Diabetes Distress Screening Among Type 2 DM Patients in Primary Care

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Abstract

Diabetes Distress (DD) is prevalent among patients with diabetes. This psychosocial phenomenon has been shown to negatively impact diabetes self-care management and can lead to poor glycemic control, increasing the patients' risk for developing complications. Despite the prevalence of DD among diabetic patients, it remains under-recognized and undertreated in the clinical practice. There is a need to screen for DD especially in primary care where majority of the DM type 2 patients are seen. Current national guidelines recommend routine screening for DD especially when treatment goals are not met or developing diabetes complications so early intervention can be instituted. In this quality improvement project, the Diabetes Distress Screening Protocol (DDSP) was developed to screen for DD using the validated Diabetes Distress Scale (DDS) screening tool among adult DM type 2 patients at the project site which was a primary care clinic. This quality improvement project evaluated if the presence of the DDSP improved the screening for DD and subsequent referral for further management among those who screened positive. Training session regarding the protocol was provided to the participants. There was a significant improvement in the participants' knowledge regarding DD based on the pre- and post-knowledge questionnaire results. This improvement resulted to full compliance of the protocol. The project participants were able to screen eighty-two DM type 2 patients and eighteen (22%) patients were identified as having DD. These patients were then referred for diabetic education and further management.

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Diabetes Distress Screening Among DM Type 2 Patients in Primary Care

Diabetes Mellitus (DM) is a complex disease process that may have psychological implications for patients. Patients diagnosed with diabetes have to cope with the demands of self-care activities such as medication adherence, blood glucose monitoring, multiple visits to providers, nutrition, and physical activities (Lim, Siaw, Tsou, Kng, & Chia Lee, 2019). For some patients prescribed insulin therapy, daily dosing and titration may cause a significant degree of stress and frustration (Polonsky et al., 2005). Another potential cause for emotional distress is not meeting their treatment goals, which can affect their ability for self-care (Beverly, Ivanov, Court, & Fredricks, 2017). Some patients diagnosed with DM are unaware of the disabling complications of their disease process. Many patients do not have any knowledge regarding the importance of maintaining glucose control. Managing this chronic disease can be overwhelming to many patients and can lead to diabetes distress. Diabetes distress stems from the worry and burden a patient experiences when coping with the demands of diabetes care (Rariden, 2019).

A screening tool can be utilized to identify diabetes distress among patients who are diagnosed with DM. This tool can assist clinicians in providing the extra resources required for the patient to successfully manage DM. The focus of this Doctor of Nursing Practice (DNP) project is to develop a protocol for primary care providers to disseminate information about diabetes distress (DD), improve screening utilizing the Diabetes Distress Scale (DDS), and improve rates of referral for further DD management. Diabetes Distress impacts patients' self-care management and behaviors and is linked to poor glucose control (Perrin, Davies, Robertson, Snoek, & Khunti, 2017). Identification and treatment of DD are considered major components of comprehensive diabetes management.

Background

In the United States (US), there are 34.2 million adults diagnosed with diabetes and majority of these adults have type 2 (Centers for Disease Control and Prevention [CDC], 2019). Almost half of these diabetic patients are not achieving their control targets (Rariden, 2019). Management of DM includes pharmacotherapy, dietary modifications, physical activity, weight reduction and psychosocial interventions (Wexler, 2019). Patients who are diagnosed with diabetes often experience a significant degree of DD (Perrin et al., 2017).

The concept of DD was first introduced by Polonsky and his team in 1995 to emphasize the negative emotional impact of living with DM diagnosis (Polonsky et al., 1995). Polonsky et al. (2005) later developed the DDS screening tool and was utilized among DM patients in three cities in the US (San Diego, Boston, and Honolulu). The DDS instrument was found to be valid and reliable in diagnosing DD among DM type 2 adult patients (Polonsky et al., 2005). DD is common and widespread that American Diabetes Association (ADA) recommended DD screenings (Li, Dai, Xu, & Jiang, 2020). A meta-analysis of fifty-five original studies suggested that 36% of patients with DM type 2 suffer from DD (Perrin et al., 2017). A cross-sectional study conducted in public and medical offices reported 44% of adults with DM type 2 reported to having significant levels of DD (Ramkisson et al., 2016). The prevalence of DD among DM type 2 patients makes it significant to examine this phenomenon closely due to the effects DD has on DM management.

Diabetes distress has been shown to negatively impact the management of the disease (Perrin et al., 2017). Patients with DD exhibit symptoms of fear, defeat, denial, loneliness, low motivation and frustration (Rariden, 2019). These emotional reactions impede the ability to manage diabetes as prescribed by healthcare providers. Studies reported that DD is associated

with poor glucose control due to the non-adherence to medications, diet and exercise (Martinez, Lockhart, Davies, Lindsay, & Dempster, 2018). It is for these reasons that screening for DD is important in clinical practice. One of the screening tools utilized in practice is the Diabetes Distress Scale (DDS). The DDS was designed by Polonsky et al. (2005) consisting of a 17-item questionnaire covering four content areas: emotional burden, regimen-related distress, interpersonal distress and physician-related distress. This instrument had been tested in multiple settings and was found to be reliable and valid in screening for DD (Polonsky et al., 2005; Chin, Siew Mei Lai, & Chia, 2017). Management of DD involves referral to a diabetes educator for counselling to assist patients in their self-care behaviors and treatment compliance (Beverly et al., 2017). Patients can be referred to a behavioral health provider for further management if treatment goals were not achieved after the initial intervention (ADA, 2020). Psychological well-being is integral for patients in managing their diabetes (Ozcan et al., 2018). Improvement of patient compliance to prescribed diabetes care regimen as it relates to DD requires guidance and additional information (Dieter and Lauerer, 2016).

National recommendations suggest to routinely monitor for DD especially when diabetes treatment goals are not met or at the early onset of complications (American Diabetes Association [ADA], 2020). However, some patients and clinicians are unaware of this condition (Rariden 2019). Providers may be unfamiliar or unaware of the DD phenomenon and lack the training in providing appropriate care. Due to this lack of knowledge, more than likely there is a lack of screenings performed to identify this condition among patients diagnosed with DM. The lack of awareness presents a barrier in providing appropriate care to address DD and improve patient outcomes (Owens-Gary et al., 2018).

Problem Statement

Close to half of the adult population in the country who are diagnosed with DM are not meeting their treatment goals (Rariden, 2019). This number is expected to increase as the number of people diagnosed with DM increases every year (Nanayakkara et al., 2018). Identification of barriers to diabetes self-care is essential as DM and its complications impose significant expenditures in our healthcare system.

The majority of patients diagnosed with Type 2 DM are examined in the primary care settings (Beverly et al., 2017). The practice of the primary care providers at the project site does not currently include screening for DD; most likely due to lack of knowledge of this condition. Providers' lack of training regarding DD or unfamiliarity of this condition are contributing factors whether they screen for DD in practice (Owens-Gary et al., 2018). Implementing a DD screening protocol for primary care providers will improve DM management and quality of care. Identifying DD and effectively managing this condition will improve adherence to the prescribed DM regimen. This will result in controlled blood glucose, preventing complications, and improve the quality of life for these patients. Regulatory organizations track quality of care through quality measurements such as Healthcare Effectiveness Data and Information Set [HEDIS] (Chazal and Creager, 2016). Hemoglobin A1C (HbA1C) level is one of the quality indicators for DM management and currently the practice site is not meeting their target. Improving HbA1C among type 2 diabetic patients will improve the HEDIS score in the practice site.

Purpose Statement

The aim of this DNP project is to improve diabetic management among patients with DM type 2 by identification of patients experiencing DD in the primary care setting. The purpose of

this DNP project is to improve the primary care clinic's HEDIS scores by expanding provider knowledge of DD, increase the rate of DD screening, and promote patient referrals for DM management. By successfully implementing this protocol, the project site will improve their adherence to the quality indicators for diabetes management based on the clinic's quality metrics. Developing DD screening protocol will assist primary care providers in identifying DD among adult patients diagnosed with type 2 diabetes particularly those who are not achieving their glycemic targets. This is in alignment with the current national guideline (American Diabetes Association [ADA], 2020).

Project Questions

Will implementing the Diabetes Distress Screening Protocol (DDSP) in a primary care clinic, improve screening rates for DD and referrals for further DM management among adult patients diagnosed with DM type 2 within the four-week timeframe?

Population: Primary care providers and clinic staff

Intervention: Screening for DD utilizing DDS

Comparison: No DDSP

Outcomes: Improve DD screening among DM type 2 adult population

Time: Within 4 weeks.

Project Objectives

The following objectives will be completed at the end of this DNP project:

1. Develop the Diabetes Distress Screening Protocol (DDSP) utilizing the validated instrument DDS
2. Educate participants in the DDSP and practice change
3. Improve participants' knowledge regarding DD

4. Evaluate providers' compliance with the DDSP

Literature Search

The literature review was guided by the question: Will improvement in DD screening utilizing the DDS by primary care providers improve referrals for further DM management among adult patients diagnosed with DM type 2? The literature search was conducted utilizing the CINAHL, PubMed, ProQuest and Psych Info for scholarly articles databases and the filter published between 2015 and 2020 was used. The search was guided by the following keywords: diabetes distress, diabetes related distress, diabetes type 2, DDS screening, intervention. Initial search produced a total of 109 articles. Articles were excluded due to topics unrelated to the project such as: Diabetes Type 1 population, pediatric population, studies utilizing other screening tools, and not being relevant to the guided question. Inclusion criteria consisted of relevant articles to the project containing adult population (ages above 18), diabetes type 2 diagnosis, DDS as screening tool, DD interventions. After applying inclusion and exclusion criteria, twelve full text articles were selected for further review. Articles selected have full text, in English language, peer reviewed and quantitative study designs. Abstracts were reviewed to identify article duplication and determine sample size and settings.

Review of Scholarly Evidence

Review of Study Methods

The findings of the literature review produced themes and were organized as follows: depression in comparison to DD; impact of DD and DD screening; interventions improved DD and DM; risk factors for DD; current management of DD and issues to be addressed. Interventions included self-management and diabetes education delivered in different modalities. All studies reviewed utilized quantitative research designs. These studies describe the

relationship of DD and DM type 2 and how improvement of DD can positively impact DM management. The studies utilized DDS, which was translated in different languages, applied in different clinical settings and proven to be valid and reliable.

Depression versus Diabetes Distress

According to Owens-Gary et al. (2018) depression and diabetes distress are the two common psychosocial conditions for patients diagnosed with Type 2 DM. Depression is a mood disorder and patients can be screened utilizing PHQ-9, which is a brief self-reported screening tool used in primary care settings. This screening instrument focuses on nine diagnostic criteria for DSM-IV depressive disorders: anhedonia, depressed mood, sleep problems, low energy, appetite problems, low self-esteem, trouble concentrating, psychomotor problems and suicidal ideation (Marc et al., 2014). Management of depression in the primary care setting may include psychotherapy, pharmacology or combination of both (Gregory, 2019). Similar to DD, depression affects almost half of patients with DM (Nanayakkara et al., 2018). The same authors added that DM patients have higher risk of developing depression compared to those without DM.

Diabetes distress on the other hand, is an emotional distress condition, which results from living with the burden of having DM (Dieter & Lauerer, 2016). DM management can be complex, demanding and sometimes confusing that DM patients can be overwhelmed, frustrated, and discouraged (Rariden, 2019). It can also be related to fears regarding long-term complications, lack of support from family and healthcare providers (Polonsky et al., 2005). Both DD and depression affect patients' adherence to DM self-care, resulting to poor glycemic control and increase their risk of having DM-related complications leading to poor quality of life (Owens-Gary et al., 2018; Dieter & Lauerer, 2016). It is important to mention the distinction

between depression and DD. While depression may originate from different aspects of the patients' internal or external environment, DD is specific to diabetes self-care (Berry, Davis, & Dempster, 2017). Fisher et al. (2010) stated that DD, not depression, is associated with blood glucose control (HbA1C). In a study conducted by Nanayakkara et al. (2018), both depression and DD were related to poor DM self-care, however DD was independently linked to higher HbA1C levels. DD and depression can overlap, and it is important to distinguish between the two (Berry et al., 2017). Diabetes distress and depression can occur simultaneously, independently and present differently from each other (Perrin et al., 2017). It is recommended for clinicians to screen DM patients for DD and depression during office visits (Dieter & Lauerer, 2016).

Impact of DD and DD screening

Recent studies provided information that psychological conditions of DM patients can influence their glycemic control and overall well-being (Chew et al., 2017; Zheng, Liu, Liu, & Deng, 2019). Although DD and depression are correlated, there is a distinction between the two. DD has a greater impact on DM and is strongly associated with DM management and outcomes than depression (Aljuaid et al., 2018; Perrin et al., 2017). People diagnosed with DM type 1 and 2 often experience DD which can lead to poor self-care, increasing their risk of complications and poor quality of life (Owens-Gary et al., 2018; Sturt, Dennick, Christensen, & McCarthy, 2015). Diabetes distress negatively impacts patients' adherence to DM self-care and consequently contribute to higher HbA1C levels (Nanayakara et al., 2018). And more importantly, DD is not limited to elder population and frequently occur among younger population and female gender (Arifin et al., 2019). Taken this into account, DD may even have a bigger impact in the wider population.

Ramkisson et al. (2016) stated that even with the known effect of DD to DM, DD is often overlooked when treating DM patients. The authors suggested clinicians to screen for DD and address this psychological condition among DM patients. Screening for DD is critically important as it enables a more comprehensive approach in DM management both clinically and psychologically. Relevance and significance of these studies to this project is to utilize a planned approach of identifying variables such as age and gender that can be contributing factors for higher DD levels among DM patients. In the proposed DNP project, adult Type 2 DM patients will be the target population for DD screening by the providers in a primary care clinic.

Interventions Improved DD and DM

There is a strong evidence that diabetes education and self-management programs are effective in improving type 2 DM self-care (Qasim et al., 2019; Zheng et al., 2019). Management of DD is primarily directed towards assisting patients in improving their self-care behaviors and increase their compliance, reinforcing education and guidance, and linking them to community resources to aid them in DM management (Dieter & Lauerer, 2016).

In a study conducted among African American women in rural areas of Southeastern United States by Cummings, et al. (2017) described the impact of reducing DD on self-care and HbA1C. This post-hoc analysis of prospective, randomized control trial recruited middle-aged women with uncontrolled DM type 2 (HbA1C $\geq$ 7.0%). Some participants were subjected to a telephone-delivered lifestyle intervention educational program by a peer advisor while another group received diabetes educational materials in the mail. HbA1C levels were measured at baseline and after 12 months including the DD levels utilizing the DDS. Medication adherence, DM self-care behaviors, empowerment and self-efficacy were measured using validated tools at baseline and after 12 months (Cummings et al., 2017). The DD prevalence among the

participants was 37% at baseline. Of the total sample, 61% improved their DD levels after 12 months of intervention. The study also suggested that improvement in DD levels resulted to improvement in HbA1C, medication adherence, self-care and self-efficacy.

An earlier study called Reducing Distress and Enhancing Effective Management (REDEEM) by Fisher et al. (2013) utilized web-based, telephone and in-person interventions and support to reduce DD. This was a pragmatic randomized clinical trial for adult DM type 2 patients who were distressed but not clinically depressed. Patients were recruited from community medical groups and diabetes education centers. Participants were randomly assigned to computer-assisted self-management (CASM); CASM plus DD-specific problem solving (CAPS) and computer-administered minimal support intervention (Leap Ahead). Interventions target improvement of their DM self-care activities (diet, activity, medication adherence). Fisher et al. (2013) suggested significant reductions in DD in all three arms after 12 months and that DD is highly responsive to interventions.

The previously mentioned studies both utilized randomized clinical trial (RCT) design. The study design is appropriate when drawing conclusions on the effects of health care interventions and provides strong evidence (Polit & Beck, 2012). Relevance and significance of these studies to this project connect the need to screen for DD in clinical practice. Once identified, patients with DD should be referred for further evaluation and management. All these mentioned studies have shown that DD improves with evidence-based interventions (Cummings et al., 2017; Fisher et al., 2013).

Risk Factors for DD

Diabetes distress is identified using DDS, which is an instrument developed by Polonsky et al. (2005). This tool uses a 6-point Likert Scale ranging from 1 (no problem) to 6 (serious

problem). Mean score of ≤2.0 indicates little or no distress; 2.0-2.9 indicates moderate distress and ≥3.0 indicates high distress (Ramkisson et al., 2016). Interventions or referral is usually indicated when patients score 2 which indicates moderate distress. Polonsky et al. (2005) stated that high DD scores in the DDS were associated with age (younger population), depressed patients, patients receiving insulin therapy, patients presenting with elevated lipid levels and those who have poor self-care activities (non-adherent to dietary requirements and sedentary lifestyle). Recent studies identified risk factors for DD as gender (females more than males), duration of the diabetes diagnosis (diagnosed within seven years compared to those diagnosed more than seven years), high glucose or HbA1C levels, and those who have complications (Aljuaid et al., 2018; Arifin et al., 2019; Kapoor & Mathur, 2015; Ramkisson et al., 2016; Tareen & Tareen, 2017). Younger population (less than 50-year-old) has less experience in managing DM, which puts them at risk for having DD (Arifin et al., 2019). Younger patients also have higher stress due to work and family responsibilities compared to the older population (Lim et al., 2019). Insulin therapy is often perceived as burden for some patients with DM (Kapoor & Mathur, 2015). Concurrent depression compounds DD. Duration of DM diagnosis is also an identified risk. Patients who had been diagnosed with DM seven years or less have difficulty managing the psychosocial implications of DM in comparison to those who had been diagnosed longer (Kapoor & Mathur, 2015). Presence of DM complications is a major predictor for high DD levels (Arifin et al., 2019). High DD levels were also seen among female population who have more gender-role responsibilities and the demands placed by the disease adds burden (Arifin et al., 2017; Ramkisson et al., 2016). Increased glucose levels or HbA1C were also a predictor of high DD levels. Fisher et al. (2010) suggested a bidirectional relationship between distress and HbA1C. High DD levels can negatively impact self-care behaviors of some patients

which can lead to poor glycemic control while in other patients, poor glycemic control can lead to DD (Fisher et al., 2010). Poor self-care behaviors include non-adherence to therapy and can lead to poor glycemic control.

Current Management of DD

Once DD is identified through initial screening, it can be reduced or eliminated with appropriate intervention. The Diabetes Self-Management Education and Support (DSMES) is proven to be effective in reducing DD (Fisher et al., 2013). This program increases DM patients' understanding and management of the disease, improving their self-care, and promoting support from the healthcare team (Rariden, 2019). In a study conducted by Zheng et al. (2019), short-term sessions of DSMES can effectively improve self-care, psychological distress, and DM control. Providing diabetes education using a peer advisor delivered through a telephone was proven to reduce DD levels, compared to patients who received diabetes educational materials in the mail (Cummings et al., 2017). The ADA (2020) recommended patients identified with DD be referred for DSMES to improve DM self-care. For unresolved DD after initial diabetes education, a referral to mental health provider is recommended for further evaluation and management (ADA, 2020). A referral for cognitive behavioral therapy or problem-solving therapy is recommended for patients with moderate to high levels of distress (Beverly et al., 2017). Diabetes distress management requires a collaborative effort from different professions such as primary care providers, nurses, diabetic educators and case workers (Owens-Gary et al., 2018). This team assists patients in achieving and redefining their treatment goals.

Issues to be addressed

Screening and identification of DD in primary care will address the psychosocial needs of DM patients. Perrin et al. (2017) stated that DD is a relatively new field of study and that further

exploration is needed to gain greater understanding. The DNP project to be implemented will address this gap in practice by implementing a DD screening protocol and educating primary care providers about DD and its impact to DM management. The use of a screening tool for DD will most likely initiate conversation between patients and providers. Studies also indicated that management of DD is successful when conversation of DD is initiated by clinicians (Nanayakkara et al., 2018). Owens-Gary et al. (2018) stated that evidence suggests early screening for DD consequently improves DM self-care. Primary care providers play a significant role in recognizing DD in their practice. It is recommended that evidence-based guidelines be incorporated into clinical practice (Owens-Gary et al., 2018).

Significance of Evidence to Profession

The number of people diagnosed with DM type 2 is increasing imposing a high disease burden to those living with the disease and to the healthcare system. Living with DM can be difficult as it can affect patients physically and psychologically. Addressing psychosocial issues such as DD is part of comprehensive DM management. Diabetes distress adversely affects DM self-care management leading to poor glycemic control and increasing patients' risks of having diabetic-related complications (Ramkisson et al., 2016). Complications such as cardiovascular diseases, nephropathy, retinopathy, and neuropathy can ensue, which can reduce quality of life and add to the increasing costs in managing DM. Early detection and management of DD is critical in improving self-care, quality of life of patients and reducing healthcare costs (Dieter & Lauerer, 2016).

Nurses have direct contact with patients, and it is important they detect DD in practice so patients experiencing DD can be appropriately managed. There is still much work to be done in translating research findings into practice. Developing and implementing best practices for

assessing and managing DD will not only improve patient outcomes but will also address the gap in practice.

Theoretical Framework

This quality improvement project will implement a change in the management of DM type 2 patients in a primary care setting. Kurt Lewin's Change Theory formed the framework for practice change (Appendix A). This theory has been used extensively to guide planned practice change (Tinkler, Hoy, & Martin, 2014). Lewin's change model postulated that individuals and groups are influenced by forces that will always exist that can either hinder, foster or maintain change (Wojciechowski et al., 2016). These forces are restraining forces, driving forces and equilibrium. Restraining forces are obstacles that counter the driving forces which facilitate change because they push the person or groups in the right direction (Tinkler et al., 2014). Equilibrium is a state where driving forces equal restraining forces and no change occurs (Wojciechowski et al., 2016). While driving forces shift the equilibrium towards change, retraining forces opposes it. Changes in equilibrium require implementing planned change activities using the three-step stages namely: unfreezing, changing/moving and refreezing.

The nursing profession is constantly modifying practices as it responds to the ever-changing healthcare environment. It is the responsibility of all nurses to advance practice to improve the delivery of healthcare. Lewin's Change Theory is relevant to nursing as it provides the framework to facilitate planned change in all types of healthcare settings.

Historical Development of the Theory

Kurt Lewin was born in 1890 in Mogilno, a small town in West Prussia which is now part of Poland. He completed his doctoral degree in philosophy and psychology at Berlin University where he served as a researcher and professor after the First World War. It was during this time

where his psychological experiments on tension states, needs, motivations, and learning were conducted (Burnes & Bargal, 2017). His work during this time focused more on individual psychology (Papanek, 2017). In 1933, he moved to the United States following Hitler's rise to power and became a researcher at Cornell University and then at the University of Iowa (Burnes, 2004). His work in the US marked a change from the individual to group dynamics (Papanek, 2017). After the Second World War, Lewin formed the Research Center for Group Dynamics at the Massachusetts Institute of Technology where the goal was to describe all aspects of group behavior and how to modify it (Burnes, 2004). Lewin's work focused on behavioral modification to manage social conflict within an organization or society as a whole (Burnes, 2004). His background played a major influence in his works. His interest and beliefs originated from his background as a German Jew growing up in Germany during the time when anti-Semitism was pervasive. Having lived and witnessed the two world wars, his works focused on resolving social conflicts and problems such as discrimination among minority or disadvantaged groups (Burnes, 2004). Resolving conflicts requires learning and understanding of group dynamics while introducing change to group behavior. Lewin conceived Action Research theory, which proposed that for change to occur, it needed action. For action to be successful, one has to evaluate the situation thoroughly, identify all alternative solutions and choosing the best course of action (Burnes, 2004). However, changing into a higher level of group performance are usually not sustained and the group sometimes revert back to its previous performance. To sustain change within a group, Lewin developed the three-step model of change (Burnes, 2004). To facilitate and sustain change as part of the group norm, it involves three steps: unfreezing, moving/changing and refreezing (Cummings, Bridgman, & Brown, 2016). Lewin died in 1947 at age of 56 but his work remains relevant and is widely used.

Applicability of Change Theory to Current Practice

Examining the current landscape of healthcare, it is clear that transformational change is needed to address healthcare delivery outcomes, increasing healthcare costs, and safety (Hall & Roussel, 2017). Nurses can address some of these issues. They are a critical component in the delivery of healthcare and must perform care that is evidence-based or best practice (Spruce, 2015). This suggests that there is a need to update or make changes in how care is delivered. Implementing a new practice policy that aligns with current best practices is an example of introducing change to current practice. Though change is important to improve clinical practice, attempts at change often fail because of a lack of structured approach to implementation (Mitchell, 2013). Kurt Lewin's change theory is commonly used by nurses from multiple specialties to guide quality improvement projects (Wojciechowski et al., 2016). This theory provides a systematic approach that addresses human responses to change at each stage (Abd el-shafy et al., 2019). Progression to the next stage is dependent upon the completion and success at the previous stage (Wojciechowski et al., 2016).

Lewin's theory of change provides the framework for implementing a practice change in managing venous leg ulceration by a community nursing team in the United Kingdom [UK] (Tinkler et al., 2014). Improving the bandaging techniques utilizing the Clinical Resource Efficiency Support Team (CREST) guideline was introduced among the community nurses. This practice change was implemented to address the increased recurrence rates of leg ulcerations among the elderly population which imposed a significant cost to the UK healthcare system (Tinkler, et al., 2014). Kurt Lewin's theory of change was also utilized when Medical Orders for Life-Sustaining Treatment (MOLST) form was implemented into practice and policy in a cancer institute (Evans, et al., 2016). This cancer center, which has inpatient and outpatient units did not

have a standard advance directive form for patients admitted. The MOLST form was used as this is widely accepted by health professionals and communicates patients' wishes accurately than any other advance directive forms (Evans, et al., 2016). The implementation of the MOLST form in practice increased communication between patients and providers and reduced conflicts among patients, families and providers in emergency situations (Evans, et al., 2016).

Major Tenets of the Theory

Unfreezing Stage

In this stage, the current balance must be interrupted in order for a new behavior or process to be learned and undoing of the old ways (Schriner et al., 2010). It consists of creating an awareness that a change is needed since the current balance is hindering the organization in some way (Evans, Ball, & Wicher, 2016). According to Burnes (2004), this stage is often difficult as people will naturally resist change. This is considered a restraining force during this stage. Driving force at this stage includes organizational protocols or guidelines. Burnes (2004) stated that for change to occur effectively, it has to be at the group level. In this stage, communication is important on the imminent change and how it affects the group and individuals. Stakeholders must be aware that change is essential as this can result to improved delivery of care. Communicating the need for change allows for stakeholders to question and reflect on their current practice (Murphy, 2006). To implement change successfully, stakeholders must feel that they are part of the change process (Welford, 2006).

Moving/Changing Stage

The moving stage marks the implementation of the change. During this step, individuals begin to learn new behaviors, processes, and ways of thinking. Motivation and guidance are needed to remind people of the reasons for change and to move toward the end goal (Abd el-

shafy, Zapke, Sargeant, Prince, & Christopherson, 2019). Burnes (2004) stated that for change to be sustained, there has to be reinforcement of desired behaviors. Training, coaching, and role modelling of new behaviors are activities that can encourage and sustain desired change in this second stage (Wojciechowski et al., 2016).

Refreezing Stage

The final stage is refreezing where it involves stabilizing and strengthening the new state after the change (Abd el-shafy et al., 2019). The changes made to organization, structure or people are accepted and integrated as the new equilibrium or status quo. This stage is especially important as individuals or groups can revert back to their old ways of thinking or processes (Burnes, 2004). Positive reinforcements such as recognizing success, re-training and monitoring allow changes to be sustained into the organizational culture (Wojciechowski, et al., 2016).

Application of Theory into the DNP Project

Unfreezing Stage into Practice

Upon learning that DD screening and management is not available in the current practice site, research findings were compiled to support the use of a DD screening protocol. In the unfreezing stage, stakeholders were convinced they need to utilize a screening tool for DD among DM type 2 patients. The ADA (2020) guideline recommended routinely screening for DD especially when target goals are not met or when complications occur however, DD screening is not performed due to lack of knowledge among providers. The introduction of a DD protocol will result in disequilibrium. This imbalance began when discussion regarding the use of DD screening protocol was introduced to the stakeholders. Stakeholders' engagement is accomplished by communicating that guideline recommendations promote best practice.

Collaborating and developing rapport with stakeholders is important in this stage in helping them realize the benefits of implementing the protocol into current practice (Evans et al.,2016).

Moving/Changing Stage into Practice

The second stage of Lewin's Change Theory is the changing or moving stage. This stage marked the implementation of the DD protocol. Attitudes and behavior are altered towards the new practice idea and consequently modifying the management of DM in practice. In this project, the change stage is the implementation of DD screening tool among DM type 2 patients. This is the stage where change becomes a reality and efforts must be directed at reducing restraining forces through communication and support to stakeholders as they become familiar with the change (Wojciechowski et al., 2016). Throughout this stage, stakeholders must be reminded of the reasons for change and how these benefits the practice and patients.

Refreezing Stage into Practice

The last stage in Lewin's Change Model is refreezing. This is the integration of the DD protocol into the current DM management at the project site. In addition, a referral will be made for intervention among those identified with DD. It is in this stage where equilibrium is established into the system. This stage is accomplished with practice changes related to DM and compliance of stakeholders at the project site. New skills and behavior are acquired and made common practice. Efforts must be made to solidify this practice change and changed behaviors must be reinforced positively through acknowledgement (Wojciechowski et al., 2016).

Setting

The project site setting is a privately-owned primary care clinic located in Tucson, AZ. Tucson is located in the southern part of AZ with a population of 548,073 in 2019 (United States Census Bureau, 2019). The clinic is located in the southwestern part of the city where patients

across lifespan are seen. The clinic was established in 2001 as a solo practice by a physician with a Doctor of Medicine degree. In 2017, a family nurse practitioner (FNP) was added to the practice due to the growing patient volumes. The clinic sees an average of 100-120 patients per week and to date the practice has approximately over 1200 registered patients. The clinic has a manager who oversees the daily operations, a front desk clerk who schedules and checks-in patients and two medical assistants (MAs) who work with the providers. The project site provides medical services to insured individuals including those under the Medicare and Medicaid programs. There is an option to pay a fee for services rendered to those who do not have medical coverage.

The project site has an electronic medical record (EMR) in place where data regarding the number of patients with DM type 2 can be retrieved. Information regarding current HbA1C levels of these patients, age, gender and ethnicity can be identified using the same system. However, the DDS screening tool is not incorporated in the EMR and paper DDS will be utilized during the project implementation.

Population of Interest

Clinic medical and support staff in this primary clinic were the selected direct population of interest for this project. The clinic has two clinical providers, a physician and a family nurse practitioner (FNP). The clinic has a manager and employs a front desk clerk and two medical assistants (MAs). This population was selected to implement the practice change and increase DD screening among DM type 2 adult patients. Inclusion criteria consist of providers and staff who are currently working and employed by the clinic and who are involved in direct patient care, scheduling, or patient intake. The front desk clerk will provide the DDS forms to the patients upon check-in. Medical assistants will provide hand-outs and provide support to patients

when filling out the forms. Providers will review results of the DDS screening tool and initiate conversations regarding DD. The clinic manager can provide support and encouragement to support staff during the implementation phase. Any staff not employed at the practice site will be excluded.

Patients diagnosed with DM type 2 are the indirect population identified for this project. The charts of patients 18 years and older, established in this practice, diagnosed with DM type 2 at least six months previously, and seen for an office visit during the implementation phase of this DNP project will be included. All patient charts that do not have the diagnosis of DM type 2 and seen at a time other than the implementation phase will be excluded. Any individual that is not established as a patient of this clinic and those with cognitive impairment will also be excluded.

Stakeholders

Identifying the key stakeholders and their influence and contribution to the DNP project is vital for the project's success (Moran, Burson, & Conrad, 2017). Stakeholder engagement throughout the process is important to sustain any project (Poe & White, 2010). The main stakeholders include the providers and support staff. The stakeholders recognized the benefit of this project and the permission to implement the DNP project at the project site was obtained from the medical director who is also the proprietor of the primary care clinic (Appendix B). Collaborating weekly with these stakeholders is imperative to address any issues prior to the implementation and to ensure the success of this project. During the implementation phase, the project lead will support these stakeholders by being available to answer questions and address any concerns.

Interventions/Project Timeline

The implementation of the DD Screening protocol will be completed within a four-week time frame. The project lead will direct the implementation process to comply with the allotted timeframe. Implementing the new protocol in the clinic requires educating the participants about the DDS protocol (Appendix C), supporting participants during the implementation, collecting data and evaluating the results. The protocol includes the use of DDS screening tool among patients with DM type 2 (Appendix D). Diabetes distress handouts will also be given to these patients during their screening (Appendix E). A questionnaire will be handed out to the participants to evaluate their knowledge regarding DDS protocol pre- and post-implementation (Appendix F).

Educating participants will involve a presentation which will be held during a monthly staff meeting. The PowerPoint presentation will discuss DD concepts, the protocol, screening tool and educational material utilized in the project (Appendix G). The project lead will encourage questions from the participants so they understand the new protocol and could verbalize any questions or concerns regarding the implementation of the intervention.

The screening process will begin with the clinic manager identifying patients with a DM type 2 diagnosis. This process will be completed weekly using reports from the EMR. The patients identified will be assigned a number to maintain confidentiality. The age, gender, ethnicity and recent HbA1C levels will be printed on the report. These patients will be given the screening tool and handout during the check in process by the front desk clerk. The medical assistants will assist patients while completing the form. The provider will interpret results of the screening tool and will initiate conversations regarding DD. The patients who are identified as having DD from the DDS tool will be referred to diabetic educator for further management. The

project lead will provide support to participants during the implementation by being present for questions and re-educate participants as needed. A weekly audit will be performed by the project lead using a chart audit tool to evaluate compliance (Appendix H). The purpose of chart audits is to evaluate if patients with DM type 2 were screened for DD and if providers were compliant with the protocol. The project timeline is shown in Table I.

Table 1

DNP Project Timeline

Date	Project Activities
Week 1 Implementation November 4-10, 2020	Provide pre-implementation questionnaire to participants prior to implementation. Arrange to make copies of handouts. Check meeting room to ensure all equipment is functioning properly. PowerPoint presentation will be presented at the staff meeting. Nov. 4, 2020 as planned staff meeting date. DDS protocol implementation after participants' training session.
Week 2 – 4 Implementation November 11-17, 2020 November 18-24, 2020 November 25- December 1, 2020	DDS protocol implementation Provide support to participants by being present for questions. Oversee activities to make sure implementation runs smoothly. Re-educate participants if needed. Perform chart audits weekly to evaluate compliance to the DDS protocol. Will audit 20-30 charts weekly.
Week 5 Implementation December 2- 8, 2020	Final week of implementation Continue providing support to participants. Final data collection

	Provide the post-implementation questionnaire to project participants. Compile data for analysis. Prepare to disseminate results to project site at a later date.

Tools

The Diabetes Distress project involves the use of existing evidence-based tools and tools that were developed by the project lead. A variety of tools may be needed during the project design and implementation as they are necessary to ensure that the project achieves its goals (Moran, Burson, & Conrad, 2017).

Diabetes Distress Protocol

The DD Screening Protocol (Appendix C) was developed by the project lead which incorporates the recommendations of the ADA (2020). The DDS protocol consists of a screening mechanism for all adult patients diagnosed with DM type 2. These patients will be screened using the DDS (Appendix D). Once the patient completes the DDS, the provider reviews and interprets the results along with recent laboratory results and patient's subjective data. The protocol offers direction to providers when patients are screened positive or negative for DD. The negative results promote continued usual diabetic care and providing DD handouts to patients as part of patient education regarding this phenomenon (Appendix E). The discussion about DD will be initiated by providers for those identified as positive for DD and DD handouts will be provided. These patients will be referred initially to the diabetic educator for further evaluation and management. Once diabetes education intervention is completed, these patients will be re-screened for DD in three to six months. According to the ADA (2020), HbA1C testing is recommended every three months for patients who are not achieving their glycemic control

and every six months for those who are stable. These time periods are also appropriate to screen and re-screen patients for DD during their DM follow up visits. If these patients continue to screen positive for DD after the initial diabetic education intervention, it is recommended that a referral to behavioral health be considered (ADA, 2020). A re-screening for DD will be completed after the behavioral health intervention. If patients refuse referral to the diabetes educator or behavioral health, providers are advised to document this in the patient chart and provide patient the DD handout.

Diabetes Distress Scale. The DDS protocol incorporates the use of the DDS (Appendix D) which is an evidence-based screening tool. Permission has been granted to use the tool in this project by the author (Appendix D). The DDS is a 17-item questionnaire and uses a Likert type response format ranging from 1 (not a problem) to 6 (a very serious problem). The results from the scale are classified into three subgroups: little or no distress (≤ 2.0); moderate distress (2.0-2.9) and high distress (≥ 3.0) (Fisher, Hessler, Polonsky, & Mullan, 2012). A score of 2 and above is clinically significant and warrant intervention (Polonsky et al., 2005). Those who score 2 and above during project implementation will be referred for further management and evaluation. The DDS has demonstrated a high internal consistency and has been validated in numerous studies (Polonsky et al, 2005). The DDS is available online and is translated in multiple languages. A paper DDS tool will be used in the implementation of this project as this tool is not incorporated in the project site's EMR system. The front desk clerk is responsible for handing the screening tool to patients upon check in. The medical assistants will provide support and answer patients' questions or concerns while they complete the screening tool. The providers will add the scores and interpret the results. The discussion of the results will be initiated by the providers.

Diabetes Distress Handout. The DD handout (Appendix E) published by the Association of Diabetes Care and Education Specialists (ADCES) will be used in this project. It is available in English and Spanish versions. The contents of the handout included symptoms of DD, how to get screened and information on how to handle DD once identified. Permission from the author was granted to utilize this tool during project implementation (Appendix E). The DD handouts will be provided to patients by the front desk clerk during check-in process. Discussion of the information within the handouts will be initiated by the providers during the visit.

Pre and Post Knowledge Questionnaire

The participants' knowledge questionnaire was developed by the project lead (Appendix F). This questionnaire was reviewed by the course instructor, academic advisor and project mentor for content validity. This tool will evaluate DD knowledge among the participants pre- and post-project implementation. The same questions will be utilized and administered at two different time periods. The questionnaire will be administered prior to participants' training session and after the project implementation during the final week. The questions are based on the information from the PowerPoint (PPT) educational presentation (Appendix G). The participants will answer ten questions utilizing the multiple-choice format. The multiple-choice format is preferred and is consistent with better performance in practice (Jong, 2019). The participants are expected to at least answer eight questions correctly to pass during the post-implementation and failure to achieve such score will require re-educating participants regarding DD. Improvement in participants' knowledge will be determined by comparing their pre- and post-implementation scores.

Educational Presentation

A PPT presentation was developed by the project lead and will be presented to the participants during the monthly staff meeting (Appendix G). The contents of this presentation were reviewed by the project team to evaluate for validity prior to implementation. The presentation will include the DD concept and its impact to patients with diabetes, signs and symptoms, screening tool and current management of DD. The discussion of the DDS protocol will be included along with the description of the roles that every participant has during the implementation phase.

Chart Audit Tool

During the implementation phase, chart audits will be performed by the project lead using a chart audit tool (Appendix H). This chart audit tool was developed by the project lead to evaluate compliance of participants to the DDS protocol. This tool will determine if DD screenings were performed to all patients diagnosed with Type 2 DM and if providers were compliant in following the protocol recommendations. This audit tool will also identify patient demographics such as age, gender, ethnicity and recent HbA1C levels. The data collected will be correlated to the prevalence of DD among the patients screened for this project. Recent studies suggested that female and younger population (less than 50-year-old) have higher incidence of DD (Arifin et al., 2017; Ramkisson et al., 2016). An elevated HbA1C level is a predictor for high DD levels (Fisher et al., 2010). These are risk factors that will be described in this project.

Content Validity Index

The pre- and post-knowledge questionnaire was reviewed by the project team to evaluate the content validity index [CVI] (Appendix I). For a survey to have an excellent content validity, an item-level CVI score of 1.00 is needed using 3-5 experts and a scale-level CVI average of

0.90 or higher (Polit & Beck, 2006). When a new tool is developed, the content validity has to be evaluated to determine if the tool accurately measures the concepts under study (Fain, 2009). The information that will be gathered during the project implementation is only helpful if the instrument is accurate and valid. The mean total of all the means was 4.0 indicating that all of the items in the questionnaire for this project were highly relevant utilizing the three experts' feedback.

Data Collection Procedures

Data collection will commence prior to DDS protocol implementation by distributing the DD questionnaire among participants to evaluate pre implementation DD knowledge. The same questionnaire will be administered at the conclusion of the project during week five. The participants will be de-identified by assigning a number to maintain privacy and confidentiality throughout this project. The scores of the questionnaire will be shared with the individual participants during dissemination. The completed questionnaires will be secured in a locked cabinet at the project site which can be accessed by the clinic manager and the project lead.

One of the project objectives is to evaluate participants' compliance with the DDS protocol. Data collection will be provided using the current electronic medical records (EMR) used in the project site. A weekly report will be printed by the clinic manager identifying patients with a diagnosis of DM type 2 using the standard International Classification of Diseases, 10th revision, Clinical Modification [ICD-10-CM] codes. The report will include age, gender, ethnicity and recent HbA1C levels. There will be no personal identification information such as name or medical record number that will be collected. These patients are the indirect population of interest for this project who will be screened for DD using the validated DDS tool. Numbers will be assigned to the patient charts during the implementation to protect privacy and maintain

confidentiality. The DDS screening tool will be scanned into the patients' charts where only essential employees in the patient's care have access. The scanning will be completed by the front desk clerk and she will dispose of the DDS screening tools in the designated shredder box. Chart reviews will be performed utilizing the chart audit tool designed for this project to evaluate if the DDS protocol was implemented among the patients identified as having DM type 2. Currently, the DD has no corresponding ICD-10-CM code. There are two ICD-10-CM codes which will be used to identify DD for this project. The codes E11.8 (DM type 2 with unspecified complications) or E11.9 (DM type 2 without complications) and R45.89 (other symptoms and signs involving emotional state) will be used to identify DD and the associated diagnosis codes to be used when referring the patients to diabetes educator for further management (Optum360, 2020).

Ethics and Human Subjects Protection

The project lead completed the Collaborative Institutional Training Initiative (CITI) Program modules, which were required by the Touro University of Nevada (TUN) for students who will be implementing social and behavioral research or quality improvement projects. The training modules included measures in protecting the privacy and confidentiality of the data collected from the participants. The project lead in this QI project must plan carefully in handling, storage and reporting of data.

The DDS protocol is a quality improvement project that does not involve collecting personal patient identifiers and does not provide direct patient care. The Institutional Review Board (IRB) determination forms were completed and submitted to the TUN project team for review to ensure this project meets the criteria for a QI project. The DDS protocol is considered a QI project and should not require IRB review. Quality improvement activities are directed at

improving quality of care and services within an organization (Poe & White, 2010). When the data are deidentified and there is minimal risk to human subjects, the project is exempt for IRB review (Moran, Burson & Conrad, 2017). Any risk or discomfort will not be beyond what is encountered in everyday activities.

The participants were recruited through convenience sampling. The project lead will collect data from subjects who are readily available and who meet the inclusion criteria (Fain, 2009). The support staff and providers in the project site were directly recruited to implement the QI project through a series of meetings providing information about the DNP project. Through these meetings, the support staff and providers realized the benefits of this project and all agreed to participate in the implementation. The benefits of the project include improvement in the DM management of patients by identifying DD and a referral for further management if needed. The participants will receive their hourly wages and no additional compensation is required to participate in this project. Failure to participate will not lead to a disciplinary action or termination of employment.

Maintaining privacy and confidentiality of patients' charts will be adhered to using the standard for preventing security breaches at the project site. Data collection and access to EMR will be protected using a password to prevent unauthorized use of health information. Data will be organized using the Excel and SPSS software. The Excel sheet will be stored in a locked cabinet in the project site which the clinic manager and the project lead have access.

Plan for Analysis

The pre- and post-knowledge questionnaire will measure improvement in the participants' knowledge regarding the DDS protocol. A t-test statistical analysis will be performed to compare pre- and post-implementation scores of the participants. Excel and SPSS

software will be utilized to organize and analyze data. This procedure will describe improvement in participants' knowledge regarding DD after the intervention which is one of the objectives for this project. The paired t-test is used when collecting data from the same group of people at two different time periods (Pallant, 2013). The assessment using the questionnaire will be completed before (Time 1) and after the intervention (Time 2). The statistical assumptions considered in paired t-test analysis include normal distribution and homogeneity of variance (Pallant, 2013). It is assumed that the data is normally distributed from a given sample and variability of scores are similar for each group (Pallant, 2013). The normality and equality of variance are tested utilizing the t-test analysis (Pallant, 2013).

In determining provider compliance to the DDS protocol, the data will be analyzed using the percentage of provider compliance with a 95% confidence interval. Interval estimation provides information about the margin of error of a parameter (Polit & Beck, 2012). Confidence interval (CI) are constructed around the estimate and provide important information about its precision (Polit & Beck, 2012). The project lead will collaborate with the statistics specialist to ensure analysis and evaluation are completed correctly.

Data Analysis

The purpose of this quality improvement project was to answer the question: Will implementing the DDS Protocol in a primary care clinic, improve screening rates for DD and referrals for further DM management among adult patients diagnosed with DM type 2 within the four-week timeframe? The project lead implemented a training session regarding the DDS protocol and evaluated improvement in participants' knowledge and compliance to the practice change.

The project participants included two medical providers, two medical assistants, a front desk clerk and a clinic manager. The DD questionnaires were completed by the participants prior to the training session and immediately upon the conclusion of the protocol implementation. The following table illustrates the improvement in knowledge among the participants after the training session.

Table 1

Participants' Pre and Post Training Scores

Participant No.	Pre-training Score	Post-training Score
1	7	10
2	8	10
3	6	10
4	7	10
5	6	10
6	6	10

Table 1 shows the participants' pre- and post-training scores. The knowledge about DDS protocol was evaluated based on a ten-item questionnaire before the training was conducted. The initial assessment showed that participants scored high with all of them scored higher than fifty percent. Post implementation, they were given the same questionnaire and evidently their scores improved.

Further testing was performed to evaluate if the pre-training and post-training scores difference are significant. Using the t-paired sample test, the results show that at t= -10.000 and p- value = .000, there is a significant difference in the pre-training and post-training scores of the participants (Appendix J). The data further show a mean difference of -3.333 in the scores with the standard deviation of .816, which is within the 95% confidence interval of the difference. Based on these results, the training improved the participants knowledge of DD.

Before testing for t-paired sample test, the sample in this study (N=6) is assumed to be normally distributed. Chi square goodness of fit was used for normality test since the size of participants is very small. The variables tested for normality was the pre-training scores to determine if there is a difference from that of other populations. The result shows no significant difference at chi square = 1.000, df =3 and p-value = .607. Therefore, the assumption of normal distribution is validated. The mean score of 6.667 and standard deviation of .816 also supports normal distribution.

The DDS protocol was implemented for four weeks. Data was collected from the EMR which was the primary source of information regarding patient demographics and to evaluate compliance of the participants to the DDS protocol. Chart audits were performed, and a codebook was developed to identify variables in data input. Data was analyzed using the SPSS software. There were eighty-two DM type 2 patients who were screened for DD during the implementation. Table 2 presents descriptive statistics of the sample of patients (N=82) and participants' compliance to the protocol.

Table 2

Patient Demographic Characteristics and Screening/Referral of DD

	Profile Variables	**Frequency**	**Percentage**
Age	31 – 40 years old	4	4.9
	41 – 50 years old	13	15.9
	51 – 60 years old	12	14.6
	61 – 70 years old	28	34.1
	71 – 80 years old	20	24.4
	81 years old and above	5	6.1
Gender	Male	34	41.5
	Female	48	58.5

Ethnicity	Asian	10	12.2
	African American	4	4.9
	Caucasian	19	23.2
	Hispanic	49	59.8
DDS Performed During Clinic Visit	YES	82	100.0
	NO	0	0
DD ≥ 2.0	YES	18	22.0
	NO	64	78.0
Referral to DM Educator if score is ≥ 2.0	YES	18	22.0
	NO	64	78.0
Health Care Provider Who Conducted the Screening	Physician (MD)	54	65.9
	Nurse Practitioner	28	34.1

N = 82

The data in Table 2 show that ages of DM type 2 patients screened range from 31 to 81 years old and most of the patients belong to the 61-70 years old (34.1%) and 71-80 years old (24.2%). There were more female patients seen 48 (58.5%) than males, 34 (41.5%) during the implementation period. There was a diverse patient population however, the Hispanics or Latinos were the majority comprising a number of 49 (59.8%) patients. Diabetes distress screening were performed to all eighty-two DM type 2 patients during the four-week implementation. Of these, eighteen patients (22%) scored ≥ 2.0 which is considered positive for DD. The table further shows that all these patients identified as having DD were referred for DM education.

There were eighteen patients identified as having DD from the population of eighty-two DM type 2 patients. The data from these DD positive patients were further subjected to statistical testing.

Table 3

Demographic Characteristics of Patients with DD ≥ 2.0

	Profile Variables	Frequency	Percentage
Age	31 – 40 years old	3	16.7
	41 – 50 years old	2	11.1
	51 – 60 years old	4	22.2
	61 – 70 years old	5	27.8
	71 – 80 years old	3	16.7
	81 years old and above	1	5.6
Gender	Male	5	27.8
	Female	13	72.2
Ethnicity	Asian	2	11.1
	African American	1	5.6
	Caucasian	4	22.2
	Hispanic	11	61.1

N = 18

Table 3 shows the demographic characteristics of patients with DD. The greatest number of patients with DD belongs to the 61-70 years old range with five patients or 27.8%. There were more females at 72.2% than males (27.8%) and more Hispanic patients at 61.1%.

Table 4

HbA1C and DDS Scores of DD Patients

Test Performed	Mean (%)	Std. Dev.
HbA1c	8.60	2.164
DD Screening Scores	2.84	.653

Table 4 shows that the mean HbA1C of patients with DD is 8.60% with a standard deviation of 2.164. This result shows that these patients with DD have a high glucose level at 8.60% and the standard deviation of 2.164 implies the deviation from the mean of the glucose

levels of these patients is quite high, which means that the patients are quite diverse in terms of their blood glucose levels. The Diabetes Distress Screening Scores (DDSS) yielded a mean of 2.84% which is classified as moderate distress in the DD Screening Tool (Fisher et al., 2012). The .653 standard deviation indicates scores of these patients close to the mean of 2.84 which are not so diverse in terms of DDS scores.

A Pearson correlation analysis was conducted to determine the relationship between the HbA1C levels of the DD patients, and their DDSS (Appendix J). At 95% CI, the result of r = .110 and p-value = .665, shows no significant relationship between HbA1C and DDSS. The slight correlation of .110 is so minimal and considered negligible as shown in the p-value of .665. The increase in HbA1C does not influence the likelihood of an increase in DD level. This can be seen in Table 4 where HbA1C levels are significantly high with diverse results while the DD level is just moderate with more homogenous results.

Discussion of the Findings

The development and implementation of the DDS Protocol in the project site aimed to improve the management of DM Type 2 patients by identifying patients with DD, which can impair their self-care management. The project question sought to determine if the implementation of the DDS protocol will improve DD screening and referral for further diabetic management. The four-week implementation was able to identify that 22% of the sample population (N=82) has DD using the validated DDS screening tool.

Participants' compliance

All participants played an essential role during the implementation of the DDSP. The increase in knowledge among the participants post-implementation was indicative that training or education sessions were effective. This increase in knowledge resulted when participants

realized the benefits of the DDSP and facilitated an increase in compliance. This QI project was the first to be implemented in the project site and the process required a change in practice from all the participants. The incorporation of the DDSP in the project site workflow provided an evidence-based guideline for the participants that validates care delivered among DM type 2 patients is considered best practice. This project demonstrated that participants quickly became comfortable with the protocol and integrated in practice among DM type 2 patients. The use of Lewin's change theory aided in complying with this practice change at this project site.

The plan of utilizing the 95% CI method was not performed during the analysis of data as there was full compliance among the providers during chart audits. The same chart audits revealed that eighteen patients were identified as having DD and were referred for DM education and further management. Overall, the DDSP was effective in screening for DD and subsequent referral for DM management among patients who were identified as having DD.

HbA1C and DD Screening Scores (DDSS)

As suggested by some studies, elevated HbA1C levels were a predictor of high DD levels (Arifin et al., 2019; Ramkisson et al., 2016). However, this DNP project did not establish a relationship between HbA1C and DDSS. The factor which may have contributed to this result was the small number of DD patients identified in this project. While the majority of the eighteen patients identified as having DD have elevated HbA1C levels (uncontrolled DM), four patients in this project who are achieving their glycemic control have been identified as having DD (Appendix J). Fisher et al. (2010) suggested a bidirectional relationship between DD and HbA1C. In some patients, DD can negatively impact their DM self-management and consequently lead to elevated HbA1C levels while in other patients, elevated HbA1C levels can lead to DD (Fisher et al., 2010). These patients with controlled DM based on their recent HbA1C

levels may be experiencing signs of DD at the time of the screening which may eventually affect their ability to manage their DM. Because of the effects of DD, these patients warrant referral to a diabetes educator for further management. It is advisable to recheck these patients' HbA1C levels at the recommended time period if DD has impacted their glycemic control.

The purpose of this quality improvement project was to answer the project question. The results of this project evidently showed that DD is prevalent among Type 2 DM patients, which is in line with other studies (Aljuaid et al., 2018; Chin et al., 2017; Ramkisson et al., 2016). The negative effect of DD on DM makes it a considerably important health issue that healthcare providers should address this during patient encounters. It is essential to screen patients for DD periodically while evaluating their glycemic control.

Significance/Implications for Nursing

For many years, the main focus has been placed on the physiological aspect of DM and how this chronic disease can lead to serious complications. The recent guideline by the ADA (2020) suggested the psychosocial aspect in managing DM is equally important if the goal is to achieve better medical outcomes and quality of life. Due to the high prevalence of DD, it is recommended that DM patients be routinely monitored for DD due to its negative impact on diabetes management (ADA, 2020). Diabetes Distress is a newly understood phenomenon and remains under-recognized and undertreated by most healthcare providers (Lim et al., 2019). The presence of the screening tool such as the DDS makes it possible to screen patients with DM type 2 for DD so interventions can be instituted early. The DDS Protocol was created to guide providers such as nurses in advanced practice in implementing change in clinical practice. The DDSP was incorporated into the workflow of a primary care practice and provided a structure for healthcare professionals to offer treatment or referrals if indicated.

Nurses assume many roles in various healthcare settings. Health information and advocacy are imbedded in every role they perform. Nurses can initiate DD conversations during patient encounters to disseminate information regarding this psychosocial phenomenon. While nurses can be responsible for helping patients recognize DD, they can also be trained in the management of DD through structured diabetic education.

A change in practice which will benefit the patients is a responsibility of every nurse. With improved practice, nurses can help advance the profession, bridge any practice gap and improve how healthcare is delivered.

Limitations

This DNP project had some limitations identified during the implementation at the project site. This section will discuss the limitations to the project design, data recruitment and collection methods and the data analysis.

Project Design

The DDS Protocol recommended screening for DD periodically while evaluating for glycemic control. The DNP project was implemented during a four-week time frame and rescreening for DD to evaluate response to DM management was not possible due to the limited time of implementation.

Recruitment/ Collection Methods and Data Analysis

Another limitation to this project is the small number of participants who were recruited. This project utilized convenience sampling at a small primary clinic with few support staff. The project site has only two medical providers. Bias can occur when sample size is too small to draw firm conclusions or participation can be viewed as part of employment responsibilities (Fain, J. A., 2009; Smith & Noble, 2014). The size and the characteristics of the sample

including the recruitment method may have affected the representativeness of the population. The project was implemented in an urban area and generalizability to other types of practice and geographic location may not be possible. Small samples may yield a large sampling error and reduce statistical validity (Polit & Beck, 2012). With a small sample, it is possible the result may not show a statistical difference even though one exists (Heavey, 2011).

The ongoing Corona Virus Disease of 2019 (COVID-19) pandemic presented a limitation to this project. The project site reduced its operating hours thereby affecting the number of patients seen and screened for this project. The project site experienced a significant reduction in the number of patients in the schedule and those who were acutely ill were not seen due to risk of exposure to the virus.

Dissemination

Dissemination of the findings is important to improve practice decisions and advance professional knowledge and practice (Chism, 2019). The project site was a small private practice and was not affiliated with other practice sites. A decision was made to disseminate the findings at a different facility. The findings of this project were presented to clinical providers employed at a community health center located in northern AZ. This site sees a large population of DM type 2 patients and may benefit from this projects' findings. The final DNP project will be presented to Touro University Nevada's faculty and students on February 22, 2021 as part of the DNP course requirements. This will also be submitted to the Doctor of Nursing Practice Doctoral Project Repository website: http://www.doctorsofnursingpractice.org/doctoral-project-repository/. There is a plan for an abstract submission for a poster presentation to the Southwest Regional Nurse Practitioner Symposium sponsored by the Arizona Nurse Practitioner Council (AZNPC) this year and the National Nurse Practitioner Symposium in July 2021. The DD

handout utilized during the project implementation was permitted for use by the Association of Diabetes Care and Education Specialists (ADCES). A hard copy was sent to ADCES, 125 S Wacker Drive, Suite 600, Chicago, IL 60606 as requested by the organization. The diabetes educators are responsible for managing the DD and may benefit from the results of this DNP project.

Sustainability

The incorporation of the DD screening in the management of DM Type 2 patients in the project site was a sustainable initiative due to its inexpensive cost. The project utilized paper copies of the DDS screening tool and required a small amount of time to completely fill out the form. Newly hired staff will be trained regarding the DDSP. The project site is transitioning to a new EMR system within this year and the clinical providers suggested incorporating the DDS screening tool in the new EMR and will be discussed with the EMR vendor. This project proved that stakeholders are willing to adopt this practice change to improve DM management in the project site.

Conclusion

The DDSP was developed based on the current recommendations by the ADA (ADA, 2020). The project site did not have a protocol to screen for DD among the DM Type 2 patients. Patients with DD were identified during the four-week implementation. The training sessions were effective in increasing participants' knowledge regarding DD and improved compliance of the protocol. Patients with DD were referred for further management. Because DD is known to negatively influence DM self-care, its early identification and management can improve patient medical outcomes and quality of life.

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Appendix A

Theoretical Framework

Source: Visual Paradigm Online. (2020). Understanding Lewin's Change Management Model. Retrieved from https://online.visual-paradigm.com/knowledge/business-design/understand-lewins-change-management-model/

Appendix B

Project Site Approval Letter

TUMAMOC HILL FAMILY MEDICINE

Fred B. Tiu, M.D. FAAFP Rachelle Usis, MSN, FNP-C

July 20, 2020

To Whom It May Concern:

This notice comes as proof that there is no need for an affiliation agreement between the school and the project site.

I am giving permission for Marvin Depas who is a Touro University DNP student to implement his project titled "Diabetes Distress Screening Among DM Type 2 Patient in Primary Care" at our clinic.

Sincerely,

Fredemio Tiu MD

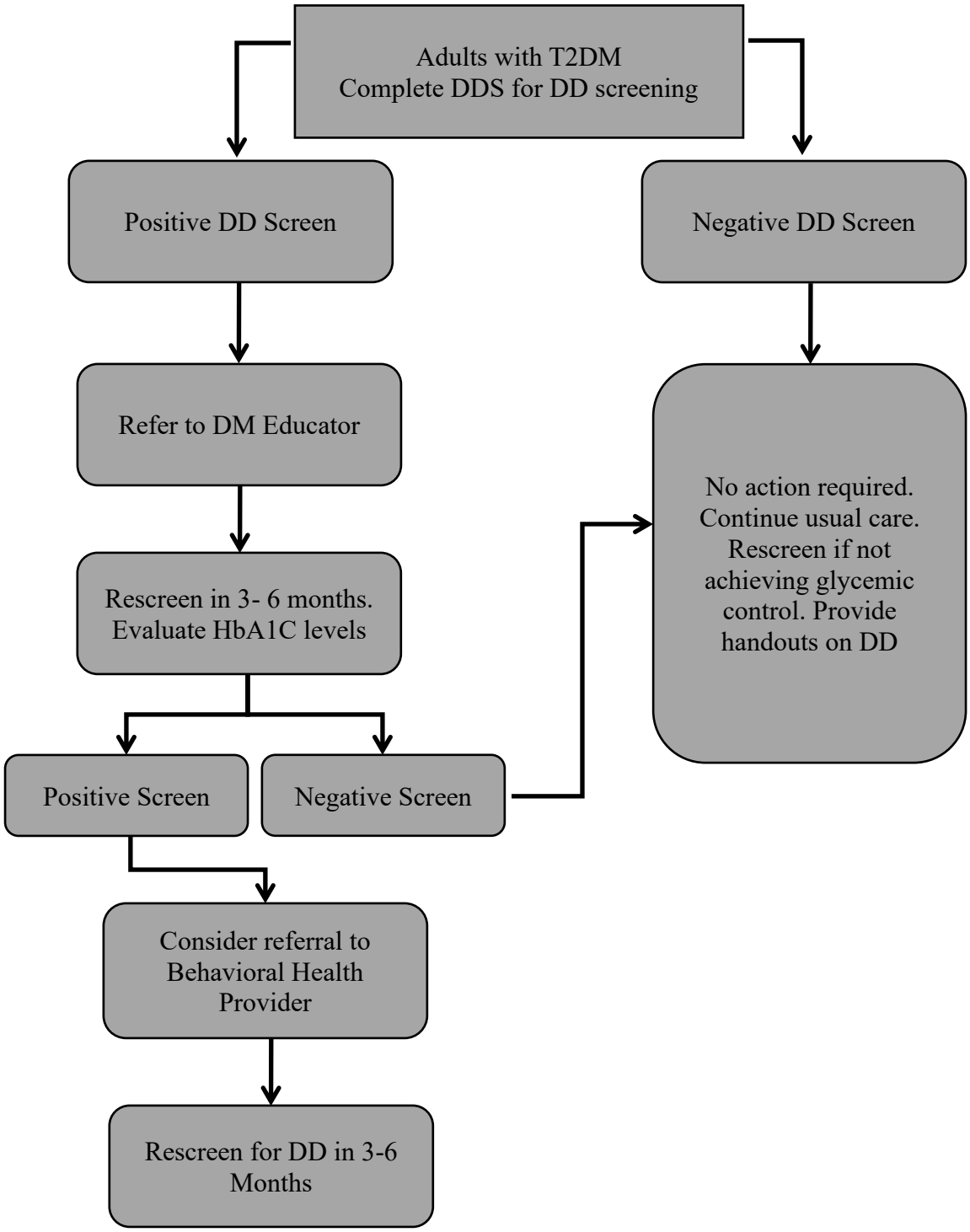
Medical Director

Email: ftiu@azacp.com

1702 W. Anklam Road, Suite 110 | Tucson, AZ 85745 | Phone 520.792.8300 | Fax 520.792.8303

Appendix C

Diabetes Distress Screening Protocol



Note: DD handouts will be given during screening. If refusing referral, document and provide handouts.

Appendix D

DDS English Version

DDS1.1

DDS

DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
3. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
7. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
8. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

DDS1.1

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10. Feeling that diabetes controls my life.	1	2	3	4	5	6
11. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

DDS1.1

DDS1.1 SCORING SHEET

INSTRUCTIONS FOR SCORING:

The DDS17 yields a total diabetes distress score plus 4 subscale scores, each addressing a different kind of distress.[1] To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale.

Current research[2] suggests that a mean item score 2.0 – 2.9 should be considered 'moderate distress,' and a mean item score ≥ 3.0 should be considered 'high distress.' Current research also indicates that associations between DDS scores and behavioral management and biological variables (e.g., A1C) occur with DDS scores of ≥ 2.0. Clinicians may consider moderate or high distress worthy of clinical attention, depending on the clinical context.

We also suggest reviewing the patient's responses across all items, regardless of mean item scores. It may be helpful to inquire further or to begin a conversation about any single item scored ≥ 3.

Total DDS Score:	a. Sum of 17 item scores.	_____
	b. Divide by:	17
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
A. Emotional Burden:	a. Sum of 5 items (1, 4, 7, 10, 14)	_____
	b. Divide by:	5
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
B. Physician Distress:	a. Sum of 4 items (2, 5, 11, 15)	_____
	b. Divide by:	4
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
C. Regimen Distress:	a. Sum of 5 items (6, 8, 3, 12, 16)	_____
	b. Divide by:	5
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
D. Interpersonal Distress:	a. Sum of 3 items (9, 13, 17)	_____
	b. Divide by:	3
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score ≥ 2)	yes__ no__

1. Polonsky, W.H., Fisher, L., Esarles, J., Dudl, R.J., Lees, J., Mullan, J.T., Jackson, R. (2005). Assessing psychosocial distress in diabetes: Development of the Diabetes Distress Scale. Diabetes Care, 28, 626-631.

2. Fisher, L., Hessler, D.M., Polonsky, W.H., Mullan, J. (2012). When is diabetes distress clinically meaningful? Establishing cut-points for the Diabetes Distress Scale. Diabetes Care. 35. 259-264.

DDS Spanish Version

DDS1.1

DDS

INSTRUCCIONES: Vivir con diabetes a veces es difícil. Habrá numerosos problemas referentes a la diabetes que puedan variar en severidad. Estos problemas pueden variar de grado, algunos pueden ser mas graves que otros. Enumerados abajo, hay 17 posibles problemas que las personas con diabetes puedan enfrentar. Considere hasta que grado le han afligido cada una de las siguientes situaciones DURANTE EL ULTIMO MES, y por favor haga un círculo alrededor del número apropiado.

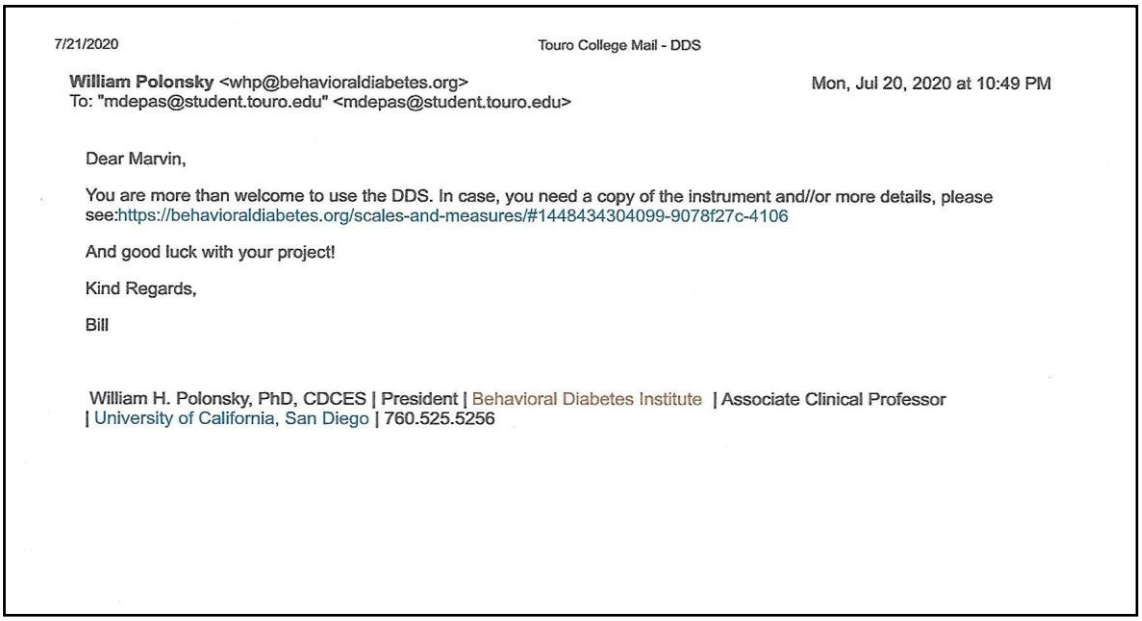
Por favor, manténgase al tanto que le estamos pidiendo que indique el grado de severidad en el cual, uno de estos elementos le complica la vida, NO simplemente si se aplica a usted. Si determina que algún elemento en particular, no es una molestia ni problema para usted, circularía el "1". Si es severamente molesto, circularía el "6".

	No es un Problema	**Es un Pequeño Problema**	**Es un Problema Moderad**	**Es un Problema Algo grave**	**Es un Problema Grave**	**Es un Problema Muy Grave**
1. Sentirme agotado mental y físicamente por el esfuerzo constante para controlar la diabetes.	1	2	3	4	5	6
2. Sentir que mi doctor no sabe lo suficiente acerca de la diabetes y del cuidado de la diabetes.	1	2	3	4	5	6
3. No sentir confianza en mi habilidad para manejar mi diabetes día a día.	1	2	3	4	5	6
4. Sentirme enojado(a), asustado(a), o deprimido(a) cuando pienso en el vivir con diabetes.	1	2	3	4	5	6
5. Sentir que mi doctor no me dá recomendaciones lo suficientemente específicas para controlar mi diabetes.	1	2	3	4	5	6
6. Sentir que no me estoy analizando la sangre con suficiente frecuencia.	1	2	3	4	5	6
7. Sentir que haga lo que haga, siempre tendré complicaciones serias a largo plazo	1	2	3	4	5	6
8. Sentir que fracaso a menudo con mi régimen de diabetes.	1	2	3	4	5	6

DDS1.1

	No es un Problema	Es un Pequeño Problema	Es un Problema Moderad	Es un Problema Algo grave	Es un Problema Grave	Es un Problema Muy Grave
9. Sentir que ni mis amigos ni mi familia me dan suficiente apoyo en mis esfuerzos para cuidarme (planean actividades que chocan con mi horario, me animan a comer comidas "impropias."	1	2	3	4	5	6
10. Sentir que la diabetes controla mi vida.	1	2	3	4	5	6
11. Sentir que mi doctor no toma en serio mis preocupaciones.	1	2	3	4	5	6
12. Sentir que no estoy manteniendo un régimen dietético saludable.	1	2	3	4	5	6
13. Sentir que ni mis amigos ni mi familia saben lo difícil que es vivir con la diabetes.	1	2	3	4	5	6
14. Sentirse abrumado(a) por la atención que requiere vivir con la diabetes.	1	2	3	4	5	6
15. Sentir que no tengo un doctor a quién puedo ver con la frecuencia suficiente para discutir mi diabetes.	1	2	3	4	5	6
16. Sentir que no tengo la motivación necesaria para controlar mi diabetes.	1	2	3	4	5	6
17. Sentir que ni mis amigos ni mi familia me dan el apoyo emocional que me gustaría tener	1	2	3	4	5	6

Permission Email



7/21/2020 Touro College Mail - DDS

William Polonsky <whp@behavioraldiabetes.org> Mon, Jul 20, 2020 at 10:49 PM
To: "mdepas@student.touro.edu" <mdepas@student.touro.edu>

Dear Marvin,

You are more than welcome to use the DDS. In case, you need a copy of the instrument and//or more details, please see:https://behavioraldiabetes.org/scales-and-measures/#1448434304099-9078f27c-4106

And good luck with your project!

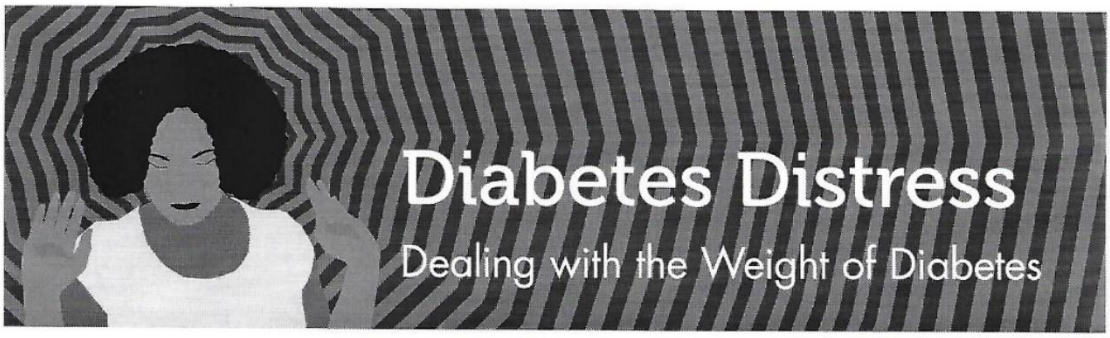
Kind Regards,

Bill

William H. Polonsky, PhD, CDCES | President | Behavioral Diabetes Institute | Associate Clinical Professor | University of California, San Diego | 760.525.5256

Appendix E

DD Handout English Version



The unpredictability in blood sugar, daily schedules, and life can make this disease frustrating. Whenever our actions have unpredictable outcomes, we can become distressed. In this case it is specific to diabetes, so it is referred to as diabetes distress.

Having diabetes is like someone handing you four balls and telling you to juggle perfectly. Then it's telling you that once you acquire that skill you will now juggle every day for the rest of your life and that there are variables that are going to influence your ability to juggle, you just don't know what and when. If you stop doing this, you will get sick and the people who care about you will become upset and tell you to start juggling again.

Those who have diabetes know this scenario far too well. You have been given a disease to manage that requires daily attention to aspects of life that never seemed controllable even before the diagnosis. In addition to these behaviors, you are often expected to look at numbers as a judgement of your success, and go to frequent healthcare appointments that evaluate you and your skill in dealing with this juggling act. Oh, by the way your family and friends get in on the act, because they know you have diabetes and you not only feel judged by them, you feel judged by yourself.

This wouldn't be such a big deal if you could get it right, but the unpredictability in blood sugar, daily schedules, and life can make this disease frustrating. The emotional ups and downs add to the daily burden.

How does this diabetes distress impact me and the disease?

Whenever our actions have unpredictable outcomes, we can become distressed. In this case it is specific to diabetes, so it is referred to as diabetes distress. We develop tension, fatigue, a sense of being overwhelmed and experience "burnout." This burnout sometimes pushes us to quit or at least not pay close attention to the things that are causing this distress. You may think "I just won't check my blood sugar, or I'll skip that medication since it doesn't seem to do much anyway." The unfortunate result is diabetes goes unmanaged, leaving you with a high A1C, not feeling well and possibly developing complications.

AADE American Association of Diabetes Educators

Friends, family and co-workers are all likely to be concerned about you and may seem to be monitoring your activities. You have the right to ask people to give you space if they are too close, but keep in mind they are usually doing this because they care, so express appreciation for their attention, then offer them ideas for how you would like them to be involved and how you don't want them involved. It's clear you are the one with diabetes, but you also have the responsibility to help those who love you be involved in appropriate ways.

What can I do if I think I have this distress?

First find out. If you think this is happening to you, don't be surprised as it happens to many people who live with diabetes.

- Talk with your diabetes educator, they can ask relevant questions.
- Get an assessment. There are simple tests that can help such as a diabetes distress questionnaire.
- The results from the test will help you identify what area in diabetes is most distressing.
- Based on those results you can develop a plan.

Diabetes doesn't go away, so what can I do to ease my distress?

- Find someone who understands your feelings surrounding living with diabetes and talk to them.
- Talk with another person who has diabetes, a diabetes support group offered by your local hospital or your diabetes educator, family member, or a mental health professional. Someone who knows diabetes will ease the burden and you won't feel so alone.
- If you feel judged by others express your concerns and find a way to ask for their help rather than their judgments.
- The medical system can sometimes make you feel that if your health is not improving, then it is something you are doing wrong. You need their support, which is different than their judgment. Tell your healthcare team and family if and how supportive they are, because they often feel helpless as family members often do not know what to say or do to help their loved ones manage diabetes.
- If you are worn out by the daily tasks and the feeling of failure, give yourself a reasonable break from the routine.
- Realize almost no one gets diabetes right. Doing diabetes tasks well will not assure you of getting the numbers you want. Striving for perfection is extremely difficult. Take some time off. Plan it, make it safe, and perhaps ask someone to help you. Do this intentionally, not out of anger.
- If you feel bothered by others or have the sense they are monitoring your behavior, ask them to stop.

Diabetes is not easy. When you feel burned out, you may not want more responsibility, but this is probably the time you most need to ask for help and let others join in the way that works best for you.

Diabetes Distress Questionnaire: www.behavioraldiabetes.org/scales-and-measures

DD Handout Spanish Version

El carácter imprevisible del nivel de azúcar en sangre, los horarios de todos los días y la vida pueden hacer que esta enfermedad sea frustrante. Siempre que nuestras acciones tengan un resultado impredecible, podemos angustiarnos. En este caso es específico a la diabetes, de modo que se denomina angustia por diabetes.

Tener diabetes es como si alguien le entregara 4 bolas y le dijera que haga malabarismos a la perfección. Luego es como decirle que una vez que adquiera esa habilidad, ahora hará malabarismos todos los días por el resto de su vida y que hay variables que influirán en su habilidad para hacer malabarismos, solo que no se sabe cuáles ni cuándo. Si deja de hacerlo, se enfermará y las personas que se preocupan por usted se enfadarán y le dirán que comience a hacer malabarismos nuevamente.

Aquellos que tienen diabetes conocen demasiado bien esta situación. A usted se le ha entregado una enfermedad para manejar que requiere prestarle atención diaria a aspectos de la vida que nunca parecieron ser controlables, incluso antes del diagnóstico. Además de estos comportamientos, generalmente se espera que mire las cifras como valoración de su éxito y que vaya a frecuentes citas de atención médica donde lo evalúan a usted y a su habilidad para manejar este acto de malabarismo. Oh, por cierto, su familia y amigos participan en el acto, porque saben que tiene diabetes y usted no solo se siente juzgado por ellos sino que se siente juzgado por usted mismo.

Esto no sería para tanto si usted lo pudiera hacer bien, pero el carácter imprevisible del nivel de azúcar en sangre, los horarios de todos los días y la vida pueden hacer que esta enfermedad sea frustrante. Los altibajos emocionales aumentan la carga diaria.

¿Cómo repercute en mí y en la enfermedad esta angustia causada por la diabetes?

Siempre que nuestras acciones tengan un resultado impredecible, podemos angustiarnos. En este caso es específico a la diabetes, de modo que se denomina angustia por diabetes. Desarrollamos tensión, fatiga, una sensación de estar abrumado y experimentamos un "desgaste". Este desgaste a veces nos empuja a rendirnos o al menos a no prestar especial atención a las cosas que nos están causando estrés. Puede pensar: "Simplemente no controlaré mi nivel de azúcar en sangre, o saltearé ese medicamento ya que no parece hacer mucho de todos modos". El resultado desafortunado es que la diabetes deja de controlarse, dejándolo a usted con un alto de A1C, no sintiéndose bien y posiblemente desarrollando complicaciones.

Es probable que sus amigos, familia y compañeros de trabajo se preocupen por usted y parezcan estar controlando sus actividades. Tiene derecho a pedirles a las personas que le den espacio si se acercan demasiado, pero tenga en cuenta que generalmente lo hacen porque les importa, de modo que manifieste su agradecimiento por su atención, luego proporcióneles ideas sobre cómo le gustaría a usted que se involucraran y cómo no le gustaría que se involucraran. Es claro que usted es quién tiene diabetes, pero también tiene la responsabilidad de ayudar a quienes lo aman a participar de forma adecuada.

¿Qué puedo hacer si pienso que tengo esta angustia?

Primero averígüelo. Si piensa que le está sucediendo esto, no se sorprenda pues le pasa a muchas personas que viven con diabetes.

- Hable con su educador en diabetes, ellos pueden hacer preguntas relevantes.
- Hágase una evaluación. Hay pruebas simples que lo pueden ayudar, como un cuestionario de angustia por diabetes.
- Los resultados de la prueba lo ayudarán a identificar qué área de la diabetes le causa mayor angustia.
- Puede desarrollar un plan basándose en esos resultados.

La diabetes no desaparece, entonces, ¿qué puedo hacer para aliviar mi angustia?

- Encuentre a alguien que comprenda sus sentimientos acerca de vivir con diabetes y hable con esa persona.
- Hable con otra persona que tenga diabetes, un grupo de apoyo para diabéticos ofrecido por su hospital local o su educador en diabetes, familiar o profesional de salud mental. Alguien que sepa sobre diabetes alivianará la carga y no se sentirá solo.
- Si se siente juzgado por los demás, exprese su preocupación y encuentre la manera de pedir su ayuda en lugar de sus opiniones.
- El sistema médico a veces puede hacerlo sentir que si su salud no está mejorando, entonces hay algo que está haciendo mal. Usted necesita de su apoyo, lo cual es diferente a necesitar de su opinión. Dígales a su equipo de atención médica y a su familia qué tanto apoyo le brindan y si se lo brindan, porque a menudo se sienten inútiles ya que habitualmente los familiares no saben qué decir o qué hacer para ayudar a sus seres queridos a manejar la diabetes.
- Si está agotado por las tareas diarias y por el sentimiento de fracaso, dese un descanso razonable de la rutina.
- Dese cuenta que casi nadie lo hace bien. Hacer bien las tareas de los diabéticos no le asegurará que obtendrá las cifras que quiere. Buscar la perfección es extremadamente difícil. Tómese un tiempo de descanso. Planifíquelo, haga que sea seguro y quizás pídale ayuda a alguien. Hágalo intencionalmente, no por enojo.
- Si siente que otros lo molestan o tiene la sensación de que están controlando su comportamiento, pídales que se detengan.

La diabetes no es fácil. Cuando se sienta agotado, tal vez no quiera tener más responsabilidad, pero este es probablemente el momento en que más necesita pedir ayuda y dejar que otros participen de la forma que mejor funcione para usted.

Cuestionario de angustia por diabetes: www.behavioraldiabetes.org/scales-and-measures

Permission Letter

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Handout to be distributed among T2DM patients while implementing the Doctor of Nursing Quality Improvement Project "Diabetes Distress screening among T2DM in Primary Care"

Project, Program or Publication

Type of project, program or publication: DNP Student Quality Improvement Project

Projected date(s) of project, program or publication: November 4, 2020 - December 2, 2020

Estimated number of copies to be printed or produced: 50 English version; 50 Spanish version

Number of times the product will be printed or material used within 1 year: 1 (one)

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Signature: eSigned Margaret Maloney : Date: 28 August 2020

Telephone: Email:

Please complete and return this form to Margaret Maloney

Appendix F

Pre and Post Knowledge Questionnaire on Diabetes Distress

1. **What is diabetes distress (DD)? (Choose one)**

   a. Persistent depressed mood and pervasive loss of interest or pleasure in living
   b. A form of depression
   c. A psychiatric condition that presents with somatic symptoms such as irritability, restlessness or muscle tension
   d. An emotional state that results from diabetes-related worry, anger, anxiety and being overwhelmed related to the demands of living with the disease

2. **A screening tool to assess for Diabetes Distress (DD) (Choose one)**

   a. PHQ-9
   b. GAD-7
   c. DDS
   d. BSTAD

3. **Diabetes Distress (DD) elicits emotional responses from diabetic patients which can include (Choose one)**

   a. Feeling that life is being controlled by diabetes
   b. Feeling of lack of support from support system/health provider
   c. Fear of having diabetic complications
   d. All of the above

4. **When should patients with DM type 2 be screened for Diabetes Distress? (Choose one)**

   a. Before the diagnosis of diabetes
   b. When glycemic control is not met
   c. During sick visits
   d. During annual wellness examination

5. **Once DD is identified, it can be reduced or eliminated with appropriate intervention which include? (Choose one)**

   a. Refer to DSME (Diabetes Self-Management Education and Support)
   b. Prescribe antidepressants
   c. Refer to endocrinologist for further management
   d. Intensify DM medications to improve HgbA1C levels

6. **A 45-year-old male patient with Type 2 DM was given the DDS screening tool during his office visit. The provider checked the tool and the patient's total score in the scale was 1.29. What would be the next appropriate action? (Choose one)**

   a. Provide DD handout, no further action required. Patient has no DD.
   b. Patient has DD and initiate conversation regarding DD
   c. Document in the chart that patient has DD
   d. Refer patient to diabetes educator

7. **A 65-year-old female patient with Type 2 DM was given the DDS screening tool during her follow up office visit. The provider checked the tool and the patient's total score in the scale was 2.41. The following are appropriate actions except? (Choose one)**

   a. Provide handout regarding DD
   b. No action required, the patient has no DD.
   c. Patient has DD and initiate conversations regarding DD
   d. Document in the chart that patient has DD

8. **You are reviewing Mrs. Smith's recent laboratory results. Her HgbA1C is 8.5%. Previous labs showed that her DM is well-controlled. Which of the following would be the most appropriate plan of care in her next follow up visit? (Choose one)**

   a. Refer to ophthalmologist to assess for retinopathy
   b. Assess for DD
   c. Refer her to behavioral health for cognitive behavioral therapy
   d. Repeat HbA1C in a year

9. **Mrs. Smith answered the DDS during her follow up visit. She scored high in the interpersonal distress subscale. Which statement made by Mrs. Smith supports this finding? (Choose one)**

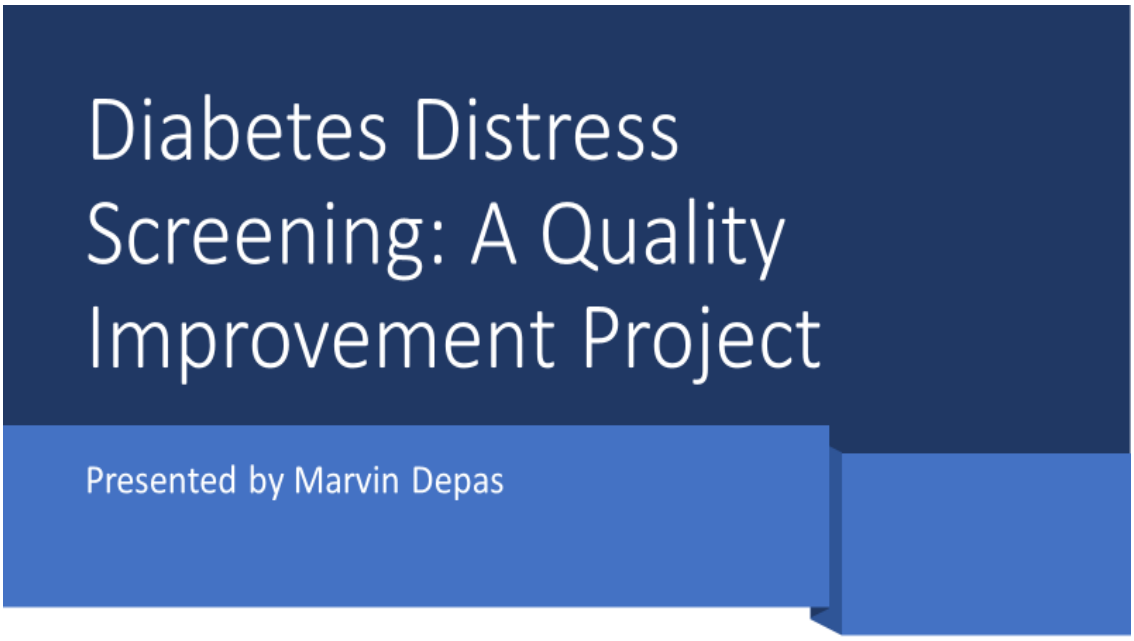
   a. "I feel that diabetes is taking up too much of my mental and physical energy."
   b. "I feel that my family does not give me support that I need."
   c. "I feel that my doctor does not give me clear directions on how to manage my diabetes."
   d. "I feel that I am often failing with my diabetes routine."

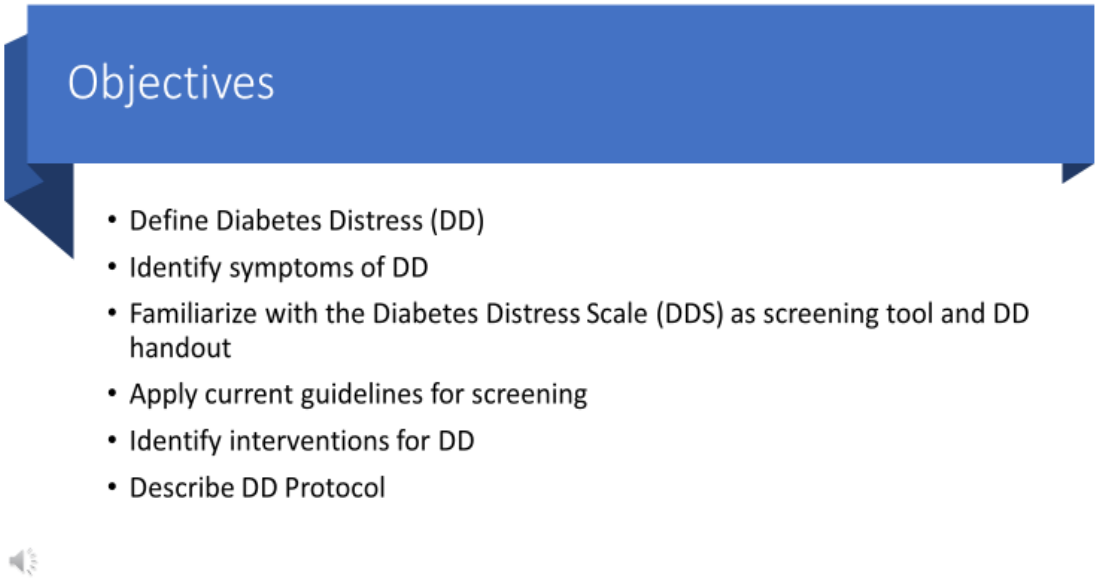
10. **Psychosocial problems such as DD can impair patient's ability to manage their DM and affect their HbA1C levels.**

    a. True b. False

Appendix G

DD PowerPoint Presentation





What is Diabetes Distress?

- American Diabetes Association definition

  "significant negative psychological reactions related to emotional burdens and worries specific to an individual's experience in having to manage a severe, complicated, and demanding chronic disease such as diabetes".

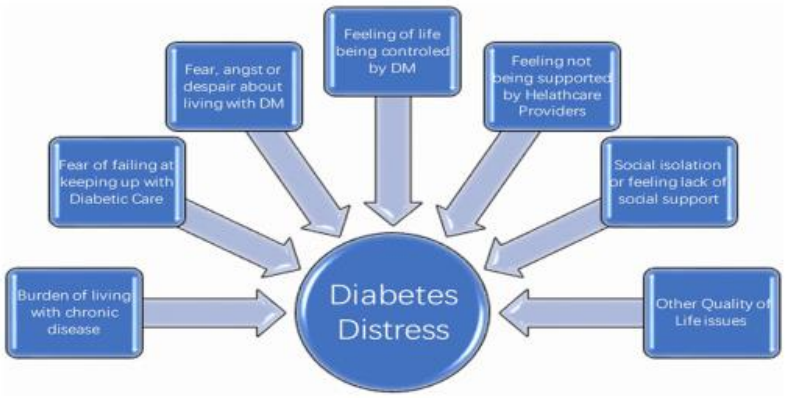
(American Diabetes Association, 2020)

Diabetes Distress

- Emotional state that results from diabetes-related worry, anger, anxiety, and being overwhelmed with demands of diabetes
- Medication dosing, frequency, titration, blood glucose monitoring, dietary adherence, and physical activity
- Fear, defeat, denial, loneliness, low motivation and frustration

(ADA, 2020)
(Rariden, 2019)

Diabetes Distress



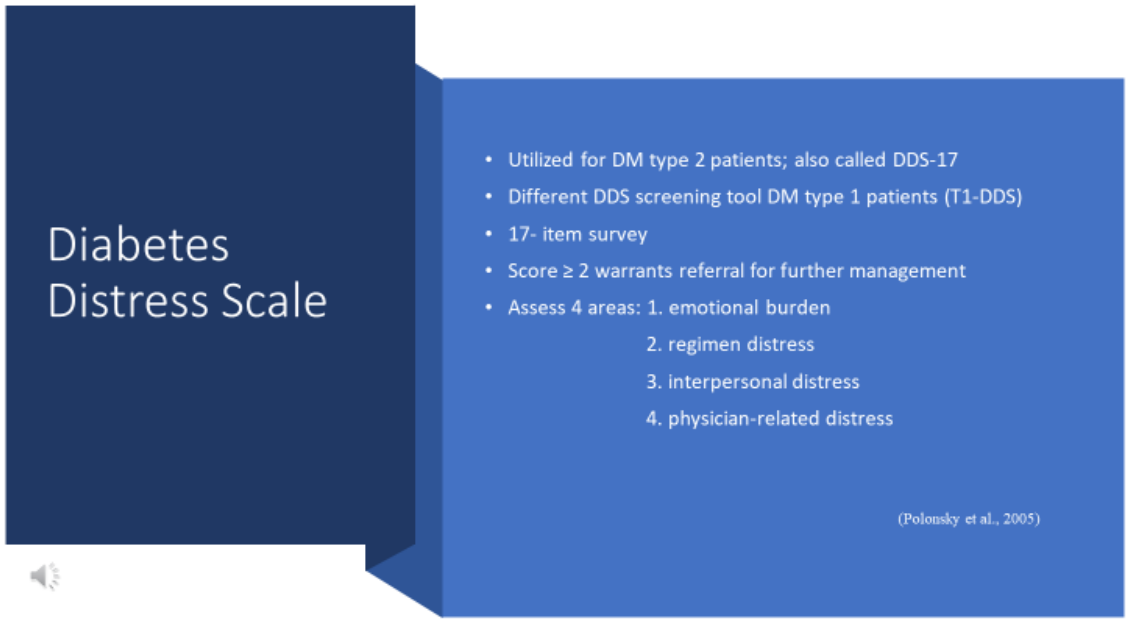
(Tareen & Tareen, 2017)

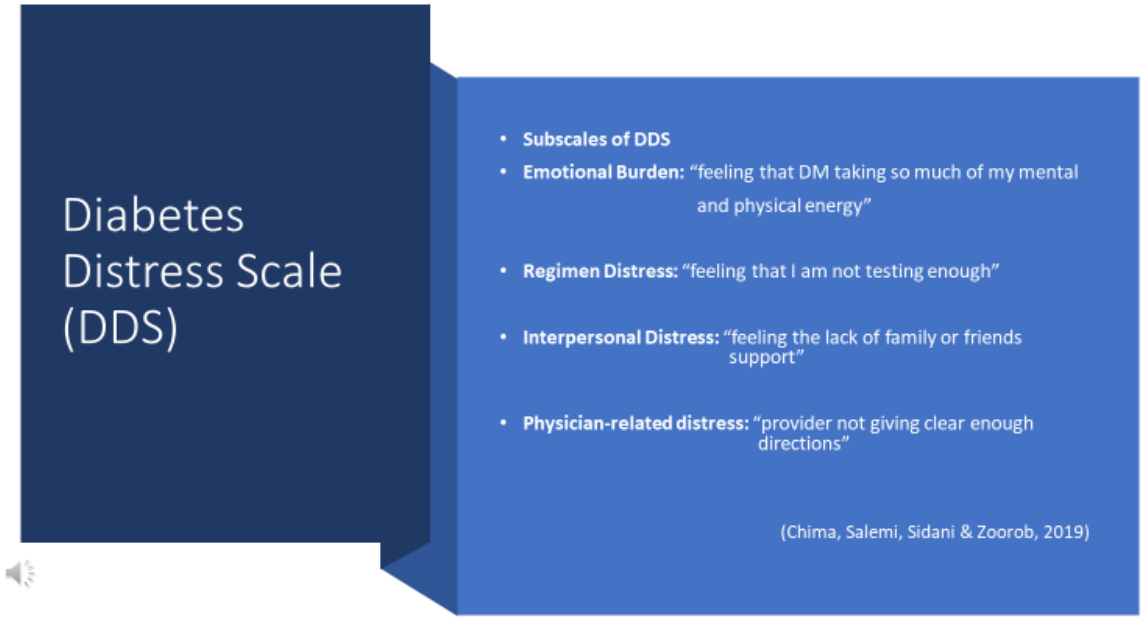
Diabetes Distress

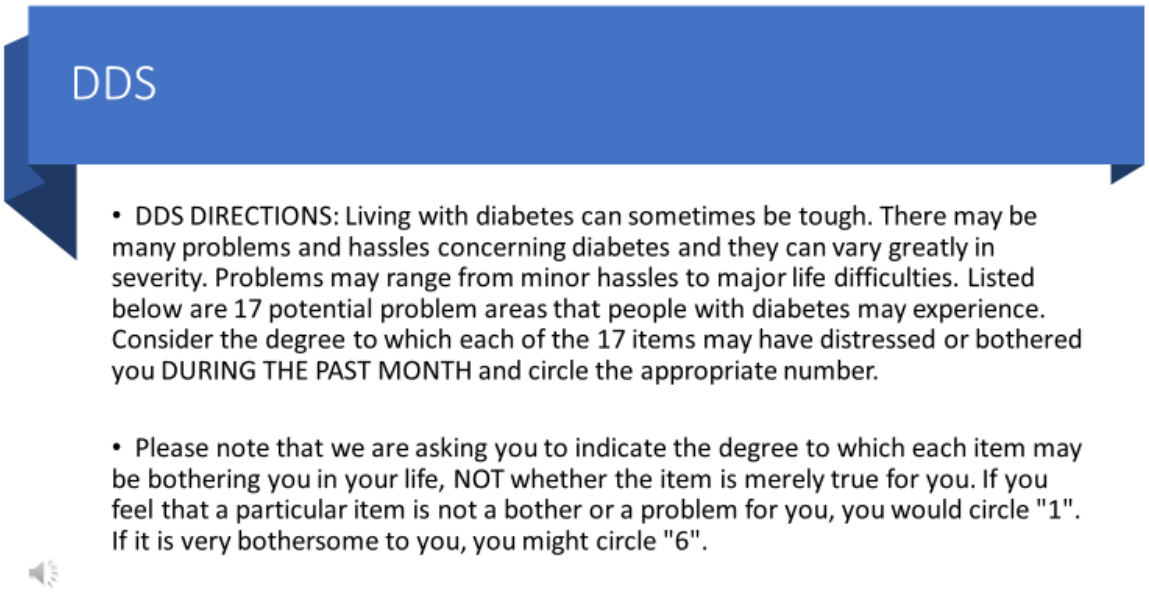
- Incidence of 36-44%
- Negatively impact the management of DM
- Impede the ability to manage DM
- Non-adherence to medications, diet and exercise
- Poor glycemic control (elevated HbA1C levels)

(Martinez et al., 2018)
(Perrin et al., 2005)
(Ramkisson et al., 2016)


Screening tools
• Depression- Patient Health Questionnaire-9 (PHQ-9)
• Anxiety- Generalized Anxiety Disorder 7-item (GAD-7)
• Diabetes Distress-Diabetes Distress Scale (DDS)
(Rariden, 2019)


Diabetes Distress Scale
• Utilized for DM type 2 patients; also called DDS-17
• Different DDS screening tool DM type 1 patients (T1-DDS)
• 17- item survey
• Score ≥ 2 warrants referral for further management
• Assess 4 areas: 1. emotional burden
2. regimen distress
3. interpersonal distress
4. physician-related distress
(Polonsky et al., 2005)


Diabetes Distress Scale (DDS)
Subscales of DDS
Emotional Burden: "feeling that DM taking so much of my mental and physical energy"
Regimen Distress: "feeling that I am not testing enough"
Interpersonal Distress: "feeling the lack of family or friends support"
Physician-related distress: "provider not giving clear enough directions"
(Chima, Salemi, Sidani & Zoorob, 2019)


DDS
• DDS DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.
• Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
3. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
7. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
8. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10. Feeling that diabetes controls my life.	1	2	3	4	5	6
11. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like	1	2	3	4	5	6

DDS1.1

DDS1.1 SCORING SHEET

INSTRUCTIONS FOR SCORING:

The DDS17 yields a total diabetes distress score plus 4 subscale scores, each addressing a different kind of distress.[1] To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale.

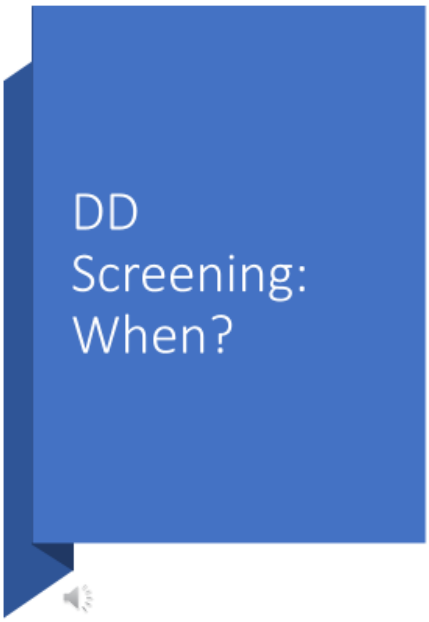
Current research[2] suggests that a mean item score 2.0 – 2.9 should be considered 'moderate distress,' and a mean item score ≥ 3.0 should be considered 'high distress.' Current research also indicates that associations between DDS scores and behavioral management and biological variables (e.g., A1C) occur with DDS scores of ≥ 2.0. Clinicians may consider moderate or high distress worthy of clinical attention, depending on the clinical context.

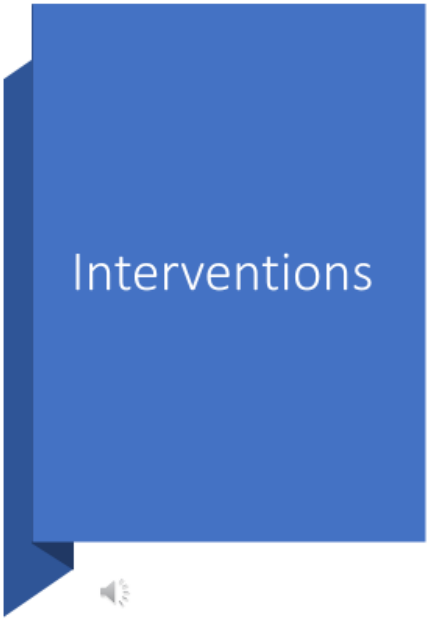
We also suggest reviewing the patient's responses across all items, regardless of mean item scores. It may be helpful to inquire further or to begin a conversation about any single item scored ≥ 3.

Total DDS Score:	a. Sum of 17 item scores.	_____
	b. Divide by:	17
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
A. Emotional Burden:	a. Sum of 5 items (1, 4, 7, 10, 14)	_____
	b. Divide by:	5
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
B. Physician Distress:	a. Sum of 4 items (2, 5, 11, 15)	_____
	b. Divide by:	4
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
C. Regimen Distress:	a. Sum of 5 items (6, 8, 3, 12, 16)	_____
	b. Divide by:	5
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score > 2)	yes__ no__
D. Interpersonal Distress:	a. Sum of 3 items (9, 13, 17)	_____
	b. Divide by:	3
	c. Mean item score:	_____
	Moderate distress or greater? (mean item score ≥ 2)	yes__ no__

1. Polonsky, W.H., Fisher, L., Esarles, J., Dudl, R.J., Lees, J., Mullan, J.T., Jackson, R. (2005). Assessing psychosocial distress in diabetes: Development of the Diabetes Distress Scale. Diabetes Care, 28, 626-631.

2. Fisher, L., Hessler, D.M., Polonsky, W.H., Mullan, J. (2012). When is diabetes distress clinically meaningful? Establishing cut-points for the Diabetes Distress Scale. Diabetes Care, 35, 259-264.

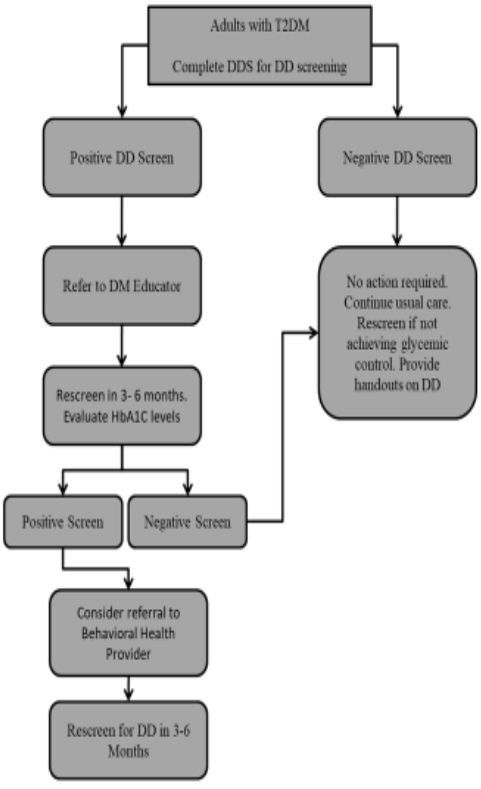

DD Screening: When?
• When treatment targets are not met and/or
• At the onset of diabetes complications
(ADA, 2020)


Interventions
• Diabetes Self-Management Education and Support (DSMES)
• Referral to Diabetes Educators
• Referral to behavioral health provider if self-care remains impaired
(ADA, 2020)

Diabetes Distress

- Emotional well-being is an important part of diabetes care and self-management
- Psychosocial and social problems can impair the individual's or family's ability to carry out diabetes care and therefore potentially can compromise health status

(ADA, 2020)



Note: DD handouts will be given during screening. If refusing referral, document and provide handouts.

Diabetes Distress

Dealing with the Weight of Diabetes

The unpredictability in blood sugar, daily schedules, and life can make this disease frustrating. Whenever our actions have unpredictable outcomes, we can become distressed. In this case it is specific to diabetes, so it is referred to as diabetes distress.

Having diabetes is like someone handing you four balls and telling you to juggle perfectly. Then it's telling you that once you acquire that skill you will now juggle every day for the rest of your life and that there are variables that are going to influence your ability to juggle, you just don't know what and when. If you stop doing this, you will get sick and the people who care about you will become upset and tell you to start juggling again.

Those who have diabetes know this scenario far too well. You have been given a disease to manage that requires daily attention to aspects of life that never seemed controllable even before the diagnosis. In addition to these behaviors, you are often expected to look at numbers as a judgement of your success, and go to frequent healthcare appointments that evaluate you and your skill in dealing with this juggling act. Oh, by the way your family and friends get in on the act, because they know you have diabetes and you not only feel judged by them, you feel judged by yourself.

This wouldn't be such a big deal if you could get it right, but the unpredictability in blood sugar, daily schedules, and life can make this disease frustrating. The emotional ups and downs add to the daily burden.

How does this diabetes distress impact me and the disease?

Whenever our actions have unpredictable outcomes, we can become distressed. In this case it is specific to diabetes, so it is referred to as diabetes distress. We develop tension, fatigue, a sense of being overwhelmed and experience "burnout." This burnout sometimes pushes us to quit or at least not pay close attention to the things that are causing this distress. You may think "I just won't check my blood sugar, or I'll skip that medication since it doesn't seem to do much anyway." The unfortunate result is diabetes goes unmanaged, leaving you with a high A1C, not feeling well and possibly developing complications.

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Friends, family and co-workers are all likely to be concerned about you and may seem to be monitoring your activities. You have the right to ask people to give you space if they are too close, but keep in mind they are usually doing this because they care, so express appreciation for their attention, then offer them ideas for how you would like them to be involved and how you don't want them involved. It's clear you are the one with diabetes, but you also have the responsibility to help those who love you be involved in appropriate ways.

What can I do if I think I have this distress?

First find out. If you think this is happening to you, don't be surprised as it happens to many people who live with diabetes.

- Talk with your diabetes educator, they can ask relevant questions.
- Get an assessment. There are simple tests that can help such as a diabetes distress questionnaire.
- The results from the test will help you identify what area in diabetes is most distressing.
- Based on those results you can develop a plan.

Diabetes doesn't go away, so what can I do to ease my distress?

- Find someone who understands your feelings surrounding living with diabetes and talk to them.
- Talk with another person who has diabetes, a diabetes support group offered by your local hospital or your diabetes educator, family member, or a mental health professional. Someone who knows diabetes will ease the burden and you won't feel so alone.
- If you feel judged by others express your concerns and find a way to ask for their help rather than their judgments.
- The medical system can sometimes make you feel that if your health is not improving, then it is something you are doing wrong. You need their support, which is different than their judgment. Tell your healthcare team and family if and how supportive they are, because they often feel helpless as family members often do not know what to say or do to help their loved ones manage diabetes.
- If you are worn out by the daily tasks and the feeling of failure, give yourself a reasonable break from the routine.
- Realize almost no one gets diabetes right. Doing diabetes tasks well will not assure you of getting the numbers you want. Striving for perfection is extremely difficult. Take some time off. Plan it, make it safe, and perhaps ask someone to help you. Do this intentionally, not out of anger.
- If you feel bothered by others or have the sense they are monitoring your behavior, ask them to stop.

Diabetes is not easy. When you feel burned out, you may not want more responsibility, but this is probably the time you most need to ask for help and let others join in the way that works best for you.

Diabetes Distress Questionnaire: www.behavioraldiabetes.org/scales-and-measures

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Appendix H

DDS Protocol Chart Audit Form

Audit after DD screen	Chart 1	Chart 2	Chart 3	Chart 4	Chart 5	Chart 6	Chart 7	Chart 8	Chart 19	Chart 10
Patient number										
Age										
Gender										
Ethnicity										
Last HbA1C result										
DDS performed during DM visit	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
DD score ≥ 2	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
Referral to DM educator if above yes	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
Provider 1= MD 2= NP										

Appendix I

Content Validity Index Table

Item	Expert 1	Expert 2	Expert 3	Mean
1	4	4	4	4
2	4	4	4	4
3	4	4	4	4
4	4	4	4	4
5	4	4	4	4
6	4	4	4	4
7	4	4	4	4
8	4	4	4	4
9	4	4	4	4
10	4	4	4	4

The procedure consists of having experts rate items on a four-point scale of relevance. Then, for each item, the item (CVI) (I-CVI) is computed as the number of experts giving a rating of 3 or 4, divided by the number of experts-the proportion in agreement about relevance.

The content validity index is calculated using the following formula:

CVR=[(E-(N/2)) / (N/2)] with E representing the number of judges who rated the item as Moderately Relevant or Highly Relevant and N being the total number of judges.

The mean total of all of the means was 4 indicating that all of the questions were highly relevant.

The calculation is as follows:

CVR = [(3-(3/2)) / (3/2)]

CVR = [(3-1.5) / 1.5]

CVR = 1.5 / 1.5

Appendix J

SPSS Statistical Data

Paired Samples Test

		Paired Differences						
					95% Confidence Interval of the Difference			
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	df	Sig. (2-tailed)
	pre-training scores - post-training scores	-3.33333	.81650	.33333	-4.19019	-2.47647	5	.000

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	pre-training scores	6.6667	6	.81650	.33333
	post-training scores	10.0000	6	.00000	.00000

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	pre-training scores & post-training scores	6	.	.

age

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	31-40	3	16.7	16.7	16.7
	41-50	2	11.1	11.1	27.8
	51-60	4	22.2	22.2	50.0
	61-70	5	27.8	27.8	77.8

	71-80	3	16.7	16.7	94.4
	81 and above	1	5.6	5.6	100.0
	Total	18	100.0	100.0	

Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	male	5	27.8	27.8	27.8
	female	13	72.2	72.2	100.0
	Total	18	100.0	100.0	

Ethnicity

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Asian	2	11.1	11.1	11.1
	African American	1	5.6	5.6	16.7
	Caucasian/ white	4	22.2	22.2	38.9
	Hispanic/ Latino	11	61.1	61.1	100.0
	Total	18	100.0	100.0	

DDS Performed in the Clinic

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	18	100.0	100.0	100.0

DDS≥2.0

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	18	100.0	100.0	100.0

Referral

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	18	100.0	100.0	100.0

Descriptive Statistics

	N	Mean	Std. Deviation
HbA1c	18	8.6000	2.16442
DDSS	18	2.8422	.65317
Valid N (listwise)	18		

Correlations

		HbA1c	DDSS
HbA1c	Pearson Correlation	1	.110
	Sig. (2-tailed)		.665
	N	18	18
DDSS	Pearson Correlation	.110	1
	Sig. (2-tailed)	.665	
	N	18	18

VAR00001

	Observed N	Expected N	Residual
6.00	3	2.0	1.0
7.00	2	2.0	.0
8.00	1	2.0	-1.0
Total	6		

Test Statistics

	VAR00001
Chi-Square	1.000[a]
df	2
Asymp. Sig.	.607

a. 3 cells (100.0%) have expected frequencies less than 5. The minimum expected cell frequency is 2.0.

Descriptive Statistics

	N	Mean	Std. Deviation
VAR00001	6	6.6667	.81650
Valid N (listwise)	6		

VAR00002

	Observed N	Expected N	Residual
10.00	6	6.0	.0
Total	6[a]		

a. This variable is constant. Chi-Square Test cannot be performed.

Ranks

	Ethnicity	N	Mean Rank
DDSS	Asian	2	14.75
	African American	1	15.00
	Caucasian/ white	4	3.88
	Hispanic/ Latino	11	10.09
	Total	18	

HbA1C and DDS Scores of DD Patients

Patient Number	**HbA1C Results**	**DD Screening Scores**
11	8.1	3.70
12	8.2	2.64
16	10.2	2.0
17	8.4	2.8
19	8.9	2.5
23	9.6	2.8
25	7.7	4.17
37	10.2	3.1
44	13	2.5
45	7.4	2.23
47	7.6	2.35
52	12.3	4.12
54	11.4	2.4
57	5.4	3.11
61	6.5	3.0
67	7.9	3.25
75	6.3	2.23
80	5.7	2.17