Ascension WI facility/department through which the project will be conducted.	Ascension Medical Group Clinic at St. Joseph Hospital's Professional Office Building
QI/Program Evaluation Determination	
Will the project involve testing an experimental drug, biologic, or device (including medical software or assay)?	__Yes _X_No
Has the project received funding (e.g. industry or federal) to be conducted as a human subject research study?	__Yes _X_No
Is this a multi-site project (e.g. there is a coordinating site, more than one site participating, and/or a study wide protocol)?	__Yes _X_No
Does the project involve living embryos or fetus', fetal tissue or the use or study of any birth control methods?	__Yes _X_No
Is this a systematic investigation designed with the intent to contribute to generalizable knowledge? For example, does the project include: a hypothesis, randomization of subjects, comparison of case vs. control, observational research, comparative effectiveness research, etc.	__Yes _X_No
Will the results of the project be published, presented, or disseminated outside of the institution conducting it?	_X_Yes __No
Will the project occur regardless of whether individuals conducting it may benefit professionally from it?	_X_Yes __No
Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?	_X_Yes __No
Determination	
Date of determination	07-13-2020
This project appears to constitute QI and/or program evaluation and does not fit the federal definition of research. Ascension Wisconsin IRB review is not required.	

Project Lead: Joanne Archer

Project Title: The Power of Words in Diabetes Care

Date of Determination: 07-13-2020

The Project lead should ensure that anyone associated with this project are aware of the activities, including obtaining approval from the leader of the department/area(s) where the project will be conducted.

It is recommended that you refer to the project as QI/ Program Evaluation, and not research, in any future presentations/publication.

You can get a copy of this completed determination below by downloading the pdf and/or entering your email address. Please safe a copy of this determination for your records.