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The Adherence of Primary Care Providers to the American Diabetes Association Guideline for Frequency of A1c Testing

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The Adherence of Primary Care Providers to the American Diabetes Association Guideline for
Frequency of A1c Testing

A Capstone Project Presented

by

Chyrise Taylor

Submitted to the Graduate School of the
University of Massachusetts-Amherst in partial fulfillment
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DOCTOR OF NURSING PRACTICE

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Abstract

Primary care providers (PCPs) are responsible for the medical management of patients with chronic illness. There are national guidelines issued by expert panels to enable PCPs to offer evidence based medical care to their patient population with chronic illnesses. Unfortunately, many PCPs do not adhere to these guidelines. This quality improvement (QI) project was designed to use the Awareness-to-Adherence theory in a Plan-Do-Study-Act (PDSA) cycle to strengthen the PCP understanding of the American Diabetes Association (ADA) guideline for the testing frequency of the Glycosylated Hemoglobin A1c (A1c) in patients with diabetes mellitus Type 2 (DM2). The patients were selected randomly from the electronic health record (EHR) of two rural primary care settings in Sullivan County, New York. The sample consisted of 22 male, and 26 female Caucasian adults (48 total) with well-established DM2. Each patient had, or should have had a baseline A1c drawn in the quarter immediately preceding the beginning of the QI project (October, November, December, 2013). A preview of the EHR revealed the PCPs ordered the A1c per ADA national guidelines on 37% of their patients with DM2. This QI project initiated an educational intervention which highlighted 1) the importance of A1c testing, 2) the concept of clinical inertia, and 3) reinforced the ADA guideline for testing patients with DM2. The PCPs used this information to decide if, and when to order an A1c on their patient population with DM2. After the intervention the PCPs ordered the A1c per ADA guidelines on 65% of patients with DM2. This represents a net gain of 28%. Further clarification of when to order the A1c in patients whose levels $\leq 7\%$ is needed. Monitoring A1c levels will reduce the incidence of co-morbidities, and health care costs in this patient population.

Keywords: hemoglobin A, glycosylated, guideline adherence, practice guidelines as topic, diabetes mellitus type 2, and medication therapy management.
Introduction and Background

The History of the Use of the A1c in Diabetes Treatment

The process of separating hemoglobin into its constituent components was discovered in 1955 (Little, & Rohlfing, 2013). Subsequently, further research found one component, the Hemoglobin A1c was found to be elevated in patients with diabetes mellitus (Koenig, et al., 1976). The knowledge of this correlation led investigators to discover if it could be useful in the diagnosis or treatment of diabetes mellitus. In 1984 Nathan, Singer, Hurxthal, & Goodson added to this growing body of knowledge of the significance of the Hemoglobin A1c by demonstrating that the A1c assay could be an important tool for the clinician to evaluate the long-term glucose level of the patient. However, since a standard process had not been established there was neither a central reference, nor an absolute value to use as an accurate, and reliable reference point. In fact because there were so many varied ways to test the assay a method of comparing data from one laboratory to another did not exist (Little, & Rohlfing, 2013).

Clearly, further examination of the A1c was needed. Therefore, the National Institutes of Health through its National Institute of Diabetes and Digestive and Kidney Diseases division conducted a 10 year study (1983-1993) of 1441 patients. This study known as the Diabetes Control and Complications Trial (DCCT) only included subjects with diabetes mellitus Type 1. However, its results have significant implications for all patients with diabetes. Notably, DCCT established the importance of maintaining a patient's A1c to a normal level (6%) to drastically
reduce the risk of complications to the cardiovascular, renal, neurological, ophthalmologic systems. In addition, the follow-up study-Epidemiology of Diabetes Interventions and Complication (EDIC) - continued to track the health of 90% of the study's participants. EDIC participants who maintained intensive control of the glucose and maintain A1c levels of 6%-7% continued to show reduced risk of cardiovascular complications. Prior to, and concurrent with the DCCT, the United Kingdom Prospective Diabetes Study (UKPDS) was a 20 year research effort from 1977 to 1997. The UKPDS had 5,102 participants who were diagnosed with Diabetes Type 2. It studied the effect of tight glucose, and blood pressure control in this population to ward off complications that were previously thought of as "inevitable" e.g. complications in the cardiovascular, neurological, renal and ophthalmologic systems. Once again, glucose control with a A1c between 6%-7% was shown to be the key to reducing complications from diabetes.

How the ADA Incorporated the A1c into the Standard of Medical Care

The ADA has included parameters for the use of the A1c since 1997 in their annual Standard of Medical Care (ADA, 1997). The most recent edition of the Standard for Medical Practice (2013) states the A1c test is "the gold standard" in diabetes management for optimal patient care (ADA, 2013). The test has several indications for clinical use including: diagnosing diabetes mellitus (diabetes), diabetic screening, as a guide to adjust treatment (diet, medications, etc.), and to evaluate the effectiveness of ongoing therapy (ADA, 2013). The test measures a 90-120 day average of how much glucose has come in contact with the hemoglobin molecules on the red blood cell. Normal ranges for the A1c test are 5.5% - 7.0% (ADA, 2013). The ADA guideline suggests A1c testing should be done semi-annually for stable patients, identified as
those whose values are < 7.0%, quarterly for patients whose A1c is \((\geq 7.0\% )\), or three months after a treatment change to assess the effectiveness of new treatment (ADA, 2013).

**Problem Statement**

The management of DM2 within primary care offices should adhere to the ADA guideline to obtain the optimal health outcomes for the patient. Unfortunately, many PCPs do not adhere to the recommended A1c testing schedule as outlined by the ADA. The ADA has specified intervals for the testing of the A1c for optimum monitoring of a patient's glycemic control. Timely A1c testing is important because patients with poorly controlled DM2 diabetes are at increased risk of urinary tract infections, fungal infections of the mucous membranes and skin, hearing impairment, osteoporosis, erectile dysfunction, glaucoma, peripheral amputations, neuropathy pain, non-healing wounds, and diabetic ulcers (Mayo Clinic, 2013).

**Diabetes in the United States**

**Evidence of the Problem**

In 2011 there were approximately 26 million diabetics in the United States (CDC, 2011). The annual direct, and indirect cost of diabetes consist of average medical costs, lost wages, disability, and premature death is estimated to be $174 billion dollars (CDC, 2011). Worse still is the effect diabetes has on the patient's body. The increased saturation of the large glucose molecules in the patient's blood stream affects the macrovascular systems, and raises the risk of cardiovascular disease including hypertension, and CVA. The long term complications are due to endothelial damage to the microvascular system (Krishna, Gillespie, and McBride, 2010; Mayo
Clinic, 2013). The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) estimates approximately 230,000 Americans die from complications of diabetes (2011).

**Diabetes Rates in Sullivan County, New York**

In 2013 the Sullivan County, New York the age adjusted mortality from diabetes mellitus per 100,000 stands at 22.9; the age adjusted mortality rate for New York state is 14.9 (County-By-County Rankings, 2013). Additionally, hospitalization for diagnoses where diabetes was a factor was 262.6 per 10,000, whereas the New York State age adjusted rate was 224.8 per 10,000 (Sullivan County Public Health Services, 2010). The disease burden upon the residents of Sullivan County (population 77,000) is deleterious, with 9.4% of the adult population diagnosed with DM2, whereas the diabetes rate in New York State is 8.2% (Sullivan County Public Health, 2013).

**Identification of the Problem in the Geographic Area of the QI Study**

Western Sullivan County is comprised of the towns of: Callicoon, Cochecton, Delaware, Fremont, Highland, and Tusten it has a population 12,567 (Sullivan County Public Health Services, 2010). The area is federally designated as a Primary Care Health Professional Shortage Area (US Department of Health and Human Services, 2013). In western Sullivan County the problem of poor diabetes management is exacerbated by the absence of endocrinologists to provide specialized care to the diabetics in the region. The closest endocrinologist offices from western Sullivan County are over thirty miles away. Additionally, the dearth of public transportation, or mass transit systems in the western portion of the county hampers access to endocrinologists. Therefore, management of diabetes in western Sullivan County is handled within 3 primary care offices. This QI project included the PCPs of two of these offices. Rural
areas such as this are known to have patient populations with the health care disparity in higher incidence of diabetes, less access to specialized medical care, minimal if any access to diabetes educators, and fewer options for engaging in activities that will increase physical activity (Massey, Appel, Buchanan, & Cherrington, 2010).

**Demographics of Western Sullivan County**

The population of western Sullivan County stands at 8,714. The majority of the patient population (71.2%) are Caucasian, and are descended from the original European settlers of the area. The ancestry of the patients are: Irish (19.7%), German (18.7%), and Italian (13.5%) (Sullivan County Public Health, 2010). The average educational attainment is high school completion (Sullivan County Public Health Services, 2013), and the median annual income for a family of four is approximately $62,000, which is $24,900 below the New York State median income of approximately $87,400 (US Census Bureau, 2014). There are three primary care offices located in the area. Two are owned, and operated by Catskill Regional Medical Center (CRMC) which is the sole hospital provider for the county; the other is a private practice. The two offices owned by CRMC are nurse practitioner led primary care family health centers. This QI project took place in these two nurse practitioner led primary care offices.

**Theoretical Framework: The Adherence-to-Awareness Model**

Pathman, et al. (1996) used physician non-adherence to the national guideline for childhood immunizations as a model to develop a theoretical framework to address physician non-adherence to guidelines. In this model Pathman, et al. identified "the sequential, cognitive, and behavioral steps" needed to achieve physician adherence to guidelines as "awareness, agreement, adoption, and adherence" (p 875 para 2; Figure 1).
### Pathman Sequence to Physician Guideline Adherence

Awareness → Agreement → Adoption → Adherence

<table>
<thead>
<tr>
<th>Awareness</th>
<th>Agreement</th>
<th>Adoption</th>
<th>Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians must become aware of the existence of the guideline. Dissemination of the guideline is critical.</td>
<td>Physicians must agree with the soundness of the guideline. If physicians do not agree with the health benefit the sequence is &quot;frozen&quot; and cannot advance.</td>
<td>Although physicians may adopt the guideline due to peer pressure or to avoid malpractice suits, Pathman, et al. posit most physicians adopt guidelines because they have become aware of it, have researched it, and agree with its value in promoting or maintaining patient health.</td>
<td>Pathman, et al acknowledge adoption and adherence have become more prevalent as practices are increasingly under scrutiny from CMS and insurers. However, Pathman, et al. states it &quot;is reasonable to conclude most physicians are in voluntary compliance with the guidelines.&quot;</td>
</tr>
</tbody>
</table>

This work was augmented by Cabana et al. in 1999. Cabana et al. (1999) did not develop a new theory, rather Cabana, et al. (1999) expanded the three step sequence used by Pathman, et al. into a broader, and multi-directional flow which illuminates the cognitive dissonance that lead to the barriers that manifest as physician non-adherence to guidelines (Figure 2). Cabana et al.’s expanded pathways are: 1) "lack of knowledge includes: lack of awareness, or lack of familiarity; 2) attitudes about the guideline includes: lack of agreement, lack of self-efficacy, lack of outcome expectancy, or the inertia of previous practice; 3) behavior: these are external barriers" (1999 p 1460 para 5).

Figure 2

When assuming diabetes management of a rural population it is crucial that the ADA guideline is followed to ensure the highest level of care is provided to patients. Unfortunately, a
study using the US National Ambulatory Medical Care Survey shows of all patients whose accompanying disease IC9 code indicates a diagnosis of diabetes mellitus (250.00-250.93) only 27% of all office visits included an order for A1c testing (Neumillier, et al., 2010).

This DNP Capstone quality improvement project seeks to increase PCP adherence to the ADA guideline for A1c testing by increasing the knowledge of the PCP of the rationale behind the guideline (awareness), teach how the A1c value can be used in clinical treatment decisions (agreement), and how to incorporate the A1c value in their patient education to increase patient awareness of the importance of glycemic control (adoption). In addition, a 10 question pre/post test was designed to test the augmentation posited by Cabana. Questions were formed to test lack of awareness, or familiarity, attitudes that could lead to a lack of agreement or clinical inertia, and behaviors that are external barriers to adherence to the ADA guideline.

**Review of Literature**

**Awareness of Guideline/Lack of Familiarity with the Guideline**

Pathman (1996) posits the first step toward adherence is knowing the guideline. The National Clearinghouse of Guidelines is the pre-eminent source for all members of the healthcare community (US Department of Health and Human Services, nd). Its database of evidenced based practice is freely available to the public (US Department of Health and Human Services, nd). Parcero, et al, 2011, Neumiller, et al.,2010 and McClellan, et al.,2003 all agree the low adherence to national guidelines is the result of lack of knowledge about the existence of the guideline, and its objectives. Glasser, 2010 discusses the low adherence rate (< 50%) in which only 21% of the patient population had a recorded A1c value over their two year chart review. McClellan, et al. (2003) concurs, and states the dissemination of knowledge about the existence of guidelines could be improved upon with including educational materials in the billing , and
remittance packets sent to providers from the Centers for Medicare and Medicaid Services (CMS). In addition, McClellan, et al. (2003) found even among PCPs who were aware of the ADA guideline, there was low documented evidence of the PCP following the guideline, this the researcher determined indicates lack of agreement with the guideline. In his survey of 195 patients Delaronde (2005) found 38.1% of the respondents answered with the response "My MD never told me I need at least 2 A1c tests per year". Compounding an additional 33.3% of respondents chose "I have never heard of the A1c test" as their answer. This lack of awareness/lack of familiarity of the PCP with the ADA guideline is confirmed by the data analysis of Neumiller, et al. (2010) whose use of the US National Ambulatory Medical Care Survey shows in 2005 only 27% of all diabetic patients had an ordered A1c in their patient health record.

**Agreement with Guideline/Lack of Self-Efficacy About the Guideline:**

According to Parcero, et al., 2011, and Schafer, 2006 adherence to the ADA guideline increases glycemic control, and reduces the incidence of co-morbidities related to DM2. Unfortunately, the lack of self-efficacy on the part of PCPs leads to clinical inertia. Clinical inertia is described as provider's unwillingness, or inability to intensify medication treatment in patients whose glycemic control is non-therapeutic (Schaefer, 2006). Clinical inertia is not related to patient non-adherence to ordered treatment. Clinical inertia is the provider's failure to advance medication management needed to maintain A1c levels of $\leq 7\%$ (Schaefer, 2006). Cabana, et al.(1999) identifies clinical inertia as an attitude barrier, which is directly attributable to lack of self efficacy. This barrier requires both knowledge, and a change in provider behavior to end the state of inertia. Vigersky (2011), and Davis, Chavez, & Juarez (2014) state lack of belief of self efficacy (clinical inertia) prevents the PCP from intensifying the medication
regimen even when they fully understood the long term danger this meant for the patients. Furthermore, Davis, Chavez, & Juarez (2014) report only 21% of patients with an A1c between 8%-9% had their treatment intensified. Whereas, Vigersky (2011) reports a lack of self efficacy, or clinical inertia resulted in an average lag of 20 months before treatment was intensified in patients with A1c ≥ 8%. Both teams of researchers conclude lack of self-efficacy (clinical inertia) can lead to a lag of nearly 2 years before the PCP initiates a change in medication regimen due to lack of agreement with the guideline.

Adoption of the Guideline/Agreement With the Guideline

Khoong, Gibbert, Garbutt, Sumner, & Brownson (2014), Parcero (2011), Massey, et al., (2010), Heisler, Piette, Spencer, Kieffer, & Vijan, (2005), and Siminero (2005) all affirm that PCP agreement with the guideline is necessary for full adoption of the guideline. With adoption of the ADA guideline PCPs fully acknowledge the A1c is the principle method to monitor the glycemic index, and increases the patient's glycemic control (Parcero, 2011; Heisler, 2005). With agreement, and adoption PCPs correctly perceived the barriers to diabetes management, and the need to overcome them (Siminero, Piatt, and Zgibor, 2005), PCPs use the A1c to make a significant change in the patient's diet, recommendations for exercise, and intensify medication (Heisler, et al, 2005). In addition, PCPs who understand the ADA guideline are more likely to engage in novel approaches to reach patients through community, and web based interventions (Massey, Appel, Buchanan, & Cherrington, 2010).

Clearly historical, and contemporary evidence establishes a pattern of lack of physician adherence to the ADA guideline regarding the frequency of A1c testing in primary care. Additional evidence points to the increased morbidity, and mortality when a patient has poorly
controlled glycemic levels (Davis, Chavez, & Juarez, 2014, ADA, 2013, McClellan, et al., 2003). This QI project embraces the model of Pathman, et al (1996) by adhering to the sequence of awareness, agreement, adoption, and adherence by the PCP; as well as the expanded pathways of Cabana, et al.(1999) lack of familiarity, lack of agreement, and behavioral barriers.

Method

Quality Improvement Project Description, and Study Design

Plan-Do-Study-Act

The Plan-Do-Study-Act (PDSA) cycle is a Model for Improvement that is an appropriate method for quality improvement projects in health care settings (Institute for Healthcare Improvement, 2011). The PDSA cycle (Figure 3) involves identifying a specific measure to change and then to implement and "test the change in the real work setting - by planning it, trying it, observing the results, and acting on what is learned" (Institute for Healthcare Improvement, 2011). The aim of using the PDSA cycle on a small project is to refine the quality improvement project, and advance through the cycles several times to eventually implement the change on a wide scale basis throughout a larger healthcare system (Institute for Healthcare Improvement, 2011).
The steps are:

- **Plan** - Gathering baseline data for the quality improvement, and posit what will occur once the project is implemented; Secondly, this stage requires a plan to test the quality improvement change.

- **Do** - Execute the project on a small scale. Revise this process as problems arise, and document this process. At this stage the data analysis can begin;

- **Study** - Adequate time must be set aside to analyze the data;

- **Act** - Analyze the data and plan a revision and restarting the PDSA cycle (Institute for Healthcare Improvement, 2011).
Project Setting

The setting for this QI project was at two primary care offices, which are owned and operated by Catskill Regional Medical Center (CRMC): the Callicoon Family Health Center, and the Livingston Manor Family Health Center. Both offices are located in rural, western Sullivan County, New York. The PCP in each of these offices a Family Nurse Practitioner.

Study Participants

The study participants are two nurse practitioners who are employed by CRMC, and are the PCPs in the family care centers in western Sullivan County, NY. The PCP in the Callicoon Family Health Care Center is a doctorally prepared nurse practitioner, and the PCP in the Livingston Manor Family Health Care Center is a master's level nurse practitioner.

Protection of Human Subjects

Due to the need to collect data about the ordering practice of the PCPs patient data must be obtained. Permission to access the EHR was obtained from the Vice President of Nursing at Catskill Regional Medical Center. All patient data was protected as stipulated by HIPPA law (US Department of Health and Human Services, 2003). No identifying patient data was divulged during, or after the course of this QI study (US Department of Health and Human Services, 2003).

Patient Population

In each practice, the ages of the patients with DM2 range from 30-90 years old, with a mean range of 30-80 years of age. The patients at the Callicoon Family Health Care Center are predominately Caucasian with ancestry from Germany, Poland, and Italy. The patients in the Livingston Manor Family Health Center are evenly divided between patients with Hispanic
ancestry, and those with ancestry from Italy, the British Isles, and Germany. These demographic mirrors the overall demographic of Sullivan County (US Census Bureau, 2014).

A random sample of patients was collected from the EHR of the practices. Criteria for inclusion in the study were adult patients with a documented history of DM2 who had, or should have had a baseline A1c drawn in the quarter immediately preceding the start of this QI study (October, November or December, 2013). The sampling yielded 60 names, however only 48 of these patients had, or should have had a baseline A1c drawn in the baseline timeframe (Table 1).

Table 1

<table>
<thead>
<tr>
<th>Period</th>
<th>Data Collected</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with A1c recorded in EHR during baseline quarter</td>
<td>44</td>
<td>91.6%</td>
</tr>
<tr>
<td>Patients with A1c not recorded in EHR during baseline period</td>
<td>4</td>
<td>8.3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>48</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Protection of Identifying Information

The patient's names were converted to numbers to protect their identity. A master log was created with the names of the patients, their number, and the date of their most recent A1c level (Table 2). This log was kept in the possession of the project manager in a locked, secured location to protect the patient's right to privacy in accordance to HIPPA law (US Department of Health and Human Services, 2003). Of the 60 patients, 48 had, or should have had a recorded A1c levels in the quarter preceding the beginning of the QI project (October, November, and December, 2013). The data from these 48 patients was used in this project (Table 1).

Table 2

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Assigned Number</th>
<th>Baseline date</th>
<th>A1c</th>
<th>Date Due</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>001</td>
<td>10/2013</td>
<td>8.1</td>
<td>01/2014</td>
<td>01/21</td>
</tr>
</tbody>
</table>
Pre-QI Project

Project Design

This project aimed to increase PCP adherence to the testing frequency of the HgbA1c of adults with DM2. During the project:

- 1) Each PCP took a pre-test which was based upon Cabana, et al. (1999) expansion of the Awareness-to-Adherence theory to determine the baseline level of knowledge, self-efficacy, and behavioral barriers to utilizing the ADA guideline for A1c monitoring.
- 2) Each PCP viewed a PowerPoint presentation as an educational component to introduce the ADA guideline of A1c testing frequency, the concept of clinical inertia, and to identify the project objective (Appendix A).
- 3) Each PCP was given the opportunity to ask questions to verify they understood the goal of the QI project was to order an A1c according to the ADA guideline.
- 4) Each PCP used a sheet supplied by the project manager to record the name of each patient with DM2, and the date the A1c is ordered. This sheet was placed into a binder and protected from view to comply with HIPPA laws.
- 5) At the conclusion of the project each PCP completed the post-test to determine if the project has increased PCP adherence to the ADA guideline for A1c testing.
Plan: Educational Components

The pre/post-test (Figure 4) was designed to assess the PCPs current level of adherence to the ADA A1c testing frequency using the Cabana (1999) expansion of the Pathman model.

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Tend to Disagree</th>
<th>Neither agree nor disagree</th>
<th>Tend to Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Describe your familiarity with the ADA DM guideline:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I offer high quality care in my office.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I like to use national guidelines to make treatment decisions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I believe national guidelines are helpful when making treatment plans.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. How frequently do you assess A1c in patients with &quot;unstable&quot; DM (e.g. A1c ≥ 7%)</td>
<td>Yearly</td>
<td>Monthly</td>
<td>Quarterly</td>
<td>Semi-Annually</td>
<td>Other</td>
</tr>
<tr>
<td>7. A current A1c is helpful in developing treatment decisions for my diabetic patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. It is important to know a diabetic patient’s A1c when I make treatment options.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. In the future, utilizing a current A1c will be an integral part of my clinical treatment decisions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Questions 1-4 assess knowledge/awareness of the ADA guideline, questions 5-9 assess self-efficacy, and outcome expectancy of the PCP when utilizing the ADA guideline's recommendation of frequency of A1c testing and questions, and question 10 assesses the effect of external barriers upon the behavior of the PCP when trying to adhere to the guideline. After the pre-test, the project manager presented a PowerPoint to introduce the ADA guideline of frequency of A1c testing, the concept of clinical inertia, the rationale for adhering to the guideline for A1c testing. After this presentation, each PCP was given a handout for quick reference in their office, and the objective of the QI project was fully explained to the PCP. The objectives of the QI project were:

a) To recognize the value of the ADA national guideline testing recommendation for obtaining the A1c

b) To order an A1c in accordance with the ADA frequency guideline.

**Plan: Obtaining Baseline A1c Values**

The patient names, their number and the baseline values were entered into a log (Table 4) which was kept in a secure, locked location known only to the project manager. This protection of identifying patient information was in accordance with HIPPA law (US Department of Health and Human Services, 2003).
Table 4  Compilation of Baseline Values

<table>
<thead>
<tr>
<th>Baseline A1c</th>
<th>Data Collected</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with A1c $\leq$ 7% at baseline</td>
<td>21</td>
<td>44%</td>
</tr>
<tr>
<td>Patients with A1c $\geq$ 7% at baseline</td>
<td>23</td>
<td>48%</td>
</tr>
<tr>
<td>Patients without a baseline A1c who should have had one at baseline</td>
<td>4</td>
<td>8%</td>
</tr>
<tr>
<td>Patients whose A1c values were collected as per ADA guideline</td>
<td>48</td>
<td>37%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>48</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Do: Start of the QI Project**

The project began in January, 2014. Each PCP had their HIPPA protected sheet, recorded the names of the patients with DM2 who came to visit, and if they ordered an A1c for the patient.

**Do: Project Mid-Point**

At the mid-point of the QI project the project manager reviewed the list of patients with DM2 who had been seen by the PCP. The list was compared to the master log to determine if each PCP followed the objectives of the QI project: ordering a current A1c in accordance to the ADA guideline.

**Do: Remediation**

To reinforce the QI objectives a second presentation of the PowerPoint, study objectives, and review of factors that foster clinical inertia was completed with each PCP for remediation.
Study: Data Analysis

At the conclusion of the project, the post-test (Figure 2) was given to each PCP to assess if there was a change in their knowledge, self-efficacy, and if they identified behavioral barriers which impeded their adherence to the ADA guideline for frequency of A1c testing.

Act: Recommendation

Possible recommendation forwarded to Vice President of Nursing for expanded implementation of QI project. The final project will be submitted to the Capstone committee, and each PCP.

Timeline and Budget

The project was conducted between January, 2014 and March, 2014. The timeline is divided into five stages. Each step embodies a portion of the cycle of the Plan-Do-Study-Act cycle of the project design model.

Step 1 January, 2014 (Plan)

- Administer pre-test to each PCP,
- PowerPoint presentation to each PCP,
- Review QI project objectives with study participants,
- Select random sample.

Step 2 January, 2014 (Do)

- Study participants resume clinical duties with expectation PCPs will fulfill study objectives.
- Return to the office to interview the PCP to see if objectives are being followed,
- Remediation with review of PowerPoint, study objectives, review of clinical inertia.
Step 3 March, 2014 (Study)

- Post-test with PCPs
- Collect all data
- Analyze qualitative data, identifying common themes, and prepare final report.

Step 5 April, 2014 (Act)

- Issue final report to the Capstone committee, Vice President of Nursing and study participants.

**Budget**

The study participant declined the honorarium, thus the total budget for this project was $50.00 which was the cost for paper products, gas to travel, and binders.

**Findings**

**Data Analysis**

Prior to the beginning of this QI project the project manager used the EHR of the practices to randomly select the names of 60 adult patients with DM2. Of these, 48 patients had, or should have had an A1c drawn in the baseline quarter (October-December, 2013). The final sample had 22 male patients and 26 female patients with age range from 34-91 years. The patient's ethnicities were Caucasian with ancestry from Germany, the British Isles, and Poland (86%), African- American (8%), and Hispanic with ancestry from Puerto Rico, Mexico and Central America (6%).

**Results**

According to Pathman, et al. (1996) PCP non-adherence to guidelines is due to a cognitive dissonance of awareness, agreement, and adoption within the PCP. Pathman, et al. (1996) posits the addition of education to help the PCP understand the importance of the
following the guideline aids the PCP to move along the continuum from awareness to adoption.

Prior to the QI project the PCPs correctly ordered A1c levels on 37% of the sample of patients collected from the EHR. After the QI intervention of an educational program (shown successive times), identification of the importance of obtaining an A1c on patients with DM2, a clear understanding of the need to break clinical inertia the PCPs correctly ordered A1c levels on 65% of their patients. This represents a net gain of 28% of A1c tests ordered in adherence to the national guideline (Table 5).

<table>
<thead>
<tr>
<th>ADA Guideline Criteria</th>
<th>Data Collected</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline A1c ≤ 7% with early repeated A1c values taken during QI project</td>
<td>8</td>
<td>17%</td>
</tr>
<tr>
<td>Baseline A1c ≥ 7% NOT taken during QI project</td>
<td>9</td>
<td>19%</td>
</tr>
<tr>
<td>Baseline A1c ≥7% taken during QI project</td>
<td>15</td>
<td>31%</td>
</tr>
<tr>
<td>Baseline ≤ 7% not repeated during QI project</td>
<td>13</td>
<td>27%</td>
</tr>
<tr>
<td>Baseline data who had A1c collected during QI project</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Patients whose A1c was ordered as per ADA guideline</td>
<td>31</td>
<td>65%</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>100%</td>
</tr>
</tbody>
</table>

Pre-Post Test Results

Cabana, et al.(1999) expanded upon Pathman idea and proposed the path from non-adherence to adherence to guidelines lies not on a linear continuum, but rather on a multi-directional flow. Review of the pre-test shows both PCPs intent is to provide high quality care to their patient population. However, on the pre-test (Figure 2) they both indicate a slight hesitance to use national guidelines indicated by choosing "Tend to agree" as their answer on the pre-test. However, on the post test both PCPs indicate they strongly agree with questions relating to
knowledge of national guidelines (Questions 1-4). Questions 5-9 investigate the PCP attitude when using national guidelines, negative answers on these can indicate level of outcome expectancy. On the pre-test the majority of the PCP answers were neither agree nor disagree. This ambivalence changed on the post test when both PCPs chose strongly agree for all questions. Responses to the pre-test for each PCP is shown in Table 6 and 7.

<table>
<thead>
<tr>
<th>Question Number</th>
<th>PCP 1 Pre Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Strongly Disagree</td>
</tr>
<tr>
<td>2</td>
<td>x</td>
</tr>
<tr>
<td>3</td>
<td>x</td>
</tr>
<tr>
<td>4</td>
<td>x</td>
</tr>
<tr>
<td>5</td>
<td>Yearly</td>
</tr>
<tr>
<td>6</td>
<td>Yearly</td>
</tr>
<tr>
<td>7</td>
<td>Strongly Disagree</td>
</tr>
<tr>
<td>8</td>
<td>x</td>
</tr>
<tr>
<td>9</td>
<td>x</td>
</tr>
</tbody>
</table>

10 Please use this space to answer this question: Please describe any barriers that exist in your practice to measure A1c for your patients with DM:
Table 7

<table>
<thead>
<tr>
<th>Question Number</th>
<th>Strongly Disagree</th>
<th>Tend to Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Tend to Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
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<td></td>
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<td>2</td>
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<tr>
<td>4</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Yearly</td>
<td>Monthly</td>
<td>Quarterly</td>
<td>Semi-Anually</td>
<td>Other</td>
</tr>
<tr>
<td>6</td>
<td>Yearly</td>
<td>Monthly</td>
<td>Quarterly</td>
<td>Semi-Anually</td>
<td>Other</td>
</tr>
<tr>
<td>7</td>
<td>Strongly Disagree</td>
<td>Tend to Disagree</td>
<td>Neither Agree nor Disagree</td>
<td>Tend to Agree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Tables 8 and 9 are the Post-test answers from each PCP:

Table 8

<table>
<thead>
<tr>
<th>Question Number</th>
<th>Strongly Disagree</th>
<th>Tend to Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Tend to Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
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<td></td>
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<tr>
<td>2</td>
<td></td>
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<td>3</td>
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</tr>
<tr>
<td>5</td>
<td>Yearly</td>
<td>Monthly</td>
<td>Quarterly</td>
<td>Semi-Anually</td>
<td>Other</td>
</tr>
<tr>
<td>6</td>
<td>Yearly</td>
<td>Monthly</td>
<td>Quarterly</td>
<td>Semi-Anually</td>
<td>Other</td>
</tr>
</tbody>
</table>
Table 9

<table>
<thead>
<tr>
<th>Question Number</th>
<th>Strongly Disagree</th>
<th>Tend to Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Tend to Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Strongly agree and am committed to using the guideline</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>5</td>
<td>Yearly</td>
<td>Monthly</td>
<td>Quarterly</td>
<td>Semi-Annually</td>
<td>Other</td>
</tr>
<tr>
<td>6</td>
<td>Yearly</td>
<td>Monthly</td>
<td>Quarterly</td>
<td>Semi-Annually</td>
<td>Other</td>
</tr>
<tr>
<td>7</td>
<td>Strongly Disagree</td>
<td>Tend to Disagree</td>
<td>Neither Agree nor Disagree</td>
<td>Tend to Agree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>8</td>
<td></td>
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<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>9</td>
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<td></td>
<td>x</td>
</tr>
</tbody>
</table>

Please use this space to answer this question: Please describe any barriers that exist in your practice to measure A1c for your patients with DM:
Lastly, in question 10 the PCPs were given the opportunity to identify external barriers that hinder their ability to adhere to the ADA guideline. The behaviors identified by the PCPs as barriers to their adherence to the ADA guideline are:

1. Weather conditions. This QI project was completed in the months of January-March, 2014. Without the option of using a mass transit system of any sort, patients in western Sullivan County have to drive to all medical appointments. The harsh snowy and bitterly cold weather prevented patients from keeping their appointments. This project recorded nine patients who had their A1c drawn in the baseline months, (October-December, 2013) and then cancelled appointments they made during the QI project.

2. Patients who fail to keep appointments. In the baseline months there were four patients who were identified in the sample who had been scheduled to have an appointment, but cancelled or did not come to the appointment. Three of these patients were captured during the QI project; two of these patients had A1c values ≥7% (9.0%, and 7.1%), and the third had a value ≤ 7% (6.2) when their A1c was tested during the QI project. The values of the patient's ≥ 7% would be indicated as not adherent to the ADA guideline, however the PCP cannot evaluate the A1c, and treat a patient that does not present in a timely manner.

3. Patients who fail to have the lab test performed. When a patient who is resistant to instruction is given a lab slip, yet fails to have the lab completed, the PCP is held accountable for not having a timely A1c value in the EHR. However, until the process of point-of-care A1c testing is established patient who are not adherent to PCP instruction to have the A1c tested remains an issue.
4. Lack of Reliable Transportation. Many patients, especially elderly patients have to rely on others for transportation to medical appointments. If the driver is unable to bring them appointment cancellations are unavoidable. Although the PCPs identified these areas of concern, the QI project was able to raise their rate of A1c testing in accordance to the ADA guidelines from 37% to 65%, which is a rate of change of 28%.

**Limitations**

Although this QI project successfully increased the PCP ordering of the A1c in accordance to the ADA guideline by 28%, an additional 17% of A1c tests were ordered incorrectly. These were A1c values that were ≤ 7% which according to the ADA guideline did not need to be re-ordered for a year. This is over utilization of resources which adds cost to the health care system. Thus, it is evident continued education is needed to support the PCP in the learning process.

The EHR of the project settings was in the process of being upgraded in the middle of the QI project. The previous EHR did not have electronic flags to indicate when a test should be ordered. Therefore, the PCP had to rely on hand-written notes, and post-its as reminders. If one was misplaced, or not seen until after the patient left the office there was a missed opportunity to order the A1c as per the guideline. However, the new EHR will have electronic flags on the dashboard of each patient to indicate when testing e.g. A1c should be ordered. This should help the PCPs in the future.
As stated by the PCPs, the effect the harsh weather encountered during the timeline of the QI project cannot be overstated. The unusually high snow amounts, and wind chills in the negative degrees for much of this project severely hampered the ability of patients to travel outside of their homes.

**Conclusion**

Diabetes mellitus is the seventh cause of premature death in the United States (CDC, 2011). PCPs must obtain a heightened awareness of the ADA Standards of Medical Care (2013) to reduce morbidity and mortality from diabetes. The ADA 2013 guideline specifies the need to perform the A1c test semi-annually on all stable diabetic patients whose A1c is \( \leq 7\% \), and quarterly on all diabetic patients whose A1c is \( \geq 7\% \).

In rural areas PCPs are entrusted with the medical care of patients with DM2. Unfortunately, as evidenced by the literature, many are not following the recommendations of the ADA guideline for monitoring their A1c. This disconnect is not a new phenomenon. Pathman, et al. identified the issue of physician non-adherence to guidelines in 1996, and 18 years later contemporary studies continue to address non-adherence to guidelines. In addressing how to fill the void between guideline recommendations, and provider adherence to guidelines new avenues must be found. These new avenues must address the reasons for provider non-adherence, and seek to enhance their adoption of the guideline into their practice(Pathman, et al., 1996; Cabana, et al., 1999).

The challenge to PCPs in western Sullivan County is to consider a "cognitive and behavior change" (Pathman, et al., 1996) of awareness, agreement, adoption, and adherence which will lead to a paradigm shift in how primary care practitioners view, and care for their
Type 2 diabetic patients. The goal of this QI project was to introduce, and reinforce the use of the 2013 ADA Guideline in Standards of Medical Care in rural, primary care settings. The QI project used an educational program to: 1) educate the PCPs to the value, and importance of adhering to the ADA guideline to monitor the A1c of their patients with DM2, 2) educate the PCP to identify lack of self-efficacy to break the cycle of clinical inertia, 3) to help the PCP identify behaviors that effect their ability to adhere to the guideline.

The economic burden of diabetes lies in the elevated health care costs associated with the incidence of cardiovascular disease, increased incidence of infections, ophthalmologic, and auditory disease which are prevalent in the population of patients with diabetes (NIKKD, 2014). Glycemic control of $\leq 7\%$ has been shown to reduce the incidence of these co-morbidities in patients with diabetes (ADA, 2013). Therefore, encouraging PCPs to adhere to the ADA guideline for A1c testing ensures they are managing their patients with DM2, and directly reducing the probability of the co-morbidity development thereby reducing healthcare costs in the US. In the final analysis it is shown the PCPs were able to use the education they received to correctly test 65% of the patients in the sample, an overall increase of 28% adherence to the ADA guideline. However, the PCPs also ordered A1c tests incorrectly on 17% of their patient sample. Therefore, additional education is needed to support the PCP's decision when to order the A1c according to the ADA guideline.

It is anticipated continued PCP adherence to the ADA guideline will reduce the incidence of co-morbidities in their patient population, and thereby decrease overall healthcare costs.
References


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Vigersky, R. (2011). An overview of management issues in adult patients with Type 2 Diabetes Mellitus *Journal of Diabetes Science and Technology* 5(2) 245-250.

Appendix A

PowerPoint Used in Educational Component

Slide 1

The Role of Glycosylated Hemoglobin A1c in Primary Care Settings: A Quality Improvement Project

Chyrise E. Taylor, RN, BSN, DNP(c)
The American Diabetes Association’s (ADA) Guidelines for Medical Practice, 2013 has established the glycosylated hemoglobin A1c (A1c) test as the gold standard in diabetes care.

- Who?
- Why?
- When?
WHO? WHY? WHEN?

• **Who?** The 2013 Standard of Care recommends the use of the A1c for all patients with diabetes mellitus.

• **Why?** Research has concluded the tight glucose control reduces the risk of complications from diabetes in the cardiovascular, renal, ophthalmologic, and neurological systems.

• **When?** The ADA guidelines suggest A1c testing should be done semi-annually for stable patients, identified as those whose values are < 7.0%, quarterly for patients whose A1c is (≥7.0%), or three months after a treatment change to assess the effectiveness of the new treatment.
Who?

General Patient Population

- Diabetes Type 1 - pediatric and adult patients.
- Diabetes Type 2 - pediatric and adult patients.
Who?

Special Populations

- Pregnant Women with Gestational Diabetes.
- Other patients with diabetes: patients with HIV/AIDS, genetic disorders with B cell dysfunction, genetic defects in b-cell function, diseases of the exocrine pancreas (such as cystic fibrosis), and drug- or chemical-induced.
Why?

- NIH performed a study of 1,440+ participants with Type 1 diabetes over 10 years. This study concludes intensive glucose control lowers the risk of cardiovascular (57%), renal (50%), neurological (60%), and ophthalmologic complications (70%).
The UK Prospective Diabetes Study by Oxford University performed a 20 year study from 1977-1997 with 5000+ participants with Type 2 diabetes. This study concludes intensive glucose control lowers: nonfatal MI, CVA by 57%, fatal MI(33%), all microvascular disease(24%).
Why?

- REMEMBER: When a patient’s blood sugar ≥ 7% the endothelial tissues of the cardiovascular, renal, ophthalmologic, and neurologic systems are under assault.
- Patients with elevated A1c levels are prone to infection, and opportunistic disease.
- A patient’s A1c = 7% translates to an average daily blood sugar of 154 with a range of 123–185 (ADA, 2010).

- A patient’s A1c = 8% translates to an average daily blood sugar of 183 with an average daily range of 147–217 (ADA, 2010).

- A patient’s A1c = 9% translates to an average daily blood sugar of 212 with an average daily range of 170–249 (ADA, 2010).
When?

- Additional times to consider ordering an A1c:
  - A diabetic patient with a non-healing wound.
  - A diabetic patient who has visual changes.
  - A diabetic patient that presents with fungal infections especially Candida.
  - When a patient with diabetes presents with S/S neuropathy.
When?

- A diabetic patient who has recurrent UTIs.
- A diabetic patient who has skin infections e.g. carbuncles, styes, boils, folliculitis, paronychia.
- A diabetic patient with recurrent sinusitis.
- A diabetic patient who has elevated blood pressure.
- A diabetic patient with a fracture.
What does this mean for my patients?

- A current A1c can end clinical inertia on the part of the PCP.

- Clinical inertia is when providers recognize a problem but fail to act.

- Providers exhibit from clinical inertia when they are unsure of treatment options, or are unsure when to change treatments, or question patient adherence to treatment options.
How Can I End Clinical Inertia?

- A current A1c is an objective clinical indicator of the patient's glycemic control.
- A current A1c can be the basis for beginning a conversation with a patient about their glycemic control.
- A current A1c is the starting point for the PCP to decide if current treatment should be intensified, or continued.
How Can I End Clinical Inertia?

- **Remember:**
  - A patient's A1c = 7% translates to an average daily blood sugar of 154 with a range of 123–185.
  
  - A patient's A1c = 8% translates to an average daily blood sugar of 183 with an average daily range of 147–217.
  
  - A patient's A1c = 9% translates to an average daily blood sugar of 212 with an average daily range of 170–249.
Remember:

- Each year that a patient’s A1c is over 7% increases the risk of complications of:
  - CAD: High blood pressure, CHF, PVD.
  - Neuropathy: Peripheral and autonomic.
  - Renal failure: May lead to dialysis.
  - Other: hearing loss, gum disease.
When a patient with diabetes comes in:

Is a current A1c in the HER?

- No, order an A1c
  - The result is less than 7%; order another A1c in 6 months.
- Yes, and it is less than 7%
  - The patient is therapeutic, re-order another A1c in 6 months.
- The result is more than 7%
  - Adjust the diabetes regimen and re-order in 3 months.

Yes, and it is less than 7%

The patient is therapeutic, re-order another A1c in 6 months.
QUESTIONS?

• Thank you for agreeing to participate in this project!
References