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Implementation of a Nurse-Led Diabetes Self-Management Education (DSME) Program in
Primary Care

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Abstract

Type 2 Diabetes Mellitus (T2DM) is a serious concern, that requires close monitoring and facilitation of self-management skills and strategies, as well as development of a sense of self-efficacy, in patients with this chronic disease. The development of nurse-led Diabetes self-management education (DSME) programs, combined with a multidisciplinary approach to care and management, is a safe and effective means of helping patients with uncontrolled T2DM to cultivate positive health behaviors, prevent long-term disability and effectively control blood sugars.

A DSME program like this was developed and implemented at Mercy Midtown Family Practice, for patients with a glycosylated hemoglobin (HbA1c) of 9% or higher, whose diabetes and related complications are managed by Primary Care. It employed a multidisciplinary approach with Primary Care Providers (PCPs), Disease Management Registered Nurses (DMRNs) and Care/Case Management (CM) coordinators to provide collaborative, comprehensive care management. This program features a comprehensive Diabetes Education program, bi-weekly follow-ups by phone or in clinic between patients and DMRNs, point of care testing (POCT) of HbA1c every 6 weeks in clinic and facilitation of self-management skills and health behaviors throughout the program.

This nurse-led DSME program resulted in an overall decrease in HbA1c of one point or more for 55% of participating patients. This includes HbA1c decreases for 22% of the participating patient cohort to below 7%. Additionally, 100% of participating patients report an increase in positive health behaviors and an increase in their sense of self-efficacy, as demonstrated through a skills self-assessment survey administered upon graduation from the program.

Implementation of a Nurse-Led Diabetes Self-Management Education (DSME) Program in Primary Care

Type 2 Diabetes Mellitus (T2DM) is a world-wide pandemic. According to the World Health Organization, or WHO (2018), an estimated 1.6 million deaths were directly caused by T2DM in 2016. Another 2.2 million deaths were attributable to high blood sugar. In those individuals who died from hyperglycemia, almost half occurred before the age of 70. In addition to these statistics, T2DM remains one of the major causes of blindness, kidney failure, heart attack, stroke and limb amputation world-wide (WHO, 2018). Because of the pervasive prevalence of this chronic disease, interventions promoting diabetes self-management skills and strategies is crucial to preventing permanent disability and improving health and quality of life (QoL) in patients with T2DM.

Problem Description

Mercy Mid-Town Family Practice has a total of six Primary Care Providers (PCPs), two Advanced Practice Clinicians, or APCs (a Family Nurse Practitioner and a Physician's Assistant), two Registered Nurses (RNs) and eight Medical Assistants (MAs). Every PCP has his or her own empanelment of 3,000 to 4,000 patients, and each APC and RN works with a team of three PCPs to support them in the care and management of each patient empanelment. Each PCP has a variance in the number of diabetic patients they manage; however, across the board the population of patients with T2DM is approximately 10% of their total patient population. Of this T2DM population, approximately 10% of patients have uncontrolled diabetes, with an HbA1c of 9% or higher. There are no established figures or precedents for an acceptable percentage of a PCPs diabetic population that is within the uncontrolled range for management of T2DM, as the

aim of all Health Care Organizations (HCOs) and PCPs is to have the entirety of their diabetic patient population within the controlled range. However, the statistics for this practice show that there is a need for closer following and management of patients with uncontrolled T2DM through the implementation of a nurse-led DSME program using a population health approach (ADA, 2018).

Available Knowledge

According to Pamungkas, Chamroonsawasdi and Vatanasomboon (2017), the worldwide prevalence of T2DM is currently greater than 422 million people. Of these individuals, approximately 85.7% fail to meet target goals for glycemic control as measured by an HbA1c level of 7% or less, and require additional education, follow-up and personalized strategies to help facilitate diabetes self-management. A study conducted by Johnson et al. (2016) found that enhanced and collaborative care strategies improve outcomes in this population, and result in a significant cost savings when compared with traditional monitoring and care delivery of the same patient population. They assert that a comprehensive, team-based program that facilitates self-management for T2DM patients saves an average of \$15,861 to \$25,368 per patient, per year in health care costs and resources (Johnson et al., 2016). Finally, the Centers for Disease Control and Prevention, or CDC (2017), assert that the 30.3 million Americans (9.4% of the US population) with T2DM will require comprehensive monitoring and follow-up to promote self-management strategies and assist this population in obtaining control their T2DM.

In a PICO assessment conducted in the Mercy Midtown Family Practice microsystem, the following population health needs were identified:

Population: Patients with uncontrolled type 2 diabetes mellitus (T2DM) and a glycosylated hemoglobin (HbA1c) of 9% or greater, whose diabetes and related complications are managed by Primary Care.

Intervention: Continuous, comprehensive follow-up and self-management teaching through a nurse-led diabetes self-management (DSME) program.

Comparison: Standard PCP follow-up every 3 to 6 months with Primary Care Providers (PCP) with a single encounter with an RN for diabetes education.

Outcome: Improvement/reduction in HbA1c of one point or more, in combination with a demonstrated understanding of diabetes self-management behaviors and comprehension, within a 3-month period.

According to Azami et al. (2018), nurse-led diabetes self-management programs have demonstrated success in helping patients to lower their HbA1c(s) within a 12-week time frame. In a study conducted by these same authors, nurse-led DSME resulted in significantly lower HbA1c values for 47.9% more of the patients in the intervention, who were participating in the program, than for those in the control group. Additionally, the rate of improved HbA1c increased to 62% of patients in the intervention group at the 24-week mark. More than one-fifth, or 21.1%, of the intervention group in this study achieved an HbA1c 7% or less at the end of the study, compared to none in the control group (Azami et al., 2018).

The established primary benefits of nurse-led DSME programs have been a reduction in HbA1c, the development of and/or increase in a sense of self-efficacy amongst participant-patients and an increase in self-management skills. Secondary benefits of these programs are

improved outcomes in blood pressure, body weight and lipid profiles. Additionally, an increase in health behaviors, quality of life and social support have been noted, as well as a decrease in rates of depression (Azami et al., 2018). Studies have reported that nurses, compared to other healthcare professionals (HCPs), are “more likely to promote preventive healthcare seeking behaviors,” which makes a nurse-led DSME program ideal for this population (Azami et al., 2018, p. 1).

Tshiananga et al. (2012) assert that nurse-led DSME programs are associated with improved glycemic control, demonstrated by an improvement in A1c, as well as a decrease in self-monitored blood sugar values. They further assert that these programs are most effective amongst adult populations, with continuous follow-up periods of approximately 1 month or sooner with Disease Management Nurses (Tshiananga et al., 2012).

Rationale

The American Diabetes Association, or ADA (2018), recommends a population health approach to management of T2DM, to promote and facilitate effective self-management. It makes the following recommendations for management of population-based health outcomes:

-Ensuring that treatment decisions are timely, rely on evidence-based guidelines, and are made collaboratively with patients based on individual preferences, prognoses, and comorbidities (ADA, 2018).

-Align approaches to diabetes management with the Chronic Care Model, emphasizing productive interactions between a prepared proactive care team and an informed, engaged patient (ADA, 2018).

-Care systems that facilitate and utilize team-based care, patient registries, decision support tools, and community involvement to meet patient needs (ADA, 2018).

-Efforts to assess the quality of diabetes care and create quality improvement strategies that include reliable data, to promote improved processes of care and health outcomes, with simultaneous emphasis on costs (ADA, 2018).

Specific Project Aim

The goal for this microsystem improvement project is to reduce the HbA1c by one point or more for 25% of patients participating in this program within three months, as well as to strengthen their self-management skills and perception of self-efficacy, as measured by a survey that patients will complete at the end of this time period. The target population for this program is patients with an HbA1c of 9% or higher, whose diabetes and related complications are managed by Primary Care. The purpose of this project is to develop a patient support program that teaches self-management skills and helps patients to develop healthy lifestyle habits through frequent, comprehensive follow-up with Disease Management Nurses. According to Cunningham et al. (2018), when developing a DSME program in the United States and globally, educators should be sensitive to the experiences of all subgroups and cultures within the larger target patient population. This will help educators to better understand how these experiences can impact diabetes self-management. Additionally, Cavanaugh (2011) asserts that all DSME programs should be designed with patients' health literacy levels in mind, to ensure improved outcomes. The foundation of health literacy rests on the principles of clear health communication, including: assessment of understanding, use of plain language, emphasizing select key points and using effective printed materials (Cavanaugh, 2011). According to

Tshiananga et al. (2012), nurse-led DSME programs are most effective when frequent follow-up is implemented, ideally anywhere from every two weeks to one month, until patients demonstrate a solid understanding of self-management strategies and concepts.

Context

After completing a SWOT Analysis and Microsystem Assessment, I've concluded that this clinical microsystem needs closer and more frequent follow-up and self-management training for people with poorly controlled T2DM. According to Azami et al. (2018), single-center nurse-led DSME programs offer lasting benefits in clinical outcomes and lifestyle changes for participating individuals. Additionally, facilitating self-efficacy has been found to improve longer-term health outcomes in patients with co-occurring chronic health conditions. In short, these programs help participants to achieve long-term success in developing health related behavior changes by enhancing intrinsic motivation and self-efficacy (Azami et al., 2018).

According to the American Diabetes Association, or ADA (2017), the majority of people with and/or at risk for diabetes do not receive DSME. While there are many barriers to implementing effective DSME programs, one of the main issues is access, as many health care organizations do not have structured programs in place. The ADA (2017) also asserts that DSME programs are a crucial aspect of any diabetes management effort. The microsystem assessment conducted for this project revealed that while there is a diabetes management program in place, it does not emphasize DDSME, and lacks structure and defined parameters for implementation.

One of the needs identified for this project was appropriate, up-to-date teaching materials, in multiple modalities, for patients with poorly controlled T2DM. Another need that was

identified was a structure for the material and education provided to patients, the frequency of nurse-led follow-up and teaching for patients, specific inclusion criteria and clearly defined parameters for when a patient has graduated from this program.

The microsystem that this nurse-led DSME program will be implemented in has an average of 10% of the total patients who have uncontrolled T2DM, as manifested by a glycosylated hemoglobin (HbA1c) of 9% or greater. This is 2% higher than the medical group average of 8%. With implementing this DSME program, the goal is to accomplish a reduction in HbA1c of one point or more for 25% of participants. As the duration of this semester is not long enough to see a reduction in HbA1c to below 7.0% for all patients, which the ADA (2017) considers to be controlled T2DM, this project will focus on consistent decreases over a three month period. These decreases in HbA1c will be measured every six-weeks in clinic, using POCT HbA1c assay tests. Additionally, this program aims to cultivate stronger self-management skills amongst participants over the designated time period. This will be measured through a survey given to all participants to rate their own feelings about their self-management skills after participating in the program.

Intervention

With consideration for all of the concepts presented in this prospectus, this nurse-led DSME program is geared not only towards facilitating self-management strategies, but also towards decreasing healthcare costs and resource utilization, through prevention of diabetes-related complications. This long-term goal will be achieved through:

1. One-on-one Diabetes Education with patients and their families using evidence-based, standardized content and materials, and comprehensive teaching about basic diabetes self-management strategies, such as: nutrition, physical activity, glucose monitoring, taking medications, solving problems, reducing risks and using healthy coping tools (Wisnewski, 2017).
2. Bi-weekly follow-up (more or less frequently depending on patient needs) between patients and Disease Management Nurses to assess patient progress, needs and barriers.
3. Collaborative care with the involvement of the Care Management/Case Management (CM) team to address psychosocial barriers that patients encounter and/or struggle with.
4. A comprehensive, team-based approach between PCPs, Disease Management Nurses, CM and the CNL to efficiently and effectively design plans of care, manage medications, ensure the completion of preventative health metrics and conduct a health literacy needs assessment.
5. Continual assessment of diabetes self-management skills and health behaviors during frequent follow-ups as described above.
6. POCT HbA1c readings in clinic every 6 weeks, using the Alere Afinion glycosylated hemoglobin assay machine.
7. Discharge from the program after two consecutive HbA1c readings below 9% within a six-month time frame, as well as demonstration of sufficient understanding of Diabetes self-management strategies and health behaviors.

8. Program debrief through a self-efficacy, skills and education quality assessment survey completed by each patient upon graduation from the program to determine his or her degree of confidence and comfort with the material and principles taught during the program.

Ethical Considerations

According to Cunningham et al. (2018) significant disparities remain in T2DM prevalence and outcomes amongst minorities and disadvantaged groups. As such, DSME programs should account for disparities in quality of life (QoL) and psychosocial barriers affecting these populations, in order to meet the needs of their patients. Additionally, Cavanaugh (2011) asserts that low levels of health literacy is a common factor affecting countless processes within healthcare, as well as health outcomes. With regards to T2DM, health literacy is related to knowledge of disease processes, feelings of self-efficacy, development of self-care behaviors and glycemic control. Understanding health literacy may also provide a better understanding of racial disparities observed amongst patients with T2DM. Strategies to address health literacy, based on this understanding of its role, provide a means to improve diabetes care and DSME programs (Cavanaugh, 2011).

Microsystem Assessment and Program Development

The initial step of this intervention included performing a SWOT analysis (Figure 1). The strengths of this microsystem include strong primary care teams and great potential for team based chronic disease management programs. Weaknesses include a large uncontrolled diabetic population and a decided lack of team-based chronic disease management programs. One of the greatest opportunities in this microsystem is the potential for developing team-based, nurse-led

chronic disease management programs to improve patient outcomes. The key threat identified in this microsystem was the lack of nurse-led disease management programs, as well as the lack of a structured diabetes management program. This is significant because, according to Azami et al. (2018), nurses are more likely to promote health behaviors than other disciplines.

Microsystem SWOT Analysis

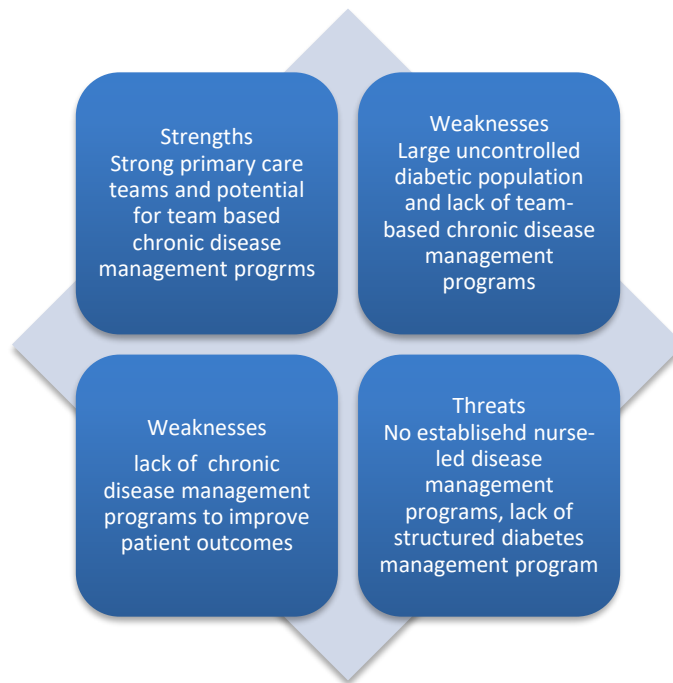


Figure 1. SWOT analysis for nurse-led DSME program at Mercy Midtown Family Practice.

PDSA Cycles

The first PDSA cycle involved implementing a nurse-led DSME program, based on the structure and recommendations gathered during literature review, as outlined above. The earliest results and outcomes noted in the implementation of a basic DSME program structure showed a decrease in home blood sugar values and an increase in self-management skills, but the noted

progress was minor (Figure 2).

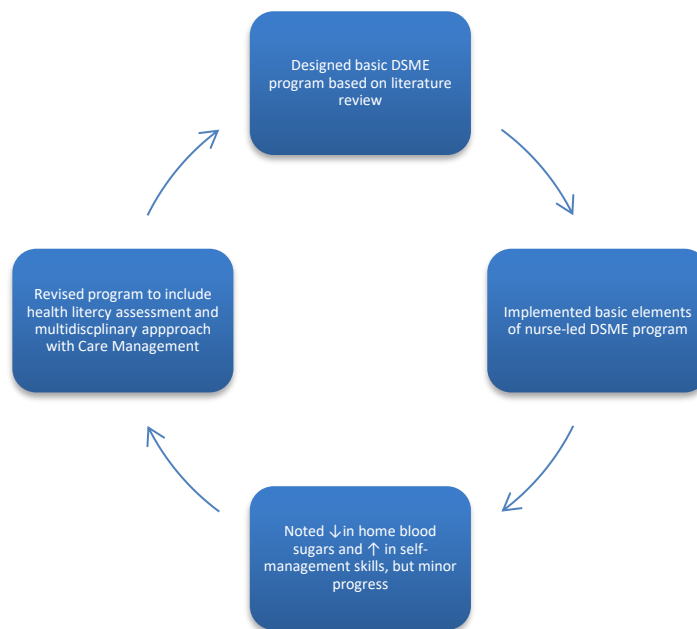


Figure 2. First PDSA cycle for the nurse-led DSME program

The program was then refined to include a health literacy assessment for every patient, and Case/Care Management (CM) collaboration for each patient at the beginning of his or her participation in the program. According to Pamungkas, Chamroonsawasdi, Vatanasomboon (2017), DSME programs that make provisions to increase social support and address psychosocial barriers improve and optimize patient outcomes with regards to control and management of T2DM. Additionally, Cavanaugh (2011) asserts that understanding the health literacy level of every patient, and tailoring DSME teaching and education to meet that level/need, will ensure improved outcomes, assist patients with optimizing their glycemic control and help to prevent future diabetes-related complications.

Once the multidisciplinary aspect of this program was added, by including CM at the outset of every patient’s participation, an increase in compliance with medication, improved

adoption of self-management skills and behaviors, and improved home blood sugars were noted. POCT HbA1c testing in clinic was implemented at this point, to determine each patient’s progress in the modified program. This occurred at the six-week mark, and was intended to be the first of two serial POCT HbA1c measurements within designated the three-month time-frame. This round of POCT testing showed a marked decrease in HbA1c for approximately 50% of patients participating in the program for a full six-weeks (Figure 3).

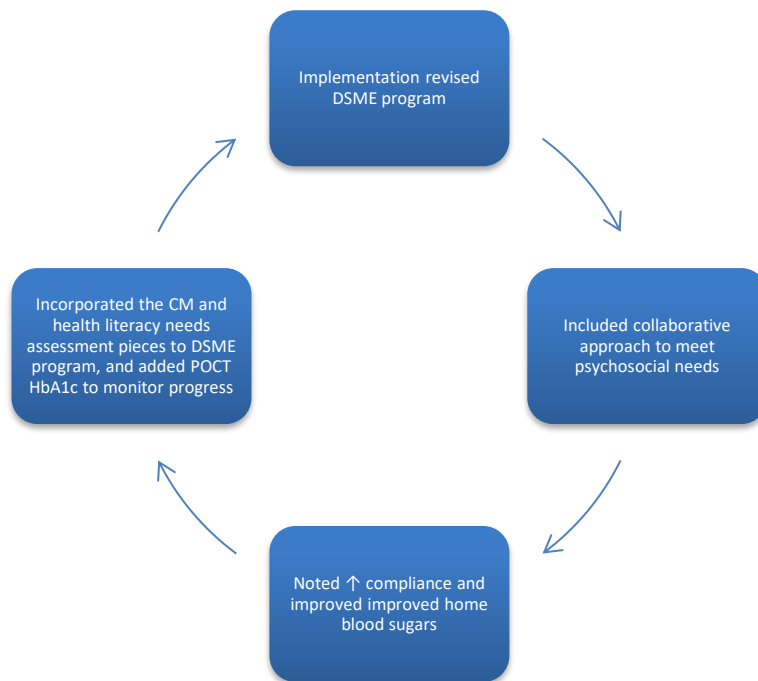


Figure 3. Second round of PDSA cycle for nurse-led DSME program

The success of the program to this point, and the improved glycemic control of participating patients, led to the finalization of the program structure. Each element of the program, as noted in the intervention section, was refined and cemented into permanence, and emerged as the final program structure. From this point, each aspect of the nursed-led DSME program was implemented permanently to assist patients in better managing their T2DM. The

original cohort of patients, who experienced the full twelve-week course of this program, were followed regularly for DSME teaching and support, and had their HbA1c measured a second time, at the twelve-week mark, to determine program success and results within the prescribed three-month time period (Figure 4).

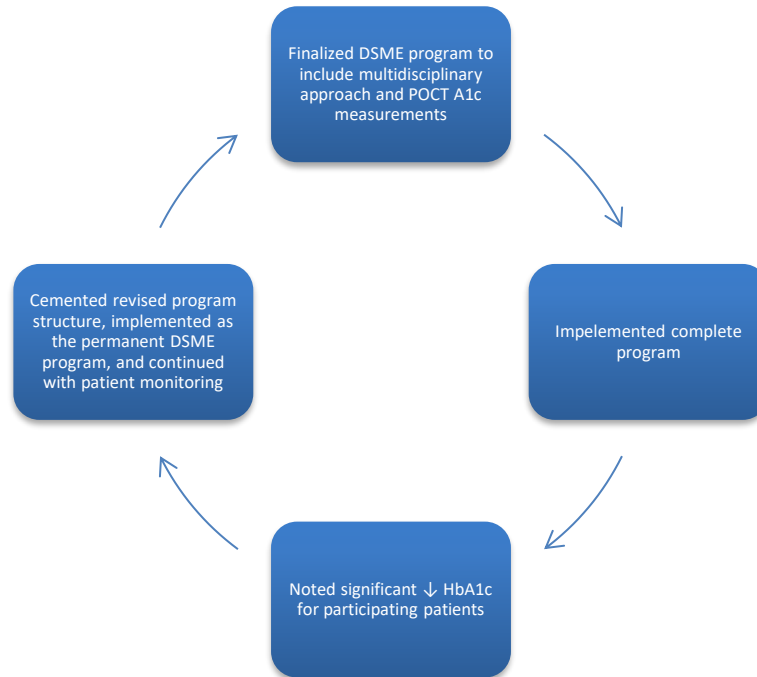


Figure 4. Final PDSA cycle for DSME program

Results Summary

This program garnered a large number of participant patients over its initial three-month implementation. Of the total number of qualifying participants, eighteen men and women were followed from the start of the program to the initial three-month goal period. At the end of this designated time period, a total of 55% of the original participating patient cohort experienced a decrease in HbA1c of one point or more: five percent decreased their HbA1c to below 9%, five percent decreased to below 8%, and twenty-two percent decreased their HbA1c to below 7%,

entering the controlled category for T2DM as defined by the American Diabetes Association (2018) (Figure 5). In addition to these results, one-hundred percent of participants adopted one or more diabetes self-management skills and/or strategies, and one-hundred percent reported an increase in their feelings/perception of self-efficacy at the three-month mark (Figure 6). Patients continued to enter this program throughout the three-month period, and all have experienced success with improved glycemc control, adoption of diabetes self-management skills and strategies and an increased perception of self-efficacy.

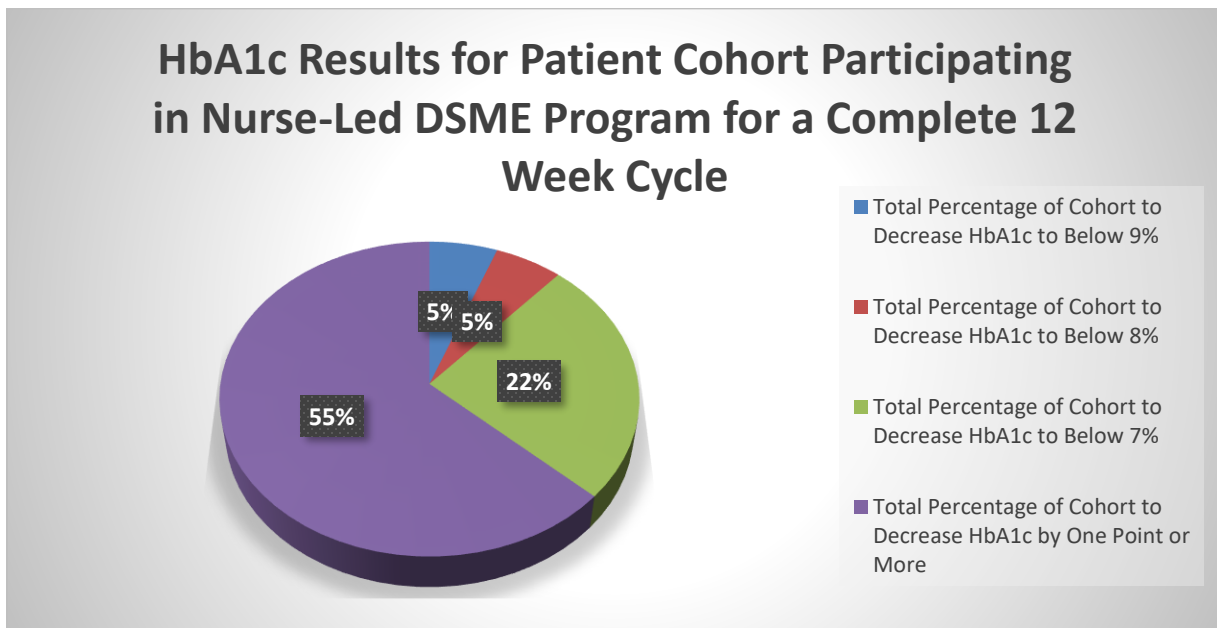


Figure 5. HbA1c results for Patient Cohort Participating in Nurse-Led DSME Program for a full 12 week Cycle

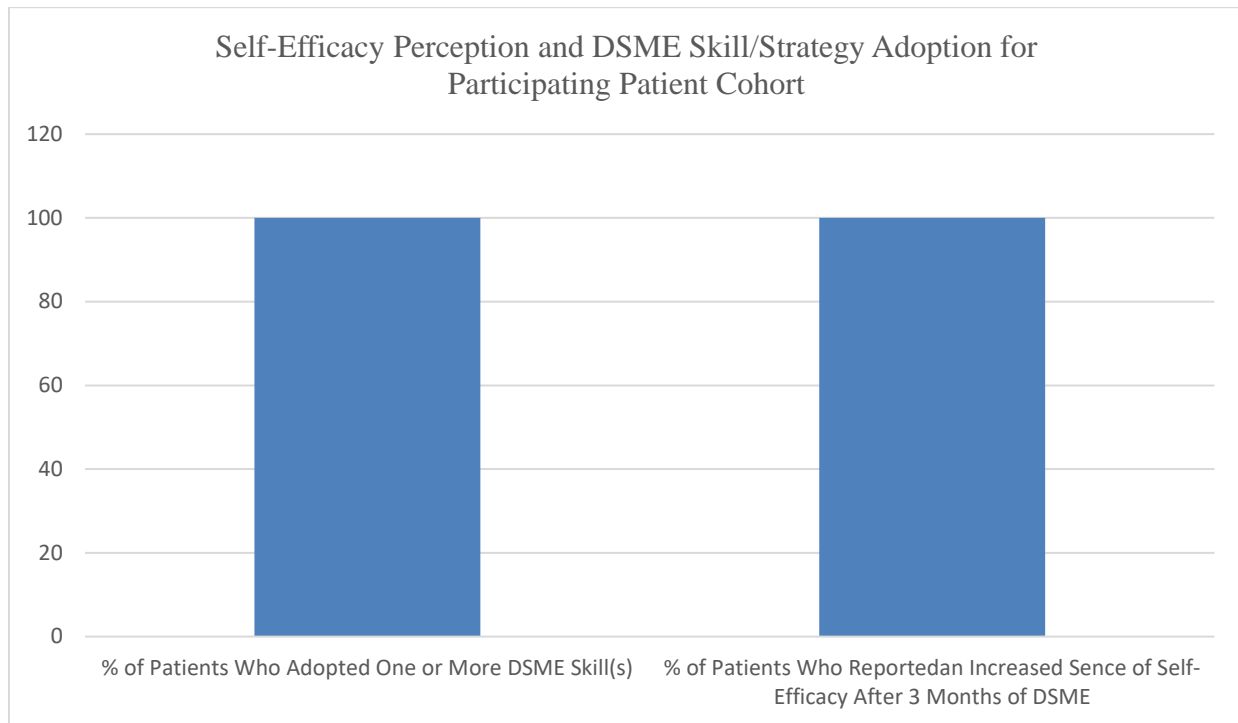


Figure 6. Results for self-efficacy perception and diabetes self-management skill/health behavior adoption in participating patient cohort.

Lessons Learned

There were many lessons learned during the development and implementation of this program. One of the most impactful lessons learned was that in order to have an effective nurse-led DSME program, a multi-disciplinary approach is necessary to ensure patient success. Johnson et al. (2016), assert that a multi-disciplinary approach to providing care for patients with uncontrolled T2DM is essential to meeting their complex needs and promoting improved outcomes. Another key lesson learned through this study was that patient driven, culturally appropriate goals and strategies are crucial to the development of an effective DSME program.

Mardanian Dehkordi and Abdoli (2017), posit that understanding the experiences of the individuals participating in DSME programs is necessary to providing effective DSME.

Conclusions

This program was tremendously successful in helping patients decrease their HbA1c by one point or more within a three-month period, as well as improving patients' health behaviors and increasing their perception of self-efficacy within the same time frame. Patients continue to enter the program, and continuously experience improvements in all of the goal areas that are addressed by this nurse-led DSME program. It has proven to be sustainable, because it facilitates self-management strategies and behaviors in patients, and has demonstrated a decrease in time-investment from team RNs as patients' progress through the program and develop and/or strengthen health behaviors and diabetes self-management skills. This renders it a sustainable and useful program. Additionally, facilitating successful diabetes self-management in patients saves an average of between approximately \$16,000 and \$26,000 in healthcare costs and resources per patient, per year by preventing diabetes related complications (Johnson et al., 2016). Finally, the concept of self-management education programs for patients with chronic diseases is translatable to many different microsystems and/or clinical environments, across a broad range of chronic diseases.

Annotated Bibliography

American Diabetes Association. (2017). 2017 National standards for diabetes self-management education

and support. Retrieved from:

<http://care.diabetesjournals.org/content/diacare/early/2017/07/26/dci17-0025.full.pdf>

This source provides evidence-based, up-to-date standards of care for patients with Type 2 diabetes Mellitus.

American Diabetes Association. (2018). Standards of Medical Care in Diabetes 2018.

Retrieved from: <https://professional.diabetes.org/content-page/standards-medical-care-diabetes>

This source reviews all national standards and guidelines for medical care of patients with Diabetes, as set forth by the American Diabetes Association, for 2018.

Azami, G., Soh, K. L., Sazlina, S. G., Salmiah, M. S., Aazami, S., Mozafari, M., &

Taghinejad, H. (2018). Effect of a nurse-led diabetes self-management education program on glycosylated hemoglobin among adults with type 2 diabetes. *Journal of Diabetes Research*, 2018, 1-12. doi: 10.1155/2018/4930157

The aim of this study was to investigate the effectiveness of a nurse-led diabetes self-management education on HbA1c. It employed two-arm, parallel-group randomized controlled trial with the blinded outcome assessors. One hundred forty-two adults with T2DM were randomized to receive either usual diabetes care (control group) or usual care plus a nurse-led DSME program (intervention group). The major outcomes of this

study showed a sustained decreased in HbA1c, improved blood pressure, decreases in body weight, improved lipid profiles, increased perception of self-efficacy, improved self-management behaviors, self-reported improvements in quality of life, better social support, and decreased depression for the intervention group. Outcomes were assessed at 12-weeks and 24-weeks. Additionally, the beneficial effect of a nurse-led intervention continued to accrue beyond the end of the trial resulting in sustained improvements in clinical, lifestyle, and psychosocial outcomes for the intervention group.

Cavanaugh, K. L. (2011). Health literacy in diabetes care: Explanation, evidence and equipment.

Diabetes Management, 1(2), 191–199. <http://doi.org/10.2217/dmt.11.5>

This article reviews the concept of health literacy, its assessment and the evidence of its impact on patients with diabetes. In diabetes, health literacy is related to diabetes knowledge, self-efficacy and self-care behaviors and blood sugar control. It offers recommended methods and tools that can improve clinical care in DSME program and diabetes management.

Center for Disease Prevention and Control. (2017). National diabetes statistics report 2017.

Retrieved from: <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>

This source is maintained by the CDC and provides statistics for the incidence of T2DM in the United States in 2017.

Cunningham, A. T., Crittendon, D. R., White, N., Mills, G. D., Diaz, V. & LaNoue, M. D.

(2018). The effect of diabetes self-management education on HbA1c and quality of life in African-Americans: A systematic review and meta-analysis. *BMC Health Services Research*, 18(367), 1-13. doi:10.1186/s12913-018-3186-7

This source conducts a meta-analysis in the effect of DSME programs on African Americans with T2DM, in the areas of HbA1c and quality of life. The results of the meta-analysis showed non-significant effects of DSME on HbA1c this population. Quality of life, however, did show improvement and is an important DSME outcome to measure in future studies. It determined that DSME program in African American populations, which re disproportionately affected by T2DM, need further research is needed to understand effectiveness of DSME on HbA1c.

Johnson, J. A., Lier, D. A., Soprovich, A., Al Sayah, F., Qiu, W., Majumdar, S. R. (2016). Cost

effectiveness evaluation of collaborative care for diabetes and depression in primary care. *American Journal of Preventive Medicine*, 51(1), 13-20. doi: 10.1016/j.amepre.2016.01.010

This article reviews strategies for care of patients with T2DM and depression. It found that in primary care patients with T2D who screened positive for depression, physician notification and follow-up was a more clinically effective strategy compared with usual care. It covers the benefits of appropriately treating depression in PWD to improve diabetes self-management at home, as well as to decrease health resource4 utilization in the future.

Mardanian Dehkordi, L., & Abdoli, S. (2017). Diabetes self-management education: Experience

of people with diabetes. *Journal of Caring Sciences*, 6(2), 111–118.

<http://doi.org/10.15171/jcs.2017.011>

This article reviews how DSME is a major factor that can affect quality of life for people with diabetes (PWD). Understanding the experiences of the individuals participating in DSME programs is necessary to providing effective DSME. The aim of the study was to explore the experiences of PWD from a local DSME program in Iran. It concluded that the current approach to DSME isn't meeting the needs and expectations of PWD attending the local program. It determined that needs assessment, interactive teaching methods, a multidisciplinary approach, current technology and appropriate physical space need to be considered to improve DSME programs.

Pamungkas, R. A., Chamroonsawasdi, K., & Vatanasomboon, P. (2017). A systematic review:

Family support integrated with diabetes self-management among uncontrolled type II diabetes mellitus patients. *Behavioral Sciences*, 7(3), 1-17. doi: 10.3390/bs7030062

This article reviews how T2DM has become a public health problem globally. Reasons for poor glycemic control in Type 2 diabetes are complex. Its objective as to determine factors contributed to poor glycemic control among Indonesian patients with T2DM. It found that as the duration of time patients have poor glycemic control increases, the following behaviors often occur: non-adherence to medications, poor dietary behavior management and decreased family support. It concludes that integration of DSME

programs with social support is necessary to help patients maintain glycemic control and prevent future health complications.

Tshiananga, J. K., Kocher, S., Weber, C., Erny-Albrecht, K., Berndt, K. & Neeser, K. (2012).

The effect of nurse-led diabetes self-management education on glycosylated hemoglobin and cardiovascular risk factors: A meta-analysis. *The Diabetes Educator*, 38(1), 108-123. doi: 10.1177/0145721711423978

This article reviews how nurse-led DSME programs are associated with improved glycemic control. The meta-analysis conducted shows that programs are most effective among seniors and with follow-up periods of 1 to 6 months. It drives home the point that culturally sensitive DSME programs provide more effective support and education. And assert that DSME programs such as these improve both glycemic control and reduce CV risk factors.

Wisnewski, C. A. (2017). Diabetes self-management education: Transitioning from hospital to home. *American Nurse Today*, 12(12), 29–51.

This article reviews the key steps necessary to transition a newly diagnosed Diabetic from the hospital to the home setting using basic DSME concepts. It covers essential topics such as nutrition, physical activity, glucose monitoring, taking medications, solving problems, reducing risks and using healthy coping tools. It is an excellent example of the basic elements of a DMSE program.

World Health Organization. (2018). Diabetes. Retrieved from: www.who.int/news-room/factsheets/detail/diabetes

This source reviews the world-wide prevalence of Diabetes Mellitus, including data related to complications, mortality rates, comorbidities and healthcare costs and resources allocated for the care of patients with this chronic condition.

Appendix A

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

STUDENT NAME: Jamie Lee

SUPERVISING FACULTY: Elina Martinez, FNP

Project Title:	YES	NO
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	Y	
The specific aim is to improve performance on a specific service or program and is a part of usual care . ALL participants will receive standard of care.	Y	
The project is NOT designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does NOT follow a protocol that overrides clinical decision-making.	Y	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does NOT develop paradigms or untested methods or new untested standards.	Y	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does NOT seek to test an intervention that is beyond current science and experience.	Y	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	Y	
The project has NO funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	Y	

<p>The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., not a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.</p>	<p>Y</p>	
<p>If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: <i>“This project was undertaken as an Evidence- based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board.”</i></p>	<p>Y</p>	

Instructions: Answer YES or NO to each of the following statements:

ANSWER KEY: If the answer to ALL of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. IRB review is not required. Keep a copy of this checklist in your files. If the answer to ANY of these questions is NO, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston

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Appendix B

IRB REVIEW OF NEW RESEARCH INVOLVING HUMAN SUBJECTS



APPLICATION FOR IRB REVIEW OF NEW RESEARCH INVOLVING HUMAN SUBJECTS

Complete the following form and upload this document to the online IRB system in Mentor. In addition to this application, you will also need to upload any survey/interview questions and informed consent documents for your protocol.

1. RESEARCH PROJECT DESCRIPTION

Provide, in lay terms, a detailed summary of your proposed study by addressing each of the following items:

Clearly state the purpose of the study (Usually this will include the research hypothesis)

The goal for this microsystem improvement project is to reduce the HbA1c by one point or more for 25% of patients participating in this program within three months, as well as to strengthen their self-management skills, as measured by a survey patients will complete at the end of this time period.

Background (Describe past studies and any relevant experimental or clinical findings that led to the plan for this project)

A study conducted by Azami et al. (2018) showed a reduction in HbA1c for 47.9 % of the intervention group with the implementation of basic DSME interventions. This figure jumped to 62% at the 24-week mark. Additionally, one-fifth of the intervention group achieved an HbA1c of 7% or less, compared to none in the control group.

According to the American Diabetes Association (2017), DSME is a crucial aspect of any diabetes management effort.

References:

Azami, G., Soh, K. L., Sazlina, S. G., Salmiah, M. S., Aazami, S., Mozafari, M., & Taghinejad, H. (2018). Effect of a nurse-led diabetes self-management education program on glycosylated hemoglobin among adults with type 2 diabetes. *Journal of Diabetes Research*, 2018, 1-12. doi: 10.1155/2018/4930157

American Diabetes Association. (2017). 2017 National standards for diabetes self-management education and support. Retrieved from:
<http://care.diabetesjournals.org/content/diacare/early/2017/07/26/dci17-0025.full.pdf>

Research plan (Provide an orderly scientific description of the intended methodology and procedures as they directly affect the subjects)

1. One-on-one Diabetes Education with patient-families.
2. Bi-weekly follow-up between patients and the Disease Management Team (DMT) to assess patient progress, needs and barriers.
3. A comprehensive, team-based approach between providers, DMT and CNL to efficiently management of medications, labs and preventative health metrics.
5. Continual assessment of Diabetes self-management skills and health behaviors during frequent follow-ups as described above.
6. Point of care testing (POCT) HbA1c readings in clinic every 6 weeks, using the Alere Afinion glycosylated hemoglobin assay machine.
7. Discharge from the program after two consecutive HbA1c readings below 9% within six months, and demonstration of understanding of Diabetes self-management strategies and health behaviors.

Give the location(s) the study will take place (institution, city, state, and specific location)

Mercy Midtown Family Practice

Duration of study project

12 weeks

2. PARTICIPANTS

2(a) Participant Population and Recruitment

Describe who will be included in the study as participants and any inclusion and exclusion criteria.

Patients with uncontrolled diabetes and an HbA1c of 9% or higher, whose diabetes and related complications are managed by Primary Care.

What is the intended age range of participants in the study?

18+

Describe how participant recruitment will be performed.

All patients that meet the above criteria will be referred to the program by his or her PCP. Each patient will be given information on the program content and structure to establish trust and transparency. Participation is completely voluntary and patient driven.

Do the forms of advertisement for recruitment contain only the title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information?

X Yes No

*If you answered "no," the forms of advertisement must be submitted to and approved by the IRB prior to their use.

2(b) Participant Risks and Benefits

What are the benefits to participants in this study?

Patients stand to gain knowledge, skills and strategies to help them control their blood sugars and diabetes. This, in turn, will empower them to HbA1c using the tools provided through the program. Participation is completely voluntary, to the degree that each patient is comfortable.

What are the risks (physical, social, psychological, legal, economic) to participants in this study?

There are no noted risks to patients, as this is a transparent study conducted on a voluntary basis

and involving only routine POCT testing. Additionally, no PHI or individual results will be reported on in this study, as all reported results are a collective average of the participating patient cohort.

If deception is involved, please explain.

No deception is involved in this study.

Indicate the degree of risk (physical, social, psychological, legal, economic) you believe the research poses to human subjects (check the one that applies).

MINIMAL RISK: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

GREATER THAN MINIMAL RISK: Greater than minimal risk is greater than minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. If you checked “Greater than Minimal Risk”, provide a statement about the statistical power of the study based on intended sample size, design, etc. to test the major hypotheses)

N/A

2(c) Participant Compensation and Costs

Are participants to be financially compensated for the study? Yes No If “yes,” indicate amount, type, and source of funds.

Amount:	Source:	Type (e.g.: gift card, cash, etc.):
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Will participants who are students be offered class credit? Yes No N/A

If you plan to offer course credit for participation, please describe what alternative assignment(s)

students may complete to get an equal amount of credit should they choose not to participate in the study.

N/A

Are other inducements planned to recruit participants? Yes No If yes, please describe.

3. CONFIDENTIALITY AND DATA SECURITY

Will personal identifiers be collected (e.g., name, social security number, license number, phone number, email address, photograph)? Yes No

Will identifiers be translated to a code? Yes No

Describe how you will protect participant confidentiality and secure research documents, recordings (audio, video, photos), specimens, and other records.

No PHI or individual results will be reported in this study.

4. CONSENT

4a. Informed consent

Do you plan to use a written consent form that the participant reads and signs? Yes No

*If "no," you must complete Section 4b or 4c below.

If "yes," describe how consent will be obtained and by whom.

If the participants are minors under the age of 18 years, will assent forms be used? Yes
No N/A

If “no,” please explain.

Upload to the online IRB system the consent form(s) that the participants and/or parent/guardian will be required to sign, and the assent forms for children under the age of 18, if applicable.

Note: All consent forms must contain the following elements (quoted directly from Office for Human Research Protections regulations, available at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>. The University of San Francisco IRB has consent templates containing all required elements, and we strongly recommend you use these templates.

If you believe it is important to create your own consent form, you are free to do so but please ensure that your consent form has each of the following elements and indicate you have done so by checking this box:

I have chosen to create my own consent form and have ensured that it contains the 8 essential elements listed below:

(1a) A statement that the study involves research, (1b) an explanation of the purposes of the research, (1c) the expected duration of the subject's participation, (1d) a description of the procedures to be followed, and (1e) identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if

injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled."

4b. Waiver of documentation of written informed consent (Complete only if answered "no" to 4a)

The regulations allow instances in which the IRB may waive the requirement for documentation of informed consent, that is, the collection of a signed consent form. If you are requesting a waiver of written documentation (signed) of informed consent, please answer the following questions:

Will the only record linking the participant and the research be the consent document and the principal risk to the participant would be from breach of confidentiality? Yes No

Do you consider this a minimal risk study that involves no procedures for which written consent is normally required outside of research (see 2B above for definition)? Yes No

Explain why you are requesting waiver or modification of documentation of written (signed) informed consent and how you plan to obtain consent.

This study will use no PHI or individual results when reporting the results of the project. All reported results are collective averages. Patients participate on a completely voluntary basis, to the degree they are comfortable with. Program structure and interventions are shared with patients prior to their decision to participate, and every step of the program is kept transparent with each participating patient.

4c. Waiver or modification of informed consent (Complete only if answered "no" to 4a)

The regulations also provide an opportunity for the IRB to waive the requirement for informed

consent or to modify the informed consent process, provided the protocol meets the following criteria:

- (1) The research involves no more than minimal risk to subjects (see 2b above for definition);
- (2) The waiver of alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If you are requesting a waiver or modification of informed consent (e.g., incomplete disclosure, deception), explain how your project meets the requirements for waiver or modification of informed consent, as outlined above.

As mentioned above, this study involves minimal risk for participating patients. It is based on education and designed to empower patients to manage their blood sugars. Only routine POCT testing will be employed. Patients only participate on a voluntary basis, to the degree that he or she is comfortable, and all steps and aspects of the program are transparent. No PHI or individual results will be reported in this study, and the only record that will associate them with it would be a written consent form.

Appendix C

Project Charter

Global Aim:

To improving outcomes for patients with uncontrolled Type 2 Diabetes Mellitus T2DM through the implementation of a Nurse-Led DSME program.

Project Aim: To teach Diabetes self-management skills and reduce HbA1c for 25% of participating patients within a three-month time span.

Background:

- Setting: a medium-sized outpatient Primary Care Clinic with a six Primary Care Providers (PCPs), two mid-level clinicians and two RNs. Each physician carries an empanelment of approx. 3,000 to 4,000 patients.

-Quality Gap: Identified gap in structured program for education, self-management teaching, and follow-up for patients with uncontrolled or worsening T2DM, as well as patients with adjustments in therapy.

Context:

A primary care team with 3 PCPs, 1 APC, and 1 RN. Each PCP has a Diabetic population of approx. 10% of their total patient population. Of those, approx. 10% have an HbA1c of 9% or greater. About 50% of this refined diabetic population is referred to specialty, and the remaining 50% is managed by Primary Care. This DSME program followed individuals in that sub-population whose comorbidities are also managed in Primary Care.

Sponsor: Mercy Midtown Family Practice

Team:

Jamie Lee	Elina Martinez
Don Yokoyama	Reena Vaid
Maria Soller	Jessica Cardenas
Schuyler Wood	Crystal Lopez

Driver Diagram:

Aim

Primary Driver

Secondary Drivers



Process and Outcome Measures:

	Measure Definition	Data Collection Source	Goal	Result
Outcome Measures				
Decrease in HbA1c	↓ of 1 point or more	POCT HbA1c	25%	55%
Increase in DSME Skills	Adopt 1 or more DSME Measure	Patient Survey	25%	100%
Process Measures				
Continued ↓ in HbA1c	Steady reduction in HbA1c after initial 6-week measure	Repeat POCT HbA1c every 6 weeks	25%	55%
DSME Skills Survey	Endorse ↑ in self-efficacy	Patient survey	100%	100%

Cost Benefit Analysis:

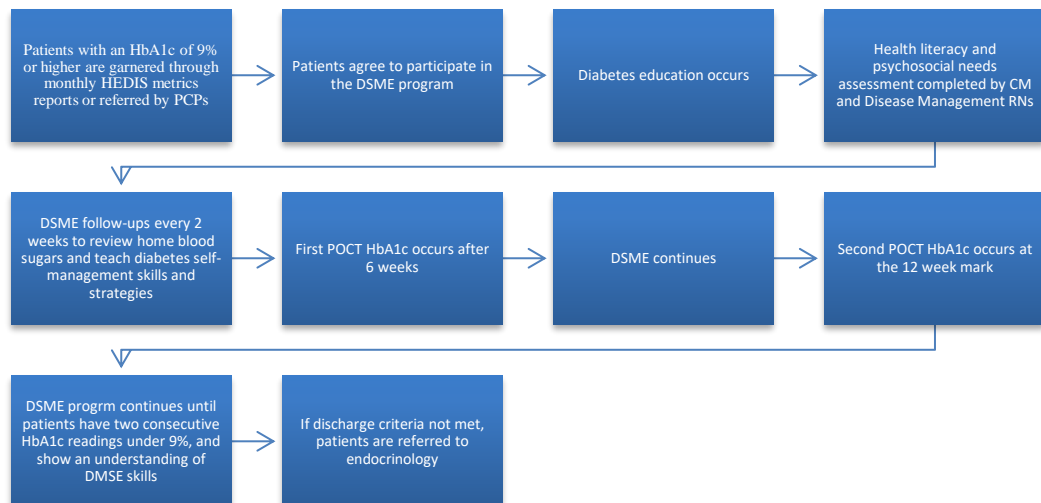
Nurse-Led DSME Program Cost Benefit Analysis	
Cost benefit analysis for:	Nurse-Led DSME Program
Cost benefit analysis prepared by:	Jamie Lee, RN, MSN
Date of submission of the analysis:	8/23/2018
Purpose of conduction the analysis: To determine the long-term cost benefit of implementing a nurse-led DSME program for an uncontrolled diabetes population. T2DM and related complication cost healthcare organizations an average of \$16,000 to \$26,000 in additional funding and resource per patient annually.	
Purpose: 1	To weigh the cost savings of improving patient outcomes.
Purpose: 2	To determine the savings in cost and healthcare resources of preventing diabetes related complications.
Purpose: 3	To test the efficacy of a self-management education program vs. traditional management models.
Various cost types incurred	-\$4,500 for an Alere Afinion HbA1c assay machine for POCT HbA1c measurements. This is a one-time purchase.
	-\$200 for 1 box per month of Alere Afinion rapid diagnostic HbA1c test kits. This averages approximately \$2,400 per year.
	-An average of 2-4 hour or total nursing labor combined, on a daily basis at approximately \$50 per hour. This will equal \$13,000 to \$26,000 per year.
Alternative options: Traditional diabetes care, and the costs incurred by diabetes-related complications and illnesses	
Alternative: 1	-Routine care of patients with T2DM, averaging about \$85,000 per patient per year
Alternative: 2	-An additional \$16,000 to \$26,000 in costs for patients with uncontrolled diabetes and diabetes related complications per patient per year
Alternative: 3	-Additional costs to the larger healthcare organization for inpatient care and treatment for acute illnesses related to T2DM.
Conclusions:	The investment in a nurse-led DSME program to promote self-management and prevent diabetes related complications costs only a fraction of the expenditures related to traditional care.

Timeline:

Nurse-Led DSME Program Development GANTT Chart

Task	8/23/18	9/7/18	10/5/18	10/6/18	10/10/18	10/12/18	10/19/18	11/20/18	11/30/18	12/3/18	12/6/18
Planning											
Implementation of Basic DSME Program											
Integration of CM											
Implementation of Revised DSME Program											
Incorporation of POCT HbA1c											
Implementation of Final DSME Program Structure											
Second Round of POCT A1C Measurement											
Program Exit Survey Administration											
Results Review and Calculation											

Process Map:



Appendix D

Post DSME Implementation Patient Survey

Name: _____

Date: _____

PCP: _____

How long have you been participating in this Diabetes self-management education program?

1. Did the materials presented during Diabetes Education meet your learning needs? Please explain.

2. Did you learn skills and strategies during this program that have helped you to manage your blood sugars at home? If so, which ones did you find most helpful? Please Explain.

3. Have you adopted new lifestyle changes or health behaviors that are helping you to improve your blood sugars and help you to manage your Diabetes? If so, what behaviors have you developed?

4. Do you feel that this program has helped you to develop a stronger sense of your abilities to effectively manage Diabetes on your own, using the skills and strategies you've learned while participating?

5. Do you have any feedback for this program, that you feel may help future participants?
