A TELEMEDICINE FOLLOW UP PROGRAM TO IMPROVE GLYCEMIC OUTCOMES FOR PATIENTS WITH UNCONTROLLED TYPE 2 DIABETES

By

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Abstract

Type 2 Diabetes is responsible for a global public health burden and affects an estimated 30 million people in the United States, many of whom have difficulty reaching glycemic targets. Approximately 15 percent of the diabetic patients in the Family Health Clinic have an A1C above 8.0. Telemedicine shows promise in improving glycemic control and enhancing access to care. Current literature supports the use of telemedicine to improve glycemic outcomes. The purpose of this project was to assess the acceptability and effectiveness of a provider implemented intense telephonic follow-up program on glycemic outcomes and self-management of patients with uncontrolled Type 2 Diabetes. This quality improvement project used a pre-test post-test design using laboratory and survey data collection methods to measure hemoglobin A1C, diabetes self-care, and a post-test provider satisfaction survey. Over a 3-month period, patients meeting criteria for the intervention were provided with telephonic provider follow-up visits at 2-3 week intervals including education on lifestyle changes, medication management and self-care. The mean change in A1C was statistically and clinically significant. The mean change in total self-care survey score was also significant. The data indicated that utilization of telemedicine follow-up improved clinical outcomes for Type 2 Diabetics.

Keywords: Telemedicine, diabetes mellitus type 2, A1C, telehealth, self-management

Table of Contents

List of Figures

Page

List of Tables

Page

List of Appendices

Page

Chapter One: Overview of the Problem

The diagnosis of Type 2 Diabetes (T2DM) is life changing and can dramatically impact the quality of life and life expectancy of those afflicted (Franco et al., 2007). Diabetes represents a massive and global public health burden (Lee, Chan, Chua, & Chaiyakunapruk, 2017). Despite the vast amount of money, resources, research, and medications focused on addressing this disease, outcomes often continue to be poor, and many patients never reach their treatment goals (Schmittdiel et al., 2008). Limited access to care, time constraints, and geographic distance often reduce the opportunity for providers to individualize and address all the aspects of diabetes care and management. To address this barrier, the use of telemedicine in clinical practice offers great potential for improving outcomes in patients with Type 2 Diabetes (Gervera & Graves, 2015). Telemedicine visits can be accomplished regardless of geographic constraints and potentially can be scheduled more frequently than in-clinic visits. Many studies that have investigated telemedicine's impact upon diabetic care have shown positive clinical outcomes such as improved glycemic control evidenced by reductions in Hemoglobin A1C (A1C) and improved diabetes self-management behaviors when compared to usual care (Crowley et al., 2016; Faruque et al., 2017; Stone et al., 2010; Trief et al., 2013, Wu et al., 2010).

The purpose of this project was to examine the acceptability and effectiveness of a provider-implemented intensive telemedicine follow-up program to improve glycemic outcomes and self-care in adult patients with poorly controlled Type 2 Diabetes, in addition to usual care. This chapter includes an overview of the problem of Type 2 Diabetes, the clinical significance of the disease, and the specific background and impacts of diabetes: globally, nationally, within Alaska, and particularly within the military treatment facility where this project will be conducted.

Background

Global and national. Diabetes Mellitus impacts public health on a global level. Over 415 million people worldwide have diabetes, and that number will likely double by 2040 if current trends continue (Lee et al., 2017). Global health costs related to diabetes are estimated to reach more than $300 billion by 2025 (Su et al., 2016). The Centers for Disease Control and Prevention (CDC) estimated that more than 30 million people in the United States currently have diabetes (2018). Diabetes also has an impact on the economy beyond healthcare costs. Reduced work productivity in the U.S. due to the effects of diabetes was estimated at $58 billion (Polisena et al., 2009). People with diabetes have a life expectancy that is six to eight years shorter than people who do not (Rasmussen, Lauszus, & Loekke, 2016).

Across the United States within the Veterans Affairs Health System, 30% of all prescriptions written are for diabetic patients, and oral diabetes medications alone result in annual pharmacy costs in excess of $103 million (Gervera & Graves, 2015). Within the U.S. Air Force, over 50,000 beneficiaries treated at Air Force medical facilities have diabetes and the majority are not on active duty (Sauerwein & True, 2016). The Military Health System overall has a 13% prevalence of diabetes (United States Department of Veterans Affairs/United States Army Medical Command Office of Evidence Based Practice [VA/Army], 2017), reflecting similar patterns of diabetes to the U.S. at large.

Alaska. Diabetes is a major public health problem within the state of Alaska. Statistics show that 7.5% of adults in Alaska are diabetic (approximately 90% of those are Type 2), and the prevalence has increased significantly in recent years (Alaska Department of Health and Social Services [AK DHSS], 2019). According to the Alaska Department of Health and Social Services (2019), diabetes (including Type 1 and Type 2) is the eighth leading cause of death within Alaska and resulted in 70,000 hospital visits in 2016. Of particular concern is that only one-third of Alaskan diabetics meet specific quality of care standards, such as being up to date on lab and health screenings (AK DHSS, 2019). Meeting care standards such as having an A1C within individualized goal range, performing recommended screenings, and maintaining self-care measures have all been shown to improve clinical outcomes (CDC, 2018).

673rd medical group. At Joint Base Elmendorf-Richardson (JBER) in Anchorage, Alaska, the 673rd Medical Group provides primary, specialty, and inpatient care to over 35,000 beneficiaries who reside across the state of Alaska. Beneficiaries include active duty military personnel from all branches and their dependent spouses and children, as well as military retirees and their dependent spouses. Patients eligible for care at this military treatment facility may reside in Anchorage and Matanuska-Susitna Borough as well as more distant communities such as Valdez (300 miles), Kodiak (250 mile flight), Seward (170 miles), Homer (220 miles), Glennallen (180 miles) and many small rural communities in between. A number of retirees and dependents split their time between Anchorage and working on the North Slope of Alaska (660 mile flight) where medical care is quite limited, or they live out of state seasonally in the lower 48 states. The Army maintains a separate medical clinic on Fort Richardson for active duty troops but does not provide services for dependents or retirees. There are also military treatment facilities in Fairbanks that serve the Interior of Alaska. At present 1,856 diabetic patients are receiving care at the 673rd Medical Group on Joint Base Elmendorf-Richardson in Anchorage, and of that population approximately 15% have an A1C over 8.0, indicating poor control of this disease (Carepoint, 2019). The vast majority of patients with diabetes are not on active duty. With a population of patients spread throughout the state of Alaska, distance and geography present a major barrier to care for some patients.

Telemedicine. Telemedicine is defined as "the use of telecommunications technology to provide clinical care and promote disease self-management" (Gervera & Graves, 2015, p.1). Telemedicine is a broad term that can involve a variety of technological methods to connect with patients. Telemedicine modalities include the use of telephone visits, video conferencing, internet applications, secure messaging/email, remote monitoring, and various electronic health applications (Gervera & Graves, 2015; VA/Army, 2017).

Telemedicine can be used to increase access to care and improve convenience for patients, especially those needing more frequent follow-up and outcomes monitoring (Gervera & Graves, 2015). Teeter and Kavookijan (2014) discussed the impact of access barriers to diabetes care especially for people living in rural areas where access to in-person visits can be challenging. These access barriers can result in reduced opportunity for disease education and management. In Alaska, the vast geography of the state along with extreme weather conditions certainly contribute to this problem, even within the military beneficiary population which can be spread throughout the state as noted above. Telemedicine can be particularly valuable in patients with uncontrolled diabetes who need a more intense level of care. Crowley et al. (2016) noted that patients with an A1C of greater than 9.0 are at the highest risk of diabetic complications, and their study demonstrated that the telemedicine intervention group had a significant reduction in A1C levels of 1.3%, compared to 0.3% in the usual care group at 3 months, and also demonstrated improved diabetes self-management scores. The United States Department of Veterans Affairs/Department of Defense Clinical Practice Guideline for the Management of Type 2 Diabetes Mellitus in Primary Care [VA/Army] (2017) states that telemedicine modalities can and should be used to enhance clinical outcomes in the management of Type 2 Diabetes. At present this recommendation has not been fully implemented within the Family Health Clinic at the 673rd Medical Group.

Clinical Significance

Approximately 1.4 million new cases of diabetes are diagnosed each year, and of those cases American Indians/Alaska Natives have the highest incidence of diabetes, followed by blacks, Hispanics, and Asians (CDC, 2018). Type 2 Diabetes occurs when the body no longer makes adequate insulin due to beta cell dysfunction in the pancreas, or when it can no longer effectively use insulin to regulate blood glucose levels due to insulin resistance (Kahn, 2003). The vast majority of people with diabetes, approximately 90% of all cases in Alaska, are classified as Type 2 (AK DHSS, 2019). Type 2 Diabetes is often related to lifestyle factors, including obesity (AK DHSS, 2019; CDC, 2018; VA/Army, 2017).

Diabetes contributes to significant morbidity and mortality. People with both Type 1 and Type 2 diabetes are at higher risk of developing high blood pressure, high cholesterol, stroke, chronic kidney disease, heart attack, blindness, and neuropathy which can lead to limb amputations (CDC, 2018; VA/Army, 2017). Type 1 and Type 2 diabetics have a two to four-fold increased risk of cardiovascular disease overall (VA/Army, 2017). Diabetes in general is the seventh leading cause of death in the U.S. (CDC, 2018). Sixty percent of non-traumatic limb amputations are the result of diabetes (Gervera & Graves, 2015).

A 0.5% reduction in A1C is generally considered clinically significant and the gold standard for assessing clinical outcomes according to multiple organizations including the American Diabetes Association and the National Institute for Health and Clinical Excellence (Little et al., 2013). However, even slightly lower reductions in A1C may provide clinical benefit to some patients (Little et al., 2013).

Evidence of telemedicine. It is clear that Type 2 Diabetes has a significant impact on health within populations, healthcare systems, and individuals. As health professionals we are obligated to use the best evidence to improve practice and ensure the best possible outcomes for our patients. A number of systematic reviews, meta-analyses, and randomized controlled trials (RCT's) have provided evidence for the use of telemedicine to improve outcomes in patients with Type 2 Diabetes (Chamany et al., 2015; Faruque et al., 2017; Lee et al., 2017; Polisena et al., 2009; Rasmussen et al., 2015; Stone et al., 2010; Su et al., 2016; Teeter & Kavookijan, 2014; Trief, et al., 2013).

In a systematic review and meta-analysis, Polisena et al (2009) compared clinical outcomes between telehealth and usual care groups; the authors reported there were significant improvements in hemoglobin A1C levels within the telehealth groups. Teeter and Kavookijan (2014) conducted a systematic review which demonstrated more broadly that telephone based motivational interviewing for medication adherence led to improved medication compliance in five of the nine studies that were included. Lee et al. (2017) conducted a systematic review and meta-analysis of over 20,000 patients which demonstrated that telemedicine provided a significant improvement in A1C levels over usual care with a mean difference of -0.43% ($p < .001$). Su et al. (2016) conducted a meta-analysis of 55 RCT's and demonstrated a significant improvement in A1C for patients receiving telemedicine services compared to those not served by telemedicine (Hedges $g = -0.48$, $p < .001$). Trief et al. (2013) conducted a five-year study, titled the Informatics for Diabetes Education and Telemedicine (IDEATel) Demonstration Project, which utilized various elements of telemedicine to improve self-care in minority populations. The study showed the telemedicine group was more adherent to self-care behaviors than the usual care group, based on the Summary of Diabetes Self Care Scale (SDSCA).

Current Clinical Problem

The clinical problem for this project was identified in practice at the Family Health Clinic at the 673rd Medical Group, Joint Base Elmendorf-Richardson, Anchorage, Alaska. The population of this clinic includes Department of Defense Tricare beneficiaries which includes active duty military members, retirees, and their dependents.

Tricare insurance allows members to receive free treatment and medications when patients are seen at a military treatment facility. Tricare beneficiaries who are seen off base have reasonable copays for care. The reduced cost of care limits the financial barriers to care that many Americans experience. Due to the lack of endocrinologists in Alaska, few Type 2 Diabetic patients receive specialist management – currently only two endocrinologists in the region accept Tricare patients. The average empanelment per provider within the Family Health Clinic is 1,250 patients but can rapidly increase when providers deploy. As previously stated, the entire medical group has 1,856 patients enrolled with a diagnosis of diabetes as of June 2019, of which 264 had a most recent A1C of greater than or equal to 8.0 (Carepoint, 2019). The JBER Family Health Clinic manages many of these patients, with smaller numbers seen in the Internal Medicine and Pediatric Clinics. Family Health had an enrollment of 1,146 patients with diabetes (June 2019) with the vast majority having Type 2 Diabetes (Carepoint, 2019). The estimated annual cost of these enrollees for care is approximately $9.9 million dollars, and the estimated pharmacy cost is $2.4 million (Carepoint, 2019).

Despite having access to numerous resources, including free/low cost healthcare visits, free medications, and access to care standards generally enabling patients to schedule a future clinic visit within seven days, many patients still have poor outcomes related to diabetes and did not meet care standards. As noted previously, approximately 15% of the patients (n = 264) have an A1C above 8.0. Military medicine utilizes the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) metrics to track clinical quality of care (Carepoint, 2019; NCQA, 2019). According to this HEDIS data the Family Health Clinic does not consistently meet A1C clinical outcome metrics (Carepoint, 2019).

The VA/DOD Clinical Practice Guidelines (VA/DOD CPG) for the Management of Type 2 Diabetes Mellitus in Primary Care (2017) provide standards for best practices within primary care and recommend "offering one or more types of bidirectional telehealth interventions (health communication via computer, telephone, or other electronic means) involving licensed independent practitioners to patients selected by their primary care provider as an *adjunct* to usual patient care" (p.21). These guidelines also provide recommendations on target ranges for A1C based on patient factors and provider discretion, therapeutic lifestyle changes, and medication management strategies. Despite the evidence-based recommendations within the CPG, telemedicine has not been fully or consistently implemented within the Family Health Clinic as a care strategy for managing diabetes. The CPG also states that support for diabetes self-management education (DSME) should be individualized to the patient and use multiple different methods to reach patients (VA/Army, 2017). DSME practices include "knowledge about diabetes and treatment options, medications, nutrition, exercise, hypoglycemia, monitoring of glucose and HbA1c, psychosocial and behavioral components, risk reduction, foot care, smoking cessation, chronic complications, and sick day management" (VA/Army, 2017, p.21).

An initiative called RESET which stands for "Reward Efficiency, Set Priorities" was started at JBER in late 2017, and involved offering limited telephonic follow-up visits to patients instead of face to face clinic appointments. In general, these visits were used for simple acute conditions or follow-ups where a physical exam was not needed. These virtual visits have generally not been used for more complex issues such as diabetes follow-up, and no specific program exists to guide provider-driven diabetes telemedicine practice. RESET was sidelined with the transition to Defense Health Agency (DHA) management in late 2019.

Anecdotal evidence has shown increased patient satisfaction, reduced wait times/improved access to care, and increased provider comfort levels with the limited telemedicine practices utilized thus far. Ongoing changes to the Military Health System, including transition to management by the Defense Health Agency on October 1, 2019 have increased the need for evidence that telemedicine can provide improved clinical outcomes for patients. The major burden of diabetes and the need for frequent follow-ups for those with poorly controlled disease has created a significant problem which supports the need for this clinical quality improvement project.

Key stakeholders for this project include patients with poorly controlled Type 2 Diabetes, Family Health Clinic providers (physicians, nurse practitioners, and physician assistants), clinic support staff (registered nurses, medical technicians), and the larger medical group including 673rd Medical Group executive leadership. Diabetic management is multidisciplinary, therefore additional stakeholders include clinical pharmacists who assist with complex medication management, Health Manager Registered Nurses who provide diabetes education, and Health Care Integrators who monitor diabetes statistics and care utilization.

Current practice for Type 2 Diabetes management in the Family Health Clinic involves face to face visits and an A1C lab test a minimum of every six months for well controlled diabetics, and every three months for poorly controlled diabetics. Historically, poorly controlled patients have only been seen every three months, with no follow-up or education between clinic visits. Often patients do not follow-up as recommended, and one reason cited is the inconvenience of traveling to the clinic – whether due to work schedule, geographic distance, weather, or wait times. Virtual visits are not systematically used for most diabetic follows ups at this time which is a gap in the current clinical practice recommendations. Health Manager Registered Nurses engage newly-diagnosed patients with diabetes for education at initial diagnosis but only provide limited follow-up with patients who have an A1C over 9.0 at this time, creating a gap for poorly controlled patients with lower A1Cs. Dieticians are also engaged at diagnosis, but do not provide any consistent follow-up care unless patients are referred back by their providers. The Clinical Pharmacist may be engaged by the primary care manager (PCM) when more intense medication management is needed, but they only provide follow up in the clinic every few months and do not perform telemedicine visits. This demonstrates a gap in care that could be bridged through provider directed telemedicine visits.

Question Guiding Inquiry

A PICOT question is a way to systematically describe the components of a clinical question and stands for **P**opulation, **I**ntervention, **C**omparison, **O**utcomes, and **T**ime frame (Stillwell, Fineout-Overholt, Melnyk, & Williamson, 2010). For this clinical problem, the PICOT question was: in adult patients with poorly controlled Type 2 Diabetes receiving care in the Family Health Clinic; will a provider-implemented intense telemedicine follow-up program, in addition to usual care, be acceptable to providers, and improve glycemic outcomes as well as diabetic self-care rating over three months.

Conclusion

Diabetes represents a major public health burden, and having uncontrolled diabetes significantly increases the risk of poor clinical outcomes. There are many potential barriers to achieving optimal glycemic outcomes. Although clinical practice guidelines and evidence-based literature support the use of telemedicine to improve diabetes outcomes, there has been inconsistent utilization of these modalities in the Family Health Clinic. This project seeks to determine the acceptability and effectiveness of a provider-driven intense telemedicine follow-up program on glycemic outcomes and self-care in poorly controlled Type 2 Diabetics.

Chapter Two: Review of the Literature

The foundation of evidence-based practice is performing a comprehensive review of the literature to determine what evidence is available to support clinical practice and implement process improvement initiatives that will lead to the best possible patient outcomes. This project addresses the use of telemedicine to improve glycemic outcomes and self-management in adults with poorly controlled Type 2 Diabetes. A comprehensive literature review was performed to determine what evidence is available to support this practice and to develop the project focus and proposal. This chapter reviews the available evidence describing the use of telemedicine to improve diabetes outcomes. Search strategies used and evaluation of the quantity and quality of evidence for this topic is addressed, as well as synthesis of the body of evidence.

Methodology

A search strategy was developed based on the PICOT question to locate relevant literature within multiple databases. The literature review targeted evidence such as systematic reviews, meta-analyses, and randomized controlled trials relevant to diabetes and telemedicine and glycemic outcomes as measured by hemoglobin A1C as well as self-management. Once the individual articles were selected, each was evaluated based on specific criteria as described below to assess for quality and clinical relevance to the PICOT question.

Strategies. Key databases were searched including PubMed, CINAHL, Cochrane Database, and Google Scholar. Keywords searched included “Diabetes Mellitus Type 2”, “Telemedicine”, “Telehealth”, “Outcomes”, “A1C”, and “Self-Management”. Different combinations of the search terms were utilized, and MeSH terms were selected within PubMed. In CINAHL search terms were exploded to broaden search results. Search terms were combined using AND/OR to narrow results. Within each database limiters were used to limit selections to peer-reviewed articles, English language, adults, and the timeframe was limited to locate the most current evidence. When broader search criteria were initially used, several studies were located that were more than five years old, and those were assessed to see if they contained sentinel information that warranted inclusion and were included if applicable. Additional limiters were used when available in each database to specify Randomized Controlled Trials, Systematic Reviews, and Meta-Analyses. Titles and then abstracts were reviewed for content relevance to the clinical topic. Applicable studies that addressed the topic were further reviewed for inclusion.

In general, the search was focused on locating higher levels of evidence such as Systematic Reviews, Meta-Analyses, and Randomized Controlled Trials (level one and two evidence). Articles selected for review had to be relevant to the use of telemedicine modalities to improve glycemic outcomes (in particular A1C as a measurement of glycemic control) or diabetes self-care management in adult patients with Type 2 Diabetes. Select articles including both Type 1 and Type 2 Diabetes were included because of data relevant to the Type 2 Diabetes population. Articles including gestational diabetes and other less common forms of diabetes were excluded. Articles that exclusively addressed mobile applications (mHealth), remote telemonitoring devices, or internet-based modes of telecommunication were discarded as these technologies were not consistent with the real time telephonic modality of this intervention. The studies included for final review had to assess A1C as a primary measure for glycemic control as the clinical outcome or improved diabetic self-care measures.

PubMed was the first database searched. An initial search was conducted without MeSH terms with the subject keywords “Diabetes Mellitus AND telemedicine” which revealed 1,506 studies. This search was then refined using the limiters of English language, adult 19+, and publication type limited to systematic reviews which led to 20 results with only one being relevant after abstract review. Adding RCT's to the limiters led to 78 articles, of which seven abstracts met criteria. MeSH terms were then used in the search including "diabetes mellitus, type 2", "telemedicine", and "treatment outcomes" to expand the search. Initially a search was conducted utilizing MeSH terms "diabetes mellitus, type 2 AND telemedicine OR telehealth AND outcomes" which resulted in 6,974 citations. These results were immediately narrowed by using the limiters of five years, English language, adults 19+, humans, and adding article type as systematic review, RCT, and meta-analysis which reduced the number of articles to 779. Further narrowing occurred by adding "A1C" to the search string, which reduced the total to 19. No additional articles were found when adding "Self-Management". Abstracts were reviewed for inclusion criteria relating to the PICOT question and a total of seven new articles were located. Duplicates were removed, which left four articles for review. Eleven total articles were retained from the PubMed search.

CINAHL was then searched using the keywords of "diabetes mellitus type 2" which was then exploded, with 26,216 articles found. The keyword "telemedicine OR telehealth" was searched and then exploded, which returned 3,496 articles. When these two terms were combined with AND a total of 103 articles remained. Utilizing the limiters for publication type "systematic reviews and RCT's" the total was narrowed down to 39 studies. Titles and abstracts were reviewed, and studies that did not meet criteria were eliminated. Multiple duplicate studies were found, and once these were eliminated four new studies were found that met the criteria for inclusion resulting in a total of 15 studies retained from PubMed and CINAHL.

Cochrane systematic reviews database was searched under the subject heading "diabetes and telemedicine", as well as combinations of "diabetes mellitus, type 2" and "telemedicine" or "telehealth" and "outcomes" and no relevant systematic reviews were located pertinent to this topic in Cochrane.

Finally, Google Scholar was searched utilizing the keywords "diabetes mellitus AND telemedicine" with a limiter of five years. Google Scholar did not have as many precise limiters as the other databases, so the initial search returned over 17,000 hits. Utilizing the feature "sort by relevance" and refining the search to "diabetes mellitus AND telemedicine AND outcomes AND systematic review" led to 14 relevant articles, of which 11 were duplicates and three were included for review after title and abstracts were assessed.

A total of 18 articles were located within PubMed, CINAHL, and Google Scholar. One additional article was added based on hand search for a grand total of 19 articles reviewed. The United States Department of Veterans Affairs and Department of Defense published a clinical practice guideline for the Management of Type 2 Diabetes Mellitus in Primary Care (2017) which was developed through a systematic review with recommendations made by a panel of clinical experts. This CPG was included in the literature review as well, since it provides evidence for the use of telemedicine to improve diabetes clinical outcomes. The gray literature and theses were not searched for this study because higher level of evidence was preferred and available to drive clinical decisions.

Data evaluation. As mentioned above, articles selected for review had to address the key elements of the PICOT question, namely improving outcomes (specifically glycemic control as measured by A1C; or diabetes self-care management) in adult Type 2 Diabetics utilizing telemedicine strategies. Once an article was selected for further review based on title and abstract, it was read through several times with key points highlighted and outlined. The Rapid Critical Appraisal Checklists from Fineout-Overholt and Melnyk (2005) were used to assess quality of the studies. Particular attention was given to the level of evidence, description of study methods and statistical analysis. Findings were assessed for both statistical and clinical significance. Although many of these studies measured more than one variable, only results relevant to A1C or diabetic self-care were included for purposes of review.

A 0.5% reduction in A1C has been considered clinically significant according to multiple organizations including the American Diabetes Association and the National Institute for Health and Clinical Excellence (Little et al., 2013). As such, outcomes that showed a mean reduction in A1C of 0.5% or greater were considered to have a stronger clinical relevance.

Critical Appraisal

The data and overall quality of each study were reviewed as described above, and all relevant points were summarized in the Evidence Table (Appendix A) and Synthesis Table (Appendix B) to search for common themes of evidence. Common themes were then assessed between articles and the overall quality of evidence was assessed.

Evaluation. Nineteen articles were assessed for evidence on the use of telemedicine in managing Type 2 Diabetes. The majority of the sources were systematic reviews or randomized controlled trials, with one outlier retrospective cohort study that tested the effect of an Endocrine Nurse Practitioner-provided telemedicine intervention, which was consistent with the purpose and approach of this project. The systematic reviews were analyzed to determine if there was an overlap with the other research studies located and overall there were no significant overlaps. Faruque et al. (2017) included the Crowley et al. (2016) and Rasmussen et al. (2015) studies in their systematic review. Lee et al. (2017), Polisena et al. (2009), Su et al. (2016), and Wu et al. (2010) had no crossover studies. Zhai et al. (2014) cited Trief et al. (2013) in their review. There were no overlaps noted with the VA/DOD Clinical Practice Guidelines (2017).

All of the reviewed articles were fairly heterogenous in design, population/sample sizes, health professionals performing the interventions, and location. Additionally, all of the studies dealt with utilization of one or more telemedicine modalities, with some comparing the impact of multiple different modalities (Faruque et al., 2017; Lee et al., 2017; Polisena et al., 2009; Su et al., 2016; Suksombom et al., 2014; Zhai et al., 2014). All but one of the studies measured the clinical outcome of glycemic control (Chamany et al., 2015; Crowley et al., 2016; Egede et al., 2017; Faruque et al., 2017; Hansen et al., 2017; Jeong et al., 2018; Kempf et al., 2017; Lee at al., 2017; Liu et al., 2016; Odnoletkova et al., 2016; Polisena et al., 2009; Rasmussen et al., 2015; Sood et al., 2018; Stone et al., 2010; Su et al., 2016; Suksombom et al., 2014; Wu et al., 2010; Zhai et al., 2014) as measured by improvement from baseline hemoglobin A1C within varying time frames, and the majority compared telemedicine to usual care or as a supplement to usual care.

Within the scope of this literature search seven systematic reviews and meta-analyses were located. According to Fineout-Overholt and Melnyk (2005) these articles provide generally strong to moderate levels of evidence (Faruque et al., 2017; Lee at al., 2017; Polisena et al., 2009; Su et al., 2016; Wu et al., 2010; Zhai et al., 2014). Suksombom et al. (2014) was graded as weak on the Rapid Critical Appraisal Checklist due to only reviewing five small population RCT's, of which two had a high risk of bias. Eleven randomized controlled trials were also evaluated (Chamany et al., 2015; Crowley et al., 2016; Egede et al., 2017; Hansen et al., 2017; Jeong et al., 2018; Kempf et al., 2017; Odnoletkova et al., 2016; Rasmussen et al., 2015; Sood et al., 2018; Stone et al., 2010; and Trief et al., 2013) providing further moderate to strong level of evidence (Fineout-Overholt & Melnyk, 2005). A single cohort trial was included by Liu et al (2016) because it specifically dealt with nurse practitioners providing telemedicine intervention. The VA/DOD Clinical Practice Guideline for the Management of Type 2 Diabetes Mellitus (2017) in Primary Care was also included in the review and considered moderate to strong evidence.

Overall, based on the Rapid Critical Appraisal Checklist (Fineout-Overholt & Melnyk, 2005), sixteen of the reviewed studies were assessed as providing moderate to strong evidence, and the rest were considered weak evidence. Significant limitations in the majority of the studies (particularly systematic reviews) was heterogeneity within the studies, the lack of blinding to treatment assignments which could have led to Hawthorne effects/bias, the variation of time frames within each study, and the varying modalities and types of health professionals conducting interventions within each study.

Synthesis. The majority (*n* = 12) of the reviewed literature reported that telemedicine resulted in a statistically significant decrease in A1C (Chamany et al., 2015; Crowley et al., 2016; Faruque et al., 2017; Hansen et al., 2017; Kempf et al., 2017, Lee at al., 2017; Odnoletkova et al., 2016; Rasmussen et al., 2015; Stone et al., 2010; Su at al., 2016; Wu et al., 2010; Zhai et al., 2014). Four of the studies showed no clinically or statistically significant difference (Egede et al., 2017; Jeong et al., 2018; Liu et al., 2017; Sood et al., 2018; Suksombom et al., 2014), and one study measured improvement in self-care which was then correlated with improvement in A1C (Trief et al., 2013). Polisena et al. (2009) reported mixed results.

Theme I: Modalities. One of the key themes of these studies was assessing the impact of specific telemedicine modalities on glycemic control, given the broad variety of telemedicine modalities available. The impact of specific telemedicine modalities was tested in a number of the studies, which is of relevance to this project because only telephonic telemedicine was available in the clinic where the project was conducted.

Chamany et al. (2015), Crowley et al. (2016), Egede et al. (2017), Kempf et al. (2017), Odnoletkova et al. (2016), Stone et al. (2010), Suksombom et al. (2014), and Wu et al. (2010) looked specifically at telephonic interventions. Of these eight articles, only one did not show a significant improvement in A1C (Chamany et al., 2015; Crowley et al., 2016; Egede et al., 2017; Kempf et al., 2017; Odnoletkova et al., 2016; Stone et al., 2010; Wu et al., 2010), while one did not show statistically significant differences (Suksombom et al., 2014). Suksombom et al. was the only systematic review to only assess telephonic interventions and the authors reviewed five small RCT's and the overall quality of this review was rated as weak given potential bias and poor discussion of the statistics analyzed.

Other systematic reviews and studies used several different modalities such as telephonic, video conferencing, messaging and telemonitoring (Faruque et al., 2017; Lee at al., 2017; Odnoletkova et al., 2016; Polisena et al., 2009; Su et al., 2016; and Zhai et al., 2014) and the authors reported statistically significant improvements in glycemic control. Studies that tested only video conferencing were also evaluated (Hansen et al., 2017; Liu et al., 2016; Jeong et al., 2018 & Rasmussen et al., 2015) and demonstrated mixed results. Liu et al. (2017) and Jeong et al. (2018) showed no statistically significant difference, while Hansen et al. (2017) and Rasmussen et al. (2015) showed a significant decrease in A1C. The overall evidence indicates that different types of interventions as well as combined intervention protocols can provide improved glycemic outcomes.

Theme II: Provider type. The type of providers giving the telemedicine intervention varied greatly between studies. Some of the studies utilized nurses or nurse case managers, while some utilized trained health coaches, and still others utilized physicians or nurse practitioners. Studies utilizing either providers alone (physician, nurse practitioner) or nurses working with providers to provide medication management and treatment recommendations were reported by Crowley et al. (2016), Jeong et al. (2018), Liu et al. (2016), Rasmussen et al. (2015), Sood et al. (2018); Stone et al. (2010). Studies utilizing nurses as educators or case managers were also common (Faruque et al., 2017; Hansen et al., 2017; Lee at al., 2017; Odnoletkova et al., 2016 and Trief et al., 2013). Except for the Liu et al. and Jeong et al. studies, all showed improvements in glycemic control. Liu et al. (2016) demonstrated no statistical difference between in person and telemedicine visits. Jeong et al. (2018) showed significant reductions in A1C in all three arms, but there was no statistically significant difference amongst the groups. Several of the systematic reviews did not differentiate the effect of different provider types. Of the three studies that utilized health coaches or health educators (Chamany et al., 2015; Egede et al., 2017; Kempf et al., 2017) the results were mixed with two studies showing improvement and the one remaining study showing no significant difference in outcomes. Further research would be needed to determine if the lack of significance was due to the intervention or the type of provider implementing the intervention.

Theme III. Intervention. The final key theme is what kind of telemedicine interventions had the greatest impact on outcomes. This was particularly difficult to narrow down in the literature because many of the studies used multiple interventions including health coaching, disease self-management education, telemonitoring of key measurements such as blood sugar, medication management and titration, nutrition education, goal setting and direct interface with clinical providers. Not every study provided specific details of the intervention protocols. The synthesis of the literature indicated that combined intervention protocols i.e. utilizing multiple different interventions via telemedicine led to improved glycemic outcomes demonstrated by reductions in A1C. Best practices of these studies included frequent direct contact with patients and providing reinforcement of diabetic self-management skills.

Limitations

Several limitations were noted in this literature review. The UAA library does not have access to EMBASE which could have been another source of studies to support this topic, although several systematic reviews accessed studies published in EMBASE.

Within the studies and systematic reviews there was a significant amount of heterogeneity of the modalities of telemedicine used, the settings and populations studied, and the types of providers performing interventions. There was also heterogeneity within the types of interventions themselves, while most included several aspects including diabetes self-management education, self-care review, and medication management in the provider driven interventions. This made it difficult to isolate exactly which intervention or modality was the most effective, however when taken as a whole the use of several combined modalities (i.e. protocols involving multiple intervention modalities) appeared to be more effective at improving glycemic control.

Conclusion

A review of the literature was conducted that provided sufficient evidence supporting the use of telemedicine modalities to improve glycemic outcomes and self-care in patients with diabetes. This review included higher level of evidence including systematic reviews, meta-analyses, and RCT's. Although there were limitations, several key themes emerged in the literature that provided evidence to support this project.

Chapter 3: Organizational Framework

Havelock's Change Theory (Havelock, 1973) provides a systematic process for developing, implementing, and sustaining change. Havelock described change as "any specific alteration in the status quo" of an organization (p. 4) and his model for change allows the user to assess the viewpoint of both the change agent implementing the change, as well as those who the change will impact. Understanding these varying viewpoints allows the change agent to identify potential barriers and gain buy-in from stakeholders, which is key given that resistance is common to any change in the status quo. Havelock discussed the stages of change in planned innovation in his model, and although it was originally used as an organizational framework for education, it has been applied to nursing as well (Udod & Wagner, 2018). Medical providers are often very ingrained in their practices so it is important to be able to demonstrate in a logical manner the value and feasibility of any new process, and garner buy-in so that the providers themselves can lead the impetus for change.

Havelock (1973) discussed the difference between reflexive change versus planned change as another key aspect to support his theory. Within the military, and medicine in general, reflexive change is often the norm, and many times the change either does not address the root cause of the problem or it can't be sustained due to poor staff buy in or poorly planned implementation. Havelock's Theory imparts the importance of using a systematic approach which also integrates well into evidence-based practice, ensuring changes are made in a way that can be sustained within the organizational culture.

Evidence-Based Practice Model

Havelock's Theory of Change (1973) was originally developed and expanded based on Lewin's Theory of Change (1951). Havelock designed his theory to provide an organizational framework for creating reforms within organizations. His theory consists of a six stage process that allows the change agent to progress through organizational change in a systematic and sequential manner (Havelock, 1973). The six phases of Havelock's Theory are Relate, Examine, Acquire, Try, Extend, and Renew (Havelock, 1973).

Havelock's theory (1973) was designed to be used by the people working within the organization, often with a bottom-up approach, which suits this project well as it is provider driven, not leadership driven. He describes how change agents can organize their work to be successful and he provided case studies throughout each step that include examples of practical ways to implement change. Havelock described four ways a person can act as a change agent – a catalyst, a solution giver, a process helper, and a resource linker. All of these aspects could be used within the six steps of Havelock's model (Figure 1). Havelock recommended starting the change process by diagramming the organization as a system to understand how it works (Appendix C), and then identifying potential stakeholder allies and involving them early. The change agent should seek to become an expert on their process and analyze the concerns of adversaries in detail so that all points of view can be understood. These processes facilitate the change process by preparing the agent to overcome potential obstacles.

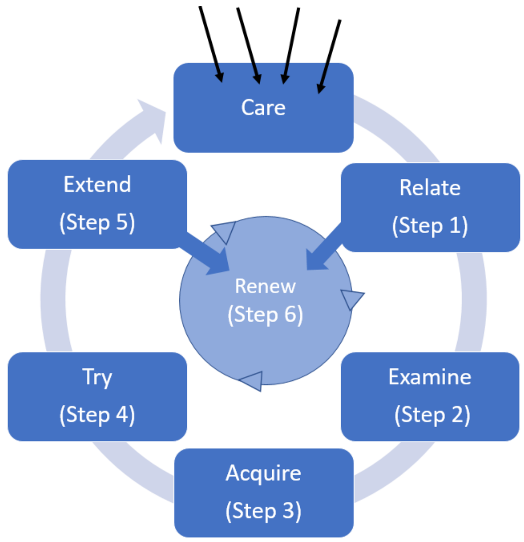

Figure 1. Adapted Illustration of Havelock's Theory of Change (1973)

Step One: Relate. The first and possibly most important step in Havelock's Theory (1973), "Relate", is the phase of determining that a need for change exists and then building relationships with clients or stakeholders. Havelock stressed that for a change agent to be successful, they must develop good relationships and involve key stakeholders early in the process. Havelock identified the importance of identifying organizational norms, leaders, influencers, and gatekeepers. Havelock encouraged frequent conversations, involvement, and inviting opposing views to the table during this step. The priority at this stage is to "know your innovation inside and out" (Havelock, 1973, p. xi) and creating alliances to allow for success.

This stage was key in developing and implementing this evidence-based project. The need was already demonstrated in clinic metrics showing a significant number of diabetics in the clinic failed to meet A1C goals despite all usual care practices (Carepoint, 2019). Providers are tracked by leadership on whether or not they meet these quality metrics as usual practice, and both leadership and providers were vested in demonstrating improved outcomes. As the Family

Health Clinic transitioned to Defense Health Agency leadership, there was even more impetus to demonstrate effective outcomes-based processes in the clinic. Key stakeholders included providers, nurses, and healthcare staff in the Family Medicine Clinic who implemented this process change, Family Medicine Clinic and 673rd Medical Group Executive Leadership who provided approval, and the patients themselves who participated in this enhanced follow-up.

Havelock's (1973) first stage involves assessing readiness for change in organizations and he provided examples of how this process could work in various case studies. In this stage, it was important to assess the motivation/knowledge of EBP principles in the clinic. As a provider in this clinic, the project coordinator already had an established working relationship with providers, staff and clinic leadership. At the time of this project, the Family Health Clinic was already utilizing limited telemedicine modalities for certain conditions, and providers and patients generally viewed this as a positive service. In addition, the clinic and leadership culture was already very proactive in accepting and implementing evidence-based medicine as evidenced by previous performance improvement projects that had been successful. This project involved additional provider time, although the follow-up visits occurred within normally templated visits during the duty day. Providers were educated on the time and resources involved ahead of implementation and given opportunities to develop a process that fit well with current practices.

As this project progressed, engagement and education occurred for the providers and clinic teams during provider and staff meetings, as well as engaging with the unit practice council to garner interest and support. The unit practice council had been significantly involved in several evidence-based practice changes previously and their recommendations carried significant influence with leadership. The medical director, providers, and clinic leadership were engaged early in project plans and were consistently supportive. The Air Force Center for Evidence Based Practice reviewed this project concept and ensured it remained within the guidelines of the Air Force for implementing a practice change of this nature. The operationalization of this project also involved a clear process for helping patients understand the potential benefits and garnering their engagement to participate in a more intensive follow-up regimen. Making this project provider-driven ensured that patients had continuity with their primary care provider team for these follow-ups.

Step Two: Examine. During the "Examine" stage, the problem is formally diagnosed or identified (Havelock, 1973). As mentioned above, a significant percentage of Family Health Clinic patients fail to meet A1C goals, likely due to a number of factors (Carepoint, 2019). One of the major factors has been patients not returning to the clinic for recommended follow-up appointments. This is likely multifactorial, however providing an alternate venue for follow-up was thought to potentially eliminate some barriers. The VA/DOD Clinical Practice Guidelines for the Management of Type 2 Diabetes Mellitus in Primary Care (2017) recommends that telemedicine modalities be utilized in improving diabetic outcomes; however, this recommendation had not been implemented in the clinic. The CPG provided evidence and recommendations to support the use of telemedicine to improve outcomes. This project addressed the lack of implementation of the CPG recommendations.

Step Three: Acquire. In the third phase, "Acquire", resources are gathered, and relevant information is used to develop solutions (Havelock, 1973). In this stage the change agent needs to identify what resources are needed and obtain them. The literature review provided the evidence and direction for the design and implementation of the project. A protocol and instrument were developed based on best evidence to provide standardization for the providers during the telemedicine encounters. No additional equipment was needed for this project. Training was developed as mentioned above for those involved in the implementation. Health Care Integrators and the Carepoint database were used to identify patients who meet inclusion criteria for the project.

Step Four: Try. **“**Try” is the step of choosing the solution and implementing the process change (Havelock, 1973). In this stage the change agent and Family Health Clinic providers made decisions on implementation. The guiding principle was to reshape solutions to meet the specific needs of the client (Havelock, 1973). In this stage the actual change was implemented.

Once agreement amongst the stakeholders was reached on the best course for implementing this project, employment commenced. During the implementation phase close contact was maintained with all of the participating providers and teams to identify any barriers that developed so they could be addressed immediately. Obstacles and barriers were documented as the project progressed. The process itself was designed in a way that made it sustainable and integrated well into workflows already used in the clinic, ensuring providers did not have to invest significant additional clinical time into these visits. Visits were scheduled onto the providers existing schedule templates, in designated follow-up (SPEC) appointments. A1C was monitored as the primary clinical measure of the project, and patients were requested to obtain the labs prior to the start of the project as deemed necessary by their PCM, and at the end of the 3 month project.

Step Five: Extend. **“**Extend” involves sharing and disseminating findings and highlighting outcomes to all involved in order to gain acceptance for the change (Havelock, 1973). In this stage the change agent should describe, discuss, develop interest, evaluate, and formally adopt the changes made (Havelock, 1973). It is important to maintain communication with all stakeholders and provide education and a support structure for those implementing the change. In this stage data was obtained and evaluated, acceptability was assessed with provider input, and barriers were identified and ameliorated when possible. Findings were disseminated to providers, staff and leadership including relevant statistical findings.

Step Six: Renew. The final phase, "Renew", involves sustaining the process, creating self-renewal, and once the process is established the change agent can separate from the process (Havelock, 1973). Havelock (1973) described this stage as the internal capability to maintain the innovation. In this stage it is important again to assess stakeholder input, client perceptions, and any resistance to maintaining the change and provide ongoing feedback and data to the teams. Monitoring for continued use of the practice change is also part of this stage. This stage is continuous after the completion of the three month project. The formal conclusion of this project coincided with the project coordinator's military move to a different location. However, regular communication continues at the time of this writing between the project coordinator and the Family Health Clinic team to discuss continued sustainment of the program.

Conclusion

Selecting an appropriate change theory to provide a project framework is an essential part of a DNP project. Havelock's Theory provided an excellent framework for this project. This theory has six steps that successfully guided the project development through the planning, implementation, data analysis, and dissemination stages.

Chapter 4: Design and Methods

Design

This quality improvement project used a pre-test post-test design with laboratory and survey data to measure A1C, diabetes self-care management (DSMQ questionnaire), and a post-test only provider satisfaction survey. Quantitative data was used for analysis. The primary metric of interest was the change in mean hemoglobin A1C over three months for the patients who participated in the telemedicine intervention program. Secondary metrics included pre- and post- diabetes self-care scores and provider satisfaction scores at the end of the project. Descriptive statistics included demographic data such as age, race, and gender of the patients. The total number of patient visits was also tracked.

Setting and Population

This project was implemented at the Joint Base Elmendorf-Richardson Family Health Clinic which is part of the 673rd Medical Group located in Anchorage, AK. The 673rd Medical Group is a United States Air Force/Department of Defense Military Treatment Facility serving active duty military personnel, their family members, as well as retired military personnel and their dependents. The clinic treats all ages from infants to geriatrics. Approximately 25% of the patients served are active duty military, with the remainder being dependents or retirees. The clinic itself serves a large region of Alaska. The entire medical group has 1,856 patients enrolled with a diagnosis of diabetes as of June 2019, of which 264 had a most recent A1C of greater than or equal to 8.0 (Carepoint, 2019). The clinic has 19 providers (13 beneficiary providers and 6 active duty providers), including nurse practitioners, physicians, and physician assistants, each managing an empanelment of approximately 1,250 patients.

This project was implemented for adult patients enrolled in the clinic with a diagnosis of Type 2 Diabetes and with an A1C at or above 8.0. Inclusion criteria for this project was adult patients (age 18 years or older) with Type 2 diabetes and most recent A1C greater than or equal to 8.0. Exclusion criteria included patients managed by an off base provider for diabetes (endocrinology, VA, or off base civilian primary care), patients not seen in the clinic within 12 months for a provider visit, patients unable or unwilling to utilize phone follow-up (lack of access, not comfortable doing virtual visits), patients with end of life care or terminal illness, and patients lacking cognitive or communication skills (language barriers, dementia) to participate in phone visits. The intervention was offered to all eligible patients empaneled to the participating providers.

A critical review of the evidence focused on diabetes and telemedicine found that glycemic outcomes could be improved using telemedicine modalities. This clinical quality improvement project was based on components of several of the studies that demonstrated improvement in glycemic outcomes, and as such was not conducted for the purpose of research. This project is not generalizable beyond the participating patients in the 673rd Medical Group Family Health Clinic, however the data from this project could be utilized to inform program development in other similar clinics. Patient agreement was sought for inclusion in the project, however declining participation did not impact a patient's ability to receive usual care; all interventions provided in this project were in addition to the usual standard care available. This project was deemed "Not Human Subjects Research" by the University of Alaska IRB. In addition, this project was approved by the 673rd Medical Group Commander and executive leadership team, and through the Air Force Human Research Protection Office.

Key stakeholders included the primary care providers, clinic and hospital leadership, and care team staff (registered nurses and medical technicians). A total of 13 providers were asked to conduct the virtual telephonic follow-up visits. They were involved in the planning process, with education provided to them prior to starting the intervention phase of the project. Training provided consisted of an overview of the project, the evidence supporting the project, and the use of the instrument developed for this project. Leadership was involved for oversight and planning of the project as well as to ensure support. Care team staff assisted the providers as needed in pre-screening of the patients for the telephone visits and were also educated on the program.

The project was cost neutral with the primary resource being provider time and commitment. Laboratory testing was already occurring at regularly scheduled intervals and therefore did not incur additional costs to the patient or clinic. Telephonic follow-up was used, and all providers in the clinic had phone and computer access. Education for providers and staff was conducted during regular duty hours, requiring no additional time investment. Documentation was the same as per a typical visit in the Armed Forces Health Longitudinal Application (AHLTA) electronic health record (EHR). An instrument (Appendix E) was given to the providers to guide the telephone follow-up intervention. The virtual visits were booked during the normal clinic day as a regularly scheduled SPEC appointment and scheduling the follow-up visits were the responsibility of each provider team. The project was designed in such a way that the visits could be accomplished within a short 10 to 15 minute telephone visit. Key facilitators included establishing provider and leadership buy in early and continuously, providing education to ensure consistency in implementation, and monitoring the implementation frequently to ensure providers stayed on track with follow ups and to address any issues that developed.

Intervention/Practice Change

This project utilized a provider implemented intense telephonic follow-up intervention. The Military Health System Carepoint database was utilized to identify patients on each provider team that had a most recent A1C of 8.0 or greater within the past year. Each patient on the list was reviewed against inclusion and exclusion criteria, and the names of those meeting criteria based on initial review were given to each participating provider. Participating providers also reviewed each patient on their list to ensure appropriateness for this intervention and final discretion was up to the provider to eliminate any patients they felt were not appropriate for this intervention.

The telephonic intervention included several components including medication management/titration, diabetes self-management education such as self-monitoring blood sugar, healthy lifestyle change counseling including healthy diet and exercise, and referral to ancillary resources such as nutrition or pharmacist if indicated. These key elements were included in the majority of telemedicine studies reviewed in the literature that demonstrated improved glycemic outcomes (Crowley et al., 2016; Hansen et al., 2017; Lee et al., 2017; Rasmussen et al., 2015; Sood et al., 2018; Su et al., 2016) as well as the VA/DOD Clinical Practice Guidelines (2017).

A diabetes screening instrument developed by Gervera and Graves (2015) for the VA telemedicine program utilized the VA/DOD Clinical Practice Guidelines and was modified for use in this project to reflect the DOD population and ensure compatibility with current VA/DOD CPG. There are no validity/reliability measures associated with this instrument. The tool was used to ensure the telephone visits met the key elements described above for each patient in order to maintain consistency. The author of the tool, Kelly Gervera DNP, RN gave her permission for the instrument to be modified and used in this project. A copy of the permission to modify is included in Appendix D, and the modified tool is available in Appendix E. The decision was made to modify this tool for the project, because it was developed based on VA/DOD evidence based guidelines for diabetes management, and the project coordinator was unable to locate a tool in the literature that specifically matched the goals for this project. This tool could not be used in its current form because it included items not related to glycemic control and had VA specific items not relevant to this project. However, the core components of the tool related well with the key items included in this project.

Providers performed telephonic follow-up calls to the identified patients during scheduled appointments in the implementation phase every two to three weeks for a three month period. The virtual visits lasted approximately ten minutes and covered items such as patients' home glucose monitoring results, medication compliance, setting goals for lifestyle changes, providing targeted education on diet and exercise, and inputting referrals for additional services such as dietician, disease educator, and clinical pharmacist. The initial DSMQ questionnaires were provided to the providers as a clinical instrument to assist them in setting goals for the virtual visits. The providers utilized the telemedicine program instrument described above as a guideline to keep the visits on track and documented the encounters in AHLTA. At the end of the three month implementation period data were analyzed and presented to stakeholders.

Measures

In order to measure glycemic outcomes in this project, the mean change in A1C for patients from baseline to end of intervention (pre-post measurements) were compared. Patients had their labs drawn at the JBER lab for the pre-test and post-test measures of A1C, and all A1C's were measured in the same lab to ensure consistency. Secondary outcome measures included a brief Likert-style survey given to participating providers regarding their satisfaction with the telemedicine intervention (measured by a post-survey). The provider survey was based loosely on content found in a survey created by Tudiver et al. (2007) to measure provider satisfaction with the ground-breaking IDEATeL project. Diabetes self-care scores were assessed pre- and post- intervention using the previously validated Diabetes Self-Management Questionnaire (DSMQ) (Appendix G) (Schmitt, 2013) to assess for change in scores. Permission was obtained to use the DSMQ in this project (Appendix J). The DSMQ is a 16 item questionnaire that measures the patient's self-care activity for the previous eight weeks on a four-point Likert scale. It contains four sub-scales that assess glucose management, dietary control, physical activity, and health care utilization. The higher the score on the DSMQ, the higher the patient's rating of self-care (Schmitt, 2016). These surveys were administered by the project coordinator via phone and scored as detailed by Schmitt et al. (2016). The DSMQ instrument has been shown to be both reliable and valid with good internal consistency and comparable to other validated diabetes self-care instruments, for patients with Type 2 diabetes (Bukhsh et al., 2017; Schmitt et al., 2013; Schmitt et al., 2016). It is scored using a total sum score for the whole instrument and broken down into the four subscales – glucose management, diet/nutrition, exercise/physical activity, and healthcare.

Data Collection

Establishing a structured process for planning, implementation, and data collection is essential to any quality improvement project. Project planning and oversight was managed by the project coordinator who maintained close communication with the clinic medical director and key stakeholders. A secure excel spreadsheet was utilized to track all data which was maintained on a secure CAC (ID) card enabled government computer that only the project coordinator could access. The pre-intervention phase began with proposal approval. Once the proposal was formally approved, the project coordinator worked within the clinic to educate key stakeholders on the project concept and goals including conducting meetings with clinic providers, the clinic leadership team and Unit Practice Council, Medical Group Chief Nurse and Command Staff, and individual teams to build support and obtain approval for project implementation while assessing readiness and educational needs from all the key players.

Training to orient staff and medical providers on the project implementation plan were conducted. This training identified each person's role in the project and ensured intervention and follow-up timeframes for each virtual visit. The training was started as formal in-person training led by the project coordinator during scheduled medical provider meetings and staff meetings but transitioned with short notice to virtual and smaller group training due to COVID-19 safety precautions. Key elements of training included use of the protocol instrument, timing of visits, content of visits, patient protection/privacy, and documentation in the medical record.

Pre-intervention data collection. Patient and provider recruitment was the responsibility of the project coordinator. Providers in the Family Health Clinic were encouraged, but not required to participate. The number of patients who were offered this intervention but declined to participate was tracked. Once provider participation was determined, eligible patients on those provider teams were identified based on the Carepoint database and criteria discussed previously. The Health Care Integrator scrubbed the list to remove patients who had not been seen in clinic in greater than 12 months, and those known to have primary care off base. Eligible patients were then contacted by phone by the project coordinator and educated on the voluntary nature of the project, and the project details including time frame for follow-up visits. If patients agreed to participate, they were scheduled for an initial phone appointment with their PCM provider and an initial A1C lab was ordered by their PCM if clinically indicated. The

DSMQ questionnaire was completed with the patient over the phone by the project coordinator. Descriptive data including age, race, and gender were obtained for each participant.

Intervention. Project oversight was managed by the project coordinator and in close consultation with the clinic medical director. The project coordinator interacted with each participating provider and their medical technicians at least weekly to ensure continued project success.

Providers utilized the instrument developed to guide telemedicine visits during this project, with the premise that providers would tailor each visit to reflect specific patient/outcomes goals. Providers conducted telephonic visits with each participant every two to three weeks at scheduled times based on provider schedule availability utilizing designated follow-up (SPEC) appointments. The instrument developed provided a guideline for goal setting with patients at each visit, and basic education and diabetes self-management topics to be discussed. Providers were also able to provide medication management/titration if indicated. All visits were documented in the medical record as per usual practice.

Post-intervention data collection. At the end of the 3 month implementation phase, providers ordered a post-A1C lab on each patient. In addition, the DSMQ questionnaire was re-administered by the project coordinator. The overall DSMQ total sum score and sub-scales were assessed. At this time providers who participated were also surveyed with an anonymous and voluntary paper survey to identify their level of satisfaction with the telemedicine project. This survey was conducted after duty hours and strictly voluntary to meet the requirements of the Air Force Survey Office. Data was then analyzed including mean change with standard deviation in A1C scores from pre- and post- intervention and mean change in DSMQ questionnaire scores from pre- and post- intervention with standard deviations. These items were assessed to demonstrate effects on glycemic control and determine change in self-care status. Appropriate statistical analysis was then performed, including paired *t*-tests and Wilcoxon signed ranks tests. Once statistical analysis was completed, information was disseminated to all key stakeholders.

Program Evaluation and Data Analysis

Demographic data was obtained on all patient participants. Documentation of obstacles and barriers was discussed. The effectiveness of the project was evaluated by assessing the change in hemoglobin A1C over three months, change in scores on the DSMQ questionnaire, and provider satisfaction.

Sample. Demographic data was collected from participants including age, race, and gender. Gender and race were measured at the nominal level (male/female; White, Black, Hispanic, Asian, Other). Age was collected at the interval level (age in years). Descriptive statistics were utilized to describe the patients in this project. Nominal data was presented as percentages (i.e. % male, % female). Interval data was presented by mean and range and standard deviation.

Outcome measures included change in mean A1C difference scores, change in DSMQ scores, and post intervention provider satisfaction. Data was obtained from pre- and post-intervention A1C lab results available in the Carepoint database, DSMQ questionnaire scores pre- and post- intervention, and mean of provider satisfaction scores using a Likert-style questionnaire.

A1C is an interval/ratio level of measurement and means were calculated at pre- and post- intervention showing mean change with standard deviations reported. A1C and DSMQ measures were analyzed using either a paired *t*-test or the nonparametric alternative Wilcoxon

Signed Ranks test. Provider satisfaction was obtained from a Likert-style survey with means and standard deviations reported.

Cost-Benefit Analysis and Budget

This project did not incur any financial costs. No additional monetary expenses are anticipated in the future. SPEC telephone visits are billable in Tricare as per current practice. Training was developed and conducted by the project coordinator and conducted at regularly scheduled intervals during the project. Provider and staff time was the primary cost. Individual provider time was estimated at five hours per provider for project duration, based on a 12 week implementation phase with virtual visits conducted on average of every three weeks for a total of four to five visits, each lasting estimated 15 minutes = 75 minutes total in direct patient contact, with an additional 10 minutes per patient for charting and administrative aspects = 50 minutes. Provider time for training included one hour for initial training, with intermittent informal follow-up discussions and virtual presentations estimated at one hour per provider. Medical technicians incurred a limited time commitment for any needed pre-screenings for each visit, estimated at one to two hours during project duration. Nurses were not directly involved in the virtual visits and were not expected to incur additional time. No additional equipment or services were anticipated for this project. Table I-1 (Appendix I) details cost versus benefit analysis for this project.

Timeline

Table I-2 (Appendix I) summarizes the timeline for this project. In Spring 2020, proposal defenses and approval occurred, followed by IRB submission and not-HSR determination. Once Medical Group approval was obtained, provider and staff education was conducted, along with provider recruitment. All preparations including stakeholder education, ensuring buy in, and preparations occurred during this time frame. The implementation phase occurred over a three month period from April 2020 to July 2020. Data analysis and outcomes measurement occurred in September 2020 and October 2020 and the dissemination of findings occurred in October and November 2020, which concluded in the project defense in November 2020. Further dissemination including planning for formal publishing and poster presentation of these findings will continue into 2021.

Ethical Considerations/Protection of Human Subjects

No significant risks to human subjects were anticipated in this study. The risk of data breach was minimized using appropriate privacy protections. The risk to patients participating in this project was no different from the risks of patients receiving standard care. All relevant DOD Clinical Practice Guidelines were followed. This clinical project delivered care according to current guidelines using telemedicine. All patients who met criteria and could be contacted by phone were asked if they would like to participate. Potential benefits to subjects included enhanced/more frequent follow-up, more targeted goal setting with follow-up, and increased access to providers versus only usual care, and potential improvement in glycemic control and diabetes self-management. No usual treatment was withheld from patients. Provider data only included the post survey, which was anonymous. Patient collected data included demographics such as age, gender, and race, with outcome data such as A1C and DSMQ scores being tracked. Patient data was completely de-identified in reporting findings and any study documents were stored on a CAC/password protected computer that only the project coordinator had access to.

The University of Alaska Anchorage Institutional Internal Review Board (IRB) and U.S. Air Force non-HSR determinations were obtained prior to initiating the DNP Project. All participants were protected by the Health Insurance Portability and Accountability Act of 1996

(HIPAA) which protects the privacy of patients' health information, and the Medical Group HIPAA Privacy Officer reviewed and approved the project. Additionally, the DNP student and practice personnel who conducted this project followed all appropriate DOD and accepted standards of care during this project. The project coordinator and committee also maintained appropriate CITI training requirements.

Conclusion

The literature supports the use of telemedicine to improve glycemic outcomes in patients with Type 2 Diabetes. This DNP project clinical quality improvement intervention was based on best practices and standards of care found in the literature. The project was conducted in an organized and structured manner, while ensuring human subjects protections, as detailed in this plan with the goal of improving diabetic outcomes.

Chapter 5: Implementation

This chapter discusses the implementation of the Diabetes Telemedicine project in the Family Health Clinic at the 673rd Medical Group. Project implementation began ahead of schedule in early April 2020 and continued through the end of July 2020. This chapter discusses the implementation process and procedures, barriers, and unexpected challenges that arose related to the SARS-CoV-2 Coronavirus (COVID-19) national public health emergency.

Implementation Process

Upon completion and approval of the DNP Proposal Defense in February 2020, University of Alaska Anchorage Institutional Review Board (IRB) Human Subject Research Self-Determination and subsequent IRB Human Subjects Research Determination were obtained and the project was deemed "Not Human Subjects Research." Approval was obtained from the entire executive leadership team at the 673rd Medical Group including the Family Health Clinic Flight Commander, Flight Chief and Medical Director; 673rd Medical Operations Squadron Commander and Superintendent; 673rd Medical Group Chief Nurse, Chief of Medical Staff, Quality Improvement Director, HIPAA Privacy Officer, Deputy Commander, and Commander. The Air Force Survey Office was consulted and gave approval to utilize the DSMQ questionnaire as a "clinical instrument" and advised that the provider survey must be anonymous and conducted after hours not using any government time or materials to be in compliance with Air Force regulations. Once the needed Medical Group approvals were received, a packet including the project protocol and IRB review paperwork was compiled and submitted to the Air Force Human Subjects Research Protection Office at Air Force Medical Headquarters, where the project proposal was appraised by the Human Research Protection Official (HRPO). Various concerns and clarifications were addressed, particularly ensuring the ability of the individual providers to diverge from the protocol when they felt clinically indicated. The project received final Air Force support to proceed in the end of March 2020.

During the IRB and Air Force review process, meetings with key stakeholders in the clinic were held in February and March 2020. The project coordinator met individually with all Flight Leadership, individual clinic providers, diabetes management nurses, the clinical pharmacist, the health care integrator, administrative support staff, and other team members to discuss and address any potential barriers to the project. The Flight Commander and Medical Director and other stakeholders were very supportive of this project, and no significant barriers were identified. The project coordinator also led briefings at the monthly Unit Practice Council (UPC) meeting and monthly provider meeting to discuss the project and obtain buy-in from unit level change agents. The project was well-received and supported by the UPC members and providers.

With final approvals received in March, the formal staff education process was initiated. Due to restrictions occurring because of COVID-19, the clinic provider meetings, UPC meetings, and staff meetings were cancelled due to social distancing requirements. This required the project coordinator to conduct last minute virtual and small group training sessions for the entire clinic. A PowerPoint educational presentation was developed which provided information on the background and evidence base for the project, project purpose and goals, and specific steps for implementation and evaluation. A detailed discussion on the use of the project instrument (developed from the instrument created by Gervera & Graves, 2015), VA/DOD CPG, follow-up requirements, and use of the DSMQ questionnaire were included. Relevant resources and handouts were provided electronically including a link to the VA/DOD CPG and other diabetes management resources from the American Diabetes Association (ADA). This was mandatory for all clinic providers participating in the project. Separate and more abridged educational information was provided to clinic RN's, technicians, and support staff as well as key stakeholders such as the clinical pharmacist, health care integrator, and disease managers. After the virtual presentations, small socially distanced group meetings were held with each participating provider team to allow the opportunity for questions and clarifications. Once the initial onboarding education was completed, providers were given the opportunity to opt in or out of the project. Out of the 13 eligible beneficiary providers in the clinic, 12 opted to participate in the project (one new provider assumed a participating providers panel during the project). The only provider not participating cited an upcoming deployment and leave scheduled as concerns for possible lack of PCM continuity.

In early April, the project coordinator met with the Health Care Integrator, and a database report from Carepoint was generated with the names of all the patients in the Family Health Clinic with a most recent A1C of 8.0 or greater. Some of these patients had not had a recent A1C in over six months. This list was cleaned by the HCI to remove patients who no longer received primary care in the Family Health Clinic and/or who had not been seen in clinic for over a year. The final list included a total of 75 patients. Of those 75 patients, eight were empaneled to the provider who opted out of the project and those patients were not contacted. Data available from the database included the most recent A1C values and basic demographic information such as age, sex, and race. The project coordinator attempted to call all of the remaining patients on the list and was able to reach 56 patients. Patients not reached either did not answer after multiple attempts, did not have a working/correct phone number, or did not call back when messages were left on their voicemails. Of the patients reached, 31 met inclusion criteria and agreed to enroll in the program, and nine were excluded based on exclusion criteria (most commonly being managed by an off base endocrinology provider). Eleven patients declined to be included in the program, and one was excluded based on PCM judgement as not being an appropriate candidate for the telemedicine project due to mental health reasons.

Once patients agreed to participate in the project, the project coordinator conducted the DSMQ questionnaire over the phone. Scores were calculated and recorded in an excel spreadsheet maintained on a secure CAC protected government computer to which only the project coordinator had access to. Scores were calculated for the total DSMQ summary score and for the four subscales which included glucose management, dietary control, physical activity, and health care utilization. The questionnaire results were also scanned into the medical record to be available for providers to review and use the information for individualized goal setting with their patients. The patients were then scheduled for a virtual (SPEC) visit with their PCM team provider.

The first virtual visits began on April 9, 2020 with staggered starting times over the following two to three weeks based on when patients could be reached/scheduled. All providers were educated on the follow-up interval goal of every two to three weeks, with a goal of at least four to five visits over three months. Providers had access to the most recent A1C in the medical record and ordered updated A1C's on patients as clinically indicated.

During the implementation phase the project coordinator conducted brief weekly virtual education (every Wednesday) for the providers including various aspects of diabetes management covered in the VA/DOD CPG such as nutrition resources, medication management guidelines, exercise guidelines, and motivational interviewing techniques. The project coordinator also reached out via email or in person with each of the participating providers weekly to ensure patients were being scheduled into follow-ups appropriately and address any concerns that arose.

During the course of the project, four patients were enrolled but never scheduled their first appointment after staff made multiple attempts to reach them. During the project three patients had their first visit with the provider but chose not to schedule additional follow-up.

Data collection for the project completed at the end of July 2020. The project coordinator contacted all participants and conducted the post-DSMQ questionnaire and A1C data was compiled over the next month. Provider surveys were conducted anonymously during off duty hours. All data was collected by the project coordinator and entered into the appropriate Excel spreadsheet. All data was de-identified in reporting to protect patient privacy.

Barriers/Challenges

The greatest barrier to implementation was the multiple levels of approval required within the Air Force system. This required frequent meetings and conversations with multiple stakeholders in a variety of different locations and units, as well as the Committee Chair to navigate the process. Fortunately, leadership and the providers in the Family Health Clinic were very supportive and agreeable to this project and even the one provider who did not participate did so mainly because of his scheduling availability and a pending deployment. Havelock's Change Theory (1973) proved to be the correct framework by recommending early and continual stakeholder engagement which helped streamline the approval process and implementation.

Impact of COVID-19 on Implementation Plan

Due to the COVID-19 National Public Health Emergency, several modifications had to be made to this project at the last minute. Access to the base and clinic became much more restrictive in order to reduce risks to patients and staff. The Defense Health Agency (DHA) allowed expansion of virtual/telephonic visits for the majority of visit types, and many of the Family Health Clinic providers began doing solely virtual visits and were assigned to telework from home. Patient volume in the clinic dropped significantly during the months of April, May, and June - attributed to many patients being afraid to come in. The increased use of telemedicine fit extremely well with the concept in this project, and it became even more important to offer virtual access to the diabetic patients since in-person clinic appointments were extremely limited.

The difficult decision was made among the providers participating in the project and the project coordinator that an across the board pre-A1C lab in April would not be obtained on every patient, due to the increased risk of coming into the hospital if the test wasn't essential to the providers medical decision making. Patients were assessed on a case by case basis by the PCM to determine if they needed an A1C or if the previously recorded A1C and home glucose monitoring were sufficient to make treatment decisions. In reviewing the database results pre-implementation, approximately half of the patients had an A1C within the past three months, and the other half were within the past year. The same challenges occurred during the timing of post-A1C's in July and August, as many patients were not willing to come into the clinic for labs. This created limitations in A1C data completeness, with eight patients not obtaining a post-A1C.

The COVID-19 crisis also created a number of rapid and sometimes chaotic workflow changes within the clinic. One participating provider had to deploy with three days-notice; another was tasked to staff a separate respiratory testing clinic full time and pulled from normal duties, and one was briefly tasked to staff an inpatient services unit. Other providers were assigned to fill in for them and fortunately all of the back-filling providers had been trained to participate in the program. A new provider also joined the clinic towards the end of the study to replace one that was transferring out. Appropriate education was provided in real time for that provider to get them oriented. All of these changes required the project coordinator to interface frequently with participating teams and leadership, which was also a challenge since the coordinator was working from home during two of the project months. Fortunately, despite all of the fluctuations during the pandemic, most of the providers remained in place throughout the project and were able to provide continuity and consistent visits for their patients. All patients who desired participation were able to complete the program.

Conclusion

Despite the challenges presented by the COVID-19 pandemic, this project was able to be successfully implemented and all patients who desired participation were able to complete the program. Although there was some expected attrition, it was minimal. The biggest limitation was the lack of consistency in the timing of A1C's both pre- and post-, however DSMQ and provider surveys were obtained as planned. The biggest strength of implementation was having supportive stakeholders, participating providers, and flexibility - which is the key to Air Power in the Air Force.

Chapter 6: Data Analysis and Outcomes

Chapter 6 discusses the data analysis and outcomes of the Diabetes Telemedicine Project conducted in the Family Health Clinic at the 673rd Medical Group. Data analysis was conducted to determine whether the project demonstrated statistical and/or clinical significance on outcomes including glycemic control (measured by mean change in A1C), self-care management (measured with the Diabetes Self-Management Questionnaire [DSMQ] instrument), and provider satisfaction (measured with the provider satisfaction survey). This chapter addresses data analysis, findings, and limitations.

Outcome Measures

The primary outcome measure of this project was the mean change in pre- and post-intervention A1C levels. Two secondary outcome measures were chosen to evaluate this project. The DSMQ questionnaire evaluated mean change in patient reported self-care including subscales for dietary control, health care utilization, physical activity, and glucose management. Provider satisfaction was measured using a voluntary, anonymous Likert-style survey designed specifically for this project. The survey included seven questions rated from one (very dissatisfied) to five (very satisfied). The survey had a minimum score of seven and a maximum score of 35 points possible, where 35 indicated the highest possible level of satisfaction. A section for written comments was also provided on the survey. Content from this narrative evaluation data were analyzed and summarized according to common themes.

Methods of Data Analysis

Data was reviewed by the project coordinator for data entry errors. Frequencies were calculated in order to determine the number of individuals who were asked to participate, those who agreed to participate, and those who completed the quality improvement project.

The initial step in the data analysis was to determine if the data sets had normal distribution, in order to determine the appropriate statistical test(s) to use. In the project design, the initial plan was to use a paired *t*-test for data elements with normal distribution (Weis, 2012) and the Wilcoxon Signed Ranks test for data with a non-normal distribution (Statistics.laerd.com, 2020; Weis, 2012). The test of normality selected was Shapiro-Wilk, which is typically used for data sets with less than 2,000 elements (Maths-Statistics-Tutor.com, 2020; Weis, 2012). Initial statistical analysis, including mean change and standard deviations for A1C and DSMQ scores were calculated in Excel, followed by a more detailed analysis using IBM SPSS version 23 (IBM, 2015). Mean scores for the provider survey were also calculated using Excel.

Outcomes/Results

Sample demographics. A total of 75 patients met the initial inclusion criteria. After excluding those patients empaneled to the non-participating provider, those who were found to meet exclusion criteria, and those who were unable to be reached, a total of thirty-one patients agreed to participate in the program. Four of those patients failed to return calls to make an initial appointment, leaving a total of 27 patients who participated in this project.

Demographic data was not kept on non-participants due to Air Force human protection requirements; however, reasons for non-participation were tracked. Non-participation included patients who declined to participate, could not be reached, or those who did not meet criteria (Figure 2). The primary reasons for non-participation were: patient declines (34%), unable to reach (23%), and PCM not participating (18%). Another common reason for non-participation was if the patient's diabetes care was managed by an off base endocrine specialist (11%).

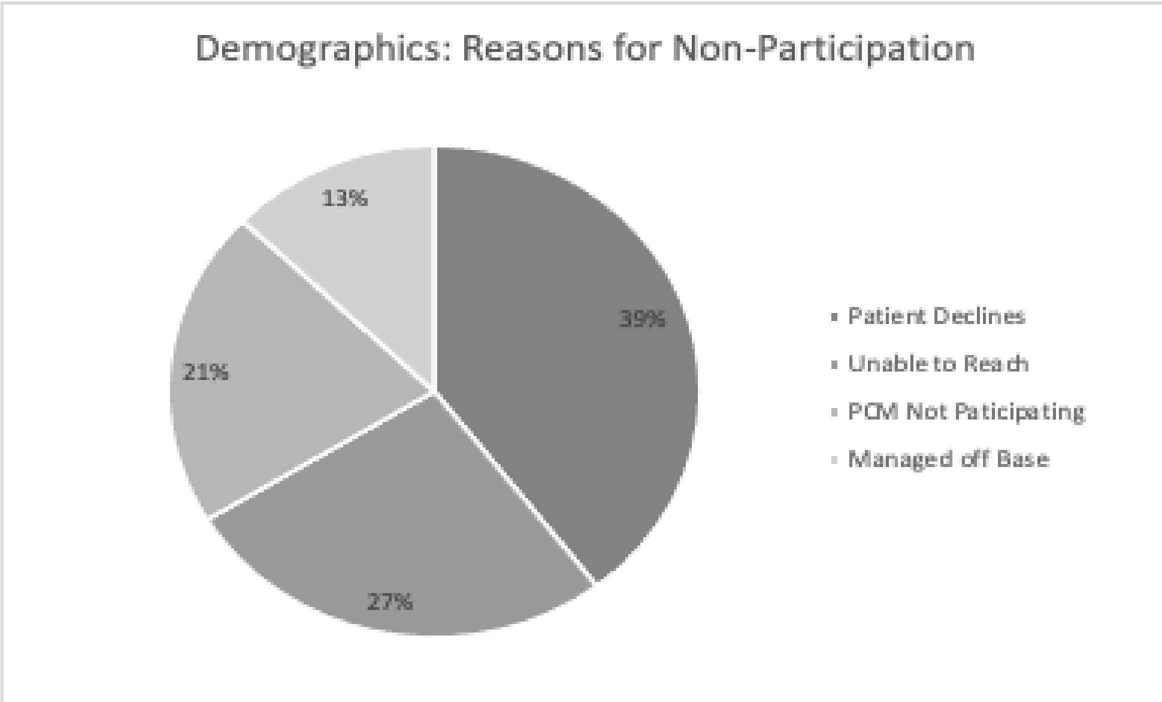

Figure 2. Demographics: Reasons for Non-participation

Descriptive statistics were used to evaluate the sample characteristics which included gender, race, and age. Females made up 56% of the sample, while 44% were male. White patients made up 82% of the sample, with black patients making up 11%, and Asian patients making up the remaining 7%. Data for sex and race are summarized in Figures 3 and 4. The mean participant age was 55 (*SD* = 9.30), with an age range of 25-72 years. This sample was representative of the clinic population.

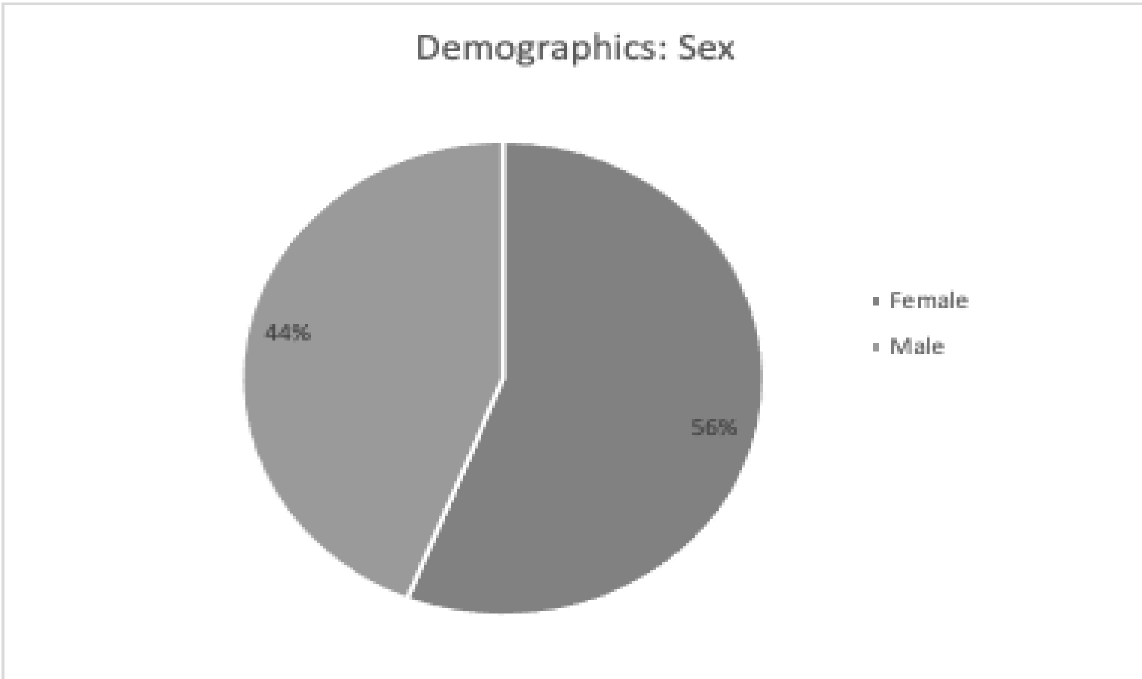

Figure 3. Demographics: Sex

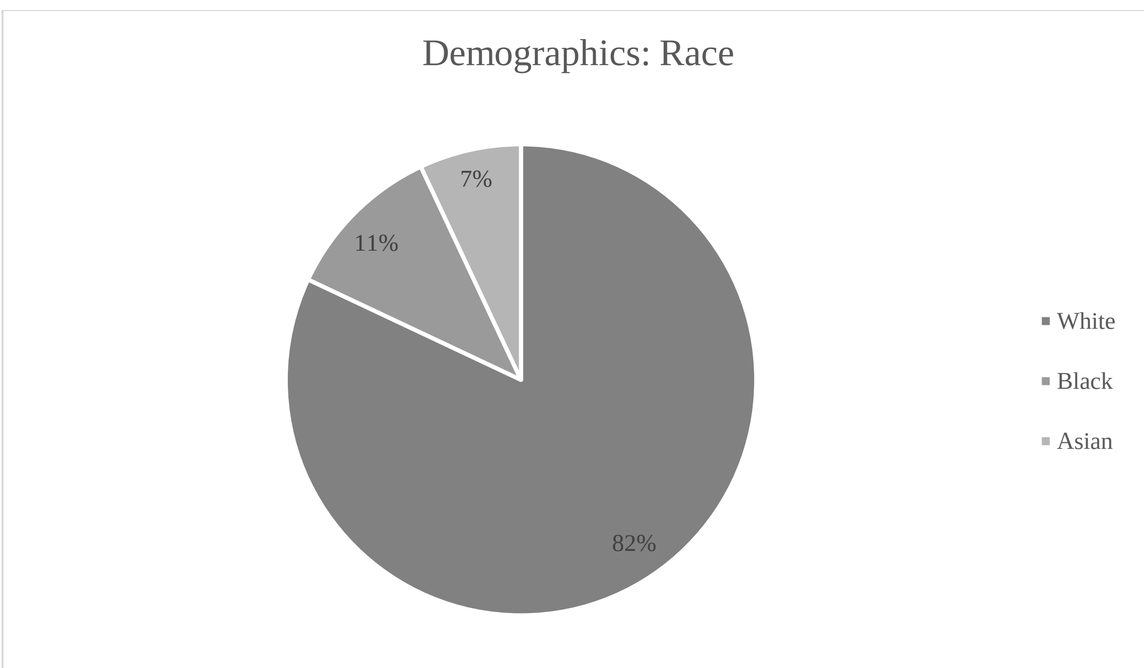

Figure 4. Demographics: Race

For the purposes of statistical testing, only complete data sets were analyzed. Four participants did not complete the post-DSMQ survey and eight participants did not complete a post-A1C lab. Seven of the thirteen participating providers completed the satisfaction surveys.

Provider visits. The goal for this program was to provide 4-5 virtual visits within 3 months. Patients participated in an average of 3.07 visits (*SD* = 1.17) and with a range of 1 – 5 visits, which indicated participants participated in less follow-up encounters than was the goal. This also demonstrated significant variability in relation to number of follow-ups from patient to patient.

A1C. The pre- and post- A1C mean difference scores (n = 19) were found to have a non-normal distribution based on the Shapiro-Wilk's test (.865, p = .012). Given the non-normal distribution, the Wilcoxon-Signed Ranks Test non-parametric alternative was used for statistical analysis. Data met the assumption of symmetry of difference scores around the mean.

The mean of the difference scores in A1C from pre- to post- was -0.75 (*SD* = 1.75). A Wilcoxon signed rank test revealed a significant difference in scores between the pre- and post-A1C (Z = - 2.38, p = .018), suggesting the intervention had a positive impact on A1Cs in this sample. Of the nineteen patients in the data set, sixteen did have a decrease in A1C, of which fourteen had a clinically significant A1C reduction (>/= -0.5%). Three patients had an A1C increase. Data are summarized below in Table 1.

Table 1

A1C Statistical Analysis

Statistic	Mean Change (Pre- to Post-)	Statistical Test	*p*-value
A1C	M = - 0.75, SD = 1.75	Z = - 2.38	p = .018

DSMQ. The DSMQ total sum score and three of the four subscales (Diet/Nutrition, Physical Activity, and Health Care) were found to be normally distributed ($p > .05$). Therefore, a paired *t-t*est was used to compare pre- and post- mean difference scores. The DSMQ total sum pre- and post- scores demonstrated a mean improvement of -1.07 (SD = 1.45) and a paired *t*-test demonstrated a statistically significant mean difference (t = -3.40, p = .002). This suggested that the intervention improved the patients' overall self-rating of diabetes self-care. The pre- and post- healthcare subscales showed a mean improvement (M = -1.30, SD = 1.86) and a paired *t*-test demonstrated a significant mean difference (t = -3.33, p = .003). This suggested that the intervention improved patients' rating of access and utilization of healthcare services/follow-up.

The diet pre- and post- subscales demonstrated a small, non-significant mean improvement (M = -0.66, SD = 2.03), (t = -1.236, p = .229). This suggested that the intervention did not have a significant impact on patients' dietary habits. The physical activity pre- and post- subscales demonstrated a small mean improvement (M = -.77, SD = 2.20) but likewise did not demonstrate a significant mean difference (t = -1.686, p = .106). This suggested the intervention did not have a significant impact on patients' self-rating of their physical activity habits.

The DSMQ glucose subscale had a non-normal distribution ($p < .05$) so the Wilcoxon signed rank test was utilized. The glucose subscale pre- and post- mean difference scores showed improvement (M = -1.75, SD = 2.30) which was statistically significant (Z = -3.212; p = .001). This suggested that the intervention led to an improvement in self-ratings of the patient's ability to manage their glycemic levels. Data are summarized below in Table 2.

Table 2

DSMQ Statistical Analysis

Statistic	Mean Change (Pre- to Post-)	Statistical Test	*p*-value
DSMQ Sum Score	*M* = -1.07, *SD* = 1.45	*t* = - 3.40	*p* = .002
DSMQ Glucose	*M* = -1.75, *SD* = 2.30	*Z* = - 3.21	*p* = .001
DSMQ Diet	*M* = -0.66, *SD* = 2.02	*t* = - 1.24	*p* = .229
DSMQ Healthcare	*M* = -1.30, *SD* = 1.86	*t* = - 3.33	*p* = .003
DSMQ Phys Activity	*M* = - 0.77, *SD* = 2.20	*t* = - 1.69	*p* = .106

Provider Survey. The provider survey mean score was 30.29 (*SD* = 3.25) out of 35 possible points, and all seven individual questions demonstrated a mean score of 4.0 or above out of 5 possible points, indicating a strong level of provider satisfaction with telehealth. Open ended comments were reviewed for common responses. One common theme was improved A1C values for the patients, exemplified by the comment *"my patient had significant A1C improvement, positive patient comments!"* Another theme was the positive aspect of having more frequent follow-ups, exemplified by the comment "*Great program allowing DM patients to be more closely monitored and motivated to make TLC and take control of their blood sugars."* Several providers commented on the impact of COVID-19 limiting follow-up labs, as exemplified by the comment "*I think follow ups are great for telemedicine, due to COVID with diabetic patients, would have wished to be able to review more labs more often, but patients were concerned for exposure."* One provider discussed the increased time commitment, stating "*I found the time commitment to go through the motivation interviewing and goal setting to take* *a lot of time, and may be difficult to maintain."* One comment that exemplifies the positive nature of the responses stated that "*every patient's A1C dropped 1-3% in 3 months, this works!!*".

Synthesis/Limitations/Discussion

Program data indicated statistically significant mean A1C difference scores pre- and post-intervention ($p = .018$). The mean decrease in A1C of 0.75% is also *clinically* significant (Little et al., 2013). Given the small number of subjects ($n = 19$) who completed both pre- and post-A1C measurements, several A1C outliers may have impacted the overall results in either a positive or negative direction. There was one significant outlier where a patient had an A1C increase from 8.3 to 12.7. In this particular case, the patient's pre-A1C was from July 2019 which was 9 months before the start of the project, although the patient did participate in three telemedicine visits. This patient did not obtain a pre-A1C early in the program as recommended, which may have been due to COVID-19 concerns, and it is possible their baseline A1C at program start may have actually been much higher. The patient with the largest decrease in A1C, from 9.9 to 6.2, also participated in three telemedicine visits and had a pre-A1C just prior to program initiation.

The overall DSMQ summary score change ($n = 23$) was statistically significant ($p = .002$), as were the subscales of glucose management ($p = .001$) and health care utilization ($p = .003$). The subscales of dietary ($p = .229$) and physical activity ($p = .106$) were not found to be significant. This may indicate that more focus is needed in future programs on diet, physical activity and/or resource education. COVID-19 lockdowns occurring in Alaska during this time may have limited some patients from engaging in exercise and/or following the recommended healthy diet. It is interesting that subscale ratings increased for health care contact/utilization, which may indicate the increased access provided by this program improved patients' self-rating of healthcare access. In addition, improved scores for glucose management coincided with the mean improvement in A1C scores.

Seven providers completed the satisfaction survey. Overall provider satisfaction was high, with an average score of 30.29/35. All seven questions received an average score of 4 or higher (satisfied or highly satisfied), indicating providers found the program to be acceptable. The provider comments reinforced the positive patient outcomes, particularly in the reductions in A1C. Comments also described frustrations regarding the lack of follow-up A1C's and scheduling issues related to COVID-19. Some excellent points about future areas for improvements including providing additional training on the approach to scheduling appointments and more structured education were provided.

A1C data were limited due to the small sample (n = 19) of individuals with complete A1C data sets. The COVID-19 barrier to patient compliance in obtaining the pre- and post- A1C labs was the biggest limitation of this project. The goal had been to obtain a pre-A1C within three months prior to the start of the program, and providers did recommend this to each patient. This project began at the same time as local "stay at home" orders began, and military base access was restricted. Due to this limitation, the most recent pre-A1C lab values within the past year were accepted for the baseline pre-A1C. The time differences in pre-A1C had potential to impact overall mean A1C change data. These same issues created limitations in obtaining a timely post-A1C, with some patients citing an unwillingness to come in for lab work due to COVID-19 safety concerns. A total of eight patients did not obtain the post-A1C.

Of the total population of 75 patients who were initially eligible to enroll in the program, fifteen patients declined to participate, and one provider did not participate which eliminated eight additional patients from participation. Four patients who initially enrolled in the program never scheduled an appointment and were excluded. Additional patients were screened out due to provider input or not meeting inclusion/exclusion criteria. In future programs, having a larger sample size with more closely controlled pre- and post- A1C lab data would further allow clinics to determine the generalizability to glycemic outcomes from this type of program.

Given that this was a clinical quality improvement project, it was important to look at the results from the standpoint of clinical significance. Given that an A1C reduction of 0.5% is known to be clinically significant (Little et al., 2013), a mean decrease in A1C of 0.75% in this program did demonstrate a clinically significant reduction in A1C, that was statistically significant as well. Looking at individual A1C scores, fourteen out of nineteen patients had a clinically significant reduction in A1C of at least 0.5% which indicates this program was successful in improving clinical measures of diabetes care.

The DSMQ is a reliable and validated survey on diabetes self-care (Schmitt et al., 2016), however as with any survey patient's may over or underestimate where their true levels lie. For example, the Hawthorne Effect (Weis, 2012) may lead patients to over-report improvements.

Conclusion

Although this program was designed as a QI project within the Family Health Clinic and was not designed to be generalizable outside this clinic, the overall data do indicate that the use of telemedicine modalities improved both A1C glycemic and self-care outcomes for patients. Given that the Military Health System utilizes the same CPG that was the foundation for this project DOD-wide, it increases the likelihood that these findings may be generalizable to other clinics with similar populations. The change in A1C was statistically significant ($p = .018$), indicating the program improved glycemic outcomes. The summary self-care score in the DSMQ was significant ($p = .002$) indicating the program improved patient reported self-care scores. The fourteen patients who demonstrated clinically significant outcomes of mean change in A1C (decrease of >/= -0.5%) further demonstrate the potential of the telemedicine program to improve clinical outcomes. Overall, the findings of this project indicated that further well designed QI projects and research studies are needed to assess the impact of these modalities. Future projects should seek to obtain larger sample sizes. Establishing programs with tighter A1C lab timing and possibly a more structured provider instrument may improve the generalizability of this type of diabetes telemedicine program. Data from this project could also be used to target future provider education in diabetes and telemedicine and validate the use of telemedicine/virtual medicine in improving diabetes care. In addition, further work could demonstrate if similar outcomes occur when an intervention such as this is conducted by other clinical staff such as Clinical Pharmacists or Registered Nurses.

Chapter 7: Implications for Nursing Practice

Chapter 7 discusses the implications for nursing practice from this project, utilizing the DNP Essentials (AACN, 2006) as a framework. The DNP Essentials are the foundation of the DNP degree program and a guide for DNP practice (AACN, 2006). In this chapter each DNP Essential will be related to various aspects of the project.

DNP Essentials

DNP Essential I. Essential I focuses on the scientific underpinnings of practice (AACN, 2006). Evidence-based practice supported by research and science is utilized to provide the best patient care, which is a fundamental priority for DNP providers (AACN, 2006). Evidence from the literature was utilized to develop the concept of this project and guide each step of its implementation. A critical review and synthesis of the literature was accomplished to determine the impacts of various telemedicine modalities on diabetes care, and to identify best practices. It was determined that the evidence supported the telemedicine modality for improving diabetic outcomes. Previous interventions (including meta-analyses, systematic reviews, and RCT's) were analyzed and utilized to guide this project's implementation. The data analysis portion of the project provided insight into the effectiveness of the interventions. This DNP project interwove the use of science and data with advanced practice nursing to implement a program that improves diabetic outcomes.

DNP Essential II. Essential II focuses on organizational and systems leadership for quality improvement and systems thinking (AACN, 2006). This project was a clinical quality improvement project. During the project, effective leadership and following a structured process within the organization helped lead to successful implementation. Utilizing Havelock's Change Theory (Havelock, 1973) as an organizational framework helped guide project planning, implementation, dissemination, and evaluation. This essential stresses the importance of looking at healthcare issues with a systems focus (AACN, 2006). This project was designed to improve a system of care (diabetes care within a primary care clinic) and has potential implications not only to the population within this clinic but also could be applicable to other military treatment facilities and civilian practices who serve similar populations. The data could be utilized to further develop this or other quality improvement projects in the future. Communication skills and working within an organizational hierarchy were required to obtain multiple approvals throughout a complex military structure. The evaluation of potential ethical and financial impacts were also important aspects of this project that could affect the system as a whole.

DNP Essential III. Essential III involves clinical scholarship and analytical methods for evidence-based practice (AACN, 2006). In this project data was collected on A1C mean change, DSMQ score mean changes, and provider survey ratings. These data were analyzed using appropriate statistical methods and software and synthesized to determine the impact the project interventions had on patient outcomes. The understanding and analysis of data is key to disseminating knowledge from this project and garnering support for practice change. AACN (2006) states that developing quality improvement projects to promote effective patient care is an essential part of DNP education and practice. This project incorporated the full spectrum of scholarship including analyzing evidence in literature, project design, implementation, data analysis, dissemination, and practice change.

DNP Essential IV. Essential IV focuses on Information Systems/Technology for the Improvement and Transformation of Healthcare (AACN, 2006). This project incorporated telemedicine - virtual visits, virtual provider education, and the use of technology to assist in data extraction and analysis. Phone visits were used in this project (as opposed to video visits or telemetry); the review of evidence showed the effectiveness of multiple technology modalities for improving diabetes care including telephone visits, video conferencing, telemonitoring, and other advanced technologies.

DNP Essential V. Essential V describes the use of health care policy for advocacy (AACN, 2006). Data from this project provides further evidence in support of the utilization of telemedicine in diabetes care and has the potential to expand the use of telemedicine within the military health system. The Defense Health Agency is driving evidence-based practice within the military and data are essential to obtaining buy-in for utilizing telemedicine modalities. This project required the project coordinator to work with multiple leaders and stakeholders at multiple levels to advocate for implementation. During dissemination, the data were provided to these same stakeholders with a strong recommendation to continue using these virtual visits for improving diabetes outcomes.

DNP Essential VI. Essential VI discussed interprofessional collaboration for improving patient and population outcomes. Interprofessional collaboration was absolutely key to the multi-disciplinary approach for this project (AACN, 2006). Many diverse stakeholders were involved throughout the medical group. This project involved physicians, physician assistants, nurse practitioners, nurses, technicians, health integrators, patient educators, pharmacists, and other allied health professionals. Collaboration with the patients involved in the study was also extremely important. A key of this essential is the ability to demonstrate leadership and communication skills within diverse groups to create change (AACN, 2006). The framework of this project also guided the early and continual involvement of stakeholders throughout the project. Several clinical pharmacists have approached the project coordinator to inquire about possibly creating a program for their own diabetes clinic that is based on this program. This is an example of how interdisciplinary programs can benefit more than one professional area of practice.

DNP Essential VII. Essential VII describes clinical prevention and population health for improving the nation's health (AACN, 2006). The overarching goal of this project was to decrease the burden of diabetes through secondary and tertiary prevention strategies, identify patients at higher risks for complications, and target these patients for intervention through telehealth visits. Certainly, the population with A1C's greater than 8 have a higher risk for complications. Improving population health and evaluating strategies that impact population health (AACN, 2006) were guiding aspects of this project.

DNP Essential VIII. Essential VIII describes advanced nursing practice (AACN, 2006). Advanced Nursing Practice is demonstrated by the project design and implementation being led by an APRN with the support of several other APRNs in the clinic. Key DNP practice essentials used in the project were: developing relationships to improve outcomes, assessing and educating patients, and designing interventions based on scientific framework (AACN, 2006).

Implications

The diabetes telemedicine project influences and promotes the field of Advanced Practice Nursing within the military healthcare system. This project involved utilizing all elements of the DNP Essentials to improve the practice of individual providers, but also to promote a larger organizational change enhancing the utilization of telemedicine. The data demonstrated that telemedicine can be used to improve certain aspects of diabetes self-management and showed a clinically and statistically significant improvement in A1C scores. As a DNP student, this project utilized and explored all of the DNP Essentials. Although it is too early to assess the long term implications of this program, the data support the continued use of this program within the Family Health Clinic and will hopefully be a useful starting point for other PI projects within the Military Health System. Although the project coordinator is no longer a provider in this clinic, communication continues on ways to continue using the key elements of this project in practice.

Limitations

The biggest limitations of this project were the small sample size and missing elements of data. The short term nature of this project did not explore the effects a longer program may have had on outcomes or whether clinical outcome improvements would be sustained over time. As discussed in the statistical analysis section, COVID-19 also significantly impacted this project. In addition to creating challenges for patients obtaining labs, COVID may have impacted other aspects of diabetes self-care. During lock-downs, gyms were closed throughout the local area and people were encouraged to stay home, which may have limited exercise capabilities for many patients. Dine in restaurants were also closed, limiting food service to take out and fast food establishments, which may have limited healthy food options. Income changes for some may have also led to changes in the ability to access healthier foods. Despite these limitations, this program demonstrates potential for improving clinical outcomes in diabetic patients.

Conclusion

The DNP Essentials provided structure and guided the development, implementation, and dissemination of this evidence based project. An understanding of the DNP Essentials (AACN, 2006) is key to DNP practice and strengthens individual health, population health, and NP practice.

Chapter 8: Summary and Conclusion

This DNP project focused on the development and utilization of a provider directed telemedicine follow-up program with the purpose of improving glycemic outcomes and self-care for uncontrolled Type 2 Diabetics. Diabetes is a global public health concern (Lee, Chan, Chua, & Chaiyakunapruk, 2017) and it is well documented that many diabetic patients never reach their treatment goals (Schmittdiel et al., 2008). Limited access to care, time constraints, and geographic distance often reduce the opportunity for providers to address all the aspects of diabetes management during face to face clinic encounters. The project coordinator developed the idea for this project after observing a lack of consistent use of telemedicine practices recommended in the VA/DOD CPG (2017) specific to diabetes follow-up in the Family Health Clinic. This chapter summarizes the key points and outcomes of the project.

Key Points

Project goals. The purpose of this project was to assess the acceptability and utilization of an intensive provider-implemented telemedicine follow-up program aimed at improving glycemic outcomes and self-care in adult patients with poorly controlled Type 2 Diabetes. The program was developed to provide a standardized approach to the follow-up care delivered by providers utilizing evidence-based telemedicine practices and included usual standards of care.

Methods. Havelock's Theory of Change (1973) was utilized as a framework for the development and implementation of this quality improvement project. The project utilized a pre-test post-test design with laboratory and survey data to measure change in A1C, diabetes self-care management scores (DSMQ questionnaire), and a post-test only provider satisfaction survey.

Adults with Type 2 Diabetes and a documented A1C greater than 8.0 meeting inclusion criteria were offered telephonic follow-up with their primary care provider every two to three weeks for three months. Providers utilized an instrument developed for this project which was based on the previous work of Gervera & Graves (2015). Telephone visits focused on medication management, diabetes self-management education such as self-monitoring blood sugar, healthy diet and exercise changes, and referral to various resources.

Implementation and resources. Once all necessary approvals were obtained, providers and staff were trained on the project goals, instrument, and the VA/DOD Clinical Practice Guidelines (2017). Project implementation began in April 2020 and continued for three months. Patients meeting inclusion criteria were contacted and pre -A1C and -DSMQ data were obtained. The timing of the program happened to coincide with the outbreak of COVID-19 worldwide. COVID-19 created a number of barriers to overcome, including the requirement for virtual provider/staff training and follow-up, and lack of complete lab data from some patients.

This project was cost neutral, and the time commitment from providers was consistent with estimates developed during the planning phase of the project. No unexpected costs were incurred. At the end of the three month program, a post-A1C and post-DSMQ were obtained as well as a post-survey from participating providers. Data were analyzed and the outcomes were disseminated.

Significance of results. The data demonstrated both statistically (p = .018) and clinically significant (mean A1C decrease of 0.75) improvement in A1C. In addition, statistically significant improvements in the DSMQ sum score and subscales of glucose management and healthcare utilization were demonstrated. This indicated that the program had positive outcomes for glycemic control and self-care for the participants. The provider surveys demonstrated overall provider satisfaction with this program. These findings demonstrate positive outcomes from utilizing telemedicine for more frequent follow-up with poorly controlled diabetics and are very promising for the future use of telemedicine to improve diabetes outcomes. Based on review of the data, the project goals were accomplished.

Self-reflection and summary of learning. The management of diabetes continues to be a challenge for clinicians. This project incorporated all eight DNP essentials (AACN, 2006) and utilized an evidence-based approach to develop an intense telemedicine follow-up program. This program demonstrated a positive impact on clinical outcomes of adults with uncontrolled Type 2 Diabetes. Educating providers and providing an instrument to guide the program helped ensure consistency. In the future, larger sample sizes and more consistency in the timing of labs may provide additional evidence to evaluate the impact of telemedicine in the management of diabetes.

Conclusion

This project demonstrated positive outcomes in both glycemic control, patient self-care, and provider satisfaction. Findings from this evidence based project support that the project goals were accomplished. This project demonstrated that Havelock's Theory (1973) provided a very successful framework for the planning, implementation, evaluation and dissemination of the project. Although Havelock's Theory is not specifically a nursing theory, it enabled successful navigation of the project within a complex military system involving multiple stakeholders and hierarchy, and through the sometimes chaotic operational tempo due to COVID-19. The success of the framework is demonstrated by the positive clinical outcomes and the successful completion of this project.

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Appendix A: Evidence Table

Table A-1

Evidence Table

Citation	Purpose of Study	Sample/Setting	Measurement of Major Variables	Data Analysis	Study Findings/Significance	Appraisal of worth to practice/ strength of the evidence + quality
Chamany et al. (2015)	Test the effectiveness of a tiered telephone intervention to improve glycemic control in adults with diabetes.	941 Adults with T1DM/T2DM w/ A1C > 7.0 in South Bronx, NY. 67% Latino, 28% AA. Intervention group rec'd 4 phone calls in 12 months if A1C > 7.0, and 8 phone calls in 12 months if A1C > 9.0. Trained health educators (supervised by physicians and diabetes educators) provided DSME.	DV = A1C; self-report Morisky Medication Adherence (four item scale), Summary of Diabetes Self-Care. Activities (SDSCA).	Random effects regression model; within person A1C change between groups, significance determined with Z-test.	Mean A1C decreased by 0.9% (SD = 0.1) in telephonic group, compared to 0.5 (SD = 0.1) in print only group. Telemedicine intervention (phone calls) associated with 0.4% A1C decrease when compared to standard print only intervention ($p = 0.01$). Those with A1C > 9.0 had more significant reductions. Percent of participants in telemedicine arm with A1C decrease of 1% was 37.4%; and 1.5% A1C decrease was 26.7% ($p = 0.01$). Both groups similar improvements in self-care activities (SDSCA) and med adherence (Morisky MA).	Limitations: may not be generalizable given somewhat homogeneous population primarily Latino in localized area of NYC; patient attrition. Strengths: large population over 1 year, RCT. Demonstrated statistical and clinical significance. Level 2 Evidence. MODERATE EVIDENCE.
Crowley et al. (2016)	Assess scalability and feasibility of implementing intense telemedicine intervention program using existing VA telemedicine capabilities.	50 Veterans; T2DM; A1C > 9.0 for at least 1 year; predominantly male; average age 60's; veterans from VA system in NC, predominantly African American. RN's delivered program w/ scheduled telephone calls every 2 weeks for 6 months - diabetes self-management education. Telemonitoring utilized. Physician guided med changes as indicated.	DV=A1C, diabetes self-care (Self Care Inventory - Revised)	Linear mixed models. Constrained intercept and unstructured covariance analysis - mean reduction in A1C and scoring on Self Care Inventory-Revised using CI's.	Telemedicine program led to A1C improvement - 1.0% at 3 months (95% CI -1.7 to -0.2%, $p = .012$). A1C improved average -1.0% at 6 months (95% CI -2.0 to -0.0, $p = .050$); Self Care Inventory-Revised estimated difference of 7, $p = .047$ - statistically significant.	Limitations: Unblinded randomization; single center pilot RCT, small and homogenous population. Designed more for feasibility than outcomes. Strengths: Limited attrition, RCT. Population translates well to the military retiree population. Statistical and clinical significance. Level 2 Evidence. MODERATE EVIDENCE.

Table A-1 (Continued)

Evidence Table

Egede et al. (2017)	Assess efficacy of combined telephone delivered behavioral skills education and intervention in reducing A1C in African American adults	African-American poorly controlled T2DM; > 18 years old; 255 participants; randomized to 4 groups - knowledge only, skills only, combined knowledge and skills, or control. South Carolina. Delivered by a trained Health Educator.	DV = A1C (measured at 3,6,12 months)	Chi square tests, ANOVA, ANCOVA for A1C change.	Significant reduction in A1C over time (- .07, P < .001) across all groups, but no significant differences were found between intervention and control groups (knowledge: 0.49, *p* = 0.123; skills: 0.23, *p* = 0.456; combined: 0.48, *p* = 0.105). Absolute change from baseline at 12 months for all treatment arms was 0.6%.	Limitations: focused only on African-American population, telemed interventions delivered by non-medical health coach (not nurse or provider). Strengths: RCT, Blinded treatment assignments, adequate statistical analysis, shows telemed interventions comparable to usual care. All treatment arms showed clinically significant A1C reduction over 12 months. Level 2 Evidence. MODERATE EVIDENCE.
Faruque et al. (2017)	To compare the impact of various methods of telemedicine versus usual care on A1C (glycemic control)	111 RCT's; adult patients; 37% in US with remainder in Korea, Canada and Australia; 13% used telephone based interventions; 37% nurses and 29% physicians.	DV = A1C	Mean difference in A1C; using random effects modeling. Univariate meta-regression.	Telemedicine lowered A1C by 0.57% within 3 months (CI not listed); telemed interventions that allowed medication adjustments (provider or nurse driven) had greater reduction in A1C (-0.23%, 95% CI -0.42% to - 0.05%, no *p* value reported but described as significant)	Limitations: assessed both type 1 and type 2 diabetes. Some statistics (CI, *p* values not fully provided in the article, however all individual study data are provided). Strengths: risk of bias assessed using Cochrane collaboration tool, when 3 specific studies were removed publication bias was not significant; large sample size, able to narrow down on specific interventions of telemedicine, identified provider/med adjustment impacts. Demonstrates clinical significance. Level 1 Evidence. MODERATE EVIDENCE.
Hansen et al. (2017)	To examine whether video consultations as ADD ON to standard care can improve diabetes control in poorly regulated T2DM.	165 patients T2DM; video telemedicine versus control as ADD ON to standard care; monthly video conference with nurse; Denmark; 32 weeks	DV = A1C	Descriptive statistics, ANOVA, normality tests, paired T-tests.	Significant decrease in A1C compared to standard care (0.69% vs 0.18%, *p* = .022). At six months, the difference was no longer significant. Two way ANOVA significant effects found (*p* = .003)	Limitations: selection bias, no medication titration. Strengths: studied telemedicine as ADD ON. Clinical and statistically significant. Level 2 evidence, RCT. Clinically and statistically significant. STRONG EVIDENCE.

Table A-1 (Continued)

Evidence Table

Jeong et al. (2018)	To determine effectiveness of SmartCare service on glucose control based on telemedicine and telemonitoring versus conventional treatment in T2DM	338 patients T2DM: usual care vs telemonitoring alone vs telemedicine video conference w/ physician instead of usual visits; Endocrinologist in telemedicine arm	DV = A1C	Mean A1C +/- SD; ANCOVA	All 3 groups showed a significant reductions in A1C, however adjusted A1C similar across all groups - no statistical significance between groups (-0.66% – 1.03% in the control group, -0.66% – 1.09% in the telemonitoring group, and -0.81% – 1.05% in the telemedicine group, $p < 0.001$ each).	Limitations: selection bias, short follow-up. Strengths: compared provider directed telemedicine to telemonitoring and usual care. Level 2 evidence, RCT. Clinically and statistically significant reductions across all groups, though no significant difference between groups. MODERATE EVIDENCE.
Kempf et al. (2017)	Assess efficacy of TeLiPro 12 week multi-modal telemedicine intervention in poorly controlled advanced T2DM patients	202 patients; Type 2 DM; Germany; ages 25-79; poorly controlled DM A1C > 7.5. Weekly care calls from diabetes coaches - self management education. F/U A1C at 26/52 weeks.	DV = A1C (primary outcome at 12 months); also reassessed at 26 and 52 weeks.	CI, mean A1C difference, Mann-Whitney for between groups.	A1C reduced by 1.1% ($p < .0001$). Estimated treatment difference in the adjusted model was 0.8% (95% CI 1.1 - 0.5, $p < 0.0001$). At 26 and 52 weeks treatment superiority at 0.6% (95% CI 1.0 - 0.3, $p < 0.0001$; 95% CI 0.9-0.2, $p < 0.001$).	Limitations: attrition, greater in control group. Multiple interventions in a program makes it difficult to attribute reduction to one specific factor. Strengths: RCT with adequate statistical analysis. Level 2 Evidence. Shows effectiveness in advanced DM. Clinically significant reduction reported. Showed effectiveness persisted over time to 52 weeks. STRONG EVIDENCE.
Lee et al. (2017)	Determine effectiveness of various telemedicine strategies in improving glycemic outcomes in Type 2 Diabetics in outpatient setting	RCT's examining telemedicine for improving outcomes in T2DM outpatient settings; pubs = 107; 20,501, mean age 42-71; studies from 1998-2016; 88% studies measured A1C; 50% studies in North America; both males and females; median follow up = 6 months or less; providers - nurses (48%), physicians (17%), allied health (15%), support staff (19%). Heterogenous.	DV=absolute change in A1C from baseline to end of study; IV=telemedicine modality	Permutation based meta-analysis with random effects model; statistical heterogeneity evaluated using I2 statistics; multivariable model with adjusted R2; mean difference A1C with 95% CI's.	Telemedicine was superior to usual care improving A1C , mean difference -0.43% (95% CI, -0.64% to -0.21%), $p < .001$; substantial heterogeneity (Q=88,052, I2=99.9%, H2=966, $p < .001$). Larger effects in shorter duration studies. Meta-regression analysis showed no statistically significant inconsistencies for all outcomes. No telemedicine strategies were significantly better than the others.	Limitations: Heterogeneous studies - variations in types of telemedicine, type of intervention provider, lengths of studies, population/locations. Usual care is not consistently defined. Variability of bias assessment in studies. Lack of long term follow-up. Strengths: reviewed large population from multiple RCT's. Largest review of kind to date. Meta-regression analysis conducted (93 trials), no statistically significant inconsistency for outcomes. Level 1 Evidence. Somewhat clinically reduction A1C 0.37% - 0.71%. MODERATE TO STRONG EVIDENCE.

Table A-1 (Continued)

Evidence Table

Liu et al. (2016)	Investigate impact of telemedicine versus face to face endocrinology NP visits	250 initial endocrine consultation patients; 94% male; mean age 62.8; Denver VA System.	DV = A1C	Student's *t*-test, Fisher's exact test, linear regression model, mean A1C change w/ 95% CI.	Decrease in A1C from baseline to visit 1 in telemed group was 0.277 percentage points greater than decrease in A1C from baseline to visit 1 in the clinic visit group (95% CI: 0.741 percentage points greater drop to 0.186 percentage points lesser drop). $p = .2347$ (not statistically significant). Showed estimated $94.79 per visit saved per patient in travel costs.	Limitations: retrospective, non-randomized design. Short term. Strengths: provider driven telemedicine consultations, indicates telemedicine care is equivalent to standard care with specialty consults for management. Veteran population, reasonable sample size. Level 4 evidence. MODERATE EVIDENCE.
Odnoletkova et al. (2016)	Study effect of target drive nurse directed COACH program telecoaching in T2DM in outpatient setting	684 participants; Belgium; outpatient setting; adults age 18-75 years; five RN led coaching sessions	DV = A1C	Linear model for repeated measures with unstructured covariance matrix - continuous outcomes. Mann Whitney U and Fisher Exact Tests	At 6 months, between-group difference in effect on A1C between intervention and control was -2 (95% CI -4 to -1) mmol/mol [-0.2 (95% CI -0.3 to -0.1)%; p =0.003.	Limitations: Authors discuss concern for positive self-selection (patients self-recruited, indicating more motivated patients/selection bias). Strengths: large sample, heterogenous, utilized reproducible program. Level 2 evidence. MODERATE EVIDENCE.
Polisena et al. (2009)	Assess benefits of home telehealth versus usual care	26 studies (1998-2008); 21 studies home telemonitoring, 5 RCT's tele support; 5,069 patients with diabetes;	DV = A1C	95% CI's, statistical heterogeneity between studies assessed using *I2*	Tele support 4 RCT's: 2 reported lower mean A1C (7.8 +/- 0.8 vs 8.9 +/- 1.0, $p < .01$) and (7.6 +/- 1.1 vs 8.1 +/- 1.5, $p = .06$) and 2 reported higher A1C (8.8 +/- 0.9 vs 7.6 +/- 1.0, $p = .252$) and (6.9 +/- 1.5 vs 6.6 +/- 1.1, p not reported)	Limitations: older SR (10 years), only tele support data is relevant to this project, heterogenous studies; assessed multiple variables not just A1C. Mixed results. Strengths: adequate statistical analysis, larger sample. Level 1 Evidence. MODERATE EVIDENCE.
Rasmussen et al. (2015)	Test implementation of home telemedicine vs usual care	40 T2DM patients; outpatient setting.	DV = A1C	Mean change A1C, *t*-test, Mann-Whitney *U* test or ANOVA.	A1C was statistically lower in telemedicine group (-15% vs -11%). Limited discussion of statistical analysis results.	Limitations: short observation period, small sample size, limited discussion of statistical analysis. Strengths: no attrition. Level 2 Evidence. WEAK EVIDENCE.

Table A-1 (Continued)

Evidence Table

Sood et al., 2018	Compare health related outcomes in patients with diabetes undergoing synchronous video conference consultation versus patients receiving specialist care via the usual diabetes clinic consultation.	199 T1DM and T2DM patients in telemed arm; 83 in usual care; outpatient specialist clinic.	DV = A1C, patient satisfaction.	Mean +/- standard deviation A1C; t-tests, chi square tests.	Both groups small decrease in A1C; Statistically insignificant differences in A1C between groups (telemedicine -1.01% vs usual group - 0.68%, $p = .19$). Surveys showed 99.3%. Patients felt easier to get care.	Limitations: A1C of both groups was not matched, smaller control group. Strengths: compared telemedicine vs usual care, provider driven consultations. No significant difference between the two groups. Level 2 Evidence. MODERATE EVIDENCE.
Stone et al. (2010)	Compare efficacy of monthly home telemonitoring visits with active medication management by a nurse practitioner versus monthly diabetes educator telephone contact.	137 T2DM; 64 NP group and 73 diabetic educator group	DV = A1C.	Mean change A1C, difference scores, between group comparisons.	A1C significantly lower in NP management arm at 3 and 6 months (0.7 % $p < .001$), both groups A1C improved significantly from baseline.	Limitations: No blinding, participant attrition, missing A1C values. Does not differentiate if increased provider contact, med management, or telemonitoring contributed to improved results in NP group. Only 1 NP did intervention. Strengths: RCT, use of NP performing intervention which includes med management, DSME education, monitoring SMBG. Level 2 EVIDENCE. STRONG EVIDENCE.
Su et al. (2016)	Assess effect of telemedicine on diabetes management (T1DM and T2DM): ID features associated with better outcomes.	55 RCT's evaluating effect of telemedicine on A1C; 9,258 pts with diabetes (T1DM & T2DM); length of study 6 months or less = 30, more than 6 months = 25; telecon = 18 RCT's, telemon = 37 RCT's; 17 in US, 14 in Europe, 13 in Asia, 1 in Australia; age range 11.9-71.	DV = A1C	Effect sizes, standardized mean difference using Hedges g - mean difference A1C between intervention and control arms. Stratified results within subgroups - type of DM, age, duration, and type of telemed intervention. Q statistics used to assess heterogeneity.	Telemedicine showed more signif. A1C reduction (Hedges $g =$ -0.48, $p = < .001$). Telemed most effective treating T2DM (g = -0.63, $p = < .001$). Telemedicine more effective in age > 40 (Hedges g = -0.53, $p < .001$); programs 6 months or less more reduction (g = - 0.56, $p < .001$). Teleconsultation is more effective than telemonitoring (g = -0.62, $p < .001$) vs (g = -0.40, $p < .001$). No statistical significance in results between low and high impact journals.	Limitations: Heterogeneity within 55 RCT's - particularly populations (T1DM and T2DM). Risk of publication bias in RCT's. Subgroup analysis did not account for differences in baseline A1C across groups. Strengths: multiple RCT's Evidence supports effectiveness particularly in T2DM/telecon/age > 40 translates to population focus. Level 1 Evidence. Clinically significant reduction in A1C. STRONG EVIDENCE.

Table A-1 (Continued)

Evidence Table

Suksombom et al. (2014)	To assess effectiveness of telephone call intervention compared to standard care on glycemic control in diabetic patients.	5 RCT's; specifically focused on telephone intervention.	DV = A1C	Mean difference in change of values for A1C with 95% CI's; fixed effect and random effect models were used. I2 was used to assess variability.	Telephone intervention did not significantly improve glycemic control pooled mean difference - 0.38%, 95% CI -0.91% to 0.16%). I2 = 85% indicating significant heterogeneity of studies.	Limitations: only 5 small RCT's - Significant heterogeneity of studies; 3 studies reported as low risk of bias, 2 studies high risk of bias; poor discussion of statistics and population. Strengths: specifically focused on telephone based interventions. Limited clinical significance. Level One Evidence. WEAK EVIDENCE.
Trief et al. (2013)	Evaluated response of elderly Hispanic and African American diabetes patients to telemedicine intervention.	1665 Medicare patients, African American and Hispanic; age 55 or >, New York. 4-6 week follow up visits with RN/Dietician for 5 years via video conference	DV = Summary of Diabetes Self Care Scale (SDSCA) - baseline and 5 year follow-up. A1C correlated to self-care scale.	Non-linear models for covariance were used.	Number days performing self-care increased in the treatment group ($p < .001$). Limited discussion of statistics.	Limitations: SDSCA is self-report scale. Population homogenous. Limited discussion of statistical analysis. Measured A1C but did not focus on glycemic change. Strengths: large sample, long term follow up. Level 2 Evidence. WEAK EVIDENCE.
Wu et al. (2010)	To examine the impact of telephone follow up interventions on glycemic control in Type 2 Diabetes	7 RCT's; specifically focused on telephone intervention; 1764 patients. 1334 with T2DM. Mean age 63 years old, 50/50 male and female. Therapy adjustment part of 4 studies. 3 with physician input/interaction. Average time visit 20 mins.	DV = A1C	Pooled standardized effects using random effects models	Mean difference A1C equivocal change - 0.44 (95% CI -0.93 to 0.06 $p = 0.08$) in favor of telephone intervention. Statistically significant finding that the more intensive interventions by healthcare provider showed standard mean difference -0.84 (95% CI - 1.67 to 0.0, p = 0.05).	Limitations: significant heterogeneity in studies. Strengths: clinically significant showing more intense provider involved interventions have better outcomes. SR/MA large diverse populations. Level 1 Evidence. MODERATE EVIDENCE.

Table A-1 (Continued)

Evidence Table

Zhai et al. (2014)	To evaluate clinical effectiveness in improving glycemic control using telemedicine modalities	35 RCT's (12 were telephone based consultation); Participants with T2DM 18 years or older; treatment duration 3-36 months.	DV=A1C	Difference in mean A1C with 95% CI; heterogeneity assessed using $x2$, Cochran Q statistic, and quantified by *I*2. Random or fixed effects models were used based on heterogeneity.	Decrease in A1C across all studies of - 0.37% (95% CI - .49 to - .25, $p < .001$). Telephone based subgroup decreased A1C -0.53 (95% CI - 0.81 to -0.26, $p < .001$).	Limitations: Significant heterogeneity in studies lengths and telemedicine modalities used; none of RCT's able to blind participants - concern for Hawthorne effect; evaluation of the studies indicated risks of publication bias; only 12/35 studies were telephone based, rest were internet based (though some of the internet studies did involve phone follow up on results) Strengths: Validity of each study assessed using risk of bias assessment tool. Detailed discussion reliability of meta-analysis; detailed discussion of statistics and process used to limit bias. Telephone subgroups had clinically significant A1C drop. Level 1 evidence. STRONG EVIDENCE.

Appendix B: Synthesis Table

Table B-1

Synthesis Table

Studies	Design	Sample	Level of Evidence	Provider	Follow Up Frequency	Telemedicine Modality	Intervention(s)	Outcome (Glycemic Control = A1C)
Chamany et al. (2015)	RCT	*N* = 941; T1DM and T2DM	Level 2 / Moderate	Health Educator	4x/12 mo or 8x/12 mo	Telephone	DSME - med compliance, goal setting, problem solving, diet, exercise.	↓ for A1C > 9.0 statistically significant
Crowley et al. (2016)	RCT Pilot Study	*N* = 50; T2DM	Level 2 / Moderate	RN w/ Physician Guided Med Mgmt	Every 2 weeks for 6 mo	Telephone/ Telemonitoring	Telephonic; RN DSME w/ physician guided medication management	↓
Egede et al. (2017)	RCT 2x2 Factorial Design	*N* = 255; T2DM	Level 2 / Moderate	Health Educator	12 telephone delivered interventions	Telephone	Telephonic; Health Educator DSME	No statistically significant difference between groups; all 4 arms showed clinically significant A1C ↓
Faruque et al. (2017)	SR/MA	*N* = 111 RCT; T1DM and T2DM	Level 1 / Moderate	Variable	Variable	Variable	Various telemedicine interventions including telephonic; nurses, physicians, and allied health	↓
Hansen et al. (2017)	RCT	*N* = 165; T2DM	Level 2 / Strong	RN	Monthly for 8 months	Video conferencing	Video telemedicine: RN	↓
Jeong et al. (2018)	RCT	*N* = 338; T2DM	Level 2 / Moderate	Physician/ Endocrinologist	24 weeks (consultation at 8/16/24 weeks)	Video conferencing and telemonitoring	Video telemedicine: Endocrinologist	No statistically significant difference between groups; all 3 groups had significant A1C reductions
Kempf et al. (2017)	RCT single blind parallel group	*N* = 202; T2DM	Level 2 / Strong	Diabetes Coaches	Weekly for 12 weeks; repeat measures at 26/52 weeks	Telephone/ Telemonitoring	Telephonic visits w/ diabetes coaches with DSME, telemonitoring.	↓
Lee et al. (2017)	SR/MA	*N* = 107 RCT; T2DM	Level 1 / Moderately Strong	Variable (Physician, RN, educators)	Variable	Variable	Multiple telemed modalities; heterogenous	↓
Liu et al. (2016)	Retrospective Cohort	*N* = 250	Level 4 / Moderate	Endocrinologist / NP	Variable	Video conferencing	Telemedicine (video) endocrine NP's	No statistically significant difference between face 2 face and video telemed Endocrine provider

Table B-1 (Continued)

Synthesis Table

Odnoletkova et al. (2016)	RCT parallel group	*N* = 684; T2DM	Level 2 / Moderate	RN Diabetes Educator	6 and 18 month measures	Telephone	Telemedicine coaching by RN - 5 sessions	↓
Polisena et al. (2009)	SR/MA	*N* = 26 studies (4 tele support)	Level 1 / Moderate	Variable	Variable	Variable	Multiple telemed modalities; heterogenous	2 ↓ and 2 ↑
Rasmussen et al. (2015)	RCT	*N* = 40; T2DM	Level 2 / Weak	RN W/ Physician Support	3 -4 visits	Video conferencing and telemonitoring	Video telemedicine; RN w/ physician support	↓
Sood et al. (2018)	Cluster RCT	*N* = 282; T1DM and T2DM	Level 2 / Moderate	Endocrinologist / NP	Variable, up to weekly consults	Video conferencing	Video telemedicine: NP and Endocrinologist	No significant difference between telemedicine and usual clinic care
Stone et al. (2010)	RCT	*N* = 137; T2DM	Level 2 / Strong	NP management and med titration versus Diabetes Educator	Monthly calls, 3 and 6 month measures	Telephone, Telemonitoring	Telemedicine and Telephone Visits monthly with NP versus monthly RN educator telephone visits	Significant ↓ A1C in NP group vs RN group; both groups ↓ A1C
Su et al. (2016)	SR/MA	*N* = 55 RCT; T1DM and T2DM	Level 1 / Strong	Variable	Variable	Variable	Multiple telemed modalities; heterogenous	↓
Suksombom et al. (2014)	SR/MA	*N* = 5 RCT	Level 1 / Weak	Variable	Variable	Variable.	Telephonic only	No statistically significant difference
Trief et al. (2013)	RCT	*N* = 1665; T2DM	Level 2 / Weak	RN educators, dieticians, supervised by Endocrinologists	Every 4-6 weeks for 5 years	Video conferencing and telemonitoring	Video telemedicine; RN/Dietician/Endocrine support	Improved self-care measure; self-reported adherence improved compared to usual care
Wu et al. (2010)	SR/MA	*N* = 7 RCT; T1DM and T2DM	Level 1 / Moderate	Variable	Variable	Telephone	Telephone follow up vs usual care	More intense telephone intervention had statistically significant A1C ↓
Zhai et al. (2014)	SR/MA	*N* = 35 RCT	Level 1 / Strong	Variable	Variable.	Variable.	Multiple telemed modalities; heterogenous	↓

Appendix C: Organizational Hierarchy (Step One of Havelock's Theory)

US Air Force HRPO

673 Medical Group Commander

673 Medical Group Deputy Commander

673 Medical Group Chief Nurse 673 Medical Group Chief of Medical Staff

673 Medical Operations Squadron Commander

673 Medical Operations Squadron Superintendent

673 Family Health Clinic Flight Commander 673 Family Health Clinic Medical Director

673 Family Health Clinic Providers 673 Family Health Clinic Care Teams

Appendix D: Permission to Modify Instrument

From: Jonathan Beatty <jrbeatty@alaska.edu>

Sent: Sunday, November 17, 2019 8:54 PM

To: Gervera, Kelly J. <Kelly.Gervera@va.gov>; agraves@ua.edu

Subject: [EXTERNAL] Integrating Diabetes Guidelines into Telehealth Screening Tool (2015)

Dr. Gervera,

I am a DNP student at the University of Alaska, and a full time FNP in the US Air Force. I am working on my DNP project which involves creating a provider directed intense telemedicine follow up program for poorly controlled type 2 diabetes in our Air Force Family Medicine Clinic. The tool you developed in your 2015 article for the EHR correlates well with some of the goals of this project. I was wondering if you would be willing to allow me to modify your instrument for use in my project. We utilize the VA/DOD clinical guidelines as well. I would make a number of additions/deletions to reflect current guidelines and it would be more provider specific. I certainly would credit your work, I just wanted to make sure it wasn't copyrighted or restricted from being shared. Either way I would enjoy hearing back from you.

Respectfully,

Jonathan Beatty

Gervera, Kelly J. <Kelly.Gervera@va.gov>

Wed, Nov 20, 2019, 3:38 AM

to me

I think it would be great. Go for it. I developed my instrument to guide nurses in their f/u calls and to get them to dig deeper in their management of patients. Of course, there is a fine line to making it simple and convenient (so as not to be rejected by staff) and still cover guidelines. And you are correct, the VA is ahead of DoD and as far as telehealth, and they are not slowing down. Not sure of your time zone but you can call me most times. My cell phone gives the best reception, [redacted]

Kelly

Appendix E: Telemedicine Diabetes Program Instrument

Telemedicine Diabetes Program Instrument

Patient Name: Date of Birth:

Encounter Date: Visit #: 1 2 3 4 5 6

A1C Goal:

Record Review (if overdue please order as clinically indicated):

Date/result of last A1C (every 3 months):

Date last lipid panel (annually):

Date of last microalbumin (annually):

Date of last CMP/BMP (annually):

Date of last eye exam (annually):

Date of last foot exam (annually):

Date of last IN PERSON provider physical exam (physical exam due every 6 months):

Date of last flu vaccination (annually):

Date of pneumonia vaccination:

Diabetes Management:

____ Discuss most recent A1C result and set patient specific A1C goal

____ Discuss/order recommended screenings listed above if due/overdue

____ Discuss home blood glucose monitoring (SBGM) results and goals

____ Discuss concerns related to weight management and set weight loss goals

____ Discuss concerns related to exercise and set personalized goals

____ Discuss concerns related to diet, and provide healthy diabetic diet recommendations (ADA, Mediterranean, etc.)

____ Refer to Nutrition or Diabetes Class if indicated

____ Review medications, assess concerns related to medications or side effects, and discuss importance of medication adherence

____ Assess for any hypoglycemic events and discuss management, if indicated

____ Adjust medications or dosing if clinically indicated

____ Refer to Clinical Pharmacist for aggressive management if clinically indicated

____ Discuss concerns related to anxiety, depression, stress management, or psychosocial issues and offer BHOP appointment if indicated

Set Individualized Goals:

1.

2.

3.

Schedule virtual follow up visit in 2-3 weeks:

Appendix F: Provider Telemedicine Satisfaction Survey

Provider Telemedicine Satisfaction Survey

Please answer the following questions using the following Likert scale:

1. Very dissatisfied
2. Dissatisfied
3. Neither satisfied nor dissatisfied
4. Satisfied
5. Very satisfied

How would you rate the overall acceptability of this telemedicine program?

1 2 3 4 5

How would you rate the acceptability in terms of the interaction with your patients?

1 2 3 4 5

How would you rate the acceptability in terms of the time spent with your patients?

1 2 3 4 5

How would you rate this intervention's impact on your patient's diabetic self-management?

1 2 3 4 5

How would you rate this intervention's impact on your patient's glycemic control?

1 2 3 4 5

How would you rate your satisfaction with the tool utilized in this program?

1 2 3 4 5

Did having the DSMQ questionnaire impact your clinical decision making?

1 2 3 4 5

TOTAL SCORE: / 35

Please provide any additional comments or feedback below:

Appendix G: Diabetes Self-Management Questionnaire (DSMQ)

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the **last 8 weeks**, please specify the extent to which each statement applies to you. Note: If you monitor your glucose using continuous interstitial glucose monitoring (CGM), please refer to this where 'blood sugar checking' is requested.	applies to me very much	applies to me to a conside r-able degree	applies to me to some degree	does not apply to me
1. I check my blood sugar levels with care and attention. ☐ *Blood sugar measurement is not required as a part of my treatment.*	☐3	☐2	☐1	☐0
2. The food I choose to eat makes it easy to achieve optimal blood sugar levels.	☐3	☐2	☐1	☐0
3. I keep all doctors' appointments recommended for my diabetes treatment.	☐3	☐2	☐1	☐0
4. I take my diabetes medication (e. g. insulin, tablets) as prescribed. ☐ *Diabetes medication/insulin is not required as a part of my treatment.*	☐3	☐2	☐1	☐0

5. Occasionally I eat lots of sweets or other foods rich in carbohydrates.	☐3	☐2	☐1	☐0
6. I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter). *☐Blood sugar measurement is not required as a part of my treatment.*	☐3	☐2	☐1	☐0
7. I tend to avoid diabetes-related doctors' appointments.	☐3	☐2	☐1	☐0
8. I do regular physical activity to achieve optimal blood sugar levels.	☐3	☐2	☐1	☐0
9. I strictly follow the dietary recommendations given by my doctor or diabetes specialist.	☐3	☐2	☐1	☐0
10. I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control. *☐Blood sugar measurement is not required as a part of my treatment.*	☐3	☐2	☐1	☐0
11. I avoid physical activity, although it would improve my diabetes.	☐3	☐2	☐1	☐0
12. I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets).	☐3	☐2	☐1	☐0

☐*Diabetes medication/insulin is not required as a part of my treatment.*				
13. Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	☐3	☐2	☐1	☐0
14. Regarding my diabetes care, I should see my medical practitioner(s) more often.	☐3	☐2	☐1	☐0
15. I tend to skip planned physical activity.	☐3	☐2	☐1	☐0
16. My diabetes self-care is poor.	☐3	☐2	☐1	☐0

Appendix H: IRB and HRPO Approval

Research & Graduate Studies

UNIVERSITY of ALASKA ANCHORAGE

3211 Providence Drive Anchorage, Alaska 99508-4614 T 907.786.1099, F 907.786.1791 www.uaa.alaska.edu/research/ric

DATE: March 26, 2020

TO: Jonathan Beatty, MSN

FROM: University of Alaska Anchorage IRB

PROJECT TITLE: [1571403-2] A Telemedicine Follow Up Program to Improve Glycemic Outcomes in Adult Patients with Uncontrolled Type 2 Diabetes

SUBMISSION TYPE: New Project

REVIEW TYPE: Expedited Review

ACTION: DETERMINATION OF NOT HUMAN SUBJECTS RESEARCH

DECISION DATE: March 26, 2020

Thank you for your submission of your HSR Determination Request. The University of Alaska Anchorage IRB has determined this project does not meet the definition of human subject research under the purview of the IRB according to federal regulations.

We wish you success in executing your program evaluation of this important intervention for our veterans facing health challenges.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact Robert Boeckmann at (907) 786-1793 or rjboeckmann@alaska.edu. Please include your project title and reference number in all correspondence with this office.

Robert J. Boeckmann, Ph.D Chair, Institutional Review Board Department of Psychology University of Alaska Anchorage 3211 Providence Drive Anchorage, AK 99508-8224

USAF Pentagon AF-SG Mailbox AFMSA-SGE-C <usaf.pentagon.af-sg.mbx.af

to Jonathan, me, Sarah, Brett, Peter, Jill, USAF

SUBJECT: Air Force Medical Readiness Agency (AFMRA/SGE-C) Human Research Protection Official (HRPO) Review of FSG20200006, “A Telemedicine Follow Up Program to Improve Glycemic Outcomes in Adult Patients with Uncontrolled Type 2 Diabetes” submitted by Jonathan Beatty, MSN, University of Alaska Anchorage

References: (a) 32 CFR 219, 19 January 2017, Protection of Human Subjects

(b) DoDI3216.02_AFI40-402, 10 September 2014, Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research

1. In accordance with Reference (a) and Enclosure 3, Section 4c(1) of Reference (b), the AFMRA/SGE-C HRPO has reviewed and concurs with the IRB’s determination that the activity does not qualify as research under Section 219.102(l) of Reference (a).
2. The activity is a clinical quality improvement project that will assess the acceptability and effectiveness of implementing the VA/DoD clinical practice guidelines for Type 2 Diabetes in the 673d Medical Group, specifically implementing an intense provider-conducted telephonic follow up program to improve glycemic outcomes and self-management of patients with uncontrolled Type 2 Diabetes. There is no intent to develop or contribute to generalizable knowledge. The results of this activity will not be generalizable to uncontrolled Type 2 diabetic

patients outside of the 673 MDG. The results will only be applicable to uncontrolled Type 2 diabetic patients within the 673 MDG and this activity was customized for the specific patients at 673 MDG. For example, while the providers will be using the same instrument to guide their telephonic visits, each provider will use the instrument solely as a guide and will customize the use of the tool for each individual patient's clinical needs. The list of eligible patients, while meeting the eligibility criteria defined within the write up, will be further narrowed at the discretion of the participating providers who will exclude patients whom they conclude are poor candidates for this approach, which is actually how the tool will be used at 673 MDG if the results of the quality improvement project are favorable.

3. Contact AFMRA/SGE-C at usaf.pentagon.af-sg.mbrx.afmsa-sge-c@mail.mil for questions regarding the conditions of this approval and to discuss any substantive change to this activity, prior to implementation, to ensure such change does not impact the determination herein or compliance with the above References.

4. In addition, please refer to the Terms of Air Force HRPO Approval referenced below regarding the responsibilities of the AF-supported Institution(s) and the Principal Investigator conducting this activity, to include reporting requirements to the HRPO. Failure to comply could result in suspension of Air Force support for this activity.

5. For questions regarding this HRPO review and approval, please contact Ms. Jill Conover, at (703) 681-8056 or via e-mail atjill.r.conover.ctr@mail.mil, Mr. Peter Marshall (E-mail: peter.j.marshall.civ@mail.mil/phone: 703-681-6277/DSN 761) or usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil.

Peter Marshall, CIP

Program Manager, AF Research Oversight & Compliance Division

Air Force Medical Readiness Agency (AFMRA/SGE-C)

7700 Arlington Boulevard

Falls Church, VA 22042

(703) 681-6277/DSN 761

peter.j.marshall.civ@mail.mil

Appendix I: Costs Table and Project Timeline

Table I-1

Costs Table

Element	Cost	Time
Equipment	0 $	0 Hours
Provider Care	0 $	3 Hours
Tech Care	0 $	2 Hours
Training	0 $	1 Hour

Table I-2

Project Timeline

Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Proposal defense		X									
IRB		X	X								
Education		X	X								
Provider recruitment		X	X								
Patient recruitment				X							
Pre-A1C and DSMQ				X							
Implementation				X	X	X	X				
Post-A1C, DSMQ, Provider Survey							X				
Data Analysis								X	X		
Dissemination										X	X

Appendix J: Permission to Use DSMQ

SPECIAL TERMS

These User License Agreement Special Terms ("Special Terms") are issued between Mapi Research Trust ("MRT") and Jonathan Beatty ("User").

These Special Terms are in addition to any and all previous Special Terms under the User License Agreement General Terms.

These Special Terms include the terms and conditions of the User License Agreement General Terms, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the Special Terms Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the User License Agreement General Terms.

These Special Terms, including all attachments and the User License Agreement General Terms contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of these Special Terms or any attachment conflict with the terms and conditions of the User License Agreement General Terms, the terms and conditions of the User License Agreement General Terms will control, unless these Special Terms specifically acknowledge the conflict and expressly states that the conflicting term or provision found in these Special Terms control for these Special Terms only. These Special Terms may be modified only by written agreement signed by the Parties.

User information

User name: Jonathan Beatty

Category of User: Student

User address XXXXX

User VAT number

User email jrbeatty@alaska.edu

User phone XXXXX

Billing Address XXXXX

General information

Effective Date: Date of acceptance of these Special Terms by the User

Expiration Date ("Term"): Upon completion of the Stated Purpose

Name of User's contact in charge of the request: Jonathan Beatty

Identification of the COA

© Mapi Research Trust, 2020. The unauthorized modification, reproduction and use of any portion of this document is prohibited.

Name of the COA: DSMQ - Diabetes Self-Management Questionnaire

Author Schmitt A.

Copyright Holder Dr. Andreas Schmitt

Copyright notice DSMQ © Dr Andreas Schmitt, 2013

Bibliographic reference:

Schmitt A, Gahr A, Hermanns N, Kulzer B, Huber J, Haak

T. The Diabetes Self-Management Questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control. Health Qual Life Outcomes. 2013 Aug 13;11:138

(Full Text Article)

Schmitt A, Reimer A, Hermanns N, Huber J, Ehrmann D, Schall S, Kulzer B. Assessing Diabetes Self-Management with the Diabetes Self-Management Questionnaire (DSMQ) Can Help Analyse Behavioural Problems Related to Reduced Glycaemic Control. PLoS One. 2016 Mar 3;11(3)

(Full Text Article)

Modules/versions needed DSMQ

Context of use of the COA

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter.

4.1 Stated Purpose

Other project:

Title: A TELEMEDICINE FOLLOW UP PROGRAM TO IMPROVE GLYCEMIC OUTCOMES FOR PATIENTS WITH UNCONTROLLED TYPE 2 DIABETES

Disease or condition Type II Diabetes

Planned Term* Start: 04/01/2020; End: 12/30/2020

Description (including format or media) Clinical quality improvement student DNP project on using telemedicine to improve glycemic outcomes

4.2 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

Version/Module Language For use in the following country

DSMQ English the UK

The User understands that the countries indicated above are provided for information purposes. The User may use the COA in other countries than the ones indicated above.

5. Specific requirements for the COA

The Copyright Holder of the COA has granted ICON LS exclusive rights to translate the COA in the context of commercial studies or any project funded by for-profit entities. ICON LS is the only organization authorized to perform linguistic validation/translation work on the COA.

In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.•

In case the User wants to use an e-Version of the COA, ICON LS shall update (if needed) and populate the COA translations into the User's or IT Company's system and the User shall send the Screenshots of the translations of the COA to ICON LS for approval. The update (if needed), population of translations and the Screenshots review may incur additional fees.