Increasing Point of Care Testing for Glycated Hemoglobin A1c Levels in a Family Health Clinic

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Abstract

Background: Adults with type 2 diabetes mellitus (DM) have and continue to increase significantly within the United States (U.S.). The current recommended glycated hemoglobin A1c (HbA1c) goal for a nonpregnant healthy adult is a value of 7% to lower the risk of DM-related complications (American Diabetes Association [ADA], 2021). Because a goal of 7% may not be feasible in many cases due to other variables, each person with diabetes should have an individualized goal and treatment plan based on their health history and age (ADA, 2021). Compared to a lab draw, which can take hours to days before the provider can see the results, point of care testing (POCT) is more convenient because it produces results in minutes.

Purpose: The goal of this quality improvement project was to enhance patient outcomes by introducing an algorithm to ensure that patients with diabetes were effectively managed according to the American Diabetes Association's current recommendations using POCT.

Results: The data was subjected to Chi-square and T-tests, but no statistical significance was found. However, analysis of the data revealed many findings consistent with clinical significance.

Conclusion: After analysis of the data from this quality improvement (QI) project, findings showed there was positive correlation between POCT for HbA1c and an increase in values <9%. It was recommended staff continue to apply the algorithm to analyze the long-term outcomes of utilizing POCT for HbA1c in the family medicine clinic.

Increasing Point of Care Testing for Glycated Hemoglobin A1c Levels in a Family Health Clinic

A total of 34.2 million Americans have DM, including those diagnosed and undiagnosed (Centers for Disease Control and Prevention [CDC], 2021). Uncontrolled diabetes has substantial health repercussions, including a lower quality of life and a higher risk of death (United States Department of Health and Human Services [HHS], 2016b). Although DM is associated with multiple health complications, those can be prevented or delayed with continuous monitoring and proper treatment (CDC, 2021). Due to the major consequences uncontrolled DM can cause, it's imperative to treat the disease with lifestyle modifications and medications to avoid or delay additional complications (CDC, 2021). Adults with DM should collaborate with their doctor to develop an individualized management plan that includes regular checkups every three to six months to ensure proper treatment is in place (CDC, 2021). The HbA1c is a crucial laboratory value that plays a key role in the management of DM (Schnell, Crocker, & Weng, 2017). As part of the treatment plan, a HbA1c test should be performed by a venous blood draw or POCT at each diabetic appointment to assess if glucose levels are being managed by the current treatment plan (Schnell et al., 2017). Because of the convenience and timeliness of POCT, a HbA1c result can be obtained during the present appointment, and treatment modifications can be made in real time, making POCT an extremely powerful tool in DM management (Schnell et al., 2017).

Background and Significance

The number of individuals living with DM globally is rising at a steady rate in most countries (International Diabetes Federation, 2020). Based on worldwide data from 2019, it is estimated that the number of adults with DM will increase from 463,000,000 to more than 700,000,000 by the year 2045 (International Diabetes Federation, 2020). According to the CDC (2020a), approximately one out of every ten people within the U.S. is diagnosed with DM. The

disease process and ramifications of DM cost the U.S. $327 billion annually (CDC, 2020b). Due to rising rates, it is vital to optimize the outcome of individuals with DM through evidence supported management such as; frequent followup to assess HbA1c levels, blood glucose trends, lifestyle modifications, and medication regimens (HHS, 2016a).

Uncontrolled DM has serious health consequences that lead to a poor quality of life and premature death (HHS, 2016b). As a result of poorly managed DM, macrovascular, and microvascular injuries occur causing heart disease, stroke, kidney disease, nerve damage, and eye disorders (HHS, 2016b). Due to these potential complications of this disease, DM is ranked as the seventh leading cause of death within the U.S. (CDC, 2020b).

Adults diagnosed with DM are not meeting the goals for preventative care practices recommended by Healthy People 2020 (CDC, 2019). Based on recommendations from the ADA (2021), individuals should receive a yearly foot and dilated eye exam, regular HbA1c checks, daily home monitoring of blood glucose levels, and attend a formal DM education management session. Based on data from 2016, only 69.7% of adult Americans report getting their HbA1c checked two or more times within the past year which is the current standard (CDC, 2019). Guidelines from the American Diabetes Association (ADA) recommend primary care providers to order and track an individual's HbA1c at patient appointments to ensure proper treatment is in place and that the HbA1c levels are within, or at least trending towards the goal range for that patient (American Diabetes Association [ADA], 2021). Doing this practice is one way a primary care provider can support the ADA's main goal to prevent comorbidities associated with DM (American Diabetes Association [ADA], 2021). A HbA1c test is a reliable way to assess an individual's glycemic control over a three-month period (Bansal et al., 2018). According to the ADA (2021), the current recommended HbA1c goal for a nonpregnant healthy adult is a value

<7% to reduce the risk of DM related complications. In many cases, a goal of <7% may not be realistic due to other factors, which is why every person with DM has an individualized goal and treatment plan based on their health history and age (ADA, 2021).

The U.S. department of HHS's Health Resources and Services Administration (HRSA) classifies a HbA1c level of > 9% as 'poorly controlled', as it is well known that patients with higher HbA1c's are at the greatest risk for DM related complications (HHS HRSA, 2012). Due to this, many third party payers use HbA1c levels that are >9% as a way to measure the quality of how well, or how poorly, DM is managed at individual clinics and if they are able to qualify for reimbursement (Pantalone et al., 2020). Based on this information, it is often within the clinics best interest to manage their patients with DM by requiring them to have their HbA1cs checked in the suggested intervals and to have well managed HbA1c's that are at least <9%. Not only does this help the organization meet their quality measures to get their funding, but it also helps their patients' overall health.

HbA1c's values can result from either a laboratory venous blood draw, or by a POCT which is completed at the office visit (Rosa et al., 2021). The POCT is convenient due to quick results within minutes as compared to a lab draw which can take hours before the provider can view the results. A POCT is done by collecting a sample of blood from the patient's finger and analyzing it by inserting the sample into the machine. Results typically will show within a few minutes. With this immediate information a provider can analyze the data and create a manageable and appropriate care plan for the patient.

Problem Statement/Clinical Question

DM is a chronic condition that leads to other lifelong and sometimes fatal diseases (HHS, 2016b). DM affects many people and costs the health care systems billions of dollars

yearly (CDC, 2020b). Similarly, quality measures for DM, which are set by reimbursement agencies, can affect the amount of funding individual clinics are granted (Pantalone, et al., 2020). All of the aforementioned reasons contribute to the importance of recognizing the need to have as few 'poorly controlled' DM patients as possible. The purpose of this project is to increase the use of the POCT machine available in office for HbA1c levels to promote compliance with HbA1c checks, allow real time results for patient and provider discussion to improve management plans, and improve overall glycemic control and HbA1c levels. The clinical question that will be assessed based on all previously diagnosed adult patients age 18 and older with DM is, will utilizing an evidenced based algorithm with a standing order for a HbA1c check at diabetic management appointments increase the use of POCT.

Organizational Assessment of Project Site

An organizational assessment of the project site was conducted using a strengths, weaknesses, opportunities, and threats (SWOT) analysis as well as a Fishbone diagram (see Appendix C) (Leiber, Stensaker, & Harvey, 2018). When attempting to thoroughly examine an organization for project implementation, a SWOT analysis is a valuable method to identify factors that can impact goal achievement (Leiber et al., 2018). Internal and external variables were considered in the SWOT analysis, as well as how they may influence project implementation (see Appendix A for SWOT Analysis; Leiber et al., 2018).

Many organizational strengths were identified when conducting the SWOT analysis for this project. The strengths were considered from a provider and patient perspective. As a patient, POCT for HbA1c is convenient because it eliminates the need to travel to a laboratory and a real time discussion can take place with the provider to make changes as needed to their treatment plan. From a provider's perspective, strengths identified included adherence to ADA guidelines,

standardized approach to DM management, convenience of results within minutes, and the ability to discuss potential treatment changes in real time with the patient.

Some of the weaknesses identified pertained to insurance coverage for POCT and a change in the current process for DM management from staff perspective. Currently, there is not a process in place for staff to obtain a blood sample to test meaning they would have to alter their workflow. Secondly, insurance coverage is based on the patient's individualized plan and the proper documentation and coding from the provider.

Many opportunities were considered within the SWOT analysis which may result in patient and clinic improvements. This project's implementation has the potential to improve patient-centered care, compliance, and outcomes. Furthermore the clinic has the opportunity to improve the overall glycemic control for patients with DM and HEDIS measures. The clinic can also get reimbursed for POCT with the appropriate documentation for the patient encounter.

Lastly, the potential threats were considered and taken into account based on project implementation. The POCT is not collected by a trained laboratory technician and there may be a lack of staff competence. There is a chance of lack of support from both the patient and staff due to a change in the current process. Pending insurance coverage, patients may be charged an out-of-pocket cost for the POCT which can be burdensome and hinder the patients' support.

The fishbone diagram (Appendix C) found four major categories of influence on the problem including; system level influence, financial influence, lack of knowledge influence, and individual influence. On a systems level, underutilization of the POCT testing is from lack of policy from the clinic as well as the increased need for telehealth services over the past year. Financially, POCT is not always covered by insurances and the supplies are a cost that must be factored in. It was also recognized that there can be a great lack of knowledge surrounding the

importance of POCT in managing DM from both the staff and the patients. Lastly, there are individual factors such as lack of appointment compliance that of course influences underutilization of POCT.

Purpose of the Project

The purpose of this quality improvement project was to optimize patient outcomes by implementing an algorithm to ensure patients with DM are properly managed according to the current recommendations by the ADA. This project created a process for staff to follow to ensure a HbA1c value is up to date within the last three months for individuals following up for their DM. A standing order will be in place for those without a HbA1c value within the proper time frame, creating a standard for staff to automatically use POCT to determine a current value. Ultimately, the project's objectives were to increase the use of HbA1c POCT which would then improve the management of DM within the practice.

Theoretical Framework/Quality Improvement Model

A Plan Do Study Act (PDSA) is a model that is often used in QI projects. The PDSA model has four distinct stages (Institutes for Healthcare Improvement [IHI], n.d.). The first stage includes the planning of how to implement an intervention (IHI, n.d). The next stage is the 'doing' stage where the intervention is executed as previously planned (IHI, n.d.). In the third stage there is analysis and deep reflection on how the plan was executed and if changes are necessary (IHI, n.d.). In the final phase of the model, the necessary modifications are completed and the plan is executed again (IHI, n.d.). Further detail regarding this process is provided in the methods section.

Review of Literature and Article Evaluation and Synthesis

A review of current accessible literature was completed in regards to this project. Databases including Pubmed and Cumulative Index to Nursing and Allied Health Literature (CINAHL) were utilized in this search. Articles qualified for this search had to be published within the last 10 years and published in the English language. Keywords for this search included; a1c or glycemic control or HbA1c, AND point of care testing AND primary care. From this search a total of 114 articles were found. Of the 114 only 8 truly pertained to the focus of study for this project. Please see appendix A for a full evaluation of each individual article. Synthesizing these articles revealed commonalities of increased benefits from POCT for HbA1c such as closer adherence to guidelines, evidence of correlation between increased frequent use of POCT and lower HbA1c results, increased patient satisfaction, and cost effectiveness.

Increased Guideline Adherence

Guidelines from the ADA recommend HbA1c screening every three months to ensure diabetes is being well managed (ADA, 2021). These guidelines drive the criteria for many reimbursement agencies. This makes adherence to the guidelines a top priority in many clinics. Research has shown that implementation of POCT for HbA1c can help providers and clinics reach the goals set by the established guidelines (Crocker et al. 2021; Egbunike & Gerard, 2013; Hirst et al., 2017; Rivo et al. 2016).

Lower HbA1c Results

Synthesis of the literature concluded POCT for HbA1c may impact overall patient outcomes and result in decreased HbA1c values. Due to real time results, patients and providers can work together at the appointment to have shared decision making on how to manage their

diabetes and make changes accordingly (Hirst et al., 2020). One study did have non significant results towards increased POCT and lower HbA1c results (Al-Ansary et al., 2011).

Patient Satisfaction

Increased patient satisfaction with the implementation of POCT for HbA1c during their clinic visit was found in multiple studies (Al-Ansary et al., 2011; Hirst et al., 2020; Lewandrowski et al., 2017). In one study, patients were found to have less anxiety towards appointments and providers could effectively reinforce positive behavior due to immediate results from POCT (Hirst et al., 2020). Patients are a stakeholder in many of these research projects and it is always imperative to consider their satisfaction when implementing a new intervention. Patient consideration allows for increased compliance due to their buy in.

Cost Effectiveness

There were mixed reviews on the overall cost effectiveness of the POCT in the synthesized literature. One study found that POCT is slightly more expensive when compared to getting an HbA1c checked at a laboratory (Rosa et al., 2021). Another study found that POCT can be less expensive when compared to laboratory testing (Al-Ansary et al., 2011). It is important to point out that there is a ten year gap of time between these two studies and they may have used different POCT machines and supplies. Overall, both studies concluded that POCT is only minimally less or more expensive, making POCT a viable and overall cost effective option.

Summary

The articles reviewed concluded that overall POCT can be beneficial in the outpatient setting by improving HbA1c goals, increasing adherence to the ADA recommendations, and promotes patient satisfaction (Al-Ansary et al., 2011; Crocker et al. 2021; Egbunike & Gerard, 2013; Hirst et al., 2017; Lewandrowski et al., 2017; Rivo et al. 2016). Because of the timeliness

of POCT, patients and physicians can collaborate during their appointment to make shared decisions to improve their DM control and make modifications as needed (Al-Ansary et al., 2011; Hirst et al., 2020; Lewandrowski et al., 2017). Ultimately, research showed that POCT can improve the management of chronic diseases leading to better patient outcomes (Crocker et al. 2021; Egbunike & Gerard, 2013; Hirst et al., 2017; Lewandrowski et al., 2017; Rivo et al., 2016). Although the cost efficacy of POCT was not clear, it is anticipated with proper documentation, most health insurance should cover the expense (Al-Ansary et al., 2011; Rosa et al., 2021). Literature reviewed for this quality improvement project included research from various levels of evidence including; III, IV, V, and VI. More research in an outpatient setting has the potential to provide further comprehensive solutions for future quality improvement initiatives increasing POCT in the clinic, which will lead to increased adherence with ADA guidelines, will ultimately lead to lower HbA1c results and better managed DM.

Outcome Goals

The goal of this project was to create an algorithm (see Appendix D) and policy that was utilized effectively to improve and increase POCT for HbA1c in the clinic. This algorithm was designed to fit seamlessly into the current workflow of the clinic. A secondary outcome goal that was analyzed is the percentage of HbA1c's >9%. Lowering the HbA1c results was not the main focus of this project, however, it was interesting and clinically important to recognize.

Methods

Clinic Description

This project took place at a university affiliated family health center in urban Mid-Michigan. This family health center offers comprehensive research driven care to all patients across the continuum. Providers within the clinic are uniquely trained to provide patient centered

care from newborns to geriatric individuals. The clinic was staffed by a combination of university providers from the college of nursing, college of osteopathic medicine, and college of human medicine. The staff of trained professionals within the clinic included eight medical and osteopathic physicians, four doctoral prepared nurse practitioners, three licensed practical nurses (LPN), and six medical assistants (MA). The licensed providers had staggered schedules throughout the week and specific days in the office, with no more than six providers in the office at one time.

This university clinic was open Monday-Friday and received over 200 phone calls per day pertaining to patient specific questions and care. Every day there were six providers in the office averaging 20 patient encounters each. Services provided at the clinic include chronic disease management, geriatric care, simple procedures, family planning and gynecological services, annual and sports physicals, preventative care for children and adults, and treatment for acute illnesses. Other services provided include POCT for HbA1c, microscopy, and immunizations.

Sampling

The population of patients included in this quality improvement project were those who fit the following criteria; 1) already had a diagnosis of type 2 DM, 2) 18 years or older, 3) had not had a HbA1c completed in >3 months either by lab draw or POCT. Patients were screened if they fit this criteria regardless of which provider they saw or their reason for the visit. Patients at this clinic were typically from the greater Lansing area. Data pulled from a 2021 electronic health record database found that 9% of all patients seen at the clinic had Medicaid, 34% had some form of commercial insurance, and 57% had Medicare. All of the patients who were

eligible for this quality improvement project should be able to have their POCT covered by their insurance as long as there was proper billing and coding completed.

Setting Facilitators and Barriers

This quality improvement project took place in an urban Mid-Michigan city with a population of approximately 50,000 (U.S. Census Bureau, 2021). The clinic's population also included individuals from multiple neighboring communities, both rural and urban. This clinic university offered and managed care for acute and chronic conditions ranging in age across the lifespan. The LPNs within the office were tasked with taking phone calls and triaging patients based on the severity of their needs or complaints. The MAs were split between completing clerical work at the front desk, rooming patients, and assisting the LPNs as needed. There was also an MA dedicated as a referral coordinator for the clinic. The manager of the clinic acted as the clinic liaison for the entirety of the project (See Appendix E).

Potential barriers for this project were considered prior to implementation and included staff and patient compliance. Staff were provided education prior to implementing this project and were asked for feedback throughout to improve the QIt project. It was standard procedure for the clinic to send reminder notices prior to patient appointments to confirm, reschedule, or cancel. This would help mitigate the potential barrier of missed appointments.

The Intervention and Data Collection Procedure

This QI project was executed in three stages. The first stage included distributing the revised workflow algorithm and policy to the staff members at the facility. It was crucial to communicate the rationale for this change in order to have stakeholder buy-in. The algorithm and policy was distributed first by email introducing the change and followed up with an invite for a 'lunch and learn' inservice to answer any questions that the staff members may have. The lunch

and learn inservice was during both staggered lunch periods in order to make it accessible to any staff members who have questions.

The second stage of the project was the implementation of the algorithm into practice. Feedback was collected from the staff members at one, three, and six weeks into the initial start of the implementation. Necessary adjustments were made to the algorithm and policy from the feedback. The third and final stage of the project was to continually analyze the outcome data at one month and three months post final implementation.

The data collected complies with the Health Insurance Portability and Accountability Act (HIPAA) regulations and safeguards the patients' privacy. Information Technology (IT) de-identified all patient information using only HbA1c values and dates when POCT was performed. Passwords were used to secure all project review and development data.

Measurement Instruments/Tools

Coordination with IT services at the clinic site allowed for easier data extraction. The data was assessed at the desired intervals to determine if HbA1c POCT compliance had improved. This data was compared to the amount of patients who had POCT for HbA1c three months prior to the intervention implementation. The success of this project was determined by the data collected, with the goal of increasing the number of times POCT was performed for patients who met the algorithm's criteria.

Timeline

The project timeline (Appendix F) was divided into a total of 30-weeks. The initial two weeks of the project included a lunch and learn session for staff, followed by implemtenting the project and applying the PDSA model to collect feedback and make adjustments if needed. In week six final adjustments were made to the algorithm. Data was collected and evaluated at

week 6 and 12. Following data collection at week 12, the reminder of the time as spent analyzing data and writing up a report to discuss the findings. The project's timeline was determined by the amount of time available between two academic semesters.

Cost-Benefit Analysis/Budget

The initial cost for the POCT HbA1c machine costs $5,950. However, this cost is typically divided across five years, putting the yearly cost for the machine to be approximately $1,190. To run the machine correctly there were added costs of HbA1c test cassettes and HbA1c control kits. The total yearly cost of the machine and supplies is $9,588. Reimbursement for HbA1c POCT varies amongst all of the different insurances averaging approximately $13.00 per test. Over the implementation period of this project there were 204 POCT completed within the timespan of three months. This projects the approximate number of POCT per year to be 800. With this approximate number, the projected total revenue from reimbursement would be $10,400, putting the clinic at a profit of $812. To see a full budget analysis table, please refer to Appendix G.

Implementation

This QI project was implemented using the project outline (Appendix F). Prior to implementation of the intervention, a virtual meeting was scheduled for the healthcare team members of the clinic to meet with the leaders of this project. During the virtual meeting, the leaders explained the outline of the project and announced the date of the lunch and learn. Staff members present during the meeting also had the opportunity to express their concerns, comments, and/or questions. All feedback from the staff was taken into consideration prior to the implementation of the project.

The lunch and learn was held at the clinic during the staff member's lunch hour. Project leaders were present and educational materials were handed out at that time. At the lunch and learn, questions and comments were encouraged in regards to the new algorithm and answered at that time (Appendix D). The intervention was well accepted by all staff members present during the session. The intervention went live the following Monday, after the lunch and learn session.

One week after the intervention was implemented, a survey was sent out to the clinic staff via email. The survey asked two questions and requested for members of the healthcare team to respond if they had any feedback. This survey had one response with no significant feedback. The leaders requested the survey be sent again to all staff members via email, with no responses. Due to this lack of feedback it was determined that no changes were needed to be made to the algorithm and that the project could continue as planned. Through help with the IT department and the Athena EHR system, the project leaders were able to analyze the data monthly. Final analysis of this data will be completed after week 30.

As expected, some anticipated roadblocks, such as employee participation, have become barriers. With only one survey response, despite two reminder emails to complete the survey, it is unclear if all members of the staff are aware of the intervention, using the algorithm, or simply have no feedback.

Data Analysis

Chi-square and T-tests were conducted and did not reveal statistical significance with the data. However, analysis of the data did reveal interesting findings that prove to have clinical significance. When comparing the three month implementation data to the three month pre-implementation data, findings proved to have clinical significance based on the following results. There was a 36% increase in total number of POCT occurrences, a 17.7% increase in total

number of laboratory testing, a 26.1% increase in HbA1c<9% results with POCT, a 68.8% increase in HbA1c<9% with Laboratory testing, a 22% increase in HbA1c>9% results with just POCT, and a 21.1% decrease with HbA1c>9% results with Laboratory testing (Appendix H).

Discussion/Implications for Nursing

It is critical to improve the outcomes of people with diabetes due to the rising rates within our country (HHS, 2016a). A three-month HbA1c test is a reliable approach to assess an individual's glycemic control (Bansal et al., 2018). Decisions regarding a patient's individualized treatment plan will be based on collected data from a HbA1c test done in the office by a POCT. It will be vital for staff members to continue to utilize and follow the algorithm designed for this QI project. POCT is a highly useful tool in DM management because of its simplicity and timeliness. A HbA1c test can be obtained during the current encounter, and treatment alterations can be done in real time (Schnell et al., 2017). This initiative established a process for staff to follow in order to ensure that a HbA1c value is current within the last three months for people who are following up on their diabetes treatment. For those who do not have a HbA1c value within the required time frame, a standing order will be placed, providing a standard for staff to use POCT to obtain a current value automatically. The project's ultimate goal was to maximize the usage of HbA1c POCT, which would ultimately improve the practice's DM management.

Clinically, the data analysis proved the intervention had some significance. Overall more patients with DM in the clinic had their HbA1c tested when compared to pre-intervention data. Most interestingly, the number of patients with DM who had a HbA1c >9% result with POCT increased. This statistic is intriguing because it shows that there was an opportunity for the patient's provider to address this elevated POCT result with the patient at the time of the visit. This quality improvement project reveals a need for a longer term study to see if this particular

group of patients will have improved compliance and decreased HbA1c levels due to the interventions that the provider was able to provide at the visit that originally detected the elevated HbA1c result.

Sustainability Plan

With consideration of the scope, cost, benefits, and final analysis of this project it can be determined that this is a sustainable intervention. Staff had no comments or suggested changes to share on the algorithm and were able to implement it into their workflow with no concerns. This specific intervention can be chosen to stay implemented if the staff choses to do so.

Based on investigator recommendations, the algorithm should be considered as a part of the onboarding process for new staff within the clinic. Staff will then understand their responsibility based on their role in the clinic. To ensure compliance, the algorithm and POCT should be included in the clinic's annual educational materials. Lastly, a quarterly quality review of the POCT data should be evaluated and discussed with staff to ensure metrics are met.

Conclusion

Diabetes that has been uncontrolled has serious health consequences, including a poor quality of life and a higher mortality rate (HHS, 2016b). While diabetes is linked to a number of health problems, they can be avoided or delayed with careful monitoring and treatment (CDC, 2021). Because of the serious effects of uncontrolled DM, it's critical to treat with lifestyle changes and medications to avoid or delay further complications (CDC, 2021).

Patients with diagnosed DM should work with their provider to create a personalized management plan that involves regular visits every three to six months to maintain optimal treatment (CDC, 2021). Based on the patient’s appointment type and the date of their last HbA1c check, if appropriate an updated value should be obtained via a POCT to reevaluate the current

treatment plan. POCT can be a valuable resource to use in the outpatient setting to allow providers to discuss the value in real time (Schnell et al., 2017).

Based on the findings within this QI project, there was a positive correlation between real time POCT for HbA1c and an increase in values <9%. It will be important for staff to continue to use the algorithm to further assess the long term effects of using POCT for HbA1c within the family medicine clinic. Utilizing available resources, such as POCT, within the primary care setting can aid to increase compliance leading to better patient outcomes.

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Appendix A SWOT Analysis Table

SWOT Table Analysis	
Strengths ● Convenience of POCT while at appointment for patient ● Convenience of results within 5 minutes for providers ● Helps adhere to ADA guidelines in regards to frequency of testing ● Creates a standardized approach to DM management ● Real time patient-provider discussion of HbA1c results	Opportunities ● Improved patient compliance ● Improved patient centered care ● Improved patient outcomes ● Improved overall glycemic control ● Improved HEDIS measures ● Reimbursement from insurance with supportive documentation
Weaknesses ● Coverage is dependant on individual insurance ● Coverage dependant on correct coding ● Change in current process for staff	Threats ● Test not performed by a laboratory technician ● Patients may be charged out-of-pocket costs for testing if their insurance does not cover it ● Lack of staff support ● Lack of patient support ● Lack of staff competence

Appendix B Literature Evaluation

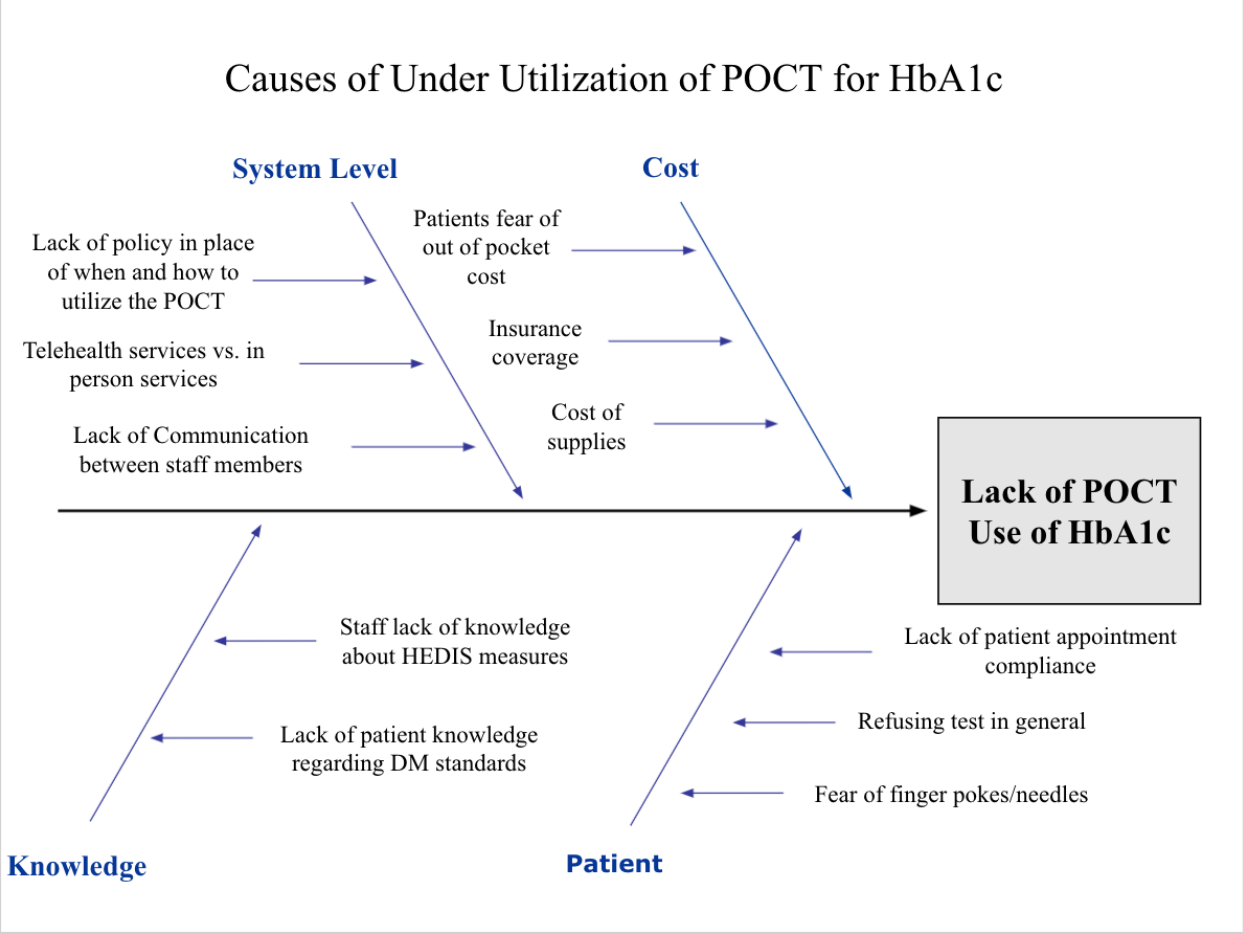
Literature Evaluation						
Author/Title	Level of Evidence	Purpose of the project/research	Framework	Results	How does this relate to your project?	Implications for Practice
Al-Ansary, et al., (2011). Point-of-care testing for Hb A1c in the management of diabetes: a systematic review and metaanalysis	Level V	To determine if POCT for HBA1c's has improved outcomes when compared to laboratory testing for HbA1c	None	A nonsignificant reduction of HbA1c results when comparing POCT and Laboratory testing	Directly contributes to the question 'will POCT testing improve HbA1c levels'. This study shows a gap in research in determining effectiveness of POCT.	The study does not provide proof of effectiveness for using POCT to lower HbA1c levels. However, it does provide incidental proof of patient satisfaction and cost effectiveness.
Crocker, et al (2021). The Impact of Point-of-Care Hemoglobin A1c Testing on Population Health-Based Onsite Testing Adherence: A Primary-Care Quality Improvement Study.	Level IV	To determine if POCT during office visits helps improve HEDIS-based HbA1c testing frequency	None	Significantly more HbA1c tests were completed when done in the office (POCT) rather than in a lab. Also, 44.9% of clinically worsening DM patients were identified by POCT.	The office implementing this intervention also adheres to HEDIS measures. This study shows that if more POCT is implemented then most likely there will be an increase in HEDIS compliance measures.	This study shows a unique implication for practice, showing that many DM patients that have clinically worsening DM can be identified in the office setting through POCT. This gives the provider an instant opportunity to intervene and help the patient with this problem.
Egbunike & Gerard, (2013). The Impact of Point-of-Care A1C Testing on Provider Compliance and A1C Levels in a Primary Setting.	Level III	To research impact of POCT HbA1c testing for patients with DM	Chronic Care Model	Implementing POCT showed a significant improvement of documented HbA1c's. Prior to implementing this providers were documenting HbA1c's at 68.3%. After implementing POCT recorded HbA1c's increased to	Providers involved in this project are expected to adhere to ADA guidelines for their DM patients. This study shows that this can help increase this adherence, as well as hopefully lower overall HbA1c scores.	This research states that monitoring with POCT allows for providers to give immediate feedback, which helps with coordinating care with the patient and discussing treatment options.

				82.9%. This helps adhere to the ADA guidelines of how to manage DM patients. Also, the mean HbA1c in the study prior to the intervention was 8.1%, and 7.4% after the study. This shows that POCT may have an impact on lowering HbA1c's overall.		
Hirst, et al. (2020). How point□of□care HbA1c testing changes the behaviour of people with diabetes and clinicians – a qualitative study.	Level VI, single qualitative study	To explore the providers and patients opinions and views on POCT for HbA1c's.	None	There were positive behavioral outcomes identified in this study. According to surveys patients feel less anxiety with getting immediate HbA1c results in the office and improved healthy behavior.	For patient centered care it is important to consider how they, as an important stakeholder, would feel during this project. This study shows that overall patients have better feelings towards managing their DM when POCT is involved.	Implementing this in practice helps lower anxiety of patients and may also help with non-adherence for those patients who find it difficult to go to a lab for testing. Goal setting and behavior reinforcement can help patients manage their DM and can be backed up by the immediate results from POCT.

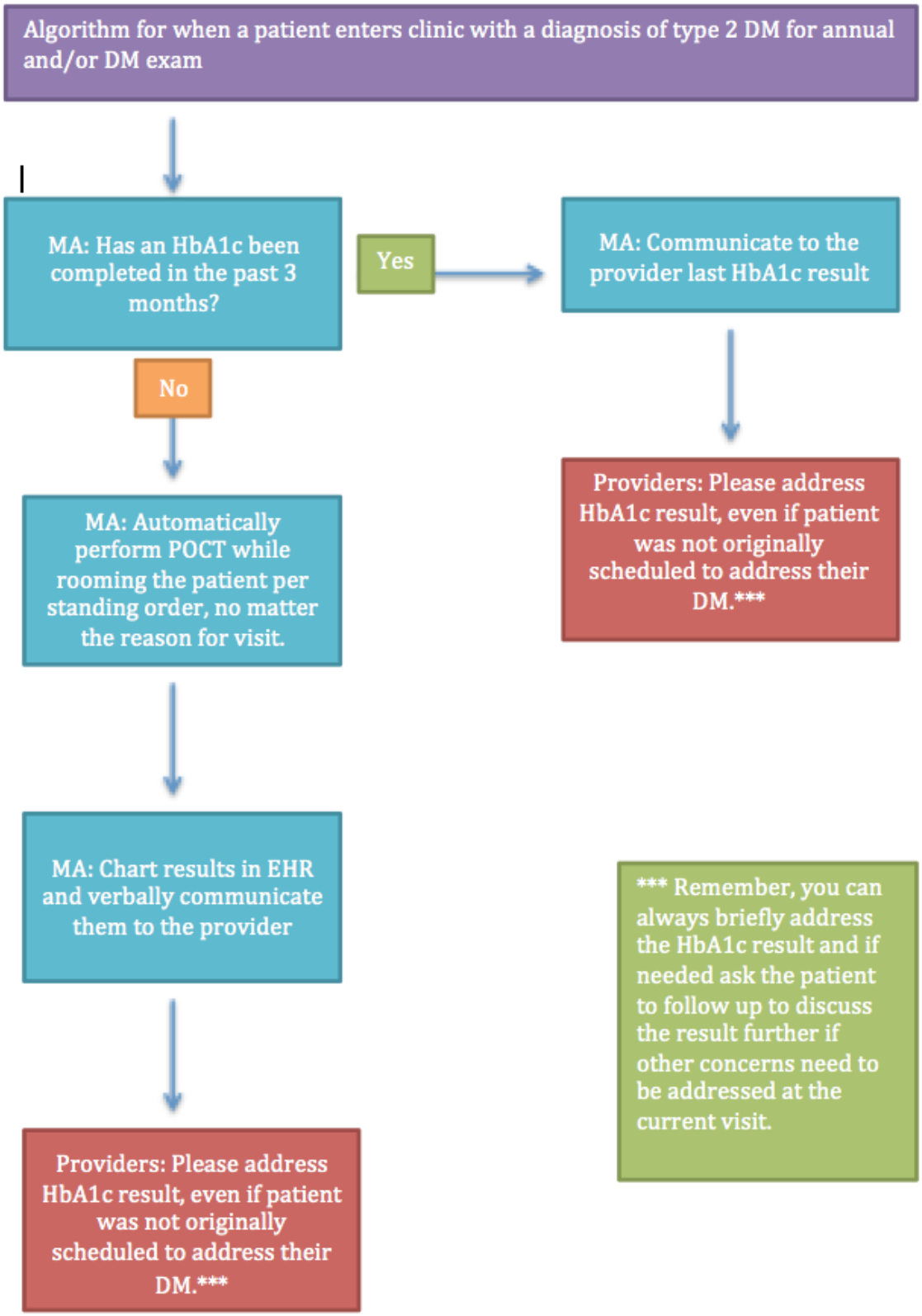
Hirst, et, al. (2017). How can point-of-care HbA1c testing be integrated into UK primary care consultations? - A feasibility study.	Level IV	To analyze the implementation of utilizing POCT for HbA1cs in the office setting,	Theoretical Framework	Implementation of POCT was successfully added to this particular clinic's workflow.	The current practice in the clinic that this paper is analyzing is not implementing POCT on a regular basis. The research from Hirst, et al. shows that implementation can be feasible and successful.	Hirst, et al. points out that for their clinical implementation they utilized diabetic specialist nurses, something that the clinic this paper is reaching for does not have access to.
Lewandrowski, et al. (2017). Implementation of point-of-care testing in a general internal medicine practice: A confirmation study.	Level IV	To follow up on a previous research study to confirm practice efficacy of POCT in primary care settings.	None	This research confirmed prior research with statistically significant results when using POCT in primary care leading to a reduction in reminder letters for lab work and a reduction in patients having to follow up after abnormal results.	This research confirms the significance of POCT in the primary care setting to improve practice efficacy ultimately leading to improved patient outcomes.	This study does not provide discussion on implications for practice, but it does mention improved patient satisfaction due to the convenience of results within minutes.
Rivo, et al. (2016). The Impact of Comprehensive Pre-visit Preparation on Patient Engagement and Quality of Care in a Population of Underserved Patients with Diabetes: Evidence from the Care Management Medical Home Center Model.	Level III	To see if pre-visit preparation has positive outcomes on the following measures; HbA1c testing compliance, influenza immunization, diabetic foot exam compliance, and low-density lipoprotein testing.	None	Pre-visit preparation intervention was extremely successful. There was 28.8% increase in HbA1c testing compliance, 14.6% increase in influenza immunizations, 27.7% increase in diabetic foot exams, and 33.2% increase in low-density lipoprotein testing,	This study shows that with increased use of POCT testing, there can be an increase in compliance with HbA1c testing goals.	This study highly recommends pre-visit preparation to be a part of the intervention to help increase compliance with POCT, amongst other things.

Rosa, et al. (2021). Cost-Effectiveness of Point-of-Care A1C Tests in a Primary Care Setting.	Level IV	To evaluate cost effectiveness when using POCT versus a laboratory for HbA1c levels for type 2 DM in primary care.	None	Research concluded POCT was slightly more expensive when compared to a laboratory but found the cost difference is offset due to a reduction in hospitalizations and other complications as a result of uncontrolled DM.	As a positive, the clinic has a POCT machine, meaning cost of supplies will be a factor to consider. As mentioned though the use of POCT can result in cost savings due to properly managed DM reducing the risk of other complications.	Despite the cost factor, POCT provides real time results can lead to achieving the HbA1c goal faster and reducing DM associated complications leading to a reduced economic burden.

Appendix C Fishbone Diagram



Appendix D Algorithm



Appendix E Facility Agreement Letter

MSU Health Care

July 28, 2021

Dr. Schrader,

I am familiar with Elizabeth Wielgos and Katie Sullivan project titled, ***Increasing Point of Care Testing for Glycated Hemoglobin A1c Levels in a Family Health Clinic***. I understand that Michigan State University Family Medicine Clinic involvement will include the mentorship of the above-named students and will require the application of the proposed process including: reviewing our current processes and/or practice, accessing records for review, protocols and practices related to the project, participation in improvement team meetings, educating staff, access to benchmark and performance data, revising current policy/procedures related to this and education of staff or providers impacted by the development of the project implementing an algorithm to improve compliance with testing for A1c in the office which ensures proper management of diabetes based on those results.

I have discussed the project with the students and am comfortable with the project taking place at our facility. I understand that this project will be carried out following sound, ethical principles. The Michigan State University Family Medicine Clinic gives permission for the students to disseminate project data and outcomes at Michigan State University College of Nursing for the purpose of academic course completion and any other place they would approve of dissemination such as department meetings etc.

Therefore, as a representative of Michigan State University Family Medicine Clinic, I agree that the project of Elizabeth Wielgos and Katie Sullivan may be conducted at our facility.

Sincerely,

Jennifer Preece MBA RN EMT

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Appendix F Timeline Table

Project Timeline in Weeks					
1	2	3	6*	12	13-30
Email staff members and host 'lunch and learn' sessions	Implement algorithm	Collect feedback and make adjustments to algorithm if necessary	Collect feedback and make FINAL adjustments to algorithm if necessary	Collect end of intervention data	Analyze data and write final report
*From week 6 on, the intervention will be fully implemented for the rest of the study and hopefully implemented into a permanent change for the facility.					

Appendix G Cost Benefit Analysis Table

Cost per Supply	
Initial purchase of HbA1c POCT machine	$5,950
HbA1c test cassette (15 test per box)	$153
HbA1c control kit (1)	$65
Reimbursements per Test	
Insurance (Medicare, Medicaid, BCN, BCBSM, Others)	$13.00
Costs of Supplies per Year (Assuming Approximately 800 POCT Completed per Year*)	
Initial purchase of HbA1c POCT machine per year over the next 5 years	$1,190
HbA1c test cassette (15 test per box) x 54 boxes	$8,262
HbA1c control kit (1) x 2 per year	$130
Reimbursements per Year (Assuming Approximately 800 POCT Completed per Year*)	
Insurance (Medicare, Medicaid, BCN, BCBSM, Others)	$10,400
Total Projected Yearly Costs and Revenue (Assuming Approximately 800 POCT Completed per Year*)	
Total costs	$9,588
Total revenue	$10,400
Total profit	$812

* 800 POCT test is a projected number based off of results from Appendix H showing 204 POCT were completed over the course of 3 months

Appendix H Data Analysis Table

Data Analysis Table			
Result Categories	**Pre-Data**	**Implementation Data**	**% Change**
Total number of occurrences POCT	150	204	36%
Total number of occurrences lab testing	192	226	17.7%
Total HbA1c results < 9% with POCT	134	169	26.1%
Total HbA1c results > 9% with POCT	16	27	68.8%
Total HbA1c results < 9% with lab testing	173	211	22%
Total HbA1c results > 9% with lab testing	19	15	-21.1%